

University of Alberta

**Patient Safety & Disclosure of Medical Error: The Legal & Ethical Implications of
Human Error in Medicine**

by

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the

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ABSTRACT

Physicians have both an ethical and legal duty to disclose medical errors to patients. Although no Canadian court has held that nurses or hospitals have a corresponding legal duty to disclose medical error to patients, it is likely that such a duty exists. To facilitate increased disclosure, significant cultural and educational changes to hospitals and the health professions are required. Health administrators must recognize that most errors are systemic (not individual) errors and must foster a system of just responses to error. To promote the disclosure of medical error, there must also be legal reform to remove barriers to disclosure and to improve the efficacy of the medical liability system. Once these steps have been taken, a full discussion and investigation of every medical error and near miss is more likely to occur, thereby allowing the health system to act to prevent similar errors from occurring in the future.

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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 in the presence of her physician and members of her family.³ Just prior to her death, Carol was alert, oriented and although her condition was serious, she 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

¹ I 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.*

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 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

⁸ *Ibid.*

⁹ *Ibid.*; see also Robert V. Johnston et al., "Responding to Tragic Error: Lessons from Foothills Medical Centre" (2004) 170 *Canadian Medical Association Journal* 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 Administrating Potassium Chloride and Potassium Phosphate" (2005) 8 *Healthcare Quarterly* 73.

¹² *Supra* note 2.

¹³ *Ibid.*

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. By promptly disclosing the error to the victims' families and publicly accepting responsibility for the deaths, the CHR acted in an appropriate and proactive manner. The CHR also 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. While the outcomes of this incident are encouraging, medical error is still a tremendous problem and significant, wide ranging improvements must be made both in error prevention and in our responses to error.

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.

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 this thesis, the specific issue of medical error will be discussed with a particular focus on the legal aspects of medical error and how reform of our legal systems could potentially contribute to a reduction in medical error and to more appropriate responses to errors when they occur.

It is a central and inescapable truth of our medical system that all health providers make mistakes. Thankfully, many of these mistakes are minor in nature, are caught before they cause injury, or do not cause any harm to the patient. Unfortunately, far too many serious mistakes are made that cause death or significant injury to the patient. In addition, contrary to popular belief, the majority of medical errors are not committed by a small group of “bad” doctors or nurses who make frequent errors, but are committed by a wide distribution of the medical profession (and other health

professions) as a whole. Accordingly, aggressive punishment through discipline, privileges suspension and lawsuits against physicians and health professionals who commit errors will have little impact on the overall incidence of medical error. Instead, what is needed is a concerted effort by health professionals and hospital administrators to improve systems and make it more difficult for errors to be committed. Much can be learned in this regard from other industries such as aviation. In addition, certain specialties within the medical profession such as anaesthesiology have made significant strides in improving the quality of their systems and reducing error. Hospital administrators are also key players in improving patient safety and must attempt to foster a culture of safety as opposed to a culture of blame. Moreover, the legal system and lawyers must make every effort to reduce the negative impact that malpractice lawsuits have on the incidence of medical error.

In the first part of this thesis, the incidence and nature of medical adverse events will be examined and the primary causes of medical error will be discussed. In the second part, the issue of disclosure of medical error will be discussed with a particular focus on the legal and ethical duty to disclose errors when they occur. In the third part, the medical-legal issues surrounding medical error will be discussed and the need for and scope of legal reform will be examined.

Throughout this thesis, I will primarily focus on the medical profession but much of the analysis applies equally to the other health professions. The primary reason for this is that when medical errors occur, rightly or wrongly, in the majority of cases,

physicians are generally considered responsible. This is often true even in circumstances when the error can more properly be 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.

PART I – MEDICAL ERROR AND PATIENT SAFETY

INTRODUCTION

While few members of modern society would believe that doctors and other health professionals never make mistakes, even fewer of us fully appreciated the scope of medical error until the release of a large scale, comprehensive report on patient safety in the United States by the Institute of Medicine (“IOM”) in 1999. This detailed report, entitled “To Err is Human: Building a Safer Health System”, has had an unprecedented impact on how the health care system in the United States is viewed by health professionals, the legal profession, politicians and the general public.¹⁴ Many other developed countries have also begun to focus on medical error and are evaluating their health care systems in an effort to increase patient safety. In particular, the United Kingdom, New Zealand, Australia, Denmark and Canada have all conducted significant medical error studies in an attempt to ascertain the full extent of the problem in their respective countries. In Canada, the status and quality of the national health-care system has become a primary political issue and in 2002, the Canadian government established the Canadian Patient Safety Institute. In this part, the recent studies and scholarship on the root causes and incidence of medical error will be reviewed and the need for systemic reform of the Canadian health system will be examined.

¹⁴ Linda T. Kohn, Janet M. Corrigan & Molla S. Davidson eds., *To Err is Human: Building a Safer Health System* (Washington D.C.: National Academy Press, 2000); for an overview of patient safety and medical error in Canada see G. Ross Baker & Peter Norton, “Patient Safety and Healthcare Error in the Canadian Healthcare System: A Systematic Review and Analysis of Leading Practices in Canada with Reference to Key Initiatives Elsewhere” Report to Health Canada, online: Health Canada <http://www.hcsc.gc.ca/english/pdf/care/report_f.pdf>.

NATURE AND DEFINITION OF MEDICAL ERROR

Any examination of the wealth of academic studies and medical literature on the issue of medical error must begin with a discussion of the relevant terminology. Medical error itself is simply one form of human error generally. Our health care systems are fundamentally human systems and as humans, we have innate limitations of the mind and body.¹⁵ As a result, we are vulnerable to: limitations in memory capacity; a limited ability to deal with multiple competing demands; weakened mental abilities, including decision-making, by things such as fear and fatigue; and influence from the effects of group dynamics and culture.¹⁶ Unfortunately, our health systems have not been designed with these inherent limitations in mind and consistently demand superhuman efforts by health providers to avoid error.

In his authoritative text, *Human Error*, James Reason provides an analytical framework for the analysis of human error in a variety of settings. In addition to the specific public concern regarding medical error raised as a result of the IOM report discussed above, Reason identifies a renewed public concern over the terrible cost of human error generally. Reason provides a number of examples of disasters caused by human error including the Tenerife runway collision in 1977, the Three Mile Island accident in 1979, the Bhopal tragedy in 1984, the Challenger and the Chernobyl disasters in 1986, the Kings Cross Tube station fire in 1987 and the Piper Alpha oil

¹⁵ David A. Wong & Stanley A. Herring, "The Role of Human Error in Medical Errors" (2003) July/August SpineLine 27 at 27.

¹⁶ *Ibid.*

platform explosion in 1988.¹⁷ Added to this list from 1990 could be the Columbia disaster, the Air Transat Canary Islands near disaster, and the Exxon Valdez disaster among others.

In his chapter entitled “The Nature of Error”, Reason provides working definitions of Error, Slips, Lapses and Mistakes as follows:

Error will be taken as a generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some chance agency.

Slips and lapses are errors which result from some failure in the execution and/or storage stage of an action sequence, regardless of whether or not the plan which guided them was adequate to achieve its objective.

Mistakes may be defined as deficiencies or failures in the judgemental and/or inferential processes involved in the selection of an objective or in the specification of the means to achieve it, irrespective of whether or not the actions directed by this decision-scheme run according to plan.¹⁸

According to Reason, slips are observable as external unplanned actions such as communication errors, documentation errors, or errors in actions.¹⁹ Lapses, however, are more subtle and covert forms of error, often involving errors of memory. Lapses do not necessarily manifest themselves in actual behaviour, and may only be apparent to the person who experiences them.²⁰ It is also clear from Reason’s definition of mistakes, that mistakes are much more subtle forms of error and as such are more

¹⁷ James Reason, *Human Error*, (New York: Cambridge University Press, 1990) at 1.

¹⁸ *Ibid.* at 9.

¹⁹ *Ibid.*

²⁰ *Ibid.*

difficult to detect. Even when a potential mistake is detected, it is often a matter of debate as to whether or not a mistake was in fact made. Not only is the quality of the plan open to a variety of opinions, it can be judged at two distinct stages: before and after it is implemented.²¹

This aspect of error generally is particularly important to medical error, as the determination of whether a medical error was made and whether it was negligent, often involves a retrospective analysis of the information available to the health provider at the time of treatment. One of the major struggles that the medical and legal systems have in dealing with the consequences of medical error is the utilization of hindsight by medical experts and judges. It is all too tempting for the legal profession, and medical experts providing retrospective opinions, to look back on actions of health providers with the benefit of hindsight and judge the alleged negligence in light of the unanticipated negative outcome. Simply because an injury has occurred does not mean that negligence can be assumed. As stated by Lord Denning, “we must not condemn as negligence that which is only a misadventure.”²²

With respect to the definition of medical error itself, criticisms have been levelled at definitions that focus on outcomes or the preventable nature of medical errors. In addition, medical error should not be tied too explicitly with negligence, as negligence is a legal conclusion based on a variety of extraneous factors. Focusing on

²¹ *Ibid.*; For a discussion by Reason of error in the medical context see also James Reason, “Safety in the Operating Theatre – Part 2: Human Error and Organisational Failure” (2005) 14 *Quality & Safety in Health Care* 56.

²² *Roe v. Minister of Health*, [1954] 2 Q.B. 88 at 87 (C.A.).

outcomes is also problematic as many medical errors occur without a discernible associated negative outcome. Simply because a medical error does not result in harm, does not mean that it should not be taken seriously and acted upon. On the contrary, we should take advantage of the learning opportunities that these “near misses” present and these types of medical errors should be treated as seriously as those errors which do result in harm.

While much more can be said about the semantic and substantive debate about the definition of Medical Error, for the purposes of this thesis, the definitions from the IOM report will be adopted. The IOM report defines Error as “the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)”.²³ The IOM report goes on to define Adverse Events as injuries “caused by medical management rather than by the underlying disease or condition of the patient.”²⁴ A Preventable Adverse Event is defined in the IOM report as “an adverse event attributable to error” and Negligent Adverse Events are defined as “preventable adverse events that satisfy legal criteria used in determining negligence.”²⁵

INCIDENCE OF MEDICAL ERROR

Although it has always been generally understood that errors occur in medicine, and that they probably happen more than they should, little effort was made by

²³ IOM Report, *supra* note 14 at 28.

²⁴ *Ibid.* at 29.

²⁵ *Ibid.* at 28.

governments, the medical profession or the legal profession to ascertain the true extent of the problem until relatively recently.

U.S. Adverse Event Studies

The first major study of medical adverse events was conducted in the early 1970's by the California Medical Association.²⁶ This study reviewed records for nearly 21,000 hospital admissions and concluded that adverse events occurred in 4.6% of all admissions.²⁷ 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. This ambitious study was a retrospective analysis of over 30,000 randomly selected medical charts for patients discharged from 51 New York State hospitals in 1984.²⁸ The results of the study indicated a disturbingly high incidence of adverse events and reported that adverse events occurred in 3.7% of all hospitalizations.²⁹ 58% of these adverse events were considered to have been caused by medical error and therefore were preventable.³⁰ Approximately 29% of the adverse events when viewed by a medical-legal expert were deemed to be negligent.³¹ Although most of these adverse events gave rise to disability lasting less than six

²⁶ California Medical Association, *Report of the Medical Insurance Feasibility Study* (San Francisco: The California Medical Association, 1977)

²⁷ *Ibid.*

²⁸ Troyen A Brennan et al., "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I" (1991) 324 *New Eng. J. Med.* 370.

²⁹ *Ibid.* at 371.

³⁰ Lucian L Leape et al., "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study II" (1991) 324 *New Eng. J. Med.* 377.

³¹ *Ibid.* at 377.

months, 13.6% resulted in death and 2.6% caused permanently disabling injuries.³² Drug complications were the most common type of adverse event (19%), followed by wound infections (14%) and technical complications (13%).³³

A study of adverse events for 15,000 randomly selected hospital admissions in Colorado and Utah in 1992 was conducted with similar techniques as the Harvard Study and was released in 1999.³⁴ In addition to estimating the incidence, morbidity and preventability of surgical adverse events, the Colorado and Utah Study sought to characterize the distribution of adverse events by type of injury and by physician specialty, and to determine incidence rates by procedure. 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.³⁵ 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.³⁶

If the results of the Colorado and Utah Study are extrapolated and applied to all U.S. hospital admissions in 1997 (33.6 million), it would imply that at least 44,000 Americans die in hospitals each year as a result of preventable medical errors.³⁷ If the results of the Harvard Study are similarly extrapolated, the number of deaths due to

³² *Supra* note 28, at 371.

³³ *Supra* note 30, at 378.

³⁴ Atul A. Gawande et al., "The Incidence and Nature of Surgical Adverse Events in Colorado and Utah in 1992" (1999) 126 *Surgery* 67.

³⁵ *Ibid.* at 70.

³⁶ *Ibid.* at 70.

³⁷ IOM Report, *supra* note 14 at 31.

preventable medical error may be as high as 98,000.³⁸ In comparison, even based on the lower extrapolated figure above, the number of deaths attributable to medical error is greater than the eighth leading cause of death in the United States, and is roughly equivalent to a commercial jumbo jet crashing every second day.³⁹

Some experts maintain that the extrapolations discussed above likely underestimate the occurrence of preventable adverse events because the relevant studies:

- (1) considered only those patients whose injuries resulted in a specified level of harm;
- (2) imposed a high threshold to determine whether an adverse event was preventable or negligent (concurrence of two reviewers); and
- (3) included only errors that are documented in patient records.⁴⁰

Other experts argue that the extrapolations from the IOM report are overstated and artificially increase the death rate.⁴¹ As a result of the methodology used by the studies relied on by the IOM report, these experts argue that the death rate is artificially exaggerated, as many of the patients who died having suffered some adverse event would have died in any event.⁴² According these experts, the IOM failed to properly incorporate the stated and unstated limitations of the studies it relied on.⁴³ As a result, they opine that the death rate due to preventable adverse events may

³⁸ *Ibid.*

³⁹ *Ibid.*

⁴⁰ *Ibid.*

⁴¹ Clement J. McDonald, Michael Weiner & Siu L. Hui, "Deaths Due to Medical Error Are Exaggerated in the Institute of Medicine Report" (2000) 284 *Journal of the American Medical Association* 93; Some authors are not so certain. See for example Harold C. Sox & Steven Woloshin, "How Many Deaths Are Due to Medical Error? Getting the Number Right" (2000) 3 *Effective Clinical Practice* 277.

⁴² McDonald et al., *ibid.*

⁴³ *Ibid.*

not be much higher than the overall death rate in each particular group studied.⁴⁴

Lucian Leape, one of the world's leading experts on medical error, provided a response to these criticisms, and concluded that the results of the IOM report are not exaggerated and in fact may be understated.⁴⁵ Leape agrees that there are inherent limitations in the Harvard Study as well as the Colorado and Utah Study, but disagrees that these limitations led to an over-interpretation of the incidence of error in the IOM report.⁴⁶ Leape suggests three reasons why the IOM report death rates are not exaggerated. First, despite the limitations of retrospective medical record reviews, it is highly unlikely that reviewers found adverse events that did not exist.⁴⁷ However, according to Leape, reviewers undoubtedly missed adverse events that did exist because many errors are never recorded in the medical record, either because they are concealed or are not recognized.⁴⁸ This assertion is supported by recent study which found that many errors that occur in intensive care units are not documented on the patient's chart.⁴⁹ Second, neither of the large studies examined medical error that occurred outside of a hospital setting.⁵⁰ According to Leape, more than half of all surgical procedures in the U.S. (numbering in the tens of millions in 2000) occur outside of a hospital setting and although error rates for these procedures have not been studied, the numbers must be substantial (and were not included in the

⁴⁴ *Ibid.* at 94.

⁴⁵ Lucian L. Leape, "Institute of Medicine Medical Error Figures Are Not Exaggerated" (2000) 284 *Journal of the American Medical Association* 95.

⁴⁶ *Ibid.*

⁴⁷ *Ibid.* at 97.

⁴⁸ *Ibid.*

⁴⁹ Lisa S. Lehmann et al., "Iatrogenic Events Resulting in Intensive Care Admission: Frequency, Cause, and Disclosure to Patients and Institutions" (2005) 118 *The American Journal of Medicine* 409.

⁵⁰ *Supra* note 45 at 97.

IOM report).⁵¹ Third, according to Leape, when prospective detailed studies are performed, error and injury rates are almost invariably much higher than indicated in large retrospective record review studies.⁵² As interesting as this debate is, the actual death rate from medical error will never be accurately ascertained, as the decision to retrospectively label an incident a preventable adverse event is invariably a question of judgement, also subject to human fallibility. While the critics of the Harvard Study methodology may have some valid concerns and rightly suggest caution in the interpretation of retrospective studies, several other large international studies support Leape's position that the death rate may in fact be higher. Whatever the actual death rate is in any particular country, it is beyond question that far too many patients die or are disabled as a result of medical error and prudent and urgent health care reform is imperative.

Australian Adverse Event Study

In Australia, in 1995, the Quality in Australian Health Care Study ("QAHCS") increased attention to adverse events and medical error in Australian health-care.⁵³ The study identified that 16.6% of patients whose hospital charts were reviewed, suffered an adverse event.⁵⁴ While these results are significantly higher than the two U.S. studies, differences in methodology may explain much of the discrepancy. One specific significant difference in methodology is that the Australian study focused on

⁵¹ *Ibid.*

⁵² *Ibid.*

⁵³ R.M. Wilson et al., "The Quality in Australian Health Care Study" (1995) 163 *The Medical Journal of Australia* 458.

⁵⁴ *Ibid.*

prevention and quality of care, whereas the U.S. studies focused on negligence and malpractice. More recent analysis of the data from the QAHCS has revealed that over 70% of the adverse events identified were the result of failures in technical performance, failures to decide or act appropriately based on available information, failures to investigate or consult, and a lack of care or failure to attend.⁵⁵ In addition to the QAHCS and the analysis of its data, there have been significant efforts in Australia to increase awareness of system issues and to target improvements in patient safety.

United Kingdom Adverse Event Study

The National Health Service (NHS) in the United Kingdom published a report in June 2000 entitled “An Organization with a Memory”, identifying the significant impact of adverse events in the national health system.⁵⁶ The report concluded that, while the picture of medical error in Britain was incomplete, there was a serious problem.⁵⁷ Since the publication of the NHS report, a preliminary retrospective record review of adverse events in British hospitals has been conducted.⁵⁸ Although this study was severely limited and reviewed only 1014 medical records at only two acute care hospitals in London, the results are comparable to the other larger studies. The British study found an overall 11.7% rate of adverse events when multiple adverse

⁵⁵ R.M. Wilson et al., “An Analysis of the Causes of Adverse Events from the Quality in Australian Health Care Study” (1999) 170 *The Medical Journal of Australia* 411.

⁵⁶ National Health Service, *An Organization with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS Chaired by the Chief Medical Officer* (Norwich, U.K.: Department of Health, 2000).

⁵⁷ *Ibid.*

⁵⁸ Charles Vincent, Graham Neale & Maria Woloshynowych, “Adverse Events in British Hospitals: Preliminary Respective Record Review” (2001) 322 *British Medical Journal* 517.

events were included.⁵⁹ About half of the adverse events were judged preventable and a third of adverse events led to moderate or greater disability or death.⁶⁰ Although it was admitted that the results could not be extrapolated with any degree of precision, the authors went on to suggest that approximately 5% of all patients admitted to hospitals in England and Wales each year experienced preventable adverse events.⁶¹ The authors further suggested that these preventable adverse events led to an additional 3 million bed days per year in England and Wales at a total cost of approximately 1 billion pounds per year.⁶² The authors conclude by suggesting that a large-scale study similar to those completed in the United States be conducted in the United Kingdom in order to more accurately assess the rate of adverse events in hospitals in Britain. To date no such study has been released, but there is no reason to believe that the rates of adverse events in the United Kingdom are substantially different than in the United States or Australia.

Danish Adverse Event Study

In Denmark, a retrospective study of medical records was conducted in 2001 on 1097 acute care hospital admissions.⁶³ These charts were randomly selected from 17 different acute care hospitals and it was found that adverse events occurred in 9% of

⁵⁹ *Ibid.* at 518.

⁶⁰ *Ibid.*

⁶¹ *Ibid.*

⁶² *Ibid.*

⁶³ Schioler T. et al., "Incidence of Adverse Events in Hospitals: A Retrospective Study of Medical Records" (2002) 164 *Ugeskr Laeger* 4377.

all admissions, causing on average a seven day prolonged hospital stay.⁶⁴ 40.4% of these adverse events were deemed preventable.⁶⁵ While most adverse events resulted in minor or transient disabilities, permanent disability or death was recorded in approximately 18% of the total adverse events.⁶⁶

New Zealand Adverse Event Study

In 2002, researchers in New Zealand also conducted a retrospective analysis of adverse events from 1998 medical records using similar methodology to the Harvard Study.⁶⁷ The New Zealand Study reviewed 6579 medical records, randomly sampled from admissions in 1998 at 13 acute care hospitals, and found that adverse events occurred in 12.9% of hospital admissions.⁶⁸ Half of these events (6.3%) were deemed preventable.⁶⁹ The researchers also concluded that half of all adverse events were associated with surgery and one third with medicine; operative incidents were predominant in the former, drug related in the latter, and system issues were present in both.⁷⁰ According to the New Zealand Study, most adverse events had minor patient impact, with less than 15% associated with permanent disability or death.⁷¹ However, the New Zealand Study also concluded that adverse events added an average of over nine days to the expected hospital stay, and the elderly were

⁶⁴ *Ibid.*

⁶⁵ *Ibid.*

⁶⁶ *Ibid.*

⁶⁷ Peter Davis et al., "Adverse Events in New Zealand Public Hospitals I: Occurrence and Impact" (2002) 115 *Journal of the New Zealand Medical Association* 271.

⁶⁸ *Ibid.*

⁶⁹ Peter Davis et al., "Adverse Events in New Zealand Public Hospitals II: Preventability and Clinical Context" (2003) 116 *Journal of the New Zealand Medical Association* 624.

⁷⁰ *Ibid.*

⁷¹ *Supra* note 67.

disproportionately affected by adverse events.⁷² One of the most important aspects of the New Zealand Study was that it reported that nearly one fifth of all adverse events occurred outside a public hospital (mainly doctor's rooms, ambulatory care facilities, patient's rooms, rest homes, or private hospitals).⁷³ This statistic is important as none of the other previous international studies addressed adverse events outside of a hospital setting. While one cannot read too much into this statistic given the methodological limitations of the study, it is an important reminder that many adverse events occur outside of hospital settings and that further non-hospital studies are required.

Canadian Adverse Event Study

Although a study of adverse events among hospital admissions and day surgeries in Ontario from 1992 to 1997 was conducted and released in 1999⁷⁴, the first and only national Canadian retrospective adverse events study was released in May 2004.⁷⁵ The Canadian researchers randomly selected four acute care hospitals (one teaching hospital, one large community hospital and two small community hospitals) in each of five provinces (British Columbia, Alberta, Ontario, Québec and Nova Scotia). In total, the study reviewed 3745 charts and concluded that an adverse event occurred in

⁷² *Ibid.*

⁷³ *Ibid.*

⁷⁴ Duncan Hunter & Namrata Bains, "Rates of Adverse Events Among Hospital Admissions and Day Surgeries in Ontario from 1992 to 1997" (1999) 160 *Canadian Medical Association Journal* 1585.

⁷⁵ G. Ross Baker et al., "The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada" (2004) 170 *Canadian Medical Association Journal* 1678.

7.5% of hospital admissions in Canada.⁷⁶ Of the 255 patients who experienced one or more adverse events, 106 (41.6%) were judged to have one or more adverse events that was highly preventable.⁷⁷ In 39 of the patients, preventability was deemed to be “virtually certain”.⁷⁸ 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 with recovery within six months.⁷⁹ However, the Canadian Study also concluded that 5.2% of the adverse events resulted in permanent disability and 15.9% resulted in death.⁸⁰ When these results were adjusted, the researchers estimated that death would be associated with an adverse event in 1.6% of patients with similar hospitalizations in Canada.⁸¹ The researchers further estimated that the rate of preventable adverse events across all of the studied hospitals was 2.8% and the rate of deaths from preventable adverse events was .66%.⁸² By extrapolation, the researchers concluded that in 2000 between 141,250 and 232,250 of 2.5 million similar admissions to acute care hospitals in Canada were associated with an adverse event and that between 9250 and 23,750 deaths from adverse events could have been prevented.⁸³

The Canadian Study also identified a trend toward higher numbers of adverse events in patients in teaching hospitals as opposed to patients in small or large community hospitals. Although the authors dismiss the quality of care in teaching hospitals as a

⁷⁶ *Ibid.* at 1681.

⁷⁷ *Ibid.*

⁷⁸ *Ibid.*

⁷⁹ *Ibid.*

⁸⁰ *Ibid.* at 1681-1682.

⁸¹ *Ibid.* at 1682.

⁸² *Ibid.*

⁸³ *Ibid.* at 1684.

likely reason for the higher adverse event rate, this issue deserves further scrutiny in future studies. Given that inexperience of practitioners along with communication and systems failures have been identified as significant causes of medical error (discussed further below) it is not altogether surprising that large teaching hospitals would have a higher rate of adverse events. On the contrary, what is perhaps more surprising is the conclusion by the Canadian researchers that the rate of preventable adverse events did not vary significantly across the three types of hospitals. Whether patients are truly no more likely to suffer a preventable adverse event at a teaching hospital than a community hospital remains to be confirmed by future adverse event studies.

CAUSES OF MEDICAL ERROR

It is important to note at the outset of any discussion of the causes of medical error, that it is an extremely complex area with no real consensus. This is not surprising given the complexity of the medical system and that our true understanding of Medicine and the human body is still severely limited despite our considerable recent advances. Although researchers regularly publish studies of medical error, adequate epidemiological evidence is limited.⁸⁴ As a result of the complexity of the issue of causation in medical error, only a relatively brief overview of the main issues can be accomplished in this thesis.

One of the most fascinating aspects of medical error, and one that likely presents the

⁸⁴ Saul N. Weingart et al., "Epidemiology of Medical Error" (2000) 320 *British Medical Journal* 774.

most significant hurdle to increased patient safety, is the culture of the medical profession itself.⁸⁵ The primary reason why physicians, nurses and other health-care practitioners have not developed more effective methods of error prevention is that individual health-care providers have a great deal of difficulty dealing with human error when it occurs.⁸⁶ Health-care practitioners and physicians in particular are socialized and taught to strive for perfection and that errors are not acceptable. This culture of infallibility adds a tremendous amount of stress to physicians' practice and can lead to an insidious pressure to be intellectually dishonest, limit discussion of error and cover up mistakes rather than disclose them.⁸⁷ As will be discussed later, although physicians have clear legal and ethical duties to disclose medical errors, errors still often go undisclosed.

Having said that, one should not underestimate the tremendous negative impact that errors have on physicians and other health professionals. On the contrary, errors cause health professionals a significant amount of stress, anxiety and shame, and physicians in particular are often left isolated and feel unable to share their feelings with their peers.⁸⁸

⁸⁵ Jonathan B. VanGeest & Deborah S. Cummins, "An Educational Needs Assessment for Improving Patient Safety: Results of a National Study of Physicians and Nurses" National Patient Safety Foundation, White Paper Report, online: National Patient Safety Foundation <<http://www.npsf.org/download/edneedsasses.pdf>>.

⁸⁶ Lucian L. Leape, "Error in Medicine" (1994) 272 *Journal of the American Medical Association* 1851 at 1851.

⁸⁷ McIntyre N. & K.B. Popper, "The Critical Attitude in Medicine: The Need for a New Ethics" (1989) 287 *British Medical Journal* 1919; see also Edgar Pierluissi et al., "Discussion of Medical Errors in Morbidity and Mortality Conferences" (2003) 290 *Journal of the American Medical Association* 2838.

⁸⁸ John F. Christensen, Wendy Levinson & Patrick M. Dunn, "The Heart of Darkness: The Impact of Perceived Mistakes on Physicians" (1992) 7 *Journal of General Internal Medicine* 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 *Quality & Safety in Health Care* 13; Craig Pollack et al., "Helping Clinicians Find Resolution after a Medical

Another important contributing factor in medical error is the practical methods by which medicine is learned in our medical schools and teaching hospitals. Teaching of western medicine is based largely on hands-on training and is very focused on clinical skills training. It is also widely accepted within the medical profession that clinical experience is critical and “practice makes perfect”. Unfortunately, there are limited ways in which simulations, cadavers and “dummies” can be used for medical students, interns and residents to practice their skills. In addition, there is a resistance among the medical profession to utilize simulations as it goes against the traditional manner in which medicine is taught, as well as the conventional wisdom that practicing on live patients is the only way for medical students and residents to truly learn. As a result, regardless of the inherent risks of inexperience, every physician has to do a procedure for the first time and the patient, who may be harmed by a mistake by an inexperienced practitioner, is rarely provided with full information. However, it appears that the courts tacitly support the need for physicians to learn as it has been held by the Supreme Court of Canada that physicians do not have a duty to disclose their inexperience to their patients, including that they will be doing the particular procedure for the first time.⁸⁹

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

Error” (2003) 12 Cambridge Quarterly of Healthcare Ethics 203; and Albert W. Wu “Medical Error: The Second Victim. The Doctor Who Made the Mistake Needs Help Too” (2000) 320 British Medical Journal 726.

⁸⁹ *Hopp v. Lepp*, [1980] 2 S.C.R. 192.

expectations and highlights that Medicine is subject to the same limitations as are all human enterprises.⁹⁰ In fact it is telling that the titles of the three Parts of the book are “Fallibility”, “Mystery” and “Uncertainty”.⁹¹ Dr. Gawande’s book as well as Craig A. Miller’s book, *The Making of a Surgeon in the 21st Century*⁹² 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 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”.⁹³ 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.⁹⁴ 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.⁹⁵ 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.⁹⁶ Moreover, if a resident under the supervision of a senior

⁹⁰ Atul Gawande, *Complications: A Surgeon's Notes on an Imperfect Science* (New York: Picador, 2002).

⁹¹ *Ibid.*

⁹² Craig A. Miller, *The Making of a Surgeon in the 21st Century* (Nevada City: Blue Dolphin Publishing, 2004).

⁹³ *Supra* note 90 at 11-34.

⁹⁴ *Ibid* at 24.

⁹⁵ *Ibid* at 23.

⁹⁶ *Ibid* at 30.

physician makes an error, it is unlikely that the patient would be provided full information regarding the involvement of the resident in the error. Dr. Gawande also goes on to admit that in his personal experience he has refused to allow residents to be involved in the care of his son.⁹⁷ This double standard of care is common in the medical system and it is clear that physicians and their family and friends are regularly provided with preferred care and choices of caregivers that the general public is not. While this is understandable from a human perspective, it is highly questionable from a professional perspective and certainly highlights the inherent tension between the rights of patients to the best possible care and the need to provide novice physicians with experience.

The issue of the need to educate novice physicians is also problematic from a medical error perspective, given that the inexperience of the practitioner can be one of the contributing factors in medical error.⁹⁸ While it is true that, given our current technology, revolutionary change to the way that medicine is taught is a long way in the future, significant strides can be made in reducing the impact of medical errors by inexperienced practitioners. As a starting point, immediate and significant steps must be taken in making systemic changes to allow experienced supervisors more time to focus on teaching and supervision of more inexperienced practitioners. Shortening of shifts, reducing patient workload and reducing the amount of on-call time would all go a long way to allowing experienced supervisors more time and energy to properly attend to their teaching and supervision responsibilities.

⁹⁷ *Ibid* at 31-32.

⁹⁸ Armando Hevia & Cheri Hobgood, "Medical Error During Residency: To Tell or Not to Tell" (2003) 42 *Annals of Emergency Medicine* 565; see also Reason *supra* note 21.

In addition, relatively minor changes to the working hours of interns and residents (and by extension all “in-hospital” physicians) could have a substantial impact on the incidence of medical error. Although previous studies on physician fatigue recognized the ill effects of sleep deprivation generally and on fine motor skills in particular, the studies were hesitant to draw a clear connection between physician fatigue and medical error.⁹⁹ It seems to defy logic to suggest that there is no connection between fatigue and medical error and in fact a recent study of interns in intensive care units has shown that a clear and disturbing connection exists.¹⁰⁰ The researchers concluded that relatively minor adjustments in the work and sleep schedules of interns, reduced the rate of attentional failures by more than 50%.¹⁰¹ In a companion study, it was also concluded that interns on the traditional schedule made substantially more serious medical errors than interns working on a modified work schedule.¹⁰² According to the researchers, interns made 35.9% more serious medical errors during the traditional schedule than during the modified schedule, including 56.6% more non-intercepted serious errors.¹⁰³ In addition, interns made 20.8% more serious medication errors, and also made 5.6 times as many serious diagnostic errors during the traditional schedule than during the modified schedule.¹⁰⁴ In their conclusions, the researchers could not resist blandly stating the obvious that

⁹⁹ Troyen A. Brennan & Michael J. Zinner, “Residents’ Work Hours: A Wake Up Call?” (2003) 15 *International Journal for Quality in Health Care* 107 at 107.

¹⁰⁰ Steven W. Lockley et al., “Effect of Reducing Interns’ Weekly Work Hours on Sleep and Attentional Failures” (2004) 351 *New Eng. J. Med.* 1829.

¹⁰¹ *Ibid.*

¹⁰² Christopher P. Landrigan et al., “Effect of Reducing Interns’ Work Hours on Serious Medical Errors in Intensive Care Units” (2004) 351 *New Eng. J. Med.* 1838.

¹⁰³ *Ibid.* at 1838.

¹⁰⁴ *Ibid.*

“eliminating extended work shifts and reducing the number of hours interns work per week can reduce serious medical errors in the intensive care unit.”¹⁰⁵

The results of these studies and others are frightening and should be a “wake-up call” for physicians and hospital administrators that fatigue caused by overwork and inhumane schedules is an important and one of the most easily addressed causes of medical error. Unfortunately, this information is not a revelation for the medical community and to date it has failed to take adequate steps to respond to the problem. Having said that, stating that over work and fatigue of practitioners is one of the most easily addressed causes of medical error admittedly is a relative statement given the complexity of other systemic changes. It is recognized that profound changes will have to be made by the medical and other health professions to facilitate significant improvements to patient safety. In addition, hospital administrators and government funders will also have to be willing to implement procedural and economic changes. Hopefully, the current political climate and focus on health care will provide sufficient impetus to promote positive action.

In addition to its impact on the attentional errors and supervision of inexperienced practitioners, systemic problems of inadequate funding and understaffing are in and of themselves significant contributing factors to medical error. For example, a recent study concluded that the ratio of registered nurses as opposed to other lesser trained

¹⁰⁵ *Ibid.*

health practitioners has a direct correlation with patient safety.¹⁰⁶ According to the researcher, there are distinct differences between outcomes in facilities with the highest versus the lowest levels of registered nurses, where better staffed hospitals have significantly lower rates of adverse events.¹⁰⁷

It is also likely that shortage of beds, equipment, scanners and properly trained staff are also significant contributors to adverse events and medical error, although there is little specific empirical evidence on this issue. Too many years of funding shortages and cutbacks have left health-care professionals straining to keep the fragments of the health-care system from coming apart at the seams. Far too much reliance has been placed on superhuman efforts by health-care practitioners working long hours, extensive overtime and endless “on-call” shifts. It should come as no surprise that fatigue, compressed shift change schedules and unreasonable demands have a significant impact on patient safety. In fact, it would not be an understatement to suggest that one of the most serious risks that patients are exposed to when entering the hospital is the fatigue of the health-care providers looking after them.

Another significant contributor to medical error and obstacle to increased patient safety is the traditional hierarchical structure of the medical profession. This structure discourages “underlings” from speaking up to “superiors” regarding perceived errors or alternate methods of treatment, and can lead to significant communication

¹⁰⁶ Sean P. Clarke, “Patient Safety Series, Part 2 of 2: Balancing Staffing and Safety” (2003) 34 Nursing Management 44.

¹⁰⁷ *Ibid.*

failures.¹⁰⁸ This historical authoritative structure, or “authority gradient”, makes it extremely difficult for medical students, residents, nurses and other health practitioners to speak up to a specialist or superior regarding errors or imminent errors. In the professional socialization process in medical education, physician trainees are inclined to value their seniors’ experience and responsibility over their own knowledge, and are also willing to give deference to personal authority over scientific merit in clinical decisions.¹⁰⁹ In addition, there is still a significant portion of the medical community that believes that junior team members should not question decisions made by more senior members.¹¹⁰ This is true notwithstanding the fact that junior team members often have a lower caseload, less responsibility and more knowledge and information about the patient. As a result, in many cases, these junior team members have a better feel for the clinical situation and greater understanding of the facts. Supervisors and superiors therefore discourage or dismiss the input of junior team members at their, and the patient’s, peril.

Aviation, another industry that holds many lessons for the medical profession¹¹¹, has learned a number of painful lessons regarding the dangers of these authority gradients. Studies in Aviation show that when officers of different ranks occupy a

¹⁰⁸ Kathleen M. Sutcliffe, Elizabeth Lewton & Marilynn M. Rosenthal, “Communication Failures: An Insidious Contributor to Medical Mishaps” (2004) 79 *Academic Medicine* 186.

¹⁰⁹ Karen S. Cosby & Pat Croskerry, “Profiles in Patient Safety: Authority Gradients in Medical Error” (2004) 11 *Academic Emergency Medicine* 1341 at 1342.

¹¹⁰ Sexton J.B., Thomas E.J. & Helmreich R.L., “Error, Stress, and Teamwork in Medicine and Aviation: Cross Sectional Surveys” (2000) 320 *British Medical Journal* 745.

¹¹¹ R. Wilf-Miran et al., “From Aviation to Medicine: Applying Concepts of Aviation Safety to Risk Management in Ambulatory Care” (2003) 12 *Quality & Safety in Health Care* 35; see also Charles Vincent, “Understanding and Responding to Adverse Events” (2003) 348 *New Eng. J. Med.* 1051; Lucian L. Leape, Donald M. Berwick & David W. Bates, “What Practices Will Most Improve Safety? Evidence-Based Medicine Meets Patient Safety” (2002) 288 *Journal of the American Medical Association* 501; and Robert L. Helmreich, “On Error Management: Lessons from Aviation” (2000) 320 *British Medical Journal* 781.

cockpit, the likelihood of a mishap increases.¹¹² In the past, many junior pilots were hesitant to relay concerns about safety to senior pilots, and when they did offer their concerns, senior ranking officers would often dismiss them without serious consideration.¹¹³ These difficulties with authority gradients were cited as factors in a number of airplane crashes, including the runway collision of two airliners at Tenerife in 1977 that killed 583 people.¹¹⁴ In another example, critical information known by NASA engineers failed to reach more senior authorities responsible for making the final decision to launch the space shuttle Challenger, leading to the disaster.¹¹⁵ In Medicine, similar mistakes and communication breakdowns occur frequently often leading to serious consequences or death for patients.

In order to truly make significant advances in reducing medical error the patient safety movement must examine other industries like aviation, space operations and nuclear power generation and incorporate the human error lessons already learned. In particular, the patient safety movement must look to the wealth of information and research into human error that is available and put it to use in modifying the health care system. Significant advances have been made in human factors research in other industries and many of the concepts are applicable to health care.¹¹⁶ One of the primary lessons that has been learned is that the enemy of safety is complexity.¹¹⁷ In order to develop a safer health care system, research must be conducted in order to

¹¹² *Supra* note 109.

¹¹³ *Ibid.*

¹¹⁴ *Ibid.*

¹¹⁵ *Ibid.*

¹¹⁶ David Woods, "Behind Human Error: Human Factors Research to Improve Patient Safety" online: Cognitive Systems Engineering Laboratory - Ohio State University < http://csel.eng.ohio-state.edu/woods/medicine/patientsafety/HFESinput_full_summit.pdf >

¹¹⁷ *Ibid.* at 6.

search out the sources of complexity, understand the current methods being used to cope with this complexity and develop better methods to reduce this complexity and increase patient safety.¹¹⁸

The health-care industry has also traditionally been reactive as opposed to proactive when dealing with human error. It has generally taken a serious adverse event to focus attention on a particular system and mobilize efforts to make changes to improve patient safety. What is required is a paradigm shift in the health-care system towards a prospective examination of our systems to identify, isolate and modify potential problems *before* they cause harm to patients. Given the complexity of our health care systems, in order to understand episodes of failure one must first conduct a detailed examination of how health-care providers learn and adapt to create safety in a system fraught with hazards and potential for error.¹¹⁹

In addition to an increased sensitivity to error issues, health care institutions need to look at technological advances in error prevention and error reporting.¹²⁰ A primary example of our failure in this regard is the lack of an electronic health record in most Canadian hospitals. While an electronic health record is not the panacea of reducing medical error, it would directly and substantially reduce the limited category of medical errors caused by a lack of access to current and historical patient records. In addition, when human error researchers examine the typical human interface of

¹¹⁸ *Ibid.* at 6.

¹¹⁹ *Ibid.* at 4.

¹²⁰ D. Tuttle et al., “Electronic Reporting to Improve Patient Safety” (2004) 13 *Quality & Safety in Health Care* 281; see also *ibid.* at 7.

computer information systems and computerized devices in health-care, they are often shocked at the complexity and the amount of training required to effectively use the computer systems.¹²¹ In order to reduce the incidence of error, computer systems in the health-care industry must be substantially modified to become more user-friendly and less complex. If this is done, these computer systems can become a part of the patient safety solution as opposed to a contributor to medical error.

In addition, governmental authorities and the Canadian Patient Safety Institute should continue the effort to determine whether a national error reporting system would help promote and encourage patient safety initiatives in Canada.¹²²

CONCLUSIONS ON MEDICAL ERROR

The current intense focus on medical error is particularly striking especially given that other professions that train their members in a similar fashion appear to go relatively unnoticed from an error perspective. One does not see, for example, national institutes being set up to examine the consequences of architectural error or legal error. While these professions have the ability to cause potential safety problems and significant financial losses, public and governmental attention to the

¹²¹ *Supra* note 116 at 7.

¹²² For a discussion on the issue of national error reporting systems and the public release of error data, see H.T.O. Davies, "Public Release of Performance Data and Quality Improvement: Internal Responses to External Data by U.S. Health Care Providers" (2001) 10 *Quality in Health Care* 104; Karin Janine Berntsen, "How Far Has Healthcare Come Since "To Err is Human"? Exploring the Use of Medical Error Data" (2004) 19 *Journal of Nursing Care & Quality* 5; Maxine M. Harrington, "Revisiting Medical Error: Five Years after the IOM Report, Have Reporting Systems Made a Measurable Difference?" (2005) 15 *Health Matrix* 329; and Joshua G. Zivin & Alexander S. P. Pfaff, "To Err on Humans is not Benign: Incentives for Adoption of Medical Error-Reporting Systems" (2004) 23 *Journal of Health Economics* 935.

errors of these and other professions has been noticeably absent. Every architect must design their first building and every lawyer must handle their first case; what makes Medicine so different? One obvious partial explanation is that medical errors are much more likely to cause physical injury to their patients. However, in my view, a fuller explanation involves examining our relationships with our physicians and recognizing the intensely personal nature of these relationships. Every time a patient sees a physician for treatment, it involves a partial surrender of autonomy. In our lives generally, most of us attempt to exercise control over our destiny and do not surrender ourselves to the care of others easily. Yet it is truly extraordinary that as patients we do this routinely and often without question. As a result of this partial surrender of control, we are totally vulnerable to the mistakes or errors in judgement made by others. Accordingly, physicians and other health care providers hold a special position of trust that is intensely personal to their patients and when that trust is broken through error or misadventure, it can cause similarly intense reactions by those patients and their families.

As part of a comprehensive strategy to reduce medical error and increase patient safety, all health-care practitioners and administrators need to be familiar with the individual and systemic aspects of medical error. In responding to medical errors when they occur, a punitive, blame culture, is counterproductive from a patient safety perspective. Unfortunately, the tendency of past responses to medical error has been to focus on individuals and to avoid a critical analysis of the systemic causes of medical error and a recognition that most errors are caused by failures of systems and

not individuals.¹²³ This tendency must be abandoned in favour of a systemic approach to error analysis that focuses on how the system could have better protected the patient, not on which individual health care provider was most to blame.

Moreover, “frontline” health practitioners and physicians should be trained in “error wisdom” and must learn to accept that errors are inevitable. This acceptance is not surrender; on the contrary, it should be a rallying cry for the entire health system to be ever vigilant and to “harden” their systems to errors. While it is true that errors are inevitable in a fallible human system like Medicine, it is also true that most errors are avoidable. Accordingly, there must also be a general recognition within the health care system that errors do not generally just “occur” they “evolve” and there are often a number of opportunities for avoidance prior to harm coming to the patient. Moreover, the health-care system must proactively search out the potential for errors and must not wait for harm to come to patients before making systemic changes. High reliability health organizations create safety by anticipating and planning for unexpected adverse events.¹²⁴ In addition, these organizations continue to invest in anticipating the changing potential for the failure of their systems because they appreciate that their knowledge is imperfect and the health-care environment continues to change.¹²⁵ Health-care organizations must also avoid the pitfalls of hindsight bias by recognizing that all errors seem more straightforward when they are

¹²³ William C. Deskin & Robert E. Hoyer, “Another Look at Medical Error” (2004) 88 *Journal of Surgical Oncology* 122; see also Lucian L. Leape, “Errors are Not Diseases: They are Symptoms of Diseases” (2004) 114 *Laryngoscope* 1320; and Lucian L. Leape & Donald M. Berwick, “Five Years after *To Err Is Human*: What Have We Learned?” (2005) 293 *Journal of the American Medical Association* 2384.

¹²⁴ *Supra* note 116 at 15-16.

¹²⁵ *Ibid.* at 16.

examined retrospectively.¹²⁶ Every effort must be made when conducting reviews of adverse events to examine the system failure from the perspective of the health-care providers of the time of the error, and with only the knowledge that they would have had at the time.

In addition, it must also be recognized that every medical error, adverse event and near miss provides critical patient safety information. As a result, in order for significant strides to be made in reducing medical error, every error and near miss needs to be fully discussed, investigated and acted upon by the medical professionals involved as well as by hospital administration. Moreover, procedures and policies to share this information with other institutions across the country must be developed and implemented. If this is done faithfully, institutions in one location can learn from unfortunate adverse events that occur across the country, and can prevent them from occurring in the future. However, in order to learn anything from errors and near misses, they must first be disclosed so they can be discussed openly. Accordingly, the issue we turn to in the second part of this thesis is the challenge that health professionals face to ensure that all adverse events are appropriately disclosed.

¹²⁶ *Ibid.* at 17.

PART II – DISCLOSURE OF MEDICAL ERROR

INTRODUCTION

As we have seen above, patient safety and medical error is an incredibly complex area and is affected by the medical and other health professions, the legal system, multiple economic factors as well as complicated political issues. In this part, the unhappy relationship between health professionals and the law in the context of disclosure of medical error will be discussed. In particular, the ethical and legal implications of the disclosure of medical error will be analyzed. 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 part 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 thesis.¹²⁷

¹²⁷ For 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” 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 *British Medical Journal* 759; Lucian L. Leape, “Reporting of Adverse Events” (2002) 347 *New Eng. J. Med.* 1633; and Gautham Suresh et al., “Voluntary Anonymous Reporting of Medical Errors for Neonatal Intensive Care” (2004) 113 *Pediatrics* 1609.

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.¹²⁸ Harm committed with the intent of healing is no less prohibited by the principle of nonmaleficence than malicious harm.¹²⁹ 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

¹²⁸ Erin 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>>.

¹²⁹ *Ibid.*

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. Ethicists clearly endorse the full disclosure of medical error to patients.¹³⁰ Moreover, 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.¹³¹ Nevertheless, it appears from the available evidence that full disclosure of medical error may be uncommon.¹³² For example, in the Wu et al study, 76% of the physicians interviewed said they had not disclosed a serious error to a

¹³⁰ See for example, Rosner F. et al., "Disclosure and Prevention of Medical Errors: Committee on Bioethical Issues of the Medical Society of the State of New York" (2000) 160 *Archives of Internal Medicine* 2089; see also Banja J., "Moral Courage in Medicine - Disclosing Medical Error" (2001) 17 *Bioethics Forum* 7; Philip C. Hebert, Alex V. Levin & Gerald Robertson, "Bioethics for Clinicians: 23. Disclosure of Medical Error" (2001) 164 *Canadian Medical Association Journal* 509; and R. Lamb, "Open Disclosure: The Only Approach to Medical Error" (2004) 13 *Quality and Safety in Health Care* 3.

¹³¹ Amy 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 *Archives of Internal Medicine* 2565; see also Thomas H. Gallagher et al., "Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors" (2003) 289 *Journal of the American Medical Association* 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 *British Medical Journal* 640; Cherri Hobgood et al., "Medical Errors - What and When: What Do Patients Want to Know?" (2002) 9 *Academic Emergency Medicine* 1156; and Vincent C.A., Pincus T. & Scurr J.H., "Patients' Experience of Surgical Accidents" (1993) 6 *Quality Health Care* 277.

¹³² See for example, Blendon R.J. et al., "Views of Practicing Physicians and the Public on Medical Errors" (2002) 347 *New Eng. J. Med.* 1933; See also Hingorani et al., *supra* note 131; Albert W. Wu et al., "Do House Officers Learn from their Mistakes?" (1991) 265 *Journal of the American Medical Association* 2089; Novack D.H. et al., "Physicians' Attitudes Toward Using Deception to Resolve Difficult Ethical Problems" (1989) 261 *Journal of the American Medical Association* 2980; Thomas H. Gallagher & Wendy Levinson, "Disclosing Harmful Medical Errors to Patients: A Time for Professional Action" (2005) 165 *Archives of Internal Medicine* 1819 at 1819; and Rae M. Lamb et al., "Hospital Disclosure Practices: Results of a National Survey" (2003) 22 *Health Affairs* 73.

patient.¹³³ 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.¹³⁴ Perhaps not surprisingly, the researchers also found that the likelihood of disclosure decreased as the severity of the harm to the patient increased.¹³⁵

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.¹³⁶ 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.¹³⁷ 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

¹³³ Wu et al., *supra* note 132.

¹³⁴ Matthew P. Sweet & James L. Bernat, "A Study of the Ethical Duty of Physicians to Disclose Errors" (1997) 8 *The Journal of Clinical Ethics* 341.

¹³⁵ *Ibid.*

¹³⁶ Gallagher et al., *supra* note 131 at 1003; see also Scott B. Ransom et al., "Reduced Medicolegal Risk by Compliance with Obstetric Clinical Pathways: A Case - Control Study" (2003) 101 *Obstetrics & Gynecology* 751 at 751.

¹³⁷ Gallagher et al., *ibid* at 1006.

minimum standard for error disclosure does not yet exist.¹³⁸ 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”.¹³⁹ Gallagher's apparent justification for arguing against a minimum standard for error disclosure is that there is a lack of consensus about the scope of disclosure and the variable nature of the desire of patients to receive health information.¹⁴⁰ 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.¹⁴¹ 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, and a perceived lack of

¹³⁸ 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>>.

¹³⁹ *Ibid.*

¹⁴⁰ *Ibid.*

¹⁴¹ American Medical Association 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>>.

consensus within the medical community, 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, and both have fiduciary responsibilities to their “clients”, 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.¹⁴²

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

¹⁴² American Medical Association 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/amal/pub/upload/mm/369/ceja_1203c.pdf>.

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*.¹⁴³ 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, regardless of whether the harm was caused by a health care error. 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.¹⁴⁴

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. Interestingly, the Opinion states that this responsibility exists even in the absence of a physician-patient relationship.¹⁴⁵ The Opinion also calls on physicians to participate in the development of reporting mechanisms that emphasize education and systems change.¹⁴⁶ Specifically, physicians are encouraged to: help establish and participate fully in effective, confidential and legally protected reporting mechanisms; develop means for objective review and analysis of reports regarding errors and to conduct appropriate

¹⁴³ *Ibid.*

¹⁴⁴ *Ibid.*

¹⁴⁵ *Ibid.*

¹⁴⁶ *Ibid.*

investigations into the causes of harm to patients; ensure that the investigation of causes of harm, and the review of error reports that result in 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 in order to prevent harm to patients.¹⁴⁷ 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.¹⁴⁸ Finally, the Opinion encourages physicians to seek changes in the current legal system to assure 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.”¹⁴⁹ While these 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 addition, as will be discussed below, there is a significant role to be played by the legal profession and legal system to facilitate the full disclosure of medical error by physicians.

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 principles specifically

¹⁴⁷ *Ibid.*

¹⁴⁸ *Ibid.*

¹⁴⁹ *Ibid.*

enunciated.¹⁵⁰ 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.”)¹⁵¹

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.”¹⁵² 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. Unfortunately, unlike the AMA Opinion discussed above, the CMA *Code of Ethics* does not provide any discussion or direction about the scope of the ethical duty to disclose medical error. However, although some further direction in the CMA *Code of Ethics* as to the scope of the duty would have been preferable, it is not strictly necessary. Even without this further direction, physicians should be able to conduct themselves in a manner which does not conflict with these ethical obligations.

In addition, several provincial Colleges of Physicians and Surgeons have instituted

¹⁵⁰ Gerald B. Robertson, “When Things Go Wrong: The Duty to Disclose Medical Error” (2002) 28 Queen’s L.J. 353 at 354.

¹⁵¹ *Ibid.*

¹⁵² 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>.

policies for their members regarding the disclosure of medical error.¹⁵³ For example, in February 2003, the Council of the Ontario College of Physicians and Surgeons (CPSO) approved a policy entitled “Disclosure of Harm”.¹⁵⁴ 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.¹⁵⁵ 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.¹⁵⁶

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 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.¹⁵⁷

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. However,

¹⁵³ As of January 2006, the Colleges in Ontario, Newfoundland, New Brunswick, Saskatchewan & Manitoba have all instituted disclosure policies.

¹⁵⁴ 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>>.

¹⁵⁵ *Ibid.*

¹⁵⁶ *Ibid.*

¹⁵⁷ *Ibid.*

leaving the determination of whether harm occurred, and therefore whether to disclose, solely in the discretion of the individual physician is potentially problematic. 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 these circumstances, leaving the subjective determination of whether harm resulted from error in the hands of the physician who erred raises obvious ethical concerns.

Of course, 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 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 questionable whether it would be ethical to not disclose the error to the patient even though it is unclear whether their health or quality of life was affected.

In setting out its “Disclosure of Harm” policy, the CPSO also stated five key principles to assist physicians in these difficult situations:

1. The patient is entitled to be kept informed about his or her health care. This includes information about harm suffered in the course of receiving health care.
2. The obligation to disclose harm flows from the fiduciary nature of the physician-patient relationship. It is part of the physician's obligation to maintain the patient's best interests and the patient's entitlement to professional and ethical health care. This entitlement arises primarily out of respect for the patient as a person. Disclosure of harm not only respects the autonomy of the patient, it also ensures that the patient can access timely and appropriate interventions for the harm suffered.
3. The patient is entitled to be informed about harm suffered even when such disclosure might prompt a complaint or a claim. Failure to keep the patient informed of all pertinent health information, except by the choice of the patient, is a failure to respect the autonomy and the well-being of the patient.
4. Professional judgment is required to determine when an unintended outcome of care does, or can be reasonably expected to negatively impact a patient's health and/or quality of life and therefore is significant enough to require disclosure.
5. Not all harm is preventable. Harm can arise from a variety of causes and is not necessarily an indicator of substandard care.¹⁵⁸

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.¹⁵⁹

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

¹⁵⁸ *Ibid.*

¹⁵⁹ *Ibid.*

disclosure may cause further harm.¹⁶⁰ The CPSO Council advocates a brief, non-technical factual description of what occurred and suggests the avoidance of speculation.¹⁶¹ 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.¹⁶² Unfortunately, the legal validity of the last statement based on the current law in Canada is questionable.

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 draft stage and has not been publicly released, it would not be appropriate to discuss it in detail.¹⁶³ However, some of the key aspects of the proposed Framework that are unlikely to change can be mentioned.

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

¹⁶⁰ *Ibid.*

¹⁶¹ *Ibid.*

¹⁶² *Ibid.*

¹⁶³ 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>

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 primarily focuses on adverse events that cause harm and would 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 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 is that the patient be provided with an apology or expression of regret as an integral part of the disclosure conversation. This aspect of the Framework 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”.¹⁶⁴ 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 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

¹⁶⁴ A completely hypothetical example of course.

and above a bare expression of regret.¹⁶⁵

Although there are significant concerns regarding the implementation of the proposed HQCA Framework, it should be recognized that it 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 the proposed 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 1989.¹⁶⁶ This was followed soon after by the Sunnybrook & Women's College Health Sciences Centre in Toronto.¹⁶⁷ Another of the McGill University Health Centre ("MUHC") hospitals instituted a policy in 1990 and the entire MUHC group did so in 2001.¹⁶⁸ In addition, the entire University

¹⁶⁵ 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.

¹⁶⁶ A. Peterkin, "Guidelines Covering Disclosure of Errors Now in Place at Montreal Hospital", (1990) 142 *Canadian Medical Association Journal* 984.

¹⁶⁷ Robertson, *supra* note 150 at 361.

¹⁶⁸ Tracey M. Bailey & Nola M. Reis, "Legal Issues in Patient Safety: The Example of Nosocomial Infection" (2005) 8 *Healthcare Quarterly* 140 at 143.

Health Network in Toronto also put a formal protocol in place in May of 2005.¹⁶⁹ 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 they remain unsatisfied with the explanation given or that no individuals were held personally accountable for the error. 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.”¹⁷⁰ Notwithstanding these laudable actions by HHSC, the Lewis family remained unsatisfied and commenced a lawsuit.¹⁷¹ In a public statement, Mr. Lewis used the analogy of a drunk driver killing

¹⁶⁹ *Ibid.*

¹⁷⁰ Ken Kilpatrick, “Apology Marks New Era in Response to Medical Error, Hospital Says” (2003) 168 *Canadian Medical Association Journal* 757.

¹⁷¹ *Ibid.*

a child with his vehicle and having the insurance company apologize.¹⁷² According to Mr. Lewis: “There's really no gratification in it. Personal accountability and responsibility is nowhere in the system.”¹⁷³ 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 and sensitive 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.

¹⁷² *Ibid.*

¹⁷³ *Ibid.*

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.)¹⁷⁴ 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 consent principles remain part of the analysis, 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.¹⁷⁵ 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

¹⁷⁴ Ellen I. Picard & Gerald B. Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 3rd ed. (Toronto: Carswell, 1996) at 170.

¹⁷⁵ *Shobridge v. Thomas*, [1999] B.C.J. No. 1747 at para. 95 (B.C.S.C.) [*Shobridge*]

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.¹⁷⁶ Québec has also approved several professional codes of ethics (which include duties to disclose) through legislation thus giving them the force of law.¹⁷⁷ 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 case to expressly enunciate this duty was *Stamos v. Davies*.¹⁷⁸ 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.

¹⁷⁶ R.S.Q., c. S-4.2.

¹⁷⁷ *Supra* note 168 at 142.

¹⁷⁸ (1985), 52 O.R. (2d) 10 (H.C.) [*Stamos*]; see also *Kiley-Nikkel v. Danais* (1992), 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.).

In *Stamos*, the Court based its analysis generally on informed consent principles and held that there was a legal duty to disclose the error.¹⁷⁹ 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 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.¹⁸⁰

In addition to informed consent principles, 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.¹⁸¹ 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 an error occurs during the patient's treatment.¹⁸²

In *Vasdani*, the defendant physician operated on the wrong level of the plaintiffs

¹⁷⁹ *Stamos, ibid.*

¹⁸⁰ *Ibid.*

¹⁸¹ *McInerney v. MacDonald*, [1990] 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.

¹⁸² See for example, *Vasdani v. Sehmi*, [1993] O.J. No. 44 at para. 33 (Gen. Div.) [*Vasdani*]; *Gerula v. Flores* (1995), 126 D.L.R. (4th) 506 at 525-526 (Ont. C.A.) [*Gerula*] and *Shobridge*, *supra* note 175 at paras. 98-100.

back.¹⁸³ 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.¹⁸⁴ 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. Ultimately, the Court refused to award damages except for the delay caused to the plaintiff's ability to bring his claim.

In *Gerula*, the defendant physician also operated on the wrong portion of the plaintiffs back.¹⁸⁵ 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

¹⁸³ *Vasdani*, *ibid.* at para. 28.

¹⁸⁴ *Ibid.* at paras. 38-41.

¹⁸⁵ *Gerula*, *supra* note 182 at 509.

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 damages are appropriate and went on to award \$40,000 in punitive damages as a result of the physician's dishonest conduct.¹⁸⁶

In *Shobridge*, the defendant physician, Dr. Thomas, performed a presacral neurectomy on Ms. Shobridge on September 13, 1995.¹⁸⁷ 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. Over the next few months Ms. Shobridge suffered from persistent infections and severe pain and 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.¹⁸⁸ 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

¹⁸⁶ *Gerula, supra* note 182 at 526-527.

¹⁸⁷ *Shobridge, supra* note 175.

¹⁸⁸ *Ibid.* at paras. 24-26.

to the abdominal roll in his operative report for the December 4, 1995 surgery.¹⁸⁹ 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 made no attempt to 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.¹⁹⁰

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 anonymous example to raise a concern about using non radio-opaque sponges and gauze. It was only when this supervisor pressed the issue and asked to meet with the surgeon involved that the matter moved towards disclosure. Subsequently, Dr. Thomas met 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.¹⁹¹ While the issue of an apology will be discussed further below, this case appears to be one of those cases

¹⁸⁹ *Ibid.* at para. 27.

¹⁹⁰ *Ibid.* at para. 32.

¹⁹¹ *Ibid.* at para. 42.

where there would have been very little legal downside to apologize and it could have had a significant impact on the well being of the patient and their 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 little or no impact on the ultimate outcome of the litigation. In addition, a timely explanation and apology would likely have prevented the aggravated and punitive damages awarded in this case.

Not surprisingly, 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 the conduct of the defendant physician in trying to conceal the error, the Court awarded aggravated damages of \$25,000 and punitive damages of \$20,000.¹⁹²

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.¹⁹³ 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.* They were anxious that he do so. They gave him time to do the obviously right thing. When it became apparent that Dr. Thomas was not going to tell the truth, Nurse Toovey constructed a scenario which she believed

¹⁹² *Ibid.* at paras. 138 and 144.

¹⁹³ *Ibid.* at para. 95.

would encourage Dr. Thomas to reveal the discovery of the recovered abdominal roll. [emphasis added]¹⁹⁴

Given that the court in *Shobridge* also found that the OR 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.¹⁹⁵ 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 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 did not extend to the nurses or the hospital. However, as a fiduciary, Dr. Thomas did have a clear obligation to disclose the error to his patient.

¹⁹⁴ *Ibid.*

¹⁹⁵ *Supra* note 174 at 366-367.

While fiduciary obligations have not been imposed on nurses and hospitals in Canada as of yet, in an appropriate case, 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.

In addition to a logical inconsistency, 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*.¹⁹⁶ 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 is told that a quantity of blood from a donor will be introduced into his system. He may ask about the risk of AIDS and so forth and will be entitled to straight answers. He consents. Suppose that, by accident, he is given a quantity of air as well as blood and suffer 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? [emphasis added]¹⁹⁷

This analysis has been cited with approval by Justice Krever in *Stamos*.¹⁹⁸ However, in that case, Justice Krever made no comment about the potential duty of the hospital

¹⁹⁶ [1985] 2 All ER 385 [*Lee*].

¹⁹⁷ *Ibid.* at 389-390.

¹⁹⁸ *Stamos*, *supra* note 178.

to disclose the error.

In the end, it remains 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. Prudent nursing managers and hospital administrators should keep this potential legal duty in mind 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. There is no 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”. 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.

For example, consider the potassium chloride cases at the Foothills Medical Centre discussed in the introduction to this thesis. 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. 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.

A more difficult scenario would be in circumstances where it is unclear whether harm was caused to the patient as a result of an error. For example, consider a situation where a surgeon nicks a blood vessel as a result of a lapse in attention during a surgery. However, the surgeon is able to repair the damage and the rest of the surgery

is completed uneventfully. The patient then recovers from the surgery normally and has suffered no discernible pain or other consequence from the surgical error. Is there a legal duty to disclose in this situation? Depending on how one defines “harm”, it could be argued that the patient suffered harm as a result of the surgical mistake and the need for repair. It could also be argued that the patient suffered no harm given there were no negative consequences as a result of the mistake. In any event, it is likely that a legal duty to disclose exists in these circumstances, as the surgical mistake is likely something that a reasonable person in the circumstances of the patient would want to be told about. In addition, given that the physician did something to the patient that was not anticipated prior to the surgery, the surgeon, as a fiduciary, likely has an obligation to advise their patient of the mistake. From a practical perspective, there is little legal downside to disclosing the error in circumstances of no harm or “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.¹⁹⁹ The legal duty is only to advise the patient as to what occurred, in a factual sense.²⁰⁰ 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

¹⁹⁹ *Fehr v. Immaculata Hospital*, [1999] A.J. No. 1317 at para. 34 (Q.B.) (QL), 1999 ABQB 865.

²⁰⁰ *Ibid.*

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.

BARRIERS TO DISCLOSURE & NON-DISCLOSURE AS A CONTRIBUTOR TO MEDICAL ERROR

Now that it has been shown that there has existed for some time, both an ethical and legal duty to disclose medical error, what must be examined is non-disclosure as a cause of medical error, the reasons for the prevalence of non-disclosure, and the barriers to full disclosure that exist in the medical and legal systems.

As stated above, the causes of medical error are multifactorial and complex. For the purposes of this discussion however, the most relevant contributing factor to medical error is the failure by the medical profession and other health professionals to openly report and discuss medical errors when they occur. The failure by the medical profession and other health professionals to effectively use errors as a learning experience and to adequately communicate the errors and their potential resolutions 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 exaggerated fear of litigation.

In medical school and residency, physicians are taught and socialized to strive for error-free practice.²⁰¹ In diagnosis, treatment and everyday hospital practice, perfection is emphasized and the message is clear: mistakes are unacceptable.²⁰² 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.²⁰³ 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.²⁰⁴

...

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.²⁰⁵

²⁰¹ *Supra* note 86; see also Cheri Hobgood, Amando Hevia & Paul Hinchey, "Profiles in Patient Safety: When an Error Occurs" (2004) 11 *Academic Emergency Medicine* 766.

²⁰² *Supra* note 86.

²⁰³ *Ibid.*

²⁰⁴ Chassin M. "Is Healthcare Ready for Six-Sigma Quality?" (1998) 76 *Milbank Quarterly* 565 at 576.

²⁰⁵ *Ibid.* at 577.

In addition, clinical professors, usually specialists and experts in their fields, reinforce this concept of infallibility.²⁰⁶ 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 done, every new generation of physicians 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.²⁰⁷

In addition, it is 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.²⁰⁸ 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.

²⁰⁶ *Supra* note 86 at 1852.

²⁰⁷ N. Berlinger & A.W. Wu, “Subtracting Insult from Injury: Addressing Cultural Expectations in the Disclosure of Medical Error” (2005) 31 *Journal of Medical Ethics* 106.

²⁰⁸ McIntyre & Popper, *supra* note 87.

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.²⁰⁹ 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.²¹⁰ 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.²¹¹

The absence of fallibility as an integral part of physicians' concepts of their profession is at least in part a product of the lack of serious discussion of medical error in medical training and practice.²¹² In order for medical error to be addressed in any meaningful way, physicians must be allowed to be human and must be provided with

²⁰⁹ *Supra* note 87; see also Richard M. Goldberg et al., “Coping with Medical Mistakes and Errors in Judgment” (2002) 39 *Annals of Emergency Medicine* 287; Kirsten G. Engel, Marilyn Rosenthal and Kathleen M. Sutcliffe, “Residents' Responses to Medical Error: Coping, Learning, and Change” (2006) 81 *Academic Medicine* 86; and Chantal Brazeau, “Disclosing the Truth About a Medical Error” (1999) 60 *American Family Physician* 1013.

²¹⁰ Christensen et al., *supra* note 87.

²¹¹ Lucian L. Leape, “Institute of Medicine Medical Error Figures Are Not Exaggerated” (2000) 284 *Journal of the American Medical Association* 95 at 97.

²¹² Dina Pilpel, Razia Schor & Jochanan Benbassar, “Barriers to Acceptance of Medical Error: The Case for a Teaching Programme” (1998) 32 *Medical Education* 3.

a non-punitive, non-judgmental method to disclose and discuss medical error.²¹³ 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 and other health professionals must be socialized, educated and trained to be more open and honest in their discussions about medical error and to routinely disclose them.²¹⁴ 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.”²¹⁵ 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

²¹³ Wu *supra* note 87; see also Paul M. McNeil & Marilyn Walton, “Medical Harm and the Consequences of Error for Doctors” (2002) 176 *Medical Journal of Australia* 222 at 224.

²¹⁴ Helen Lister & Jonathan Q. Titter, “Medical Error: A Discussion of the Medical Construction of Error and Suggestions for Reforms of Medical Education to Decrease Error” (2001) 35 *Medical Education* 855; see also *supra* note 212; and Françoise Baylis, “Error in Medicine: Nurturing Truthfulness” (1997) 8 *The Journal of Clinical Ethics* 336.

²¹⁵ James Reason, “Human Error: Models and Management” (2000) 320 *British Medical Journal* 768; see also Bryan A. Liang, “A System of Medical Error Disclosure” (2002) 11 *Quality & Safety in Health Care* 64.

appropriate because most errors are, in substance, systemic errors.²¹⁶ In their article, Deskin and Hoye refer to the approach of focusing on individual accountability of physicians as the “bad apple” approach. According to the authors, “bad apple” physicians should not be targeted, especially when it is now recognized that the traditional responses to error are no longer enough.²¹⁷ 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.²¹⁸

While 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 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

²¹⁶ See for example William C. Deskin & Robert E. Hoye, “Another Look at Medical Error” (2004) 88 *Journal of Surgical Oncology* 122.

²¹⁷ *Ibid.* at 128.

²¹⁸ *Ibid.* at 128.

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.²¹⁹

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

²¹⁹ *Supra* note 132.

errors can include discipline, retraining or suspension of privileges, but would only include criminal prosecution in extremely rare cases.²²⁰ What is critical is that our responses to individuals who commit errors form part of an overall system of accountability that focuses on the systemic aspects of error as opposed to individual blame.

As a self-regulating profession, Medicine must continue to fulfill its obligation to the public to ensure the competence of its individual members. As a result, the medical profession and the health care system can and should move substantially towards a more open and non-punitive medical error reporting and investigation system. However, at the same time, it must maintain an appropriately balanced and just system of accountability for individual health providers who have made errors.

CONCLUSIONS ON DISCLOSURE OF ERROR

If we are to move forward with reducing medical error and increasing patient safety, health providers must be free to disclose medical error both to patients and to hospital administrators. In order to facilitate these changes, significant cultural and educational changes to the health professions and health system are required. Physicians and other health providers must be socialized and educated to discuss errors in an open and forthright manner with a view to learning from them and

²²⁰ 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 British Medical Journal 1118.

promoting positive systemic change. The medical profession can no longer afford to perpetuate the culture of infallibility or to view errors as failures of character. In addition, health administrators must build and foster a system of just responses to medical error. They must also recognize that most errors are system errors and individual scapegoating is counterproductive. It is only with these changes that full discussion and investigation of every medical error and near miss will occur. This will in turn allow physicians and hospital administrators to learn from medical errors and make systemic changes in order to prevent similar errors from occurring in the future.

In addition to the changes required of the health system, the legal profession must also take positive steps to help promote the disclosure of medical error and remove legal barriers to disclosure. The legal profession should be creative and work closely with the medical and other health professions to come up with innovative and sustainable solutions that promote and enhance patient safety. Considerable efforts must be made by both the medical and legal professions to educate health providers, and physicians in particular, on the true risks of litigation. If health providers are made to understand that, particularly in Canada, medical negligence actions are relatively rare, they would be less concerned about being sued for potential errors and more likely to disclose them. With this in mind, we now turn to an examination of the role played by the medical liability system and a discussion of medical liability reform initiatives.

PART III – LEGAL IMPLICATIONS OF MEDICAL ERROR & THE NEED FOR MEDICAL LIABILITY REFORM

INTRODUCTION

As we have seen, medical error is a significant problem and the number of patients injured in North America alone every year is staggering. Once these patients have been injured, it then becomes necessary to treat their iatrogenic injuries and compensate them for the damages they have suffered. Not only is it necessary to compensate them for their pain and suffering but also many patients require extensive treatment and expensive long term care. Unfortunately the process of recovering compensation for their injuries can lead some patients to feel like victims again.

In both the United States and Canada, in order to receive compensation, victims of medical negligence generally only have access to the traditional tort system of compensation. Given the scope of the problem of medical error and the number of patients injured each year, the number of persons who would be entitled to compensation is enormous. However, the tort system, as a method of victim compensation, is expensive and inefficient and relatively few victims of medical error actually recover compensation for their injuries.

Unfortunately, although significant efforts are being made to reduce medical error and increase patient safety, and there are also substantial efforts being made in the area of medical liability reform, the two movements are for the most part occurring in isolation from each other. While there are obviously different issues that need to be

addressed in each area, there are also significant linkages between them. It would be a mistake for our patient safety efforts to ignore the legal implications of their improvements. Similarly, any medical liability reform must take into account the potential impact on medical error and make every effort to remove legal obstacles to increased patient safety. In this part, the relationship between the legal system and medical error will be discussed. In particular, the impact that the legal system has on inhibiting disclosure of medical error will be examined. In addition, the current challenges facing the medical liability system, including the calls for significant reform will be discussed. Finally, suggestions for reform of our current medical liability system will be made.

MEDICAL LIABILITY SYSTEM

As stated above, victims of medical negligence in North America as a general rule only have access to the tort system of compensation.²²¹ The traditional objectives of tort law generally are deterrence of wrongful conduct and full compensation of victims of wrongful conduct. In order to be successful in a medical negligence action, the plaintiff must show that the defendant owed them a duty of care, the defendant breached the relevant standard of care and that the breach of the standard of care by the defendant was the actual and legal cause of the plaintiff's injury.²²² In addition, if the mistake is considered by the court to be a mere error in judgement on

²²¹ Although there has been significant discussion regarding alternate methods of patient compensation for medical negligence, there are few situations in North America where patients have an alternative to the tort system. One of the notable exceptions is the Veterans Administration hospitals in the U.S., which will be discussed briefly below.

²²² *Supra* note 174 at 174.

the part of the physician as opposed to a negligent breach, the plaintiff will not be entitled to recovery.²²³ The plaintiff also has the burden to satisfy the court as to the appropriate quantum of damages. All of these requirements must be proven on a balance of probabilities in order for the plaintiff to be successful.

The traditional tort system of compensation for victims of medical negligence has been criticized for decades in both the United States and Canada. Interestingly, these criticisms have come from both sides of the debate. On the one hand, plaintiffs in medical malpractice cases have reason to complain that the current system is extremely expensive and is ineffective as a deterrent of wrongful conduct and as a compensation scheme for victims of medical negligence. Key weaknesses of the current system from the plaintiff's perspective are the inordinate expense of medical malpractice litigation, the length of time that it generally takes to obtain judgment, the difficulty in obtaining medical experts who are prepared to testify on behalf of the plaintiff and the often insurmountable obstacle of proving causation in medical negligence cases.²²⁴ In addition, only a small percentage of individuals injured by medical negligence actually commence a lawsuit and only a small fraction of those are ultimately successful in obtaining compensation.²²⁵ As a result, there is good

²²³ Regarding the protection for liability for errors in judgment, see for example *Wilson v. Swanson* (1956), 5 D.L.R. (2nd) 113 (S.C.C.); and *Challand v. Bell* (1959), 18 D.L.R. (2nd) 150 (Alta. S.C.)

²²⁴ For a general overview of some of the complaints by both sides of the debate see generally Christine O. Jackiw, "The Current Medical Liability Insurance Crisis: An Overview of the Problem, its Catalysts and Solutions" (2004) 13 *Annals of Health Law* 505.

²²⁵ Localio A. 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; see also Troyen A. Brennan, Colin M. Sox & Helen R. Burstin, "Relation Between Negligent Adverse Events and the Outcomes of Medical-Malpractice Litigation" (1996) 335 *New Eng. J. Med.* 1963.

reason to question the effectiveness of the fault based tort system as a method of victim compensation.

On the other hand, physicians groups, governments, health care groups and medical defence counsel are often of the view that significant reform of the medical liability compensation system is urgently required, albeit for different reasons.²²⁶ These groups also often criticize the traditional tort system for its inordinate costs in expert and legal fees.²²⁷ However, they also go on to criticize the system for failing to keep the size of medical negligence damage awards from spiralling out of control.²²⁸ In Canada, we are seeing the growth in the number of awards in excess of one million dollars and in the United States multi-million dollar awards are common. For example, in the U.S. in 2001 and 2002, seven of the top twenty jury verdicts were in medical malpractice cases.²²⁹ Five of the verdicts ranged between \$80 million and \$115 million with two other verdicts coming in at \$312 million and \$2.2 billion.²³⁰ These increasing awards have had many detrimental impacts on the health care system including significant increases to health care costs, dramatic increases to malpractice insurance rates and physicians making specialty choices or leaving

²²⁶ See for example American Medical Association, *Medical Liability Reform - Now!*, online: American Medical Association <<http://www.ama-assn.org/ama1/pub/upload/mm/1/mlrnw/june142005.pdf>>

²²⁷ *Ibid.*

²²⁸ *Ibid.*

²²⁹ Robert P Hartwig, "Trends in Medical Malpractice Insurance: Behind the Chaos" Presentation to the American Academy of Orthopedic Surgeons – April 25, 2003, Online: Insurance Information Institute <[http://server.iii.org/yy_obj_data/binary/695260_1_0/medmal.ppt#585,1,Trends in Medical Malpractice Insurance Behind the Chaos](http://server.iii.org/yy_obj_data/binary/695260_1_0/medmal.ppt#585,1,Trends%20in%20Medical%20Malpractice%20Insurance%20Behind%20the%20Chaos)>

²³⁰ *Ibid.*

jurisdictions as a result of concerns about liability.²³¹ This is obviously a much greater problem in the United States, but Canada is not immune to these effects.

Unfortunately, it is a sad reality of our health-care system that patients often suffer unexpected complications which arise from the medical treatment of their underlying disease and not from any negligence on the part of their health-care providers. In many of these cases, there is no doubt that the patient has suffered a serious injury which may lead to lifelong disability and a significantly reduced quality of life. Although it is often extremely difficult to determine whether the injury to the patient was caused by the fault of their health-care provider or by an unexpected complication with their underlying disease, this analysis is critical to the current fault based tort system. A patient who is able to establish that their injury and resulting disability was caused by the negligence of a health-care provider will be entitled to full compensation for the impact of that injury on their lives; the patient who is not able to prove this is not entitled to any compensation and will be required to rely on their own funds and any social safety net that may exist.

As a result of this, the current medical liability system has also been criticized for a tendency by some judges or juries to undermine the system by finding negligence where none exists, particularly when faced with especially sympathetic plaintiffs.²³² In many cases, there will be a significant temptation to hold physicians and health care providers to an inappropriately high standard of care or to relax the test for

²³¹ *Supra* note 226.

²³² *Supra* note 226; see also Troyen A. Brennan & Michelle M. Mello, "Patient Safety and Medical Malpractice: A Case Study" (2003) 139 *Panels of Internal Medicine* 267 at 269.

causation in order to provide awards to sympathetic plaintiffs who would otherwise go without compensation. This is a more significant issue in the U.S. as the social safety net that exists is much less comprehensive. An American patient who is injured as a result of a medical error but who is unable to prove negligence will be subject to dramatically higher health care costs than a similar Canadian patient. In cases where the American patient does not have private health insurance, medical injuries can often lead to financial ruin. Accordingly, the stakes are much higher in the U.S., which can lead to a greater temptation to compensate plaintiffs in borderline cases.

The current system is also criticized for its tendency to cause a fear of litigation on the part of medical providers.²³³ These critics go on to suggest that this fear of litigation has the potential to cause physicians to practice “defensive medicine”. Defensive medicine is essentially the practice by physicians in ordering tests and providing treatment, not because the patient's condition necessarily requires it, but because the physician is afraid of being sued. Obviously, if a significant number of physicians were practicing defensive medicine, the potential unnecessary costs to the health-care system would be enormous. It is also exceedingly difficult to determine whether or not a significant number of physicians are in fact practicing defensive medicine and if so, the true extent of the resulting cost to the health-care system.

²³³ Harris Interactive Inc., “Common Good Fear of Litigation Study the Impact on Medicine – Final Report April 11, 2002” Common Good online: < <http://cgood.org/assets/attachments/57.pdf> >

However, a recent study concluded that defensive medicine may in fact be a significant problem.²³⁴ To the extent that physicians are practicing defensive medicine, it is primarily a result of a fear of litigation and unpredictability and instability in the malpractice system. According to the authors, not only is the practice of defensive medicine wasteful, it can also reduce access to care and even poses a risk of physical harm.²³⁵ Proponents of the status quo may suggest that the potential tendency of physicians to practice defensive medicine is simply a result of the current tort system doing one of its principal jobs, namely deterring wrongful conduct. If physicians are thinking twice about the treatments they recommend and the tests that they order as a result of a fear of being sued, some would say that this is not necessarily a bad thing and may lead to less negligence. Of course, the corresponding concern is that, in the reality of finite health-care dollars, money spent on unnecessary tests will not be available to be spent on other priorities.

On the other hand, the current tort system viewed solely as a method of victim compensation is extremely inefficient. Contrary to the perceptions of the medical profession and the general public, only a very small percentage of persons injured by medical error actually commence a lawsuit and only a small portion of those ultimately end up receiving compensation.²³⁶ The most obvious reason that patients would not sue is that they never discover that they are the victim of medical error. This could be as a result of a failure to disclose on the part of the health providers or

²³⁴ David M. Studdard et al, "Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment" (2005) 293 *Journal of the American Medical Association* 2609 at 2617.

²³⁵ *Ibid.*

²³⁶ Localio, *supra* note 225.

because the health providers do not believe or recognize that an error occurred.

In addition, the legal system itself acts as a significant barrier to injured patients. The burden of proof on plaintiffs in medical malpractice cases is such that plaintiffs' lawyers will usually take only the strongest cases and will not take cases that do not have the potential for a significant damage award. Moreover, the cost of pursuing medical malpractice litigation in expert and legal fees is prohibitive for many potential plaintiffs. This is especially true in jurisdictions that do not allow contingency arrangements. Accordingly, as a general rule, only those claims which have the potential for fairly significant damage awards are pursued. Many plaintiffs who have been injured by medical negligence simply make the pragmatic decision that the amount that they could ultimately obtain is not worth the financial risk and emotional consequences of litigation.

LEGAL IMPLICATIONS OF DISCLOSURE OF MEDICAL ERROR

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.²³⁷ However, studies have consistently shown that only an extremely small minority of patients injured by medical error actually file a

²³⁷ *Supra* note 233.

lawsuit.²³⁸ In fact, the Harvard Study found that less than 2% of negligent adverse events led to malpractice claims.²³⁹ 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.²⁴⁰ It has been shown that what patients really want is an explanation of what happened to them, reassurance that steps have been taken to rectify the problem, and an apology.²⁴¹

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.²⁴² 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.²⁴³ 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

²³⁸ Marshall B. Kapp, "Medical Error Versus Malpractice" (1997) 1 DePaul Journal of Health Care Law 751 at 765; see also, *supra* note 225.

²³⁹ Localio, *supra* note 225.

²⁴⁰ Charles Vincent & Magi Young, "Why Do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action" (1994) 343 Lancet 1609.

²⁴¹ *Ibid.*; see also G.B. Hickson et al., "Factors That Prompted Families to File Medical Malpractice Claims Following Perinatal Injuries" (1992) 267 Journal of the American Medical Association 1359; and Nancy Berlinger, "Broken Stories: Patients, Families, and Clinicians after Medical Error" (2003) 22 Literature and Medicine 230;

²⁴² Vincent & Young, *ibid.*

²⁴³ *Ibid.*

significant percentage of respondents answered yes to this question (41.4%).²⁴⁴ 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.²⁴⁵ The results of this study would seem to indicate that an increase in the disclosure of medical error would not 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 2004.²⁴⁶ 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.²⁴⁷ 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).²⁴⁸ The researchers were therefore only able to conclude that full disclosure may reduce the likelihood that patients will seek legal advice under some, but not all, circumstances.²⁴⁹

²⁴⁴ *Ibid.*

²⁴⁵ *Ibid.*

²⁴⁶ Kathleen M. Mazor et al., "Health Plan Members' Views about Disclosure of Medical Errors" (2004) 140 *Annals of Internal Medicine* 409.

²⁴⁷ *Ibid.* at 416.

²⁴⁸ *Ibid.*

²⁴⁹ *Ibid.*

Nevertheless, physicians continue to mistrust the legal process and risk managers focus more on reducing potential liability than on reducing error.²⁵⁰ 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.²⁵¹ 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 be provided with more information, in a more open and timely fashion and, as discussed above, may in fact be less likely to sue.

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

²⁵⁰ Edward A. Dauer, "A Therapeutic Jurisprudence Perspective on Legal Responses to Medical Error" (2003) 24 *The Journal of Legal Medicine* 37 at 39.

²⁵¹ 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 *Georgia State University Law Review* 1227.

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 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 that contemplated by the HQCA 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

As a result of the substantial number of patients injured by medical error every year in North America and the criticisms of the tort system discussed above, reform of the medical liability systems has become a significant issue. In the U.S., the medical liability system is in crisis and there is a widespread movement by physician, hospital and insurance groups to cap damages and limit recovery by plaintiffs. On the other hand, plaintiffs' groups argue that the system is inefficient at compensating victims of medical negligence and are suggesting fewer restrictions on recovery. In Canada the medical liability system is stable, albeit expensive. Nevertheless, reform of the medical liability system continues to be an ongoing issue. In this section, the current status of the medical liability insurance systems in the U.S. and Canada will be contrasted. In addition, the current state of medical liability reform in common-law Canada and the United States will be reviewed and the disparities between the experiences of the two systems will be highlighted. Finally the issues of a no fault compensation system, the protection of quality assurance activities and a disclosure/apology privilege will be examined and specific suggestions for reform made. Ultimately, while selected reform of the current medical liability system in Canada is required, wholesale changes to the medical malpractice system are unnecessary and inadvisable.

Medical Liability Insurance Crisis?

Common Law Canada

While medical liability insurance costs have been increasing for physicians and hospitals in Canada over the last several years, it cannot be said that Canada is suffering from a medical liability insurance crisis. As a result of previous financial difficulties, there has been a consolidation of the medical liability insurance system in Canada. Most hospitals and health regions in Canada are now insured through publicly funded or partially publicly funded entities. Moreover, the percentage of physicians insured by the Canadian Medical Protective Association (“CMPA”) has steadily increased to the point that 66,477 of Canada’s physicians (approximately 95%) are insured by the CMPA.²⁵² While there is little public information available with respect to the financial health of the entities that ensure hospitals and health regions, the CMPA publishes detailed information every year in its annual report. In stark contrast to its U.S. counterparts, the CMPA over the last several years has been able to fully fund its claims expenses on an annual basis and has increased its total consolidated net assets to \$2.3 billion.²⁵³ The CMPA uses an occurrence based fee structure and attempts to collect from its members, in each year, sufficient funds to cover the anticipated liabilities relating to that year, even though the expenses may

²⁵² CMPA, *CMPA Annual Report 2004* at 6, online: CMPA < http://www.cmpa-acpm.ca/portal/cmpa_docs/english/resource_files/admin_docs/common/annual_reports/2004/pdf/com_annual_report-e.pdf >

²⁵³ *Ibid* at 17.

not be incurred for several years.²⁵⁴ In addition, it appears that the overall number of claims filed on an annual basis has levelled off and has actually decreased in the past several years.²⁵⁵

Even though the CMPA is financially stable, it has had to adopt a regional rating system and significantly increase its overall rates charged to physicians over the past several years to maintain this stability.²⁵⁶ In 2000 the CMPA released the results of an actuarial analysis of its regional costs.²⁵⁷ The CMPA found that there were substantial regional differences and Ontario was by far the most expensive region.²⁵⁸ Interestingly, Ontario had only 39.3% of all CMPA members yet was responsible for 53.53% of the CMPA's overall costs.²⁵⁹ On the other hand, Québec had 22.8% of all CMPA members yet was responsible for only 11.27% of the CMPA's overall costs.²⁶⁰ On an individual level, the difference in CMPA membership fees for high-risk specialties is striking. In Canada, the most expensive area to practice from an insurance perspective is Obstetrics. According to the CMPA fee schedule, an obstetrician in Ontario will pay \$78,120 for 2006 whereas an obstetrician in Québec will only pay \$25,950.72 (an obstetrician anywhere else in Canada will pay

²⁵⁴ *Ibid.*

²⁵⁵ *Ibid* at 11.

²⁵⁶ CMPA, *A Briefing Document on the CMPA Council's Move to Regional Rating – February 2000*, online: CMPA < http://www.cmpa-acpm.ca/portal/pub_index.cfm?LANG=E&URL=cmpa%5Fdocs%2Fenglish%2Fresource%5Ffiles%2Fml%5Fissues%2Fcommon%2Fcom%5Fbriefing%5Fregional%5Fcosts%5Fbackground%5F2000%5F02%2De%2Ehtml>

²⁵⁷ *Ibid.*

²⁵⁸ *Ibid.*

²⁵⁹ *Ibid.*

²⁶⁰ *Ibid.*

\$24,768).²⁶¹ According to the CMPA, the reason for this disparity in costs is primarily a function of the size of court awards and settlements and is not a function of a difference in the quality of healthcare.²⁶²

Although physicians are generally required to pay their CMPA fees upfront, the majority of these expenses are subsequently reimbursed to the physicians by the provincial or territorial governments. Accordingly, in Canada, the malpractice insurance fees are a direct cost to the health-care system and consume dollars that could otherwise be spent on other health priorities like diagnostic imaging and reducing wait times. For 2004 the CMPA collected \$281 million from its members, the majority of which was paid by the health-care system.²⁶³ From 2000 to 2004, the amount collected by the CMPA from its members increased by over 20% from \$236 million to \$281 million.²⁶⁴ During the same time period, the CMPA's membership increased by approximately 10% from 60,099 members to 66,477 members.²⁶⁵ Accordingly, in real terms, the cost to the health-care system of physician membership in the CMPA increased by approximately 10% from 2000 to 2004. While this increase represents a significant amount in dollar terms, it cannot be said that the cost of medical liability insurance in Canada has increased dramatically in the last five years. However, added to this must be the legal expenses and settlement costs of all of the hospitals and regional health authorities across the country.

²⁶¹ CMPA, *CMPA Fee Schedule for 2006*, online: CMPA < http://www.cmpa-acpm.ca/portal/cmpa_docs/english/resource_files/admin_docs/common/fees/pdf/2006cal-e.pdf >

²⁶² *Ibid.*

²⁶³ *Supra* note 252 at 14.

²⁶⁴ *Ibid.*

²⁶⁵ *Ibid.*

Although the actual amount of these expenses is difficult to ascertain, based on the amount spent by the CMPA each year, the expenses and settlement costs of hospitals and regional health authorities must be well in excess of \$100 million annually.

Given the financial stability of the CMPA and the fact that overall claims filed have been decreasing in the past several years, it can hardly be said that the Canadian medical liability insurance system is in “crisis”. However, there does remain a significant question as to whether or not the current system is the most cost effective method of patient compensation.

United States

Although the tort system in the United States is substantially similar to the tort system in Canada, the experiences of the two nations with respect to medical liability insurance could not be more different. As discussed above, Canada's medical liability system, while expensive, is stable and sustainable. In contrast, according to many experts, the medical liability system in the United States is in crisis and has been, to a lesser or greater extent, for the past 35 years.²⁶⁶

The medical liability insurance system in the United States experienced a period of crisis in the early 1970's when several private insurers left the market because of

²⁶⁶ *Supra* note 226; see also Richard L. Abbott, Paul Weber & Betsy Kelly, “Medical Professional Liability Insurance and its Relation to Medical Error and Healthcare Risk Management for the Practicing Physician” (2005) 140 *American Journal of Ophthalmology* 1106.

rising claims and insufficient premiums.²⁶⁷ This reduction in capacity resulted in an availability and affordability problem for physicians and hospitals in the U.S.²⁶⁸ In California, between 1968 and 1974, the number of medical liability claims doubled and the number of losses in excess of \$300,000 increased 11 times.²⁶⁹ Losses amounting to \$180 for each \$100 in premiums led most commercial insurers in California to refuse to provide medical liability coverage at any price.²⁷⁰ Ultimately, access to care was threatened and a special session of the California legislature led to the enactment of the Medical Injury Compensation Reform Act of 1975 (MICRA) which will be discussed further below.

The medical liability insurance system in the U.S. also experienced a crisis of affordability in the 1980's as claim frequency and severity increased again and premiums rose significantly.²⁷¹ This had a dramatic effect on the medical system as physicians in high-risk specialties cut back on high risk patients and procedures to reduce their exposure and premiums.²⁷² Some physicians moved their practices out of states where premiums and liability exposure were particularly high.²⁷³

Although there have been substantial efforts to reform the system and reduce or stabilize insurance premiums, these efforts have had little impact in most states. The current medical liability insurance system in many states is volatile and subject to

²⁶⁷ *Supra* note 226 at 2.

²⁶⁸ *Ibid.*

²⁶⁹ *Ibid.*

²⁷⁰ Richard E. Anderson, "Defending the Practice of Medicine" (2004) 164 *Archive Of Internal Medicine* 1173 at 1173 – 1174.

²⁷¹ *Supra* note 226 at 2.

²⁷² *Ibid.*

²⁷³ *Ibid.*

significant premium increases. From 1997 to 2003, the overall median medical liability jury award increased from \$157,000 to \$300,000 and the average award increased from \$347,134 in 1997 to \$430,727 in 2002.²⁷⁴ From 1997 to 2002, the growth in settlements mirrored that of jury awards with the median settlement increasing from \$100,000 to \$200,000 and the average settlement increasing from \$212,861 to \$322,544.²⁷⁵ According to a recent study by the Blue Cross/Blue Shield Association, insurers in “crisis” states believe that inappropriately large jury awards are the primary factor contributing to the increase in medical liability insurance premiums.²⁷⁶ However, there remains some considerable debate as to the cause of the increase in medical liability insurance premiums in the United States.²⁷⁷ Proponents of an unrestrained tort system generally cite competitive practices by insurance companies and market losses as the primary reason for increasing malpractice insurance premiums.²⁷⁸ These groups and individuals oppose damage caps and other medical liability reforms as they feel that these reforms will not have the desired impact and will simply provide greater profits to the insurance industry.

²⁷⁴ *Ibid* at 3.

²⁷⁵ *Ibid*.

²⁷⁶ Blue Cross/Blue Shield Association, *The Malpractice Insurance Crisis: The Impact on Health-care Cost and Access* 3 (2003) cited in *Medical Liability Reform Now!* *supra* note 226 at 3.

²⁷⁷ Kenneth E. Thorpe, “The Medical Malpractice ‘Crisis’: Recent Trends and the Impact of State Tort Reforms - Do Recent Events Constitute a Crisis or Merely the Workings of the Insurance Cycle?” (2004) 4 *Health Affairs* 20.

²⁷⁸ See for example Jay Angoff, *Falling Claims and Rising Premiums in the Medical Malpractice Insurance Industry* - July 2005 (Report Commissioned by Center for Justice & Democracy), online: CJ & D <<http://www.centerjd.org/ANGOFFReport.pdf>>; and Melissa C. Gregory “Recent Developments in Health Care Law: Note: Capping Noneconomic Damages in Medical Malpractice Suits is not the Panacea of the “Medical Liability Crisis”” (2005) 31 *William Mitchell Law Review* 1031; for a critical response to the Angoff Report see James D. Hurley & Gail E. Tverberg, *Comments on Report by Jay Angoff* - August 30, 2005, online: Physician Insurers Association of America <http://www.piaa.us/pdf_files/050830_Angoff_Med_Mal_Overview_Hurley.pdf>

In any case, as of June 2005, the American Medical Association (AMA) has identified 20 states that it considers to be experiencing a medical liability insurance crisis: Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Massachusetts, Mississippi, Missouri, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, Rhode Island, Washington, Nevada, West Virginia and Wyoming.²⁷⁹ According to the AMA, 24 other states and the District of Columbia are seeing the warning signs of a potential crisis.²⁸⁰ As of June 2005, the AMA considers only six states to be stable from a medical liability insurance perspective: California, Colorado, New Mexico, Louisiana, Wisconsin and Indiana.²⁸¹ As an example of the disparity in malpractice premiums between states, according to the AMA, an obstetrician in Los Angeles pays approximately \$69,000 per year in malpractice premiums whereas an obstetrician in Miami, Florida (which lacks comprehensive liability reforms) pays as much as \$269,000 per year.²⁸²

In addition to increasing costs, access to care is being reported as a significant problem arising from the medical liability insurance crisis. In a recent survey, 45% of hospitals surveyed reported that the professional liability crisis has resulted in the loss of physicians and/or reduced coverage in emergency departments.²⁸³ In addition, a recent study published in November 2005 which surveyed surgeons and other

²⁷⁹ *Supra* note 226 at 9.

²⁸⁰ *Ibid.*

²⁸¹ *Ibid.*

²⁸² Donald J. Palmisano, "The Physician's Perspective: Medical Liability Reform Is Essential for Access to Medical Care", presented to the 2nd annual Pharmaceutical, Biotech and Device Colloquium, Princeton University, June 2, 2005, online: American Medical Association <<http://www.ama-assn.org/ama/pub/category/print/15300.html>>

²⁸³ American Hospital Association, *Professional Liability Insurance Survey* (2003) cited in *Medical Liability Reform Now!* *supra* note 226 at 4.

specialists in Pennsylvania concluded that the supply of surgeons and other specialists in that state would likely decrease, perhaps substantially in some areas, over the next two years.²⁸⁴ According to the authors, this decrease is primarily attributable to concerns regarding liability and the cost of professional liability insurance and the decrease may also be contributing to a decrease in patient access to care.²⁸⁵ However, the authors of the study went on to suggest that previous reports of a mass exodus of specialists from “crisis” states were overstated.²⁸⁶

In addition, the growing concerns of U.S. medical residents about liability issues may cause them to avoid choosing high-risk specialties or practicing in states that are suffering from a liability insurance crisis. More than any other issue, medical residents in the U.S. are now reporting concerns regarding liability issues as their top concern. In a 2003 survey of medical residents, 62% reported that liability issues were their top concern, which represents an enormous increase from 2001 when only 15% of residents said liability was a concern.²⁸⁷ According to a recent AMA study, medical students are similarly affected by the current liability insurance crisis.²⁸⁸ According to the survey, half of the respondents indicated that the current medical

²⁸⁴ Michelle M. Mello et al., “Effects of a Malpractice Crisis on Specialist Supply and Patient Access to Care” (2005) 242 *Annals of Surgery* 621.

²⁸⁵ *Ibid.* at 626; see also Michelle M. Mello et al., “Caring for Patients in a Malpractice Crisis: Physician Satisfaction and Quality of Care” (2004) 23 *Health Affairs* 42; and Michelle M. Mello et al., “Hospitals' Behavior in a Tort Crisis: Observations from Pennsylvania” (2003) 22 *Health Affairs* 225.

²⁸⁶ *Supra* note 284 at 621.

²⁸⁷ Meritt, Hawkins & Associates, *Summary Report: 2003 Survey of Final Year Medical Residents 5* (2003), cited in *Medical Liability Reform Now!* *supra* note 226 at 4.

²⁸⁸ American Medical Association - Division of Marketing Research & Analysis, *AMA Survey: Medical Students' Opinions of the Current Medical Liability Environment* (2003), online: AMA <<http://www.ama-assn.org/ama1/pub/upload/mm/31/msmlrhighlights.pdf>> cited in *Medical Liability Reform Now!*, *supra* note 226 at 4.

liability environment was a factor in their specialty choice.²⁸⁹ In addition, 39% responded that the medical liability environment was a factor in their decision about which state they would like to complete their residency in.²⁹⁰ Finally, 61% reported that they are extremely concerned that the current liability environment is decreasing physicians' ability to provide quality medical care.²⁹¹

According to the U.S. Department of Health and Human Services, medical liability adds billions to the cost of health care in the United States each year.²⁹² In 2002, the U.S. Department of Health and Human Services estimated that the direct costs of medical liability coverage and indirect cost of defensive medicine practices increases the amount the federal government must pay for Medicare, Medicaid, the State Children's Health Insurance Program, Veteran's Administration health-care, health care for federal employees and other government programs by as much as \$47.5 billion per year.²⁹³ In its 2003 *Addressing the New Health Care Crisis* report, the U.S. Department of Health and Human Services estimated that reasonable limits on non-economic damages would reduce the amount of money the federal government spends on health care and liability insurance by up to \$50.6 billion per year.²⁹⁴

²⁸⁹ *Supra* note 226 at 4.

²⁹⁰ *Ibid.*

²⁹¹ *Ibid.*

²⁹² Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, *Addressing the New Health Care Crisis: Reforming the Medical Litigation System to Improve the Quality of Health Care* 11 (2003)

²⁹³ Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, *Confronting the New Health Care Crisis, Improving Health Care Quality & Lowering Costs by Fixing our Medical Liability System* 8 (2002), online: U.S. Department of Health and Human Services <<http://aspe.hhs.gov/daltcp/reports/litrefm.pdf>>

²⁹⁴ *Supra* note 292 at 11.

In light of the above, it is not surprising that medical liability reform is one of the most important issues facing the U.S. health system today. Regardless of which side of the debate one sits, it is difficult to argue that the medical liability system in the U.S. is not in need of significant reform. The nature and extent of that reform, however, is another issue altogether.

Medical Liability Reform in Canada & the United States

In light of the high incidence of medical error and the problems facing the medical liability systems in North America today, one of the most important issues in health policy today is whether significant medical liability reform is required and, if so, the proper scope of that reform. At present, governments around the world are struggling to develop innovative and effective strategies to address the competing interests involved in any medical liability system. On the one hand, we have the recognized need of appropriately compensating victims of medical negligence. On the other, we have the need to maintain an economically viable and effective health system. While these competing interests need not be mutually exclusive, finding and maintaining an appropriate balance has been extremely difficult for most governments. This has been particularly true for the United States where many health experts are of the view that their malpractice insurance industry is in crisis and their medical liability system is fundamentally flawed. By contrast, in Canada, the malpractice insurance industry is relatively stable and our tort liability system is often seen as a model for other nations.²⁹⁵

²⁹⁵ The Canadian Medical Protective Association, *Medical Liability Practices in Canada: Towards the Right Balance – A Report Prepared by the Canadian Medical Protective Association August 2005* at

Common Law Canada

In comparison to the United States, very little has been done in the area of medical liability reform in Canada. The primary reasons for this disparity are the existence of a judicial cap on non-economic damages, legislative and judicial restrictions and restraint on the scope and quantum of available damages, the financial stability of the CMPA and the rarity of civil jury trials for medical malpractice in Canada. In this section I will review past efforts that have been made with respect to medical liability reform and will then address some current issues that exist.

Judicial Cap on Non-economic Damages

One of the primary reasons behind the relatively stable medical liability insurance system in Canada is the capping of non-economic damages by the Supreme Court of Canada at \$100,000 in 1978.²⁹⁶ Although this amount is adjusted for inflation and in 2006 is now approaching \$300,000, this cap has led to a much more conservative quantification of damages in Canada as opposed to the United States. Not only is the maximum amount only given in the most serious cases (generally catastrophic physical injuries where the plaintiff's mental status is relatively undamaged), but this maximum is used as a benchmark to assess less serious injuries resulting generally in

15, online: CMPA <http://www.cmpa-acpm.ca/portal/cmpa_docs/english/content/issues/common/piaa/pdf/com_medical_liability_canada-e.pdf>

²⁹⁶ Robert G. Elgie, Timothy A. Caulfield & Michael L. Christie, "Medical Injuries and Malpractice: Is It Time for No Fault?" (1993) 1 Health L. J. 97; see also the Supreme Court of Canada "Trilogy" cases of *Thornton v. Prince George*, [1978] 2 S.C.R. 267, *Andrews v. Grand and Toy* [1978] 2 S.C.R. 229, & *Arnold v. Teno* [1978] 2 S.C.R. 287.

much lower awards for non-economic damages. Accordingly, Canadian insurers of health providers are at risk for much lower total damages in each claim and cannot be subjected to a runaway jury who is sympathetic to the plaintiff's case.

Prichard Report - Liability and Compensation in Health Care

The Prichard Report was commissioned in 1990 by Canada's deputy health ministers to review other medical liability systems, literature and legal precedent, Canadian malpractice claims trends and Canadian stakeholder opinion.²⁹⁷ The Prichard Report reviewed previously enunciated reform options including changes to the tort system, alternate dispute resolution and no-fault compensation schemes.²⁹⁸ The Prichard Report then developed four normative benchmarks for judging reform proposals: reducing the frequency of avoidable medical injuries; enhancing social justice; promoting efficiency and long-term cost reduction; and ensuring fairness among patients and health care professionals and institutions.²⁹⁹

In the end, the Prichard Report made 79 recommendations with respect to reform of the medical liability system in Canada. Among these numerous recommendations, the two most important recommendations are the retention of the tort system and the

²⁹⁷ *Supra* note 295 at 36.

²⁹⁸ Gerald Robertson, "Reform of the Law of Medical Liability: The Position in the Common Law Jurisdictions of Canada", Canadian Reports to the 1990 International Congress of Comparative Law, Montréal, 1990 at 192-195.

²⁹⁹ Report of the Federal/Provincial/Territorial Review on Liability and Compensation Issues in Health Care (Chairman: J.R.S. Prichard), *Liability and Compensation in Health Care* (Toronto: University of Toronto Press, 1990) at 21 [Prichard Report]; see also Chris Hubbard, "Culpability and Compensation in Canadian Health Care: Much Ado about No Fault?" (2000) 5 McGill Journal of Medicine 111 at 115.

development of a no-fault compensation scheme for “significant avoidable health care injuries”.³⁰⁰ Although the Prichard Report proposed a number of substantive and procedural changes to the tort system (such as changes to limitation periods, calculation of damages, contingency fees, structured settlements and legal aid as well as the availability of expert witnesses), it concluded that the present medical negligence action should be retained.³⁰¹ The Prichard Report recommended the retention of the current tort system “both as a useful incentive for higher-quality care and as a fundamental means of redress for injured patients.”³⁰² In addition, the Prichard Report also recommended the development of a no-fault compensation scheme for significant avoidable health care injuries. The Prichard Report intended this to be an alternative to the present tort system, with the patient being required to elect whether to receive no-fault compensation or to pursue legal action.³⁰³ Under this regime, the compensation available would be much more limited than the damages available in the court system. The primary focus would be on economic losses with only nominal compensation awarded for non-economic losses.

To date, very few of the Prichard recommendations have been implemented in Common Law Canada and those that have, have been done in a piecemeal fashion. Having said that, some of the recommendations still resonate today, particularly those

³⁰⁰ Prichard Report, *ibid.*

³⁰¹ *Ibid.*; see also *supra* note 174 at 430; and SECOR Consulting & CMPA, *Alternative Patient Compensation Models in Canada - Summary Report* at 10-11, online: CMPA < http://www.cmpa-acpm.ca/portal/cmpa_docs/english/content/issues/common/secor/pdf/com_secor-e.pdf>.

³⁰² Prichard Report, *supra* note 299 at 21.

³⁰³ *Ibid.*, at 28-31.

regarding subrogation and structured settlements, which will be discussed further below.

Recent Medical Liability Reform Initiatives in Canada

In 1997, in response to increases in medical liability damages and legal costs, the CMPA commissioned the Honourable Mr. Charles Dubin to examine the Canadian medical liability system.³⁰⁴ The Dubin Report found that the existing medical liability tort system was soundly based and recommended against broad no-fault initiatives.³⁰⁵ However, the report did recommend further examination of limited designated compensable event approaches, such as those undertaken elsewhere for compromised infants.³⁰⁶

Two areas that have been identified as in need of reform are the issue of provincial subrogation for health-care costs and court involvement in ordering structured (periodic) payments. In 1990, the Prichard Report recommended that the practice of provincial subrogation for health-care costs arising out of medical negligence be discontinued and that courts be entitled to order structured (periodic) payments without the consent of both parties. These recommendations have yet to be followed in Common Law Canada but continue to be pursued by various stakeholders, particularly the CMPA. In fact, these were the primary recommendations arising out of the report of the 2000 Joint Tort Reform Working Group of the Canadian Medical

³⁰⁴ *Supra* note 295 at 9.

³⁰⁵ *Ibid.*

³⁰⁶ *Ibid.*

Association and the CMPA.³⁰⁷ In that report, the joint working group estimates that the CMPA's damages costs might be reduced by approximately 8% if courts were allowed to order a structure as part of the compensation package and by as much as 4.2% if the provincial practice of subrogation was discontinued. The CMPA once again reiterated this position regarding tort reform in its submission to the Romanow Commission dated December 21, 2001.³⁰⁸

The CMPA also recently conducted a comprehensive review of the medical liability system in Canada as well as various alternative methods of patient compensation used internationally. In its report entitled "Medical Liability Practices in Canada: Towards the Right Balance", issues of alternate dispute resolution, subrogation and structures remain at the forefront of reform initiatives.³⁰⁹ However, the report concludes that:

The current medical liability system in Canada is fundamentally sound and is very likely the best possible model for our circumstances. Alternative patient compensation models require significant additional financial resources and yet do not, by themselves, advance patient safety efforts. While this realization should cause decision-makers to pause before considering drastic changes to the existing model, it should not deter the application of commonsense reforms.

...

The sensible approach, in a resource-constrained environment, is to refine the existing medical liability system while focusing effort and resources on patient safety and risk management. Only by reducing

³⁰⁷ CMA and CMPA, *Tort Reform 2000 Structures and Subrogation: Background Paper Prepared by the Joint Tort Reform Working Group - CMA and CMPA*, online: CMPA < http://www.cmpa-acpm.ca/portal/cmpa_docs/english/resource_files/admin_docs/common/pdf/tort_backgrounder_2000-e.pdf >

³⁰⁸ CMPA, *CMPA Submission to the Commission on the Future of Health Care in Canada (Romanow Commission)*, at 13-14, online: CMPA < http://www.cmpa-acpm.ca/portal/cmpa_docs/english/resource_files/ml_issues/common/pdf/letter_to_romanow_2001_12_e.pdf >

³⁰⁹ *Supra* note 295.

the probability of adverse medical events will the health-care system ultimately decrease system costs and improve patient outcomes.³¹⁰

To date, very few substantive medical liability reforms have been made in Common Law Canada. Presumably this is at least partially as a result of the fact that the medical liability insurance system in Canada is relatively stable and economically viable. However, at present in Canada there is much that can be done within the current tort system to promote open disclosure and more timely and equitable compensation for victims of medical error. In particular, the current trend of increasing access to alternative dispute resolution in civil litigation should be continued. Additional methods of achieving early settlement of medical negligence claims such as early exchange of expert reports and judicial mediation should be actively pursued. In addition, the current trend towards more frequent and open disclosure of medical error may increase the number of lawsuits commenced but should help ameliorate one of the traditional weaknesses of the tort system, which is comprehensive victim compensation. Moreover, in appropriate cases of clear negligence, the early disclosure of medical error should be followed by an early settlement offer. If this is done, although the total number of lawsuits may increase, the actual costs of settlement and legal fees may in fact decrease

³¹⁰ *Ibid* at 22.

United States

As discussed above, the situation with respect to medical liability reform could not be more different in the United States and Canada. In the United States, individuals and groups on both sides of the debate have been working tirelessly to advance their respective positions. Significant reforms have been implemented in many states with mixed success and medical liability reform continues to be a significant issue in all but a few states. In this section I will address the primary medical liability reform initiatives that have been proposed or implemented in many states. I will then briefly examine the specific example of the Veterans Administration hospitals and the experiment undertaken with early disclosure of error and a mixed tort and modified no-fault liability regime.

Caps on Non-Economic Damages

In total, 25 states have enacted caps on non-economic damages with mixed success.³¹¹ As of June 2005, the following states all had enacted legislation establishing a cap on non-economic damages: Alaska, California, Colorado, Florida, Georgia, Hawaii, Idaho, Illinois, Kansas, Maryland, Massachusetts, Michigan, Mississippi, Missouri, Montana, Nevada, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, West Virginia, and Wisconsin.³¹²

³¹¹ *Supra* note 226 at 24; see also American Tort Reform Association, *Tort Reform Record – July 22, 2005*, online: ATRA < http://www.atra.org/files.cgi/7927_Record7-05.pdf>.

³¹² *Supra* note 226 at 24.

While it appears that many states have made significant strides in capping non-economic damages, the effectiveness of these caps varies greatly depending on the specific provisions of the legislation. However, a recent study suggests that caps may have a measurable impact on malpractice insurance premiums and also may impact the supply of physicians within the state that is subject to the cap.³¹³ Much of the effectiveness of the caps depends on whether the cap is a “hard” cap or a “soft” cap. A “hard” cap is characterized by a lack of exceptions, applies irrespective of the number of plaintiffs or defendants and generally does not adjust over time for inflation.³¹⁴ On the other hand, a “soft” cap may be subject to numerous exceptions, may apply individually to each defendant or plaintiff, thereby allowing multiple maximum awards in each action and may increase annually with inflation.³¹⁵

California is often held out by the champions of medical liability reform as a positive example of the effectiveness of medical liability reform on reducing medical liability insurance premiums. California's \$250,000 cap on non-economic damages that was instituted with MICRA is an example of a “hard” cap.³¹⁶ There are no exceptions to this cap that would allow juries or judges to award additional pain and suffering damages in sympathetic cases. In addition, the cap is fixed at \$250,000 and does not increase over time with inflation. While the appropriateness and fairness of this legislation may be debated, it is fairly clear that it has had a significant impact on the total medical liability insurance premiums paid by physicians in California since its

³¹³ William E. Encinosa & Fred J. Hellinger, “Have State Caps On Malpractice Awards Increased the Supply of Physicians?”, (2005) 5 Health Affairs 250.

³¹⁴ *Supra* note 226 at 24.

³¹⁵ *Ibid.*

³¹⁶ *Ibid.* at 40.

enactment. Between 1976 and 2002, medical liability insurance premiums in the rest of the United States rose approximately 750% while premiums in California rose only 245% over the same time period.³¹⁷ Critics of the legislation argue that state insurance reforms that increased regulation of the insurance industry in California in the 1980's have had a much greater impact. While this increased scrutiny may have also had an impact, there can be little doubt that the MICRA reforms have been effective in keeping medical liability insurance premiums from spiralling out of control in California.

There are many examples of states with “soft” caps and the success of those caps is mixed and depends largely on the specific provisions of the legislation. For example, after several years of concerted effort, Florida enacted a cap on non-economic damages in 2003. The legislation provides for a separate cap for practitioners (\$500,000) and non-practitioners (\$750,000) and can be increased to \$1 million and \$1.5 million respectively if the negligence results in death or a permanent vegetative state or if the court finds that a manifest injustice would occur if the cap was not increased.³¹⁸ It remains to be seen what the true effect of this cap will be but as of today, Florida's medical liability insurance system remains in crisis.

³¹⁷ *Ibid.* at 41.

³¹⁸ *Ibid.* at 25.

Caps on Total Damages and Punitive Damages

In a further attempt to address the medical liability insurance crisis, several states have gone further and enacted caps on total damages. At this time, only six states have enacted caps on total damages for medical liability actions - Colorado, Indiana, Louisiana, Nebraska, New Mexico, and Virginia.³¹⁹ In addition, the following states have enacted caps on punitive damages in a further effort to reduce unreasonable jury awards: Alabama, Alaska, Arkansas, Colorado, Connecticut, Florida, Georgia, Idaho, Illinois (declared unconstitutional in 1997), Indiana, Kansas, Mississippi, Montana, Nevada, New Hampshire (punitive damages abolished in 1986), New Jersey, North Carolina, North Dakota, Ohio, Oklahoma, Oregon (medical negligence punitive damages abolished against physicians), Pennsylvania, Texas and Virginia.³²⁰

Modification of the Joint and Several Liability Rule

Another main goal of the tort reform initiative in the United States has been to abolish or modify the rule regarding joint and several liability of defendants. Proponents of these reforms assert that joint and several liability is unfair to co-defendants as the plaintiff is entitled to collect the entire judgment from any one of multiple defendants even if that defendant was only assigned a small percentage of the overall liability. Some states have abolished the rule entirely while others have attempted to modify its impact on defendants by enacting legislation which only requires defendants to pay

³¹⁹ *Ibid.* at 24; see also ATRA Record, *supra* note 311.

³²⁰ ATRA Record, *ibid.*

their proportionate share of liability. At this point, the majority of states have enacted legislation modifying or abolishing the joint and several liability rule either generally or for medical negligence actions in particular, they include: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Hawaii, Idaho, Illinois (declared unconstitutional in 1997), Indiana, Iowa, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Texas, Utah, Vermont, Washington, West Virginia, Wisconsin and Wyoming.³²¹

Modification of Collateral Source Rule

Many states have also introduced legislation to require plaintiffs to disclose compensation they receive from collateral sources as a result of injuries allegedly sustained as a result of medical negligence. In certain circumstances, this compensation can then be deducted from the overall judgment available to the plaintiff in the medical malpractice action. In addition to the District of Columbia, the following states have enacted legislation modifying the collateral source rule: Alabama, Alaska, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New

³²¹ *Ibid.*

Jersey, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Utah, Washington and Wisconsin.³²²

Limitations on Attorney's Fees and Contingency Arrangements

In addition to the reforms discussed above, many states have attempted to reduce the financial incentive for plaintiffs' medical negligence lawyers by reducing or abolishing contingency arrangements and placing overall caps on attorney fees. The following states have placed some limitation on attorney fees or restricted or abolished contingency arrangements: California, Connecticut, Delaware, Florida, Illinois, Indiana, Maine, Massachusetts, New Jersey, New York, and Wisconsin.³²³

Structured Settlements and Periodic Payments

Until relatively recently, few states had legislation in place that would allow the court to order periodic payments or structured settlements without the consent of both parties. The following states have legislation that either requires periodic payments or allows the court to order periodic payments upon the application of one of the parties: Arkansas, California, Colorado, Connecticut, Delaware, Florida, Idaho, Illinois, Iowa, Louisiana, Maine, Maryland, Michigan, Missouri, Montana, Nevada, New Mexico, New York, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina,

³²² *Ibid.*

³²³ *Ibid.*

South Dakota, Utah, Washington and Wisconsin.³²⁴ Arizona and Kansas had legislation in place but it was declared unconstitutional in 1994 and 1988 respectively.³²⁵

Recent Attempts at Federal Legislative Reform

As can be seen from the above discussion, medical liability reform in the U.S. is a loose patchwork with significant differences from state to state. This has resulted in a disparity in access to health care among the states. In addition, these differences have also resulted in the movement of physicians between states in an attempt to find a more stable medical liability environment. As a result of these problems, there has been a recent push to enact Federal legislation to provide a more comprehensive and cohesive medical liability regime throughout the U.S.

On February 5, 2003, the Help, Efficient, Accessible, Low-cost, Timely Healthcare Act of 2003 (HEALTH Act) was introduced in the U.S. House of Representatives.³²⁶ The provisions of the HEALTH Bill are intended to ensure that patients receive 100% compensation for their economic losses if harmed by a physician's negligence.³²⁷ The HEALTH Bill also places limits on non-economic damages of \$250,000 and allows states the flexibility to establish or maintain their own laws on damages whether

³²⁴ *Ibid.*

³²⁵ *Ibid.*

³²⁶ *Supra* note 226 at 42.

³²⁷ *Ibid.*

higher or lower.³²⁸ The HEALTH Bill also establishes a sliding scale for attorney's fees and allows periodic payments for future damages.³²⁹ The HEALTH Bill also addresses the joint and several liability issue and establishes a "fair share" rule that allocates damages in proportion to fault.³³⁰ The HEALTH Bill was passed on March 13, 2003 by a vote of 229-196. However, despite attempts on similar proposed legislation introduced in the U.S. Senate on June 26, 2003 and February 24, 2004, the Senate has failed to pass any meaningful medical liability reform to date.

Reforms Initiated at Veterans Administration Hospitals

Although the Veterans Administration (VA) hospitals in the U.S. operate under the federal system and under legislation which provides a modified tort and no-fault style compensation scheme, lessons learned regarding the impact of early disclosure and early settlement offers in the VA system could also be applied in the traditional tort system. Many VA hospitals instituted mandatory error disclosure systems combined with early offers of settlement and have found that while the number of claims made has increased, the overall liability costs have decreased.³³¹ The primary difficulty in instituting some of the policies from the VA hospitals in the traditional tort system will be the resistance of private malpractice insurers whose primary goal is a reduction in claims and a maximization of profit.

³²⁸ *Ibid.*

³²⁹ *Ibid* at 42-43.

³³⁰ *Ibid* at 43.

³³¹ Steve S. Kraman & Ginny Hamm, "Risk Management: Extreme Honesty May Be the Best Policy" 131 *Annals of Internal Medicine* 963.

Notwithstanding the similarities in the essential structure of the tort system between the United States and Canada, the experiences of the two nations with respect to medical liability are strikingly different. In the United States there exists a national medical liability insurance crisis. The reasons for this crisis arise from the use of juries and the size of damage awards as well as the nature of the insurance industry, the nature of and relationship between the medical profession and the legal profession and general public attitude and expectations. In addition, this crisis exists notwithstanding the significant medical liability reform strides made by many states in the last 30 years. There is a general consensus by most governments and healthcare providers in the U.S. that the medical liability system is broken and in need of drastic reform. In contrast, in Canada the current medical liability system is not perfect but is sustainable. In the end it remains to be seen whether more drastic reforms and alternate methods of patient compensation gain sufficient momentum in Canada in order to ultimately be implemented.

No Fault Compensation System?

Some scholars argue that the current tort system for medical negligence is ineffective as a method of compensation of injured patients and advocate a no-fault system.³³²

However, the implementation of a no-fault system for medical malpractice claims

³³² See for example Bryan A. Liang, "The Adverse Event of Unaddressed Medical Error: Identifying and Filling the Holes in the Health-Care and Legal Systems" (2001) 29 *Journal of Law Medicine & Ethics* 346; David M. Studdert & Troyen A. Brennan, "No-Fault Compensation for Medical Injuries: The Prospect for Error Prevention" (2001) 286 *Journal of the American Medical Association* 217; David M. Studdert & Troyen A. Brennan, "Toward a Workable Model of "No-Fault" Compensation for Medical Injury in the United States" (2001) 27 *American Journal of Law & Medicine* 225; and David M. Studdert, Michelle M. Mello & Troyen A. Brennan, "Medical Malpractice" (2004) 350 *New Eng. J. Med* 283.

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.³³³ Moreover, any move to a no-fault compensation system would necessarily require a drastic decrease to the compensation available to patients. Most no-fault compensation systems focus on limited compensation of economic losses and severely restrict amounts for noneconomic damages. Although, a no-fault system would generally compensate a greater number of patients, the compensation for those that receive it would be a small fraction of what they may have received through the tort system.

Advocates of a medical no-fault system, in the process of making their case for reform, rarely provide specific details as to how the system would actually work.³³⁴ These proposals, even when fairly detailed, invariably focus on clear system or medication errors and avoid a discussion of how a no-fault system would deal with the majority of medical error cases, which are multifactorial and complex.³³⁵ In the medical liability context, it is easier to envision a no-fault system being effective when dealing with systems errors such as harm caused by the administration of the wrong drug. In these cases, the error is usually clear, is often attributed to a system breakdown, and there is rarely a significant causation issue. However, many medical error cases do not fit neatly into this category. Many medical error cases, perhaps

³³³ Vincent & Young, *supra* note 240.

³³⁴ *Supra* note 332; and *supra* note 232 at 271-272; For an introductory discussion and some suggestions as to how a no-fault style system would work see also Mimi Marchev, "Medical Malpractice and Medical Error Disclosure: Balancing Facts and Fears" 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>;

³³⁵ See for example *supra* note 332.

most, involve a complex clinical presentation and often require detailed examinations, potentially involving medical expert evidence, to determine if an error occurred at all. Once this determination has been made then a further examination must occur to determine the cause of the error.

In contrast to the erroneous drug administration discussed above, consider a case of delayed diagnosis of cancer as a result of a challenging clinical presentation and pathological examination. Even setting aside the issue that it would be extremely difficult to determine if an error occurred at all in this circumstance, in a no-fault regime, the determination of compensation would still be extremely complicated. Given that the patient may have had an extremely poor prognosis regardless of any delay in diagnosis, any principled determination of compensation would involve a complex and detailed investigation, likely involving multiple experts.

In addition, medical malpractice litigation is almost never as clear-cut as most motor vehicle or workplace accident cases. These are areas where no fault schemes have been successful primarily because most workplace or motor vehicle injuries are generally readily ascertainable and it is usually quite clear what caused the injury. In the medical context, cases are almost always much more complex. In most cases a significant investigation will be required to determine whether the patient's injury was a result of a preventable adverse event or if it was simply an unfortunate outcome or a development of the patient's underlying condition.

This type of investigation does occur routinely in New Zealand and Sweden, two countries that are often held out as having workable no-fault systems.³³⁶ In fact, both countries have had significant difficulties administering their systems and have had to make significant changes to control costs.³³⁷ The New Zealand system requires a determination of fault for a medical error by the Accident Compensation Corporation or that a medical mishap occurred and caused a “rare and severe” injury under an accepted treatment.³³⁸ The Swedish system requires that the medical error must have been “unintended and avoidable” in order to obtain compensation.³³⁹ Accordingly, both systems have some requirement for an element of fault and therefore neither system can truly be considered a pure no-fault system. In addition, both systems exist within larger, overarching compensation systems and social safety nets, and therefore the portability of these systems to Canada is questionable.

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

³³⁶ *Supra* note 301 at 4.

³³⁷ *Ibid.* at 16-19.

³³⁸ *Ibid.* at 16.

³³⁹ *Ibid.* at 18-19.

involved to determine appropriate awards, treatment plans etc., would be staggering.

Moreover, 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.³⁴⁰ The CMPA commissioned an independent report by SECOR Consulting, which determined that admitting all medical treatment injuries in Canada to a no-fault compensation system would increase the CMPA's annual program costs from \$225 million to \$40 billion.³⁴¹ The \$40 billion figure was based on an assumption that patients under the no-fault system would be compensated at half the average level of the current tort system.³⁴² Accordingly, if patients under a no-fault system were compensated more than that, the \$40 billion figure could increase significantly. By limiting the number of cases entering the system to “unintended and avoidable” injuries and reducing per-case indemnities to 25% of today's level for smaller claims and 50% of today's level for larger claims, SECOR Consulting found that the total annual cost of the program would be \$2.6 billion.³⁴³ These amounts also did not include the initial administrative costs associated with creating and staffing an entirely new national system of patient compensation, which would likely be significant. These amounts also do not include the corresponding increase to the litigation and settlement costs of the various health regions and hospitals across the country, which would also be significant. As a result of the potential overall costs of a national no-fault patient compensation system in

³⁴⁰ *Supra* note 295 at 22.

³⁴¹ SECOR Report, *supra* note 301 at 10.

³⁴² *Ibid.*

³⁴³ *Ibid.*

Canada, the more prudent financial decision would be to focus our efforts on reform of the current system.

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.

One author has reviewed the benefits and detriments of a potential no-fault system for medical error and suggests that a no-fault regime for clear systems errors could be combined with the traditional tort system.³⁴⁴ This is an interesting concept that merits further examination. It may, in fact, be possible to incorporate aspects of a no-fault regime into the current tort system for clear cases of medical error and most adverse drug events. However the potential ramifications of any proposed reform should be carefully studied and the other reforms to the current tort system discussed above should be given a full opportunity to take effect before any drastic changes are implemented.

³⁴⁴ *Supra* note 251.

Protection of Quality Assurance Activities

Once a potential medical error has occurred, in most hospitals an internal investigation is commenced by a quality assurance or similar 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. These 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, this tension can be ameliorated by clear policies on what information is required to be disclosed to the patient after an adverse event. As discussed above, only the facts of the adverse event as well as its impact on the patient's treatment need be disclosed to the patient. It is not necessary and in fact inadvisable for there to be a discussion about cause or blame. 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. In this section, the issues surrounding the protection of quality assurance activities will be discussed. In particular, the current legislative scheme in Alberta will be examined with a view to

determining whether there is sufficient protection for quality assurance activities in the province.

In order to encourage openness and full disclosure in internal incident reviews as well as reviews of the conduct and competence of physicians, strong protection for quality assurance and peer review activities must be maintained. It is only through this openness and full disclosure that health-care providers can fully examine adverse events and develop policies, procedures and systems in order to prevent them from occurring in the future. If the protection for quality assurance activities is eroded, health-care providers will be concerned that any information that they provide during these processes could be used against them or their colleagues in subsequent litigation. If this is the case, it will encourage health-care providers to be circumspect and hold back information for fear of negative consequences. Ultimately, patient safety will be compromised as a significant amount of useful information that can be learned from adverse events will remain undiscovered. While a detailed discussion of quality assurance issues across Canada is beyond the scope of this paper, I will discuss the central issues and will focus on the specific legislation in place in Alberta.

The formal conduct of quality assurance reviews by hospitals and the corresponding movement towards protection of these activities from disclosure in legal proceedings are relatively recent phenomena in Canada. In essence, there are two specific functions of hospital quality assurance programs:

- (a) ongoing review of patient care, and

(b) appropriate follow-up mechanisms to maintain the quality of care.³⁴⁵

Properly functioning hospital quality assurance programs focus on patients and the quality of patient care being delivered and are not, strictly speaking, risk management activities. In contrast, hospital risk management programs are concerned with actual and potentially compensable events and the protection of the institution against liability claims and losses.³⁴⁶

The work of quality assurance committees and peer reviewers involves detailed analysis of outcomes of patient care and the treatment provided by individual physicians and other health-care providers. In order for these reviews to be effective, participants in the process must be free to honestly and critically assess the care provided. As a general rule, physicians are usually reluctant to criticize each other or to interfere in the practices of others.³⁴⁷ This reluctance to report substandard care is primarily a result of a fear of a disproportionately severe punishment or being involved in a lawsuit.³⁴⁸ In my view, this reluctance would be exacerbated by non-existent or weak protections for quality assurance activities.

All jurisdictions in Canada have enacted legislation that prohibits the admission of information, documents or records that arise out of a quality assurance review by an appropriately constituted quality assurance committee in the context of an action. Prior to the enactment of this legislation, arguments regarding the production of

³⁴⁵ Marion Stevens, "Protection of Quality Assurance and Peer Review Data" (1989) 9 *Health Law in Canada* 167 at 167.

³⁴⁶ *Ibid.*

³⁴⁷ *Ibid.* at 168.

³⁴⁸ *Ibid.*

quality assurance information usually centered around common-law privilege and the Wigmore criteria. In *Slavutych v. Baker*, the Supreme Court of Canada adopted and applied the following four Wigmore principles:

- 1) the communication must originate in confidence with assurance that it will not be disclosed;
- 2) the element of confidentiality must be essential to the full and satisfactory maintenance of the relation between the parties;
- 3) the relation must be one which, in the opinion of the community, ought to be sedulously fostered; and
- 4) on balance, the injury that would be caused by disclosure of the communication must be greater than the benefit thereby gained for the correct disposal of litigation.³⁴⁹

Prior to the enactment of the legislated protection for quality assurance activities, parties opposing production of quality assurance information had to rely on the above principles of privilege. Parties opposing production of this information would have no difficulty meeting the first three criteria but the fourth criterion posed a much greater problem. The fourth criterion required the courts to be convinced that the benefits of full and free disclosure in quality assurance committees outweighed the benefits of having this information produced in the litigation. Eventually, the various legislatures stepped in and through legislative protection, answered the fourth criterion of the Wigmore test. In essence, by statute the legislatures deemed that the injury caused by disclosure of quality assurance information would be greater than the benefit gained in the correct disposal of litigation.

³⁴⁹ [1976] 1 S.C.R. 254.

In Alberta, the statutory protection for quality assurance activities is found in section 9 of the *Alberta Evidence Act*.³⁵⁰ Section 9 states:

9 (1)(a)"quality assurance activity" means a planned or systematic activity the purpose of which is to study, assess or evaluate the provision of health services with a view to the continual improvement of

- (i) the quality of health care or health services, or
- (ii) the level of skill, knowledge and competence of health service providers;

(b)"quality assurance committee" means a committee, commission, council or other body that has as its primary purpose the carrying out of quality assurance activities [...];

(c) "quality assurance record" means a record of information in any form that is created or received by or for a quality assurance committee in the course of or for the purpose of its carrying out quality assurance activities, [...]

(2) A witness in an action, whether a party to it or not,

(a) is not liable to be asked, and shall not be permitted to answer, any question as to any proceedings before a quality assurance committee, and

(b) is not liable to be asked to produce and shall not be permitted to produce any quality assurance record in that person's or the committee's possession or under that person's or the committee's control.

[...]

(5) Neither

(a) the disclosure of any information or of any document or anything contained in a document, or the submission of any report, statement, memorandum or recommendation, to a quality assurance committee for the purpose of its quality assurance activities,

nor

(b) the disclosure of any information, or of any document or anything contained in a document, that arises out of the quality assurance activities of a quality assurance committee,

³⁵⁰ R.S.A. 2000 c. A-18.

creates any liability on the part of the person making the disclosure or submission.

Section 1 of the *AEA* provides the following definitions:

- (a) "action" includes
 - (i) an issue, matter, arbitration, reference, investigation or inquiry,
 - (ii) a prosecution for an offence committed against an Act of the Legislature or in force in Alberta, or against a bylaw or regulation made under the authority of any such Act, and
 - (iii) any other proceeding authorized or permitted to be tried, heard, had or taken by or before a court under the law of Alberta;

- (b) "court" includes a judge, arbitrator, umpire, commissioner, provincial judge, justice of the peace or other officer or person having by law or by the consent of parties authority to hear, receive and examine evidence;

- (c) "witness" includes a person
 - (i) who in the course of an action is examined orally on discovery, or is cross-examined on an affidavit made by the person,
 - (ii) who makes answer by affidavit on any interrogatories, or
 - (iii) who makes an affidavit of documents on discovery.

It is clear that section 9 of the *AEA* (and the equivalent provisions of the other provincial statutes) provides an express prohibition against the use and admissibility of information and documents arising out of quality assurance activities. Further, even quality assurance information or records that are intentionally or inadvertently disclosed to the plaintiff or others remain inadmissible in a subsequent civil proceeding.

Surprisingly, in Alberta, the statutory prohibition contained in section 9 has rarely been the subject of judicial interpretation. In *Goad (Guardian Ad Litem) v.*

Cavenagh, Madam Justice Trussler, in dealing with an application to obtain the minutes of a medical advisory committee meeting where a summary of an investigation had been discussed, made the following comments regarding section 9:

The Legislature has seen fit to pass legislation in the form of the Alberta Evidence Act and to include therein section 9. In doing so the Legislature has obviously, as elected representatives, made a decision of public policy. This section may be restricted in an age of fuller disclosure, but the section does exist and it is up to the Legislature to make any amendments to it. The object of this section is obviously to promote full discussion by the groups mentioned therein with the purpose of creating an atmosphere in which matters can be investigated and improvements can be made.

[...]

Section 9(1)(b) creates a prohibition against the production of these documents. It is, therefore, not a question of whether or not there is a privilege with respect to these documents, it is a question of an outright prohibition. [...] As a result the hospital and the doctors are prohibited by legislation from producing the documents in question.³⁵¹

However, it is important to note the limitations of this express prohibition. Unlike provisions in other information statutes, section 9 of the *AEA* does not attempt to limit the *disclosure* of quality assurance information. On a plain reading, section 9 only deals with the *admissibility* of information and production of documents once an “action” has been commenced. This is not surprising given that the provision is contained within an evidence act and not a health information act. However, the practice by most physicians, hospitals, health regions and defence counsel in Alberta has traditionally been to interpret section 9 more broadly to prohibit *disclosure* of quality assurance information in any circumstance. This interpretation is certainly in accordance with the statutory purpose of section 9 as it seems unreasonable that

³⁵¹ [1992] A.J. No. 1268 at paras. 7-9 (QL).

information the legislature saw fit to protect with a statutory prohibition after an action is commenced would be subject to discretionary disclosure prior to the commencement of an action. Unfortunately, as will be discussed further below, it appears that this is the current legislative situation in Alberta. However, given that section 9 prohibits the use of quality assurance information in “actions”, even if that information is intentionally or inadvertently disclosed, the health care providers are still protected from being asked questions about it in the context of an action. Unfortunately, this may be small comfort to many health care providers. If quality assurance information is routinely disclosed, it could cause significant damage to the effectiveness of the quality assurance process as individuals would likely become much more reluctant to provide damaging information or speak freely. While defence counsel may wish to interpret section 9 as an outright prohibition against disclosure at any stage, it is unlikely that this interpretation would withstand judicial scrutiny. Accordingly, in order to determine whether quality assurance information can be disclosed and if so under what circumstances, we are required to look to the *Health Information Act* (HIA) and the *Freedom of Information and Protection of Privacy Act* (FOIPPA).

Quality assurance records (within the meaning of section 9 of the *AEA*) have been specifically exempted from the application of *FOIPPA*.³⁵² Therefore a quality assurance committee, hospital or health region cannot be compelled to release quality assurance information under a *FOIPPA* application. That does not mean that under the *FOIPPA* quality assurance information cannot be disclosed voluntarily. However,

³⁵² Section 4 (1)(c), *Freedom of Information and Protection of Privacy Act* R.S.A. 2000 c. F-25.

even if this information is disclosed voluntarily to a public body that is subject to the *FOIPPA*, the exemption for Quality Assurance records would nevertheless apply and use of that information in an action would be prohibited. In addition, the *FOIPPA* does not apply to health information as defined in the *HIA*.³⁵³ If a patient or other interested party wishes access to Health Information as defined in the *HIA*, then they must make an application under the *HIA* not the *FOIPPA*. Accordingly, the *FOIPPA*'s potential application in areas of Quality Assurance is extremely limited and would be restricted to any information or records that do not meet the definition of Health Information in the *HIA* or the definition of a Quality Assurance Record in the *AEA*.

As discussed above, in Alberta the other major piece of legislation that regulates the disclosure of information in the health setting is the *HIA*. It is important to note however that the *HIA* only applies to health information as defined in that Act. Section 1 (1) defines Health Information as any or all of the following: (i) diagnostic, treatment and care information; (ii) health services provider information; (iii) registration information.³⁵⁴ It is important to note that quality assurance information that is not Health Information such as opinions or recommendations would, as a general rule, be beyond the scope of the *HIA*. The *HIA* does not refer specifically to quality assurance information but there are two sections that would apply in certain circumstances.

³⁵³ *Ibid.*, section 4 (1)(u).

³⁵⁴ Section 1 (1), *Health Information Act* R.S.A. 2000 c. H-5.

Section 11 (2) states that a custodian *must* refuse to disclose health information to an applicant:

(b) if the health information sets out procedures or contains results of an investigation, a discipline proceeding, a practice review or an inspection relating to a health services provider.³⁵⁵

However, it is important to note the limitations of this section given that it refers only to a “health services provider” as defined in the legislation. Section 1 (1)(n) defines “health services provider” as an *individual* who provides health services.³⁵⁶ Accordingly, section 11 (2) creates a prohibition against the disclosure of health information only when that health information relates to an individual health services provider and would not apply to quality assurance information more generally. For example, a quality assurance review of operating room practices or procedures would not relate to an individual health service provider and therefore would not be subject to the prohibition under section 11 (2). In addition, even in a review that is within the scope of section 11 (2), it is unlikely that the prohibition could be reasonably extended to include opinions or recommendations of the participants or the committee as they are not technically “Health Information”. Section 11 (2)(d) also prohibits disclosure in circumstances where the disclosure is prohibited by another enactment of Alberta. However, this is of little assistance with respect to quality assurance information as the prohibition contained within section 9 of the *AEA* is not a prohibition against disclosure but only a prohibition against the use of quality assurance information in the context of an “Action”. Therefore, since the outright prohibitions in section 11 (2) do not apply to most quality assurance information, we

³⁵⁵ *Ibid.*, section 11 (2).

³⁵⁶ *Ibid.*, section 1 (1)(n).

must look to other provisions of the *HIA* to determine whether this information can be protected from disclosure.

Section 11 (1) provides discretion to custodians of health information to refuse disclosure in certain circumstances. Section 11 (1) states:

11 (1) A custodian may refuse to disclose health information to an applicant

[...]

(b) if the disclosure could reasonably lead to the identification of a person who provided health information to the custodian explicitly or implicitly in confidence and in circumstances in which it was appropriate that the name of the person who provided the information be kept confidential,

[...]

(d) if the disclosure could reasonably be expected to reveal advice, proposals, recommendations, analyses or policy options developed by or for a custodian referred to in section 1 (1)(f)(iii), (iv) or (vii),

These provisions certainly provide discretion to refuse disclosure in circumstances where the requested Health Information meets the requirements of the subsections. However, the same weaknesses discussed previously apply here in that the discretion to refuse disclosure contained in section 11 (1)(b) & (d) only applies to Health Information as defined and would not apply to recommendations or opinions.

As has been made clear in the above discussion, the statutory framework in Alberta with respect to disclosure of quality assurance information is complex and lacks coherence. It is evident that the Alberta legislature made a clear policy decision in favour of the protection of quality assurance information when it enacted section 9 of

the *AEA*. As stated by the B.C. Court of Appeal in discussing the equivalent provision of the British Columbia legislation:

...the Legislature intended to protect this area of hospital activity by preventing access by litigants. Rather than striking a balance of interests, the Legislature made a clear choice in favour of one interest, hospital confidentiality.³⁵⁷

The clear purpose of these types of provisions is to promote full discussion by the participants in quality assurance reviews in order to create an atmosphere where matters can be investigated fully and improvements made.³⁵⁸ It is only through a free and open discussion that the root causes of adverse events can be determined. In addition, these free and open discussions can only take place if the participants are confident that their opinions and the documents created will be protected from disclosure. Unfortunately, the Alberta legislature has failed to follow through by putting in place adequate protection for quality assurance in its subsequent information legislation.

In Alberta, as it stands now, prior to an action being commenced, disclosure of Quality Assurance Records that are not Health Information cannot be compelled as a result of the fact that they are specifically exempted from the application of the *FOIPPA*. Quality Assurance Records that are considered Health Information are either prohibited from disclosure under the *HIA* if they relate to a Health Services Provider or can be disclosed on a discretionary basis if the provisions of section 11 (1)(b) or (d) are met. Accordingly, the only statutory prohibition against disclosure of quality assurance information is found in the limited scope of section 11 (2)(b) and

³⁵⁷ *Sinclair v. March*, [2000] B.C.J. No. 1676 at para. 26 (QL).

³⁵⁸ *Supra* note 351.

only applies to information regarding individual health service providers. As stated above, the statutory prohibition found in section 9 of the *AEA* is only a prohibition against the use of quality assurance records in the context of an “action” and does not prohibit hospitals, health regions or individual health care providers from disclosing this information to patients. As a result, the decision as to whether to disclose quality assurance information is generally discretionary and is left open to individual health regions, hospitals or health care providers. From a policy perspective, this is problematic in that the free and open participation of individuals in the quality assurance process may not be adequately protected.

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 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 the 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.

Apology/Disclosure Privilege

An 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. If statements made by health providers 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 open and honest with patients after an adverse event. This would facilitate a much more open discussion of the incidence and causes of medical error. It would also facilitate more widespread dissemination of information learned from error throughout the hospital and to other institutions. An apology and disclosure privilege would also allow physicians to more freely address the concerns raised by patients, which 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.³⁵⁹ Interestingly, Colorado has recently instituted a statutory apology privilege and, although it is not yet certain whether it

³⁵⁹ 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 131; *supra* note 251; and *supra* note 331; Some authors are not so sure - see for example *supra* note 246.

will have a significant impact on the number of lawsuits filed, it will certainly encourage a more open system of error disclosure.³⁶⁰

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.³⁶¹ 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 civil proceedings, the statutory privilege would free physicians to apologize and provide patients with the information that they desire.

³⁶⁰ Jonathan R. Cohen, "Toward Candor After Medical Error: The First Apology Law" (2004) 5 Harvard Health Policy Review 21.

³⁶¹ *Supra* note 241.

PART IV – CONCLUSIONS

As part of a comprehensive and strategic response to medical error and patient safety, all health-care practitioners and administrators need to familiarize themselves with the individual and systemic aspects of medical error. In particular, “frontline” health practitioners and physicians should receive error avoidance training, be familiar with “error wisdom” and be prepared:

- to accept that errors will inevitably occur;
- to assess the potential ramifications before embarking on a task;
- to have contingency plans ready to deal with anticipated and unanticipated problems;
- to seek more qualified assistance when necessary;
- to be assertive and not let professional courtesy get in the way of challenging the decisions, knowledge or experience of colleagues, particularly when they are strangers; and
- to fully appreciate that the path to adverse incidents is paved with false assumptions.³⁶²

In addition to an increased sensitivity to error issues, health care institutions need to look at technological advances in error prevention and error reporting. In addition, governmental authorities and the Canadian Patient Safety Institute should look to whether national error reporting systems or the public release of performance and medical error data would help promote and encourage patient safety initiatives in Canada.³⁶³

³⁶² Adapted from James Reason, “Beyond the Organizational Accident: The Need for “Error Wisdom” on the Frontline” (2004) 13 *Quality & Safety in Health Care* 28 at 32.

³⁶³ For a discussion on these issues in the U.S., see *supra* note 122.

While a punitive, blame culture, is counterproductive from a patient safety perspective, so too is a culture of avoidance, denial and minimization. The tendency of past responses to medical error has been to focus on individual aspects of error and to avoid a critical analysis of the systemic causes of medical error.³⁶⁴ However, in order for there to be meaningful reform of the health-care system and a reduction in medical error, substantial and wide ranging systemic changes must occur. There are five key areas that every health-care institution should look to in guiding patient safety efforts:

- 1) reduction of system complexity;
- 2) information processing should be optimized;
- 3) automation should be pursued but implemented cautiously, not just for the sake of technological advancement;
- 4) physical, procedural and cultural constraints to make it difficult to commit error should be implemented; and
- 5) attempts should be made to mitigate the unwanted side effects of change.³⁶⁵

In addition, every medical error, adverse event and near miss needs to be fully discussed, investigated and acted upon by the medical professionals involved as well as by hospital administration. More importantly, every error and near miss provides critical patient safety information and must be learned from. Procedures and policies to share this information with other institutions across the country must also be developed and implemented. If this is done faithfully, institutions in one location can learn from unfortunate adverse events that occur elsewhere, and can also prevent them from occurring in the future.

³⁶⁴ *Supra* note 216.

³⁶⁵ Thomas W. Nolan, "System Changes to Improve Patient Safety" (2000) 320 *British Medical Journal* 771.

In order to reduce medical error and increase patient safety, health providers must also feel less constrained in disclosing medical errors both to patients and to hospital administrators. Without more open disclosure, many errors will go uninvestigated and the opportunity to learn from these mistakes will be lost. 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. In particular, the medical profession can no longer afford to perpetuate the culture of infallibility or to view errors as failures of character. 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 addition, attempts at reforming the medical liability system should not be made in isolation from patient safety efforts. In order for significant strides to be made in increasing patient safety, it is critical that the medical liability reform movement and patient safety movements work together and consider the broader impact of the proposed changes to the health and legal systems.³⁶⁶

³⁶⁶ Peter P. Budetti, "Tort Reform and the Patient Safety Movement: Seeking Common Ground" (2005) 293 *Journal of the American Medical Association* 2660.

However, in Canada, as opposed to the U.S., widespread reform of the medical liability system is unnecessary and inadvisable. Currently, our medical liability insurance system is stable and sustainable and implementation of a widespread no-fault compensation system could have catastrophic financial consequences. While it is clear that the current medical liability system is inefficient as a method of victim compensation, much can be done to improve this efficiency without pursuing a no-fault compensation system. In particular, early exchange of expert reports, further pursuit of alternative dispute resolution mechanisms and early settlement offers in circumstances of clear negligence are all critical to improving efficiency of the tort system and providing plaintiffs with just compensation. In addition, the current movement towards more timely and open disclosure of medical error must be fostered and will ensure that more patients are provided with the information necessary to determine whether or not they should pursue compensation through the tort system.

While more timely and open disclosure of medical error carries with it the risk of increased lawsuits, this is by no means clear. What most patients want when they have been injured by a medical error is an explanation and an apology, and compensation falls fairly low on the priority list. In any event, disclosure of medical error is both legally and ethically required and is simply the right thing to do. Even if more open disclosure of medical error causes an increase in malpractice lawsuits, this will simply mean that the tort system will be doing a better job of providing compensation for victims of negligence.

In order to facilitate this more free and open disclosure of medical error, a critical requirement is the enactment of a statutory apology/disclosure privilege. 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. It is likely that many physicians would want to apologize to the patient or their family after a medical error has occurred, but many would 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.

Another important legal aspect of patient safety efforts is the protection of quality assurance activities. Quality assurance and critical incident reviews are an integral part of the patient safety and quality improvement efforts on the part of hospitals and health regions. By enacting evidentiary protection for quality assurance information, the provincial legislatures have made a clear policy choice that free and open discussion in quality assurance reviews is of paramount importance. Unfortunately, with the advent of privacy and health information legislation in most provinces, this protection envisioned by the legislatures may no longer be as clear as it should be. In particular, legislative reform is required in Alberta to clarify the statutory framework

and ensure that the free and open exchange of information within the quality assurance system is protected. The more solid the protection for quality assurance activities, the more likely it will be that physicians and other health-care providers will provide critical and constructive information regarding medical errors. Armed with this critical analysis of medical errors, quality assurance committees can more effectively conduct their quality improvement duties and make recommendations that will have a significant positive impact on patient safety. If the protection for quality assurance activities is weakened or there is a broad discretionary authority to disclose, individual health-care providers will be inclined to be less open and critical of their colleagues and systems for fear that this information will be disclosed.

Ultimately, it remains to be seen what positive impact the 1999 Institute of Medicine “*Too Err is Human*” report and all of the other international adverse event studies will have on overall patient safety. As of yet, we have not seen a significant decrease in the incidence of medical error in the more recent studies as compared to the Harvard study conducted in the early 1990’s. In addition, several experts have expressed disappointment at the progress that the patient safety movement has made, particularly in the U.S., more than five years after the IOM report.³⁶⁷ However, there can be no doubt that reducing medical error has become a primary goal of the governments of many industrialized nations and considerable financial and human resources have been invested in finding effective strategies to increase patient safety. Admittedly, it is unrealistic to expect that we will be able to eliminate medical error

³⁶⁷ Leape & Berwick, *supra* note 123; see also Troyen A. Brennan et al., “Accidental Deaths, Saved Lives, and Improved Quality” (2005) 353 *New Eng. J. Med.* 1405.

completely given the uncertainties of Medicine and that our health-care systems are inherently human systems, subject to human fallibility.

In the end, significant strides in reducing medical error can only be made if governments, the health professions and the legal profession work together to develop comprehensive patient safety strategies. The implementation of these strategies must be accompanied by legislative change and focused financial investment by governments. In addition, health professionals must be trained in error wisdom, teamwork and safety. The methods by which physicians are educated and our hospitals are staffed must also be re-examined. Moreover, implementation of electronic health records must be pursued and appropriate, user-friendly, computer systems must be developed. We must also ensure that appropriate procedures and practices are in place to disclose medical errors and that the legal system is not a barrier to increased patient safety. Finally, procedures and methods for sharing patient safety information throughout the country must be developed and implemented. All of these goals are within our grasp and with sufficient will and leadership we can all ultimately benefit from a safer and more effective health care system.

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