THE IMPACT OF DISCLOSURE OF ADVERSE EVENTS ON LITIGATION AND SETTLEMENT

A REVIEW FOR

THE CANADIAN PATIENT SAFETY INSTITUTE

Prepared by: Jill Taylor, B.N., LL.B.

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As promised, your requests for a change to disclosure practices have been conveyed. With time, and the commitment of those involved in the promotion of patient safety, in particular The Canadian Patient Safety Institute will work toward honouring your sincere desire to see patients and families impacted by adverse events respected and treated with dignity and honesty.

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Executive Summary

This project was undertaken for the Legal and Regulatory Advisory Committee of the Canadian Patient Safety Institute and involved a review of the literature and case law, as well as an informal survey. The information gathered was then synthesized to inform the threefold objective:

- Provide insight into the effect/impact of an open disclosure process on organizational and/or health professional rates of litigation, settlements, judgments and costs;
- Provide insight into the effect of discretionary compensation offered along with disclosure on organizational and/or health professional rates of litigation, settlements, judgments and costs; and
- Outline learnings that can be applied to the Canadian healthcare system inclusive of the Canadian Patient Safety Institute and other healthcare organizations.

The predominant view in the literature related to disclosure of adverse events and litigation is that disclosure has little or no impact on litigation. Where the harm suffered by the patient is described as mild to moderate full disclosure will either decrease the frequency of litigation or have no impact. Where harm is described as severe the frequency of litigation with full disclosure appears to be unchanged. Conversely, the absence of disclosure or ineffective disclosure does increase the likelihood of litigation or claims irrespective of the category of harm.

Perceptions that disclosure alone reduces the likelihood of litigation appear to be derived from assumptions about the disclosure in the US, frequently cited as the "Veterans Health Administration Lexington Study Process".[1] In that process, early offer of compensation is an integral component. The rate and amount of claims in the Lexington study remained consistent with hospitals that were not following the same approach. The decrease in litigation is due to settlement which prevents the need to turn to litigation.

Specific factors that have been determined as drivers of litigation or claims following adverse events include: transparency; compassion; apology; and accountability. Where patients/families chose to make a claim, litigate or pursue discipline through a professional body, the least important reported factor is financial compensation. Further research, involving patients and families impacted by adverse events and who elected not to take litigation steps, is seen as highly desirable by numerous authors.

Learnings that could be applied in Canada relate to enhancement of disclosure communication and legislative amendment

In order to reduce the likelihood of litigation or claims, disclosure communication practices must be enhanced to address the motivating factors or drivers of litigation. Apology is perceived by patients and families affected by adverse events as essential. Risk management, insurance and legal professionals advise against apology due to the belief that such a statement could be used in subsequent litigation. One method of meeting the needs of both groups is to implement apology protection legislation. Two Provinces in Canada have passed legislation for the protection of apology. Other Provinces have legislation pending.

Other significant learnings for consideration

Tort reform, other than the implementation of alternatives to court resolution processes, is not recommended without prior close scrutiny of the potential impact of any change on the Canadian culture and legal system. No-fault based systems are viewed as not feasible due to cost.

A further issue that merits address is the bifurcation of insurers. In Canada, most instances of an adverse event will involve different groups of healthcare providers and healthcare delivery organizations. Each will have their own insurer and legal counsel where litigation or claims arise. This is viewed by most risk management, insurers and legal counsel as a significant barrier to rapid resolution of litigation or claims.

1.0 Background

This project was undertaken on behalf of the Legal and Regulatory Committee of the Canadian Patient Safety Institute (the "CPSI Project"). The objective is threefold:

- Provide insight into the effect/impact of an open disclosure process on organizational and/or health professional rates of litigation, settlements, judgments and costs;

- Provide insight into the effect of discretionary compensation offered along with disclosure on organizational and/or health professional rates of litigation, settlements, judgments and costs; and

- Outline learnings that can be applied to the Canadian healthcare system inclusive of the Canadian Patient Safety Institute and other healthcare organizations.

The CPSI Project entailed an extensive literature review, case law review and a survey of: healthcare risk management professionals; insurers; legal counsel working within healthcare organizations or involved in medical malpractice litigation; and patients and/or their families who experienced harm caused by an adverse event.

The following discussion and summary of insights and learning are a synthesis of the literature, case law, legislation and results of the survey.

The CPSI Project was undertaken between March and July 2007 with the insights and learnings formally presented in October 2007 to the Legal and Regulatory Committee of the Canadian Patient Safety Institute.

2.0 Terminology

The terms for this project were defined as follows:

Adverse Event:	Harm that results from an unexpected and unintentional occurrence in healthcare delivery.
Disclosure:	The communication of information to the patient, by healthcare providers, about an adverse event.

3.0 Method

3.1 Literature Search

The literature search included a scan of English and French case law, and searches in the electronic databases Medline and Quicklaw/Lexis Nexis focussing on the concepts of patient safety, disclosure, and litigation. . Reference lists of relevant documents were reviewed to capture further resources. General internet searches were also conducted in English and French and revealed a large number of commentaries that were helpful in developing insights. The complete literature search methodology, is outlined at Appendix A..

Within the literature, two dominant categories of work emerged: empirical and non-empirical resources. To inform the synthesis of the literature reviewed, the empirical literature is discussed separately from the larger body of literature as it was found to provide a more objective source of information. The selected studies for discussion are further sub-divided for ease of reference, to correspond with their informing purpose. The balance of the literature reviewed is also sub-divided into two categories related to their primary informing focus. Although numerous articles were reviewed, few were directly helpful in addressing the questions posed by the objectives. Those that were on point and directly assisted with the development of insights referenced in the objective are specifically discussed, also at Appendix A.

3.2 Case Law Search

The initial case law search focused on Canadian jurisdictions using English and French search terms referenced in Appendix B. Additional case law searches were conducted using similar search terms for Australia, the UK and the US. Subsequent searches were conducted to determine further consideration by Canadian Courts of any relevant judicial decisions.

3.3 Survey

It was determined prior to the commencement of the literature and law review that limited Canadian content was available. In order to determine whether Canadian perceptions, attitudes and actions differed in any significant manner from the international literature available, a brief survey was conducted. The survey consisted of open-ended questions with the described purpose of "taking the temperature of the Canadian climate".

3.4 French Language Literature Search and the Quebec Perspective

In order to ensure that this CPSI Project met the needs on a national level, a bi-lingual lawyer was contracted to complete research by specifically reviewing French language publications and to review the correlation between disclosure and litigation in Quebec. A summary of the Quebec Perspective is found in Appendix C.

Quebec is unique; it was the first province to address disclosure requirements through legislation. The Quebec experience demonstrates that following implementation of mandatory disclosure requirements there has been no increase in frequency of litigation. Empirical data is not yet available.

Literature written only in French is rare. The conclusions reached by the French language legal consultant are consistent with those from the English language literature review as well as from the survey results.

4.0 Discussion

4.1 Summary of Literature

To facilitate synthesis of the literature, studies selected for review were divided into two sub-categories based on their primary influence on informing the objectives: "Disclosure Specific Studies" and "Factorial Studies". Together these categories provide insight into the correlation between disclosure and litigation, and trends in litigation, settlements and related costs. Each of the articles selected as being particularly informative is explored in detail in Appendix A.

Whether or not disclosure of adverse events itself will prompt litigation or claims remains an unknown. Further empirical research involving patients and/or families, who made the decision not to pursue claims or litigation after having received full disclosure, is required. This would augment current data and is needed to fully assess the impact of an effective disclosure of adverse events process.[2,3,4]

Only one study projected that disclosure will prompt claims, thus having a negative financial impact.[5] This study has come under attack due to its methodology and the fact that it is counter to experience.[6] Two healthcare organizations in the U.S. have publicly shared the

results of their policies and practices for disclosure of adverse events and the positive financial impact.[i]

The Veterans Health Administration (VHA) and the University of Michigan Health Services (U of M) have both reported significant savings in litigation-related costs as a direct result of their use of a full disclosure process. [1,7] The administrative cost of a law suit has been estimated at $250,000 for each case that proceeds to trial. Risk management at U of M report a savings of over $2 million annually post-implementation of a disclosure practice. [7]

The policies and practices seen as originating from the VHA Lexington Hospital have often been referred to as authority that open disclosure of adverse events decreases litigation. However, this approach includes an early offer of compensation as part of the process and the subsequent decrease in litigation rates is a direct result of settlement. The frequency of claims and amount of damages paid remains consistent with VHA and other hospitals that do not use the same process. [1]

Factorial studies and related literature demonstrate that non-disclosure or ineffective disclosure will cause patients and/or families to turn to litigation. Often the reported purpose of litigation is to obtain something other than financial compensation. All of the factorial studies reviewed suggest that respectful, honest and accurate communication following an adverse event is paramount to patients and families. [2,8,9,10,11] This was of particular significance in cases of minor to moderate harm. In cases of severe harm caused by an adverse event, there was a link to the claim being made for financial compensation irrespective of disclosure.

Prevalent litigation driving factors include the absence of apology and statements of accountability. The Sorry Works! Coalition and others, in specific response to the Studdert Study, [5] suggest that there would be an increase in litigation and claim rates from disclosure, have strenuously argued that effective communication including an apology has a deterring effect on litigation. [6,12,13]

Apology (or its absence) has been found to be a major factor in the decision by patients and/or families to pursue claims. [8,9,11,14] In spite of this evidence, lawyers and risk managers

[i] In testimony before the Tennessee General Assembly by Doug Wojcieszak, spokesperson for The Sorry Works! Coalition - Similar positive results have been reported at 28 Kaiser Hospitals, 39 hospitals in the Catholic Healthcare System, and Stanford University Hospital system. Accessed March 2007 from - http://www.sorryworks.net/article32.phtml.

continue to advise against apology as it may be used against the defendant healthcare provider in the event of future litigation. Apology is discouraged unless there is clear evidence of sub-standard or negligent care. [13,15,16,17,18,19]

To alleviate the conflict between the need for apology and the withholding of apology, protection of apology legislation has been implemented. Such legislation is one way of facilitating apology and more transparent communication. [16,18,20,21] Apology Protection Legislation is explored further in the section of Case Law and Legislation.

Other suggestions for managing the financial impact of medical malpractice litigation and its inherent costs are tort reform and alternative dispute resolution processes. The literature does not generally support tort reform in Canada without significant consideration of the Canadian culture and legal systems. [18,22,23]

Alternative dispute resolution processes have been proposed as a method of resolution. One important factor noted in support of alternative dispute resolution is that mediation and similar forums are more conducive to providing the apology and full explanation being sought.[24]

The factors stimulating litigation and claims have been taken seriously along with the experience of the VHA and U of M healthcare delivery organizations. One major medical malpractice insurer in the U.S., "COPIC", has developed and implemented a program for managing medical errors referred to as the 3R's - Recognize, Respond, Resolve, that is similar to the VHA approach.[25] A second major insurer, Crittenden, has recently announced that it will be following suit.[ii]

In Canada, the trend in medical negligence litigation appears to be toward a decline in the number of legal actions being commenced. Conversely, the financial impact of litigation and claims is on the rise. At this time it is difficult to determine if the costs are increasing due to claim and settlement amounts or, as learned by the VHA and U of M organizations, related to the administrative (including legal) costs.

[ii] Sorry Works! Website announcement, last accessed May 2007. www.sorryworks.org

5.0 Case Law and Legislation

To further explore the correlation between disclosure and litigation, an extensive search of Canadian and international legal data bases, articles and texts was conducted. In addition to informing the objectives, this research was expanded around two more specific issues raised during discussion with survey participants:

1. Does a hospital or healthcare organizations (in addition to a provider) have a positive legal duty to disclose error?
2. To what extent has disclosure been considered as an admission of liability?

The first issue is included in response to questions about jurisdictions where hospitals and healthcare organizations are connected to professionals in law due to employer/employee or ownership status. In Canada, healthcare delivery organizations are most often separate in law from the physicians providing care within the organization.

The predominant Canadian model is that physicians provide service under a privileging relationship with healthcare delivery organizations and are paid by government on a "fee for service" basis. Private and public hospitals in the U.S. appear to have a myriad of legal relationships with physicians. Most other care providers in an organizational setting are employees. In civil liability law, employers and employees are essentially treated as one.[iii]

The second issue emerged because it was noted that one of the primary barriers to disclosure is fear of litigation. [26,27] The literature review and comments from the survey participants suggested that the primary concern about litigation was more connected to the components of disclosure, such as apology and statements of accountability, rather than the overriding concept of disclosure.

5.1 Duty to Disclose and Healthcare Delivery Organizations

The general duty of healthcare providers to disclose will not be discussed as it is well known that health care providers have an ethical obligation to disclose errors to their patients, even though it may not be clearly stated in a code or practice manual. [13,27,28] It is also firmly entrenched in law that a physician, dentist or other primary care provider has a legal duty to disclose errors. This duty extends beyond the time the patient remains in the care of the

[iii] The principle of "vicarious liability" applies such that an employer is liable for any negligence of its employees provided they were acting in the capacity of an employee at the time of the negligence. For additional information on vicarious liability, see the report by Professor Joan Gilmour.

physician who held the legal duty of disclosure. [18,28,29,30] Disclosure to differing degrees is also mandated by some Provincial legislation.[iv]

The duty to disclose is not limited to court enforcement; at least one professional body has publicly reported that non-disclosure will not be tolerated.[31] To date, there are no reported cases of nurses or healthcare organizations being held liable for failure to disclose although this trend appears to be changing. [18]

In 1994, Timothy Caufield published a paper entitled "Suing Hospitals, Health Authorities and Government for Health-care Allocation Decisions".[32] The predictions made in this article are astoundingly accurate.

To date, hospitals (applicable to health regions, etc.) have been held directly liable to a patient for:

1. injury from inadequate or improperly maintained equipment;
2. failing to provide proper measures for protecting a disturbed person from injuring himself or others;
3. failing to provide sufficient personnel;
4. *failing to enforce policies*; and,
5. failing to insure an adequate reporting system was in place.[33,34,35]

These types of cases have evolved since 1980 and the liability has generally been apportioned between the hospital and its employees or agents (i.e., physicians practicing under a privileging regime). Prior to this, it was a rare that a hospital would be found to owe a specific and direct duty to a patient.

Given this trend, it is certainly possible that in the future a healthcare organization could be held liable for non-disclosure where a policy is in place but not enforced.

5.2 Disclosure as an Admission of Liability

Healthcare providers and organizations are often reluctant to provide an apology for fear that it will be used against them if litigation arises. Canadian courts have affirmed that an apology and related statements could be considered an admission of liability in some circumstances; [36,37] however, no Canadian cases related to medical negligence and apology/admission of liability were located.

US Courts have also affirmed that apologies and related statements could be considered an admission of liability yet the trend over the past 15 years is that evidence, in addition to the admission or apology, must be proven. Except in the most egregious and obvious cases, an

[iv] Quebec and Manitoba have implemented mandatory disclosure legislation as of July 2007.

apology or a statement considered to be an admission is not enough to establish the legal components required to prove negligence.[v]

Two of the US cases of interest are summarized below. In both cases, the Court found that an admission or apology made by the physician was not evidence in itself of malpractice. As with the Canadian, albeit non-medical related, jurisprudence the Courts have held that all elements of negligence must be proven.

Senesac v. Associates in Obstetrics & Genecology (1982) Vt. Lexis 530

In Senesac, the physician made an error while performing a therapeutic abortion. The physician told the patient that she "made a mistake, that she was sorry, and that [the error] had never happened before". The Vermont Court held that:

> The fact the physician may have believed, and, if so, verbalized the belief that her performance was not in accordance with her own personal standards of care and skill, is not sufficient in the absence of expert medical evidence showing a departure from the standards of care and skill ordinarily exercised by physicians in similar cases.

The case was originally tried before a jury and then appealed by the plaintiff (patient). The appeal was denied.

Cobbs v. Grant (1972) Cal. Lexis 278

The reasoning in this case is similar to the Senesac case. This was also an appeal from a trial and the Court stated that:

> Since a medical doctor is not an insurer of result, such an equivocal admission does not constitute a concession that he lacked or failed to use the reasonable degree of learning and skill ordinarily possessed by other members of the profession in good standing in the community, or that he failed to exercise due care.

Although these cases from the U.S. could be used in a Canada to some degree of influence they have not, to date, been referred to.

[v] US evidentiary law refers to this as the doctrine of admission of a party opponent. Canadian reference is more often referred simply as an extra-judicial admission. Both are primarily related to when statements can be admitted into evidence and overlap hearsay rules.

5.4 Legal Claims Prompted by Disclosure

Significant literature has indicated that empirical research into the prompting of litigation from disclosure has not yet been conducted and would be welcome. [2,8,9,10,11] Anecdotal evidence of the impact of full disclosure practices appears to indicate that disclosure does not tend to prompt claims or litigation. [26] One published literature search and a statistical analysis study, with methodological limitations have suggested that disclosure may prompt litigation. [5,38]

In discussions with legal counsel and insurance/risk management groups as part of the survey conducted, fear that multi-patient disclosure would prompt litigation was expressed. No cases were found that specifically referenced that disclosure itself was a cause of legal action. That said, it seems simplistic to state that where the individual has no knowledge of potential or actual harm resulting from an adverse event, there would not be litigation or claim. The legal action may have been framed in some other manner such as mental anguish or other allegation of harm from the disclosure itself.

When specifically asked about the issue of prompting legal claims in situations of multi-patient disclosure, others in the legal and insurance/risk management groups agreed that litigation would be less likely if the disclosure was made by the healthcare provider or organization rather than the patient(s) learning from another source.

5.5 Legislation

At the time of the research being conducted for this project, 34 states in the US and all of the states in Australia had implemented apology protection legislation. [3,21,39] In Canada, British Columbia and Saskatchewan had recently enacted apology protection legislation and similar legislation is being considered in other jurisdictions.[vi]

In contemplation of its legislation the government of British Columbia received two exceptional documents on the issue of apology and disclosure. [40,41] Both are highly recommended as additional information on the significance of this type of legislation, the scope of legislation and review of legislation in other jurisdictions.

The B.C. Apology Act and the amendment to the Saskatchewan Evidence Act are similar and broad in scope. Both capture protection related to the potential for insurers to deny

[vi] The British Columbia Apology Act [SBC 2006] Chapter 19 came into force 2006. Saskatchewan amended its Evidence Act (S.S. 2006, c. E-11.2) to include protection of apology, effective May 2997.

coverage if an admission of liability is made by the insured. The legislation is brief and is included for ease of reference in Appendix D.

A very recent article published in the US provides an extensive overview of apology legislation and related issues. Wei concludes that apology legislation alone may not affect rates and methods of disclosure although it may remove a significant legal barrier. [16] Wei suggests that culture and attitudes would need to be changed to facilitate effective disclosure.

In the survey conducted as part of this CPSI Project, those canvassed on the issue of apology legislation unanimously agreed that it may be helpful in increasing the frequency and content of disclosure. Patients/families were specifically canvassed as to whether apology legislation would be considered negatively replied with statements similar to: "Anything that is needed to improve disclosure would be a benefit".

5.6 Summary - Case Law and Legislation

It is certainly possible that an apology and statements of accountability may be used as evidence against the party making the statement. However; the legal trend is toward finding that an apology or statement of accountability alone is not enough to establish negligence except in the most egregious and obvious case. Additional evidence of the requisite legal requirements to find a defendant negligent must also be proven.

Protection of apology legislation (Apology Law) would assuage the fears around apology and would free a professional to apologize which is desired by patients and/or families. A significant amount of literature suggests that apology protection law is a welcome legislative reform that ought to be seriously considered in all jurisdictions.

British Columbia and Saskatchewan are the only Canadian Provinces that have enacted Apology Law in Canada. Apology protection legislation has been widely implemented in Australia and the U.S. but; it is too early to determine its impact. In response to the third stated objective for this CPSI Project, implementation of apology protection legislation may be the most significant learning for enhancement of disclosure in Canada.

Where Apology Law is being considered, the broad form of protection is preferred. [17]

6.0 Survey

An informal survey consisting of open-ended questions was conducted to determine Canadian attitudes about the correlation between disclosure and litigation. The purpose was not to provide empirical evidence related to disclosure and its relationship to litigation; it was, as described to the participants - to "take the temperature of the Canadian disclosure climate".

Participants included: healthcare insurance industry professionals; risk management and patient safety professionals; legal counsel working with individuals (plaintiff), insurers, or healthcare organizations; and patients or families having had experiences with adverse events causing harm.

The survey was conducted in confidence and participant responses were placed in one of three categories, based upon their primary survey/key informant role.[vii] To ensure confidentiality only the author of this CPSI Project learned the identity and contact information for the participants. All interviews were conducted by telephone and responses were carefully summarized. The initial documents and written notes from the interviews were destroyed.

Participation was generally and specifically invited. A document briefly outlining the purpose of this project and the general questions for discussion was circulated to the legal community, insurers and through the networks of patients and families who have become involved or interested in patient safety.

See Appendix E for a copy of the interview questions.

A total of 24 interviews were conducted within a 3 week period. Participants included risk management/insurance providers (n=8), legal counsel (n=6) and patient/families (n=11). The responses are summarized as they relate to the questions posed.

[vii] Some participants met the criteria for more than one group. For example, patients or families may also have been employed in healthcare/patient safety or other roles. The choice of category was based on the predominant focus of comments during the telephone interview.

6.1 Litigation Trends

6.11 Patients and Families

Patients and families were more likely to state that they strongly believed that a practice of open disclosure would decrease the frequency of litigation. Their statements though, were unequivocally qualified by comments that to be truly effective in decreasing rates of litigation, disclosure practice must be: compassionate; sincere; immediate or as soon as learned; and patient-centered. Apology was considered the most significant factor in ensuring that disclosure was both compassionate and patient-centered.

When the concept of apology was explored further, the expectation was that a statement of accountability, but not an admission of fault, be included. More often than not, patients/ families voluntarily expressed that they understood that "everyone makes mistakes, including healthcare professionals". They stated that they understood that a mistake or error did not always add up to negligence. The apology they were looking for included: "I/we made a mistake" and "I/we am very sorry that this happened".

The patients/families who had commenced litigation expressed that they did so because they wanted to:

a) Obtain information;

b) Receive an acknowledgement that the harm was caused by an error;

and/or

c) Address the way they were treated following an the adverse event.

Financial compensation was not considered to be helpful and was not a primary motivator of litigation. Litigation was seen as a means to get the attention of the organization or healthcare provider and to force someone to take responsibility for the event and for ensuring system improvement.

Specific Comments Included:

- "Receiving an apology from a department chief didn't mean much, he wasn't even involved - it felt empty."
- "I wanted some hand holding during a scary and difficult time; instead they treated me like I had done something wrong."

- "I got different stories depending on who I was talking to - it felt like nobody was taking responsibility."
- "If they hadn't started acting so weird around me I would never have known anything was wrong - as I learned I got more and more [angry].
- "When one of the physicians involved said during [formal proceedings] that he was very sorry for what had happened and then listed the ways his practice had changed because of it, we asked for everything against him to be dropped."

In response to query as to why litigation or professional organization proceedings were not dropped following full disclosure, including apology, having been provided:

> "We had worked for years having meetings with [medical directors and senior executives] before they even acknowledged a problem - by then it was too late."

6.12 Legal/Risk Management/Insurer

The other participants believed that disclosure would slightly increase or not affect rates of litigation. Other than statistics from the Canadian Medical Protective Association (CMPA), specific data was not available. The CMPA data indicates that litigation frequency has not increased over the years even though disclosure has become more prevalent.

Participants in a position to comment on actual trends in frequency of litigation mentioned that any increase in frequency may not be directly related to disclosure practices. A change in culture and that the general public now tends to view legal action as being socially acceptable were considered more significant. Participants believed that increases in rates of litigation may well be attributed to the cultural aspects than disclosure. Specific comments from the risk management/insurer group included:

- "Litigation rates will increase where there is no disclosure or disclosure is not done effectively."
- "Class actions may contribute to overall costs being increased where there is multi-patient disclosure" (expressed as perhaps due to an increase in administrative costs in addition to knowing that some payments are made, in class action suits, to plaintiffs that were not actually harmed).
- "Multi-patient disclosure may increase litigation but not as much as if the error was learned from the media or some other source."

The insurer/risk management group noted that their organizations were providing or involved in developing education to improve the quality of disclosure practice as the actual method and components of disclosure were recognized as a significant issue.

Specific comments from the legal group included:

- Some scepticism that disclosure will not decrease litigation because the primary motivator is financial - "There has been no situation where litigation was dropped following full disclosure".
- "There is an increase in consultations with lawyers, but numerous constraints, especially financial, make litigation unattainable. This is not true of cases where there is severe injury but certainly with cases of minor or moderate harm - as contingency relationships are not affordable and the costs that may be awarded to the defendant could be significant."
- "Multi-patient disclosure may increase litigation only because a class action makes it financially feasible because the group shares the cost or is able to obtain contingency arrangements."

6.2 Settlement Trends

Patients and families declined to express an opinion based on their actual experience or the experiences of others they had contact with because they did not have knowledge of trends. Those that ventured a "guess" believed that there would be no change in frequency or amounts of settlement whether before or after commencement of litigation.

The remaining groups stated that there does not seem to be any change in patterns of settlement. The consensus was that with few exceptions, settlement would not be explored without a formal demand for compensation or commencement of litigation. It is difficult to obtain information specific to settlement amounts as generally a confidentiality agreement is required as part of the settlement. However, it is anticipated that some specific financial information will be published by the CMPA late 2007.[viii]

6.3 Changes to the Legal System Seen as Desirable

6.31 Apology Protection Legislation

Protection of apology legislation was unanimously supported where this was canvassed (all but 2 participants were specifically asked). The insurer/risk management and legal group members working within organizations expressed concerns about apology. An expression of regret was seen as acceptable, yet a "full apology" was perceived as something that could too easily be construed as an admission of liability.

Patients and families value receiving an apology. This group expressed that legislation protecting apology would be helpful "if that is what was needed for an apology [by

[viii] Personal communication; Canadian Medical Protective Association.

healthcare professionals] to be provided". Where the limitation period for commencing litigation had passed, making litigation impossible, the patient/family participants indicated that they noted a change in attitudes and in the way in which they were treated.

6.32 Bifurcation of Insurers

Bifurcation of insurers was noted by healthcare organization insurers and legal counsel as an issue that needs to be addressed.[ix] This was seen as particularly important where settlement was desired by one insurer but not the other (where organizations were represented by one insurer and healthcare professionals by another insurer). In some cases, two or more insurers could be involved in one litigation matter. The involvement of different legal counsel by each insurer as well as what may be general policy was also stated as an impediment to continuity in developing or maintaining a relationship with the patient/family.

Some patients/families expressed that they found a significant difference in the manner in which they were treated by the differing insurers and its respective legal counsel. Conflict between two or more insurers was sensed by the patients/families involved in litigation and/or settlement discussions.

6.33 Tort Reform

Patients/families did not express a desire for tort reform. They tended to express that the issues for them were more related to the healthcare system. The other groups suggested that systems such as the no-fault system implemented in Florida and specific to severe harm caused to during childbirth, would be a possible method of decreasing litigation and overall costs.

A general no-fault system was not generally seen as feasible from a cost perspective. Tort reforms being considered in the US were considered as not applicable to Canada given that medical care systems are significantly different (public vs. private).

Having continuity of legislation across Canada was seen as highly desirable by the legal and the insurer/risk management groups. This included reporting systems, disclosure practices (especially apology law) and the protection of quality assurance processes.

[ix] Bifurcation of insurance references the fact that healthcare delivery organizations, physicians and other professionals are generally insured separately. Thus more than one insurer is involved in adverse event issues involving more than one party.

The implementation of alternative dispute resolution processes was seen as desirable by both the legal and insurer/risk management groups. It was frequently stated that a significant factor that would be to make ADR mandatory. It was also seen as being most effective where it could be made available prior to the commencement of litigation.

Legal counsel and patients/families saw the availability of mediation very early in the process, rather than after readiness steps for litigation such as obtaining expert opinions, as highly desirable.[x] Patients/families believed this would be opportunity to avoid talking just about money which was the only remedy they understood would be available to them through a legal process.

6.4 Changes to the Healthcare System Seen as Desirable

Patients and families focussed more on changes to the healthcare system than on the legal system to prevent an increase in litigation. The other groups tended to focus on changes to the legal system.

The primary change desired by patients and families was the implementation of "patient-centered care before and after an adverse event". Patient-centered care was described as healthcare delivery that is responsive to patient and family needs rather than the needs of healthcare providers or healthcare delivery organizations

Involvement in enhancing the healthcare delivery system, to prevent future adverse events, was seen as positive and desirable for patients and families. Most suggested that patients/families should be included in discussions related to system-wide change, including local and national initiatives.

National continuity in the management of adverse events, including disclosure, was also seen as highly desirable for the healthcare system. All groups indicated that enhancement of continuity among all healthcare delivery organizations, to ensure that effective open disclosure practice was routine and that reporting systems were implemented to make the systems safer by sharing information, were very important.

[x] This is also an issue related to bifurcation of insurance as one insurer may desire obtaining expert opinion prior to mediation which could take a considerable amount of time. It was also noted that where the expert opinion provided assurance that the adverse event was not caused by negligence, one insurer may not want to proceed with mediation at all.

6.5 Litigation and Professional Organization Disciplinary Processes

Patients/Families that had been involved or were involved in litigation or professional body complaints were asked to comment on their experience. All expressed high levels of dissatisfaction. As noted above, they were unsure of how these processes could be changed. They found that neither litigation nor professional discipline processes provided them with what they were truly seeking: open, honest and transparent communication; apology; and accountability.

Of the patients/families that had pursued professional organization complaint processes, it was indicated that a discipline process was only helpful where there was an education requirement imposed as a remedy that would ensure changes in practices. Where the result was sanction rather than education, it was seen as little value.

The litigation process was also noted to be problematic where individual practitioners and organizations had to be included in the legal action due to procedural requirements.

> "I meant no ill will against them; they just had to be included because of the legal rules". "[The focus on financial compensation was not considered beneficial] because we really only wanted to find out what happened and to receive an apology and acknowledgement of responsibility".

6.6 Motivators of Litigation

A list of motivators taken from the literature search was provided to participants as examples of reasons why patients/families chose to litigate. Participants were then asked to provide comment about primary motivators of litigation or claims, whether included in the list or not.

Patients/Families identified primary motivators as:

- Need for information; and
- Desire of apology and statement of accountability ("I/we made a mistake").

The other groups identified primary motivators as:

- Need for financial compensation related to the degree of harm (i.e., where harm significantly affected the life of the patient);
- Anger and frustration with the manner in which information was made available; and
- The general communication style used in disclosure conversations.

These responses were highly consistent with the literature.

7.0 Insights and Learnings

7.1 Effect of Open Disclosure on Organizational and/or Health Professional Rates of Litigation, Settlements, Judgments and Costs

- Rates of litigation have not significantly changed over the past few years. Where there have been slight increases they are not attributed to disclosure. While total costs have increased,[xi] there is no available evidence to determine if these costs are related to actual awards or settlements, or if the increase is related to the related costs to managing litigation (e.g., legal costs).

- At least two U.S. healthcare organizations have published data on the results from implementation of policies and practices for full disclosure. Both the Veterans Health Administration and University of Michigan Health System have released data on the impact of their disclosure practices and demonstrate a decrease in litigation rates and overall costs. Both, however, include a process of early offer of compensation as part of their practice. While the overall savings have been significant, the settlement amounts and frequency of claims paid is not significantly different from other healthcare organizations. [6,7] The decrease in frequency of litigation and the lower costs are attributed to the settlement component of the disclosure process utilized rather than the actual disclosure practice alone.

- Where the harm caused by an adverse event is severe, disclosure does not appear to have any impact upon frequency of claims. Disclosure does appear to impact rates of litigation where the harm is categorized as mild to moderate; the trend is a decrease in frequency. [2,8,9,10]

- There is significant evidence that non-disclosure and ineffective disclosure does increase the potential for litigation and claims. Specific factors that have been determined as drivers of litigation or claims following adverse events include: transparency; compassion; apology; and accountability. Where patients/families chose to make a claim, litigate or pursue discipline through a professional body, the least important reported factor is financial compensation.

[xi] See survey results discussion - frequency and costs as reported by insurers/risk management group do not appear to have changed in any significant way. See also CMPA, supra

- No empirical analysis has been conducted to determine if litigation is prompted where the cause of harm, or a potential for harm is unknown by the patient. Emperical research has not been conducted to determine specific factors where patients harmed by healthcare delivery have elected not to make a claim commence litigation or, involve a professional body. This type of research has been recommended by numerous authors. [2,3,4,5,42]

- Judgements are specific to the type of injury sustained and projection of loss of income, costs of care, etc. rather than the cause of the injury. Therefore, measurement of judgements specific to medical negligence is not feasible. However; there is a real potential that punitive damages could be awarded, which would increase the total amount of the judgement, where disclosure is withheld.

7.2 Effect of Discretionary Compensation Offered with Disclosure

- Discretionary compensation is not generally provided in Canada. Insurers, legal counsel and risk management professionals all reported that it is extremely rare for any compensation to be paid, or offered, prior to a formal demand or commencement of litigation.

- The results of the implementation of full disclosure practices that include early offer of settlement (e.g. VHA and U of M) demonstrate that the overall costs decrease. The overall rates of claim frequency and settlement amounts remain consistent with rates where this practice is not done. The rate of litigation will decrease when there is early offer of compensation and settlement is reached because there is no longer a purpose to seek court intervention.

7.3 Learnings for Canadian Healthcare System

Two significant learnings that could enhance the Canadian healthcare systems are noted from the synthesis of literature, case law and survey results. First, ensuring that post adverse event communication will address the factors known to be litigation motivators could decrease the frequency of litigation. Second, legislative reforms to implement apology protection legislation and to create alternatives to litigation in resolving patient and healthcare provider or organization disputes, could eliminate a significant barrier to effective disclosure of adverse events.

Post Adverse Event Communication

Apology is seen as a critical element in the effectiveness of disclosure processes. Unfortunately, most organizations and professional bodies suggest or require that an apology not be made. Communication of factual information and a "statement of regret" is the limit generally imposed. This may be perceived by patients/families as uncaring which, in turn, results in litigation and/or complaints to professional discipline bodies.

Treating patients and/or families with respect and compassion following an adverse event is imperative to prevent the conflict that may ultimately lead to a formal claim, litigation or the seeking of professional body intervention. Significant empirical and anecdotal evidence exists to establish that financial compensation is not a significant motivator of litigation. Anger, frustration, information seeking and needing to ensure prevention of re-occurrence have a far greater impact on decisions to seek external intervention.

As stated by Sparkman (supra), "apology subtracts the insult from the injury". The literature and anecdotal comments establish that it is the "insult" rather than the "injury", at least in cases of mild and moderate harm, that drive litigation.

Enhancement of disclosure practices to ensure the known litigation drivers are diminished or eliminated will have a positive affect on rates of litigation and claims.

Implementation of Apology Protection Legislation

Apology protection legislation removes at least one barrier to effective communication following an adverse event. Although the risk of an apology being successfully used to establish liability without other compelling evidence is unlikely, no one individual or organization wants to be the test case. The implementation of apology protection legislation has occurred in most US states, all Australian states and in two Canadian provinces.

The British Columbia Apology Act came in to force in 2006. Saskatchewan's amendment to its Evidence Act came into force in May 2007. No evidence is yet available to determine what impact this has had for healthcare providers, organizations or for patients. No obvious opposition to such legislation by healthcare professionals, organizations or the public has been expressed. That said, literature supports this type of legislation being broad enough to protect both the actual apology as well as statements that may be construed as admission of liability made contemporaneously. The extent of the protection does generate debate.

The BC and Saskatchewan legislation protect statements in addition to apology. Both also remove a further barrier to disclosure and apology; the potential for insurance coverage to be withdrawn where an admission of liability is made.

The implementation of apology protection legislation across Canada appears to be the most expedient and powerful way of facilitating what patients and families are seeking and what healthcare organizations are trying to achieve with disclosure policy.

Tort Reform

Gilmour [22] conducted an extensive review of international legal systems to inform questions related to tort reform in Canada. This review refers to much of the literature and studies selected in this CPSI Project.

The findings and recommendations are echoed here. Caution against tort law reform without extensive analysis of the application of those undertaken in other jurisdictions and their applicability to the Canadian culture and systems cannot be overstated. Some of the jurisdictions that have implemented no-fault type systems for compensation and resolution of claims and complaints related to harm caused by adverse events have already modified their processes primarily due to the cost of such systems.

One aspect of the tort system which may impact resolution of disputes resulting from adverse events is implementation of alternative dispute resolution processes. Some jurisdictions in Canada have mandatory mediation requirements for all civil claims. Reports from legal counsel in Saskatchewan, where the requirement has been in place for a relatively long time, indicate that this is a helpful mechanism.

There is considerable literature on ADR as an effective method of managing conflict between patients, healthcare providers and organizations. It is considered a safe venue by mediators where apology and explanation can be provided without concern for the statements to be used in court proceedings.

Given that an alternative dispute resolution process was expressed as desirable by lawyers, insurers and risk managers in the survey, there is merit in reviewing alternate resolution methods to augment the current tort system. Other tort reform is not recommended unless research in regard to the fit with Canadian culture and legal systems is undertaken.

8.0 Application of Learnings to The Canadian Patient Safety Institute and other healthcare organizations

1. Facilitate the enhancement of disclosure practices such that motivators of litigation are effectively addressed. These motivators include:
    - Need for apology
    - Need for acknowledgement and assurances that steps have been taken to prevent future occurrence.
2. Facilitate the implementation of Apology Protection Legislation to remove a significant barrier to effective disclosure of adverse events.
3. Prior to implementation of general tort reform, ensure that research is conducted to determine the impact on Canadian culture and legal system; consider the significant costs related to "no-fault" insurance programs.
4. Consider further research into the prompting of litigation by disclosure and research involving patients who have experience adverse events and elected not to litigate.
5. Share learnings about education requirements being viewed as more effective than sanction by patients and families harmed by adverse events.

APPENDIX A

Disclosure of Adverse Events Literature Search

Initial Search Completed by Orvie Dingwall, Librarian / Information Specialist

Canadian Patient Safety Institute

April – July 2007

Disclosure and Litigation Search Summary

The literature search included a scan of case law by the primary investigator, and a literature search in the electronic database Medline by the Canadian Patient Safety Institute's (CPSI) Librarian. The original Medline search retrieved 173 English language records and was designed to retrieve records that combined the concepts of patient safety, disclosure, and litigation. The primary investigator screened the 173 Medline records and identified 18 relevant results. She then screened the reference lists of the relevant results and identified 112 additional results. When all relevant results had been determined, the CPSI Librarian created a final search that maximized sensitivity, precision, specificity and accuracy (see Appendix). Additional search terms considered are also described.

Though the focus of this paper was on the relationship between disclosure of adverse events and litigation, the MeSH term "malpractice" was used in 62% of the records retrieved from the final Medline search, as well as 62% of the indexed records from the final reference list. The final search therefore focuses heavily on the term "malpractice" because that is (unfortunately) the associated MeSH term, and not because malpractice is our term of choice. This use of the term "malpractice" is of considerable interest because disclosure is not always associated with malpractice. Whereas malpractice will always be associated with negligence and negativity, disclosing adverse events is a very positive and pro-active communication process. As the MeSH

terms are currently assigned, it is challenging to create a search which differentiates between disclosing an adverse event, and disclosing an instance of malpractice.

Disclosure and Litigation Search Results

Database	Initial Search	Relevance Screening
Medline	173	18/173
Reviewer Nominated	112	
Cited in Discussion/Synthesis	45	

Final Medline Search Strategy, July 2007

#	Search History	Results
1	*medical errors/	4524
2	*medication errors/	4056
3	(adverse$ adj3 event$).tw.	33440
4	*iatrogenic disease/	4152
5	*communication/	18245
6	*malpractice/	15345
7	or/1-6	78093
8	*disclosure/	2699
9	*truth disclosure/	4534
10	disclos$.tw.	33291
11	apolog$.tw.	462

12	*jurisprudence/	18336
13	or/8-12	57119
14	7 and 13	1701
15	limit 14 to english language	1451
16	or/1-5	63408
17	or/6,13	71670
18	16 and 17	1567
19	limit 18 to english language	1243
20	15 or 19	1884

Additional MeSH Terms Considered

Exp professional-patient relations/

Liability, legal

Risk factors

exp *jurisprudence/ - relevant works within jurisprudence

lj.fs.

exp *insurance/ - relevant headings within

Additional Text Words Considered

(expression$ adj3 regret$).tw.

being open$.tw.

sorry.tw.

(truth adj4 tell$).tw.

(say$ adj3 right$).tw.

((duty or duti$) adj2 cooperat$).tw.

jurispruden$.tw.

litigat$.tw.

negligen$.tw.

liab$.tw.

tort$.tw.

Summary of Studies

Disclosure and Litigation Specific Studies

Studdert, D M et al. 2007. "Disclosure of medical injury to patients: an improbable risk management strategy." Health Affairs, 26(1): 215-26.

A recent study by Studdert et al created significant controversy among advocates of disclosure who argue that disclosure has a positive impact on litigation rates and related costs. The researchers concluded that disclosure will actually increase the frequency of litigation and therefore the costs to healthcare providers and organizations. Their results indicated that claim volume and amounts would be significantly increased by disclosure.

Four hypothetical scenarios were presented to participants who were comprised of a convenience sample group of healthcare risk managers, patient safety officers, legal counsel and others described as senior experts. For each scenario, participants were asked to estimate the likelihood of the patients' responses. All scenarios referenced potential legal action and were prefaced as either having involved negligent or non-negligent injury. Data obtained was combined for statistical analysis with existing data about the frequency of adverse events, the ratio of negligence to adverse events and frequency of claims in negligent and non-negligent care injuries. The findings included:

- In the four scenarios presented participant responses predicted that disclosure would, on average, deter claims in 32% of cases and prompt claims in 31%.
- There was a 94% chance that claim volumes would increase.
- Compensation costs were estimated to double (45% chance) or triple (24% chance).

Critics of this study claim that the method was flawed.[i] Some argue that statistical analysis is not applicable to situations largely determined by emotion. The Sorry Works! Coalition has been very critical of this study which conflicts with their experience (anecdotal, plus the

demonstrated results from studies of processes based on the VHA Lexington model of disclosure (that open disclosure, with early offer of settlement where appropriate

To their credit, and not generally acknowledged by critics, the authors clearly outlined the limitations of the study which included:

- Disclosure was not defined for participants; they were asked to apply the policies in their own environments. Additionally, the policy applied by the participants may or may not have included apology or taken in account the factors that tend to motivate litigation learned in other research;
- The significance of administrative costs was not factored into the total costs for organizations, but was estimated at .54 cents on the dollar; and
- Lack of evidence related to the prompting of legal claims is a major issue and makes it difficult to assess actual impact of disclosure.

The authors' conclusion is that disclosure remains “the right thing to do” and therefore, organizations should prepare for the financial impact.

Mazor KM, Reed GW, Yood RA, Fischer MA, Baril J and Gurwitz JH. 2006. Disclosure of medical errors: what factors influence how patients respond? Journal of General Internal Medicine, 21(7): 704-710.

A similar method study (i.e., hypothetical scenarios followed by questions) was conducted by Mazor et al. Mazor found that non-disclosure increases the likelihood of seeking legal advice. Full disclosure was found to have either a positive effect or no effect in cases of minor to moderate harm. In cases where the harm was deemed severe, disclosure did not change the frequency of seeking legal advice.

This study is helpful in understanding the motivators of "claiming and litigating" patients and/or families. Although the study is also based on information from persons not involved in adverse events, the results seem intuitively accurate and were substantiated by the survey conducted as part of this CPSI Project.

Mazor and colleagues surveyed 407 members of an insurance program. They were asked to view videotaped vignettes and then respond to questions related to the likelihood of changing physicians (trust/satisfaction rating) and/or seeking legal advice. The vignettes involved situations of varying degrees of harm, with and without full disclosure.

Severity of harm was correlated to the potential for physician change and litigation, and full disclosure did not impact the rates for physician change or litigation. With minor and moderate harm, disclosure did appear to have an impact.

The Mazor study has a well presented discussion and provides comparison or comment to other studies related to motivators of litigation. The authors recommend further studies be

conducted to determine the prompting and deterrent effect of disclosure. Other significant points taken from this study include:

- Full disclosure results in a more positive response toward the physician (trust, satisfaction and likelihood of physician change);
- Disclosure tends to have a positive effect on satisfaction and seems to diminish the desire to seek legal advice;
- Overall results suggest that disclosure is likely to have a positive impact or no impact on patients and family members desire to seek legal advice; "we found no evidence that full disclosure increases the risk of negative consequences for physicians" (p.708); and
- The need for additional research is underscored by this study. "It would be very informative to query patients who believe they have been harmed but decided not to sue" (p.709).

Hobgood C, Tamayo-Sarver JH, Elms A and Weiner B. 2005. Parental preferences for error disclosure, reporting, and legal action after medical error in the care of their children. Pediatrics, 116(6):1276-1286.

This study also used the method of presenting hypothetical scenarios followed by questions. Hobgood et al selected a convenience sample of parents who presented with children to an emergency department. Four scenarios were provided to participants who were asked to imagine that their own child was involved. The Hobgood findings were consistent with the comments provided in the survey conducted for this CPSI Project.

Significant findings include:

- Parents want disclosure irrespective of the event type or level of severity; and
- Parental likelihood of seeking legal action decreases where disclosure is provided by the physician rather than the parent learning of the adverse event from an outside source.

Hobgood noted that parental preference was consistent with studies involving adults.

In contrast to the Mazor (2006) and Studdert (2007) studies, Hobgood and colleagues found that disclosure decreased the potential of legal action in even the more severe harm scenarios. Further research related to disclosure that would take into account specific factors such as apology was recommended.

Kaldjian LC, Jones EW and Rosenthal GE. 2006. Facilitating and impeding factors for physicians' error disclosure: a structured literature review. Joint Commission Journal on Quality & Patient Safety, 32(4): 188-198.

This article is referenced under the studies heading because of the extensive synthesis of findings related to factors leading to litigation. The authors conducted a comprehensive literature search and published in 2006. While there are some informing articles subsequent to those referenced, the themes and conclusions summarized in the Kaldjian article are consistent.

The authors concluded:

> "Although there is some evidence to suggest that candour about errors may decrease liability costs, reasoned assessments caution against the conclusion that transparency about errors will generally result in fewer lawsuits. The possibility that disclosure may actually increase the risk of malpractice claim is suggested by data showing that 64% of patients support reprimands for error-committing physicians and 39% support punishment for the same (p. 195)."

Factorial Studies

Witman AB, Park DM, and Hardin SB. 1996, How do patients want physicians to handle mistakes? A survey of internal medicine patients in an academic setting. Archives of Internal Medicine, 156(22): 2565-2569.

Witman et al conducted a study of how patients want physicians to handle adverse events. Participants were selected randomly from an academic general internal medicine out-patient clinic in California, and had not been involved in an adverse event causing harm.

Written scenarios were provided to participants followed by questions. For each of minor, moderate and severe harm, opinions were solicited related to the likelihood of changing physicians, reporting the physician to their disciplinary body and of filing legal action. In one-half of the scenarios, disclosure was presented as having occurred.

Witman concluded that the likelihood of filing a legal action increased in both the minor and moderate harm categories where there was no disclosure. In the severe category, disclosure did not change the frequency of legal action being taken.

Hickson, GB, Clayton EW, Githens PB and Sloan FA. 1992. Factors that prompted families to file medical malpractice claims following perinatal injuries. JAMA, 267(10): 1359-1363.

The study conducted by Hickson et al involved mothers whose infants suffered permanent injury or death. All had closed medical malpractice claims in Florida between 1986 and 1989. Parents (n = 127) were interviewed using both closed- and open-ended questions.

Hickson et al found that each litigant had numerous reasons for filing a legal claim. Communication was found to be a very significant factor.

Our study suggests that patients who sue physicians are not a homogeneous group in that they offer an array of reasons for claiming. The reasons offered for filing [a legal action] are, in turn, affected by families' views of their relationships with physicians. Frequently patients are disappointed or angered when they perceive problems in communication with their doctors (p. 1363).

The most frequent reason for commencing legal action was that the parent had been advised or influenced by someone outside of their immediate family. Of the 41 cases where this had occurred only 8 were influenced by a member of the legal profession. (p. 1361)

- Other significant factors included:
- Need for money (which increased with severity) to pay for long-term care (24%);
- Recognition of a "cover up" (24%);
- Realized that their child would have no future (23%);
- Needed information (20%); and/or
- Wanted revenge or to protect others from harm (19%) [p. 1360].

The findings from this study were also consistent with the survey answers provided by patients/families in the survey conducted for this CPSI Project.

Vincent C, Young M and Phillips A. 1994, Why do people sue doctors? A study of patients and relatives taking legal action. Lancet, 343(8913): 1609-1613.

This was the second study involving experience with actual adverse events causing harm to patients. Patients and relatives (n=227) were identified through 5 legal firms with practices in civil litigation and particularly medical malpractice. Invitations to participate were distributed and the identity of the participants and their answers were kept confidential. The legal firms did not know which, if any, of their clients were involved.

Seventy percent of the participants had suffered severe harm with long-term effects on their work, social life and family relations (p. 1609). The results from this study were also echoed in the survey conducted as part of this CPSI Project.

Vincent et al hypothesized that there must be significant motivation to commence legal action because the participants are prepared to "endure a long and often frustrating legal process". Four predominant factors were identified as specifically related to commencing a claim:

- Accountability – the wish to see staff disciplined and called to account;

- Explanation – a combination of wanting an explanation and feeling ignored or neglected after the incident;
- Standard of care – wishing to ensure that a similar incident did not happen again; and
- Compensation – wanting compensation and an admission of negligence (p. 1612).

All of the participants in this study suffered severe harm with long-term effects which has previously been, absent of all other factors, determined prompt litigation. Nonetheless, most cases involved what Vincent referred to as secondary problems which also contributed to the decision to sue. “They were disturbed by the absence of explanations, lack of honesty, the reluctance to apologize or being treated as a neurotic”.

The Vincent Study concludes that patients and relatives are hoping for more than compensation when they take legal action; “communication assumes a special importance when things go wrong” (p. 1613).

Bismark M, Dauer E, Paterson R and Studdert D. 2006, Accountability sought by patients following adverse events from medical care: the New Zealand experience: **Canadian Medical Association Journal, 175(8): 889-894.**

Factors driving litigation have also been analyzed using data from the New Zealand system of resolving issues related to harm caused by adverse events. In New Zealand patients and/or families have the option of making a “complaint”, “claim” or both. Complainants are those who, by analogy to the Canadian system, would be reporting to a professional disciplinary body. The process does not deal with issues of financial compensation. Claimants refer to those seeking financial compensation. In this study, some of the participants had elected to make a complaint and claim. Both options are available simultaneously and are administered by different authorities. Complaints are managed by the Health and Disability Commission, whereas claims are managed by the Accident Compensation Board.

Both groups were studied in an effort to determine the motivation to litigate. The results determined that there are significant differences between claimants and complainants. Patients and/or families were more likely to seek monetary compensation where injury was severe or there were permanent effects from the injury. This was significant where the injured party was between the ages of 30 – 64 which was interpreted as having had an effect on "income earning years".

In the complaints group, the most common form of accountability sought was a desire for correction of the system to prevent reoccurrence as well as a desire for communication which included both an explanation and an apology was also significant.

> "The offering of apologies, explanations and assurance of system change, where appropriate, may address many patients' true concerns without the need for expensive litigation. However, for some injured patients (e.g., for those whom the financial consequences of injury are particularly devastating no monetary remedies will be inadequate. They should be viewed as supplementing, not supplanting, the need for effective compensation mechanism" (p. 893).

Bismark et al, in applying the data to the Canadian avenue for dealing with harm caused by an adverse event, notes that:

> "Patients have little choice other than alleging negligence and suing for monetary damages, whatever the specific nature of their concern. These are extremely difficult environments in which to disentangle the different forms of accountability sought by those taking medico-legal action" (p.889).

Schwappach D L and Koeck CM. 2004. What makes an error unacceptable? A factorial survey on the disclosure of medical errors. Int.J.Qual.Health Care, 16(4): 317-326.

This study examined German citizens' attitudes toward errors and their likely response. The survey was conducted via the Internet and was based on the review of hypothetical vignettes.

Significant findings included:

- The severity of the outcome of errors remains the most important single factor in the choice of actions to be taken;
- The unequivocal statement that an error occurred and taking on responsibility for it has as much a preventative effect on litigation seeking as does apology; and
- Recent approaches to medical error which requires system thinking (no name, blame and shame) must also be accompanied by a strategy for clear naming, accountability and explanations to be successful in decreasing the desire for legal sanction.

Disclosure/Litigation Relationship Specific Literature

Kraman SS and Hamm G. 1999. Risk Management: Extreme Honesty May Be the Best Policy. Annals of Internal Medicine 131(12): 963-67.

The most widely referenced impact of disclosure on litigation rates and costs reported by the Veterans Health Administration (VHA). The initial statistics were reported following the

implementation of a full disclosure policy and practice at the Lexington, Kentucky VHA Hospital.

The Lexington facility instituted its policy and practice of open disclosure in 1987. Under this policy, upon the discovery of an adverse event causing harm investigation is carried out by the facility to determine root causes and deviations from accepted standards of care. In the event the investigating committee finds sub-standard care caused an error resulting in loss of function, earning capacity or life, notification of the patient and/or family is initiated. All details including the identities of persons involved in the adverse event are disclosed.

The policy requires an expression of regret and early offer of compensation. The patient and/or family are assisted with making a claim and receiving guidance to ensure a fair financial settlement is achieved.

The authors report on 7 years of financial statistics related to settlement and malpractice claims subsequent to the implementation of the 1987 disclosure policy. Kramm and Hamm reviewed the trend of litigation, amount of settlement and administrative costs and conducted a comparison to other VHA facilities and public data sources.

Kramm and Hamm report that litigation involving the Lexington facility was substantially reduced. The hidden costs of litigation, legal and administrative costs, estimated at $250 000/case prior to the policy implementation, were substantially reduced. The amount of claims paid, however, were found to have been “moderate and comparable to those of similar facilitates”. In conclusion, the authors cautioned that the experience at the Lexington facility “suggests but does not prove” the financial superiority of a full disclosure process.

The experience of the Lexington Hospital has been referred to in Canada as demonstrating a cause and effect relationship between open disclosure and decreased litigation.[i] The Lexington study does not establish this. The disclosure practice utilized at Lexington includes early offer of settlement; where settlement is reached there is no need to commence litigation.

The amount and frequency of claims, rather than frequency of litigation is key to understanding the impact of this disclosure practice. The most significant savings were in the cost of carrying out litigation and may mean that settlement amounts are maintained at a lower level than a court would find particularly in the case of having punitive damages awarded.

Boothman RC. 2006. "Apologies and a strong defense at the University of Michigan Health System." Physician Exec, 32(2): 7-10.

Boothman is the Chief Risk Officer for the University of Michigan Heallth System in Ann Arbor, Michigan. The Michigan Health System is the only organization other than the VHA Lexington Hospital that has reported on its financial results following implementation of an open disclosure practice.

This brief article is a case study and narrative by Boothman on the policy and practice, its implementation and results. The practice is more specifically described on the University of Michigan Health System website.

"The U-M Health System approach to malpractice claims" available at: http://www.med.umich.edu/news/umhsm.htm (last accessed June 2007)

It is the U of M process that i Clinton and Obama used to support the attempt to reform legislation in the U.S.: Medical Error Disclosure and Compensation Act of 2005 (MEDIC).[i]

The U of M Health Systems has developed and implemented a policy of open and direct communication with patients "when a patient complains, or a staff person realizes that a mishap or near miss has occurred".

Their process includes an investigation, apology and where sub-standard care was found to have caused and error resulting in harm, an early offer of settlement.

The U of M reports that as a result of their practice:

> *"The number of claims and lawsuits has dropped dramatically***.** In July, 2001 we had more than 260 pre-suit claims and lawsuits pending, already an enviable number in our region. We currently [have] just over 100.
>
> *Our legal costs appear to be down dramatically, with the average legal expense per case down by more than 50 percent since 1997***.** We went to court over seven cases between Aug. 2001 and Sept. 2002, using the principle of court as the last resort. If we had lost all of them, we estimate the verdicts would have cost us more than $8 million. If we had settled all seven at the lowest pre-trial settlement demands, it would have cost about $2.5 million. We won six, and in the seventh the verdict called for a penalty of $150,000, far less than the $550,000 settlement demanded before trial. Trying all seven cost us $320,000 in legal fees. So, if you combine the settlement and the legal fees we paid, and compare it with the cost of settling all seven, we saved $2 million just in the first year of using this approach. We are still tallying results from later years.
>
> *The severity of our claims is rising far less rapidly than the national average.* Nationally, the predicted severity of malpractice suits is rising by more than 10 percent each year. We're also seeing an increase, but it's about 2.6 percent each year. The slope of our claim severity graph began to change for claims arising from care in 2000, coinciding with our claims management changes in 2001 and 2002.
>
> *Opening-to-closing times for claims are dramatically shorter***,** down to about 10 months from more than 20 months in 2001".

Weber D.O. 2006. "Outcry over outcomes." Healthcare Forum J. 35.4 (1992): 16-26.

This article specifically references both the VHA and U of M Health System practices and the impact on litigation rates and costs of litigation and claims. These results are contrasted to a survey conducted for the American College of Physician Executives in 2006. The survey responses are from both physicians and the general public.

Weber quotes physicians who have offered opinions on disclosure, apology and the risk of litigation. Tort reform and the implementation of apology protection legislation are among the topics he discusses and the quotes are not only informative but demonstrate the conflict that continues around disclosure, apology and medical error.

Wojcieszak D, Banja J and Houk C. 2006. "The Sorry Works! Coalition: making the case for full disclosure." Joint Commission Journal of Quality and Patient.Safety, 32(6): 344-50.

This article introduces and discusses the work and purpose of The Sorry Works! Coalition, an organization that was launched in 2005 with the following stated goals:

> "The coalition has three goals: 1) educate all stakeholders in the medical malpractice debate about the Sorry Works! approach to reducing liability costs from medical errors; 2) serve as an organizing force and a central clearinghouse for information, news, ideas, and research on Sorry Works! and related full-disclosure efforts; 3) promote and push for the development of Sorry Works! pilot programs in different states…"

The Sorry Works Coalition maintains an active and informative website. The website is a valuable resource and provides links to literature and studies related to disclosure of harm caused by adverse events.

The practice for disclosure endorsed by "Sorry Works" is based on the model used at the VHA Hospitals and now at the University of Michigan healthcare sites. In addition to disclosure education, the Coalition has developed a tool kit for the development of protection of apology legislation.

"Sorry Works! Coalition" Web site: www.sorryworks.net. Unnamed author: Response to Harvard Study. Accessed at: http://www.sorryworks.net/article47.phtml (last accessed June 2007)

In response to the Studdert et al (2007) study, the Coaltion comments include the following:

> "The real experts are not medical, insurance, and legal professionals in a simulated study but the patients and families who have actually experienced adverse medical events. Unfortunately, not even the most gifted researcher can replicate the positive

emotional impact of disclosure on patients and families and how those feelings influence financial decisions and litigation. If this sounds "touchy feely" it is, because in the words of Sorry Works! board member Dr. John Banja disclosure "is all about the feelings." By constructively addressing feelings after adverse events, disclosure mitigates anger among patients and families and the urge to financially punish doctors, hospitals and insurers. This "touchy feely stuff" is the reason that disclosure reduces lawsuits and settlement costs.

Yes, claims (not lawsuits) may increase with disclosure, as the Harvard researchers suggested in their study. However, it appears that the Harvard researchers operate in the typical mind frame that medical malpractice is "all about the money." …

Simply assuming that every disclosure event will result in a claim where significant sums of cash are paid - as the Harvard researchers did - is a bad assumption and shows a total lack of understanding of what truly motivates patients and families after adverse medical events.

Furthermore, the Harvard researchers did not quantify the reduction in litigation expenses for meritorious claims as well as the decrease in non-meritorious litigation with disclosure. Across the med-mal industry, seventy to eighty percent of claims are closed with no compensation being paid…

… the only feasible way to measure the financial impact of disclosure is to directly study institutions conducting disclosure. However, this was the most surprising facet of the study: The authors did not study real-world institutions conducting disclosure!

Future studies should more closely study the phenomenon of disclosure and apology in medical and insurance organizations that are actually operating disclosure programs…"

Kraman SS and Hamm G. 2007. "Bad modeling?" Health Aff (Millwood.) 26(3): 903-05.

This is a short commentary in response to the Studdert (2007) study, also referenced as the Harvard Study. The authors claim that the method was flawed because of the use of statistical analysis. They argue that their experience does not align with the findings in the Studdert study.

Quinn R. COPIC Presentation Slides; The 3R Program. Accessed May 2007 at http://www.sorryworks.net/article33.phtml.

COPIC is a medical malpractice insurer in Colorado and Nebraska. This insurer has gained notoriety through its "3R's" program for resolution of medical malpractice claims.

The program philosophy is to: "Compensate negligently injured patients; Minimize waste of resources in tort system; and defend defensible medicine regardless of cost. The process used is the origin of the program title - Recognize, Respond, Resolve.

COPIC reports that its costs are significantly lower than traditional claim resolution practices. Feedback from patients and physicians involved in the 3R program has been positive because the needs of the patient are specifically taken into account. COPIC also notes additional benefits include: "learn from this patient to protect the next patient".

Gallagher TH, Studdert D and Levinson W. 2005. "Disclosing harmful medical errors to patients: a time for professional action." Archives of Internal Medicine, 165(16): 1819-24.

This recent article reviewed is a comprehensive summary of the status of disclosure practices, studies and legislation. The authors conclude that:

> Disclosure programs and practices are in their infancy. The fast pace at which they have developed over the past 5 years appears to be set to continue and perhaps even accelerate during the next 5 years. There will be ongoing experimentation with disclosure by health care delivery organizations and some malpractice insurers. This work will yield useful information about the impact of various disclosure approaches on key outcomes such as patient satisfaction and the rates and costs of litigation.

The authors support more research to facilitate an understanding of the impact of disclosure practices, and on the significance of each if the components (e.g. apology) of disclosure communication.

Leape LL. 2006. "Full disclosure and apology--an idea whose time has come." Physician Executive, 32(2): 16-18.

Dr. Lucian Leape is a well known advocate of disclosure. In this article Leape focuses his comments on the significance of apology as a component of disclosure. In regard to the relationship between disclosure and litigation Leape observes the following:

> For decades, lawyers and risk managers have claimed that admitting responsibility and apologizing will increase the likelihood of the patient filing a malpractice suit and be used against the doctor in court if they do sue.

> However, this assertion, which on the surface seems reasonable, has no basis in fact. There is to my knowledge not a shred of evidence to support it. It is a myth (p.17).

Leape also reviews and comments on the factors in disclosure which are helpful and those that may increase the potential for litigation. This includes the apology being a "true apology" as opposed to showing sympathy. "Showing sympathy ("I'm sorry you were hurt.") is much easier, but lacks the essence of true apology…" p. 18).

Tort Reform/Legislation Specific Literature

Gilmour JM. 2006. Patient Safety, Medical Error and Tort Law: an International Comparison. Health Policy Research Program: Health Canada.
This is the most comprehensive report available on alternative processes dealing with medical error by courts or other decision makers. The authors reviewed Canadian, United States, United Kingdom, Australia and New Zealand systems and provide an in-depth analysis of each. In conclusion the authors recommend:

- Protection of apology and of reporting from admission of fault in judicial proceedings; (qualified privilege for error reporting and disclosure)
- Expanded alternative dispute resolution mechanisms;
- Exploring a no-fault compensation system to determine if it would be suitable to Canada; and
- Legislation extending hospital liability to include non-employee treating physicians be explored (refers to the issue of bifurcation of insurance mentioned in the survey).

Secor Consulting. 2005. Alternative Patient Compensation Models in Canada, Summary Report. Prepared for the Canadian Medical Protective Association.
This 2005 report summarizes alternatives to the Canadian tort-based compensation system for medical liability. The report summarizes and contrasts systems utilized in other jurisdictions including New Zealand, Sweden, French, United Kingdom and the United States general and case-specific systems (such as the Florida Birth-Related Neurological Injury Compensation Association).

The report reviews four scenarios of alternative models and discusses their implications for Canada. The four scenarios are:

- A pure, all-in no-fault compensation system;
- A combination of tort and no-fault (based on the Prichard recommendations);

- Government indemnification with a tort-based filter (similar in principle to the NHSLA [United Kingdom]; and
- A program for severely-compromised infants" (p.9).

Secor concluded that "none of the modelled scenarios result in sustainable reductions to Canada's medical-treatment-related injury indemnification costs; Rather, their potential costs present a serious threat to the quality of healthcare in Canada" (p.13).

CMPA. 2006. Medical liability: a physician primer. Canadian Medical Protective Association Report. Accessed April 2007 from: http://www.cmpa-acpm.ca/cmpapd02/pub_index.cfm?LANG=E&URL=cmpa_docs%2Fenglish%2Fcontent%2Fissues%2Fcommon%2Fcom_medical_liability_a_physician_primer-e.html
This report is authored and published by the Canadian Medical Protective Association. The report discusses disclosure and other responses to adverse events. The inclusion of this report in this summary is primarily related to the data on frequency of claims and the financial impact of medical claims and litigation.

The CMPA reports that the trend in commenced legal action is downward. Total costs are increasing. The costs are not broken down to determine if the increase is related to the administrative costs rather than settlement or awards as indicated by the VHA statistics. In personal communication with CMPA, it was learned that the report expected to be released in August 2007 will breakdown the total costs.

Cohen JR. 2007. Toward candor after medical error: the first apology law: Harvard Health Policy Review, 5(1): 21-24.

Cohen reviews the benefits of Apology Law generally and more specifically the Colorado legislation protecting apology and other statements. The benefits of having apology legislation that include statements of admission of fault in addition to apology are summarized and viewed positively.[i]

Waite M. 2005. To tell the truth: the ethical and legal implications of disclosure of medical error: Health Law Journal, 13: 1-33.

This Canadian perspective offers an exceptional overview of disclosure issues, ethics and law. The author supports the addition of error disclosure and apology privilege to evidentiary laws.

> “Most physicians would want to apologize to the patient after a medical error has occurred, but feel constrained as this apology may be considered to be an admission that could be relied upon by the patient in a negligence action… 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" (paragraph 88).

Pillsbury M. 2007. Say sorry and save: a practical argument for a greater role for apologies in medical malpractice law. Trends and Issues in Scientific Evidence, 1: 171-200.

This is a comprehensive review of the impact of apology in disclosure. Evidentiary law is reviewed and explained (the law that makes statements/apologies admissible in court proceedings). Case law related to admissions of fault is also reviewed. In conclusion Pillsbury argues for the use of settlement negotiations and alternatives such as mediation to ensure that a full apology is provided to the patient. He also emphasizes that apology legislation is important and "As for situations where apologies are admissible, courts and lawmakers across the country can learn from the strides made by their counterparts in other states".

Wallace G. 2006. How to apologize when disclosing adverse events to patients: CMPA Information Sheet, September (no. ISO664E).

This information sheet was prepared for Canadian physicians. In addition to instructional information, the author supports the implementation of apology legislation.

> "Such legal advances should be supported, particularly those providing protection for apologies that include admissions of fault in the setting of all civil legal and administrative proceedings. Such legislation would help reassure health professionals the words of an apology would not later be used against them."

Runciman WB, Merry AF and Tito F. 2003. Error, blame, and the law in health care--an antipodean perspective: Annals of Internal Medicine, 138(12): 974-979.

This article examines the motivational factors of litigation and contrasts tort systems to the New Zealand process of resolution. The authors argue that a balance between the two systems is necessary to satisfy the needs of patients/families harmed by adverse events.

> Understanding the distinction between blameworthy behaviour and inevitable human errors and appreciating the system factors that underlie most failures in a complex system are essential for the response to harmed patient to be informed, fair and effective in improving safety. (@ p.974)

Wu AW. 1999. Handling hospital errors: is disclosure the best defense?: Annals of Internal Medicine, 131(12): 970-972.

Referring to empirical evidence and experience, Wu suggests that protection of apology legislation and enterprise risk management (i.e. where the hospital covers all losses instead of an individual physician) be implemented.

Wu also notes that barriers to disclosure are not limited to fear of litigation and urges culture change. "Only by changing the expectations of both patients and physicians can we achieve the solutions that will decrease medical errors and their devastating consequences" (p. 972).

Wei M. 2007. "Doctors, apologies, and the law: an analysis and critique of apology laws." Journal of Health Law, 40(1): 107-59.

Wei provides a very extensive review and analysis of the concerns related to apology as admission of fault and the legislative reforms intended to eliminate this as a barrier to apology. Wei argues, though, that while apology protection legislation may assist to a limited degree the underlying issues around apology must be addressed.

Sparkman CA. 2005. "Legislating apology in the context of medical mistakes." AORN Journal, 82(20): 263-66.

Sparkman argues that "apology subtracts the insult from the injury". She convincingly refers to studies and other literature to inform her opinion on apology; specifically those that demonstrate effective apology can decrease the chance of litigation. Sparkman explores the value of apology protection legislation and summarizes the legislation in place at the time of her article in the U.S.

Sparkman also reviews the types of apologies and acknowledges that there is debate related to what kind of apology is permitted in cases where there is a potential for litigation.

Banja JD. 2007. Does medical error disclosure violate the medical malpractice insurance cooperation clause?, Advances in Patient Safety: From Research to Implementation. AHRQ: Agency for Healthcare Research and Quality, Volume 3 (Implementation Issues): 371-381.

Banja offers insight into what some perceive as a barrier to disclosure, the potential loss of insurance coverage where an admission of fault is made by the insured. This article is from a U.S. perspective but is relevant to Canadian insurance law.[i] Banja reviews case law in U.S. and notes that he was unable to locate a case "in which an insurer successfully denied coverage to an insured party whose ethical code required truthful error disclosure and who did so" (p.374).

Alternative Dispute Resolution in Medical Cases Literature

Tena-Tamayo C and Sotelo J. 2005. Malpractice in Mexico: arbitration not litigation: BMJ, 331(7514): 448-451.

In 1996 the Mexican government created a functionally independent national institute to manage cases of concern or conflict between physicians and patients. The resolution process includes cases where medical negligence is at issue as well as other concerns. Their goal in creating the institute is to have a specialized team to manage these conflicts using mediation to arbitration methods. Observations of interest:

- Arbitration is done by relying on peer review of records and information provided by both parties;
- Over one-half of all issues are resolved without recourse to Courts; and
- Many conflicts are resolved within 2 days with immediate intervention by a specialized consultant or upon contact with the hospital or physician.

This article also provides a good summary of the pros and cons of this type of alternative dispute resolution process compared to the judicial process.

Liebman CB and Hyman CS. 2005. Medical error disclosure, mediation skills, and malpractice litigation: a demonstration project in Pennsylvania. Available at http://www.pewtrusts.org/pdf/LiebmanReport.pdf

Project on Medical Liability in Pennsylvania, funded by the Pews Charitable Trusts.

This extensive report reviews empirical and non-empirical literature. The project reviewed was undertaken to assist with the implementation of disclosure legislation requirements in the state of Pennsylvania requiring written notice to patients where an error or adverse event is discovered.

The authors explore why mediation is a desirable process for resolution and further summarize recommendations for effective disclosure discussions (achievable in mediation) as follows:

- Apologizing;
- Describing the error instead of avoiding specifics;
- Giving basic information known at the time of the error, but not guessing;
- Explaining what additional inquiries will be made and what questions need to be answered; and
- Showing the feelings they have experienced as a result of the error.

APPENDIX B

Case Law Search Terms - Used in Initial Search of Canadian, US and UK data bases using *Quicklaw*

negligence/physician

negligence/patient

negligence/medical error

negligence/nurse

negligence/dentist

negligence/hospital

medical error

Malpractice

adverse event

Disclose

Disclosure

Inform

Apology

Insurance/duty to cooperate/relief from forfeiture

- Various combinations of the above terms were used. Cases located were noted up to determine judicial consideration and references to other case law.
- Cases referenced in texts and articles were then entered a search terms to determine judicial consideration and to reference full decision.

In total 52 cases were reviewed related to tort law and insurance law; 1 decision from a professional body, specifically referencing disclosure requirements was located.

APPENDIX C

THE QUEBEC PERSPECTIVE

Prepared by: François Sauvageau, LL.M.

To date, Quebec is one of two Canadian provinces having adopted legislation that forces physicians and other healthcare professionals to disclose adverse events or as referred to in its legislation -"accidents" occurring in the provision of care. One could imagine that such a change in legislation would entail an enormous increase in legal action against healthcare providers. But did it really have an impact on rates of litigation and settlement? According to some Quebec lawyers representing healthcare institutions and victims of medical errors, it did not, nor did a Quebec judgment recognize the disclosure of adverse events as being equivalent to an admission of liability. However, to assess the complete impact that mandatory disclosure has had on Quebec would require an extensive compilation and study of Quebec jurisprudence before and after the implementation of what is best known as Bill 113[xii]. Such a study would consider Quebec's various disclosure legislations and provisions but would also give specific consideration to the many different factors that influence victims of adverse events to seek legal action.

In the few paragraphs that follow, we summarize the legal situation in Quebec with respect to the disclosure of adverse events as well as share the opinions of Quebec lawyers and their clients regarding their motivations behind seeking legal action.

A committee to study adverse events

In 2000, Madame Pauline Marois, the Quebec Health and Social Services Minister, reacted to a series of tragic adverse events by launching a committee responsible for the study of adverse events in the province. Mr. Jean Francoeur, the first Health and Social Services Ombudsman, was selected to Chair this new committee that made numerous recommendations with respect to all aspects of patients' safety. Amongst other things, the recommendations included: leadership, information to patients, research, management of healthcare facilities, risk management, accreditation and competency and were detailed in a document entitled "La gestion des risques, une priorité pour le réseau », best known as "Le rapport Francoeur" ("Francoeur Report")[xiii].

As a direct result of the Francoeur Report, the Quebec National Assembly unanimously adopted Bill 113 (L.Q. 2002, c. 71), on December 19, 2002, the provisions of which made

[xii] Bill 113, *An Act to amend the Act respecting health services and social services as regards the safe provision of health services and social services*, 2nd session, 36th legislature, Québec, 2002 [hereinafter "Bill 113"]
[xiii] Comité ministeriel sur les accidents évitables dans la prestation des soins de santé 2001. La gestion des risques, une priorité pour le réseau. Québec, QC: Ministère de la santé et des Services Sociaux. Retrieved August 3, 2005. Available at: http://publications.msss.gouv.qc.ca/acrobat/f/documentation/2000/00-915.pdf

amendments to the *Act Respecting Health Services and Social Services* (AHSSS)[xiv], the legislative framework governing the provision of healthcare services in public institutions. Specifically, within the meaning of the act, institutions providing services are defined at section 79 as:

- local community services centres;
- hospital centres;
- child and youth protection centres;
- residential and long-term care centres;
- rehabilitation centres.

Bill 113

Bill 113 imposed obligations not only on physicians, but on various individuals involved in the provisions of patient services within the above-mentioned institutions, their administrators and institutions themselves. Amongst other things, Bill 113 defines healthcare facilities' obligations with respect to accidents, declaration of accidents and incidents, allowance for support measures to patients, their families and healthcare workers involved in the accident, creation of risk and quality management committees, accreditation on patient safety, quality and risk management and the development of a local registry.

The explanatory notes of Bill 113 read as follows:

> This bill makes amendments to the Act respecting health services and social services as regards the safe provision of health services and social services.
>
> It provides that a user has the right to be informed of any accident having occurred during the provision of services that has potential consequences for the user's states of health or welfare. Furthermore, any person working in an institution will be under obligation to report any incident or accident as soon as possible after becoming aware of it.
>
> Every institution will be required to form a risk management committee, responsible for seeking, developing and promoting means to ensure the safety of users and to reduce the incidence of adverse effects and accidents related to the provision of health services and social services.
>
> In addition the board of directors of every institution will be required to make rules concerning disclosure of all necessary information to the user when an accident occurs, and to establish support measures to be made available to the user as well as measures to prevent the recurrence of such an accident.
>
> Finally, the bill makes regional boards responsible, in their region, for ensuring users the safe provision of health services and social services.

With respect to patients' right to be informed, Bill 113 added the three following paragraphs to the AHSSS, which now read as follows at section 8 of the Act.

[xiv] R.S.Q., c. S-4.2 [hereinafter "AHSSS"]

User's consent.

8. Before giving his consent to care concerning him, every user of health services and social services is entitled to be informed of his state of health and welfare and to be acquainted with the various options open to him and the risks and consequences generally associated with each option.

Right to information.

The user is also entitled to be informed, as soon as possible, of any accident having occurred during the provision of services that has actual or potential consequences for the user's state of health or welfare and of the measures taken to correct the consequences suffered, if any, or to prevent such an accident from recurring.

Definition.

For the purposes of this section and sections 183.2, 233.1, 235.1 and 431 and unless the context indicates otherwise,

“accident”.

“accident” means an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personnel member, a professional involved or a third person.

1991, c. 42, s. 8; 2002, c. 71, s. 4.

With respect to the requirements of reporting adverse events to hospital authorities, Bill 113 added two paragraphs to the AHSSS, which now stipulate that all physicians, nurses, residents, students, and any person providing services to a patient within a healthcare institution must report adverse events. The paragraphs read as follows at section 233.1 of the Act:

Report.

233.1. Any employee of an institution, any person practicing in a centre operated by an institution, any person undergoing training in such a centre or any person who, under a service contract, provides services to users on behalf of an institution must, as soon as possible after becoming aware of any incident or accident, report it to the executive director of the institution or to a person designated by the executive director. Such incidents or accidents shall be reported in the form provided for such purposes, which shall be filed in the user's record.

> Director's report.
>
> The executive director of the institution or the person designated by the executive director shall report, in non-nominative form, all reported incidents or accidents to the agency at agreed intervals or whenever the agency so requires.
>
> 2002, c. 71, s. 10.[xv]

Bill 113 also amended the AHSSS to include provisions that obligate healthcare institutions to create risk and quality management committees that would be responsible for:

1) identifying and analyzing the risk of incidents or accidents in order to ensure the safety of users

2) making sure that support is provided to the victim and the close relatives of the victim; and

3) establishing a monitoring system that would include the creation of a local registry of incidents and accidents for the purpose of analyzing the causes of incidents and accidents, making recommendations on preventative measures to the board of directors of the institution as well as any appropriate control measures.

With respect to litigation and complaints to a professional order, it is specifically provided in sections 183.3 and 183.4 of the AHSSS that any answers, information or documents supplied by a person in the context of investigations, deliberations or other activities of the committee cannot be used in judicial or other adjudicative proceedings as evidence against the person providing the information or against any other person. Furthermore, in order to encourage full and effective reporting of incidents and accidents, the AHSSS specifically precludes the use of any information contained in the risk and quality management record as a declaration, recognition or extra-judicial admission of misconduct for the purposes of establishing civil liability. The records and minutes of the risk and management committee are also made confidential by the AHSSS.

[xv] The definition of incident is provided at section 183.2 of the Act and read as follows: “incident” means an action or situation that does not have consequences for the state of health or welfare of a user, a personnel member, a professional involved or a third person, but the outcome of which is unusual and could have had consequences under different circumstances.

Code of *Ethics of Physicians* and Other Health Care Professionals in Quebec

Also in 2002, the Quebec legislative assembly made use of the major reform to the *Code of Ethics of Physicians*[xvi], to reinforce physicians' ethical obligation to disclose adverse events to patients. Section 56 of this Code now reads as follows:

> **Code of ethics of physicians, R.Q. c. M-9, r.4.1**
>
> 56. A physician must, as soon as possible, inform his patient or the latter's legal representative of any incident, accident or complication which is likely to have or which has had a significant impact on his state of health or personal integrity.
>
> O.C. 1213-2002, s. 56.

As opposed to the amendments proposed by Bill 113, this obligation created by the *Code of Ethics of Physicians* applies to physicians of any type of practice and not limited to those practicing in the institutions covered by the AHSSS.[xvii]

Such an amendment requires all other Quebec Health professionals to disclose all r report errors, complications, incidents or accidents. Reproduced below are the sections of the different Codes of Ethics promoting a culture of transparency, open communication and systemic approach to patients' safety:

> **Code of ethics of nurses, R.Q. c. I-8, r.4.1**
>
> **12.** A nurse shall report any incident or accident that results from her or his intervention or omission.
>
> The nurse shall not attempt to conceal such incident or accident.
>
> When such an incident or accident has or could have consequences for the client's health, the nurse shall promptly take the necessary measures to remedy, minimize or offset the consequences of the incident or accident.
>
> O.C. 1513-2002, s. 12.

> **Code of ethics of pharmacists, R.Q. c. P-10, r.5**

[xvi] R.S.Q., c. M-9, r. 4.1

[xvii] For a discussion as to the similarities and distinctions between section 56 of the Code of Ethics of Physicians and the amendments imposed by Bill 113, see Chénier, Robert-Jean and Jensen, Linda, *Disclosure and Adverse Event Reporting in Québec*, Critical Issues in Health Law: A National Summit, Conference organized by the National Health Law Section and the Continuing Legal Education Committee of the Canadian Bar Association and the Ontario bar Association, Toronto, May 2007

3.02.04. A pharmacist must inform his patient as soon as possible of any error he has made in rendering a professional service to that patient.

R.R.Q., 1981, c. P-10, r. 5, s. 3.02.04.

Code of ethics of chiropractors, R.Q. c. C-16, r.2

3.02.06. A chiropractor must inform his patient as early as possible of any error that might cause the latter prejudice and which cannot be easily rectified made by him while rendering a professional service to that patient.

R.R.Q., 1981, c. C-16, r. 2, s. 3.02.06.

Code of ethics of physiotherapists, R.Q. c. C-26, r.136

3.02.05. A physiotherapist must immediately inform his client of any prejudicial error which cannot be easily rectified committed by him while rendering a professional service to that client.

R.R.Q., 1981, c. C-26, r. 136, s. 3.02.05.

Code of ethics of optometrists, R.Q. c. O-7, r.2.2

19. An optometrist must inform his patient of any error, complication or incident that occurred while he was providing him with his professional services.

O.C. 643-91, s. 19.

Code of ethics of podiatrists, R.Q. c. P-12, r.3

3.02.06. A podiatrist must inform his client as early as possible of any error that might cause the latter prejudice made by him while rendering a professional service.

R.R.Q., 1981, c. P-12, r. 3, s. 3.02.06.

Code of ethics of dispensing opticians, R.Q. c. O-6, r.3.1

3.02.05. The dispensing optician must inform his client, as soon as possible, of any error, complication or problem arising while providing him professional services.

Decision, 83-02-09, s. 3.02.05.

Code of Ethics of the Ordre des denturologistes du Quebec, R.Q. c. D-4, r.4.1

20. A denturologist shall correct any mistake made by him in providing a professional service and prejudicial to his patient.

O.C. 1011-85, s. 20.

Code of ethics of the Ordre des orthophonistes et audiologistes du Quebec, R.Q. c. C-26, r.123.1

19. A member shall inform the client as soon as possible of any error that he commits in rendering a professional service and that is potentially detrimental to the client and difficult to rectify.

O.C. 577-96, s. 19.

Has there been an increase in litigation in Quebec due to Bill 113?

This question was posed to a lawyer representing victims of adverse events in the province of Quebec as well as to a few lawyers representing various healthcare institutions and healthcare professionals. According to them, there has been no increase in litigation since the adoption of Bill 113 by the Quebec National Assembly. On the contrary, all noted a decrease of the legal action against healthcare professionals since 2005.[xviii]

According to Me Jean-Marc Ménard, one of the most avid supporters and precursors of Bill 113, and who represents approximately half of all victims of medical errors in the province of Quebec, what motivates people to commence legal action is their strong desire to make their case known to the public in order to prevent a recurrence of their misfortune. Me Ménard also added that “if anything, it is the failure to disclose that will usually lead victims

[xviii] See statistics collected by the ACPM in its 2006 Annual Report: http://www.cmpa-acpm.ca/cmpapd02/pub_index.cfm?LANG=F&URL=cmpa_docs/french/resource_files/admin_docs/common/annual_reports/2006/com_numbers-f.html . The author was also advised that the McGill University health Center has also conducted its owns independent study, which apparently confirms that there has been no increase in litigation since the adoption of Bill 113.

to commence legal actions once the errors or accidents have been discovered".[xix] The Collège des médecins du Québec, in its memorandum discussing Bill 113, also recognized that the lack of transparency regarding adverse events and the surrounding circumstances was often the basis for anger and resentment.[xx]

Testimony from victims of adverse events or their close relatives

What most patients, victims of adverse events and their families want is to be treated with dignity and provided with the appropriate information as well as emotional and financial support in a timely manner.[xxi] They also want to ensure that their misfortune will not happen to others and that corrective measures will be taken promptly. For the majority of victims or their relatives, a lack of energy and financial resources ensures that legal action is not even an option.[xxii]

[xix] Our free translation. See *Les erreurs médicales: une réalité importante*: http://pilule.teleQuebec.tv/pages/Categorie-de-sujets-dun-emission/dossier-de-la-semaine.aspx?emission=67&date=2006-09-21

[xx] Mémoire du Collège des médecins du Québec présenté à la Commission des affaires socials en regard du Projet de loi n° 113: Loi modifiant la Loi sure les services de santé et les services sociaux concernant la prestation sécuritaire de services de santé et de services sociaux, p. 5

[xxi] See Agence de la Santé et des services sociaux de Montréal, *Grille de collecte et d'analyse des attentes des usagers*, par Caroal Ladeuix, Service performance et relations avec le réseau Carrefour montréalais d'information sociosanitaire, Janvier 2006: http://www.cmis.mtl.rtss.qc.ca/pdf/publications/isbn2-89510-287-2.pdf

[xxii] See Annex A of the Francoeur's Report where detailed and moving testimony of victims of adverse events and their relatives are directly transcribed.

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APPENDIX D

Apology Legislation

British Columbia Legislation

APOLOGY ACT, SBC 2006, CHAPTER 19

Contents

Section

HER MAJESTY, by and with the advice and consent of the Legislative Assembly of the Province of British Columbia, enacts as follows:

Definitions

1 In this Act:

"apology" means an expression of sympathy or regret, a statement that one is sorry or any other words or actions indicating contrition or commiseration, whether or not the words or actions admit or imply an admission of fault in connection with the matter to which the words or actions relate;

"court" includes a tribunal, an arbitrator and any other person who is acting in a judicial or quasi-judicial capacity.

SBC 2006-19-1, effective May 18, 2006 (R.A.).

Effect of apology on liability

2 (1) An apology made by or on behalf of a person in connection with any matter

(a) does not constitute an express or implied admission of fault or liability by the person in connection with that matter,

(b) does not constitute a confirmation of a cause of action in relation to that matter for the purposes of section 5 of the Limitation Act,

(c) does not, despite any wording to the contrary in any contract of insurance and despite any other enactment, void, impair or otherwise affect any insurance coverage that is available, or that would, but for the apology, be available, to the person in connection with that matter, and

(d) must not be taken into account in any determination of fault or liability in connection with that matter.

(2) Despite any other enactment, evidence of an apology made by or on behalf of a person in connection with any matter is not admissible in any court as evidence of the fault or liability of the person in connection with that matter.

SBC 2006-19-2, effective May 18, 2006 (R.A.).

Saskatchewan Legislation:

The Evidence Act

S.S. 2006, c. E-11.2

Effect of apology on liability

23.1(1) In this section, "apology" means an expression of sympathy or regret, a statement that one is sorry or any other words or acts indicating contrition or commiseration, whether or not the words or acts admit or imply an admission of fault in connection with the event or occurrence to which the words or acts relate.

(2) An apology made by or on behalf of a person in connection with any event or occurrence:

(a) does not constitute an express or implied admission of fault or liability by the person in connection with that event or occurrence;
(b) does not constitute an acknowledgment of the existence of a claim in relation to that event or occurrence for the purposes of section 11 of The Limitations Act;
(c) notwithstanding any wording to the contrary in any contract of insurance and notwithstanding any other Act or law, does not void, impair or otherwise affect any insurance coverage that is available to the person or would be available to the person in connection with

that event or occurrence but for the apology; and

(d) must not be taken into account in any determination of fault or liability in connection with that event or occurrence.

(3) Notwithstanding any other Act or law, evidence of an apology made by or on behalf of a person in connection with any event or occurrence is not admissible in any action or matter in any court as evidence of the fault or liability of the person in connection with that event or occurrence.

2007, c.24, s.2, effective May 17, 2007 (R.A.).

Note the definition of Court, Section 2:

"court" includes any person or body that is authorized pursuant to any Act to hear witnesses, take evidence, make any order, decree, finding, decision or report or exercise any judicial or quasi-judicial function; ("tribunal")

APPENDIX E

SECTION I

Background and Contact Information

Name _____

City/Province: _____

Phone: _____

Fax: _____

E-mail: _____

1. Please select a informant category that best describes you:

- O Patient affected by an adverse event
- O Family (and other close relationships) of a patient affected by an adverse event

Insurer/Professional Body

Primarily in the area of:

- O Medical - physicians
- O Medical - other health care professionals
- O Health Care Organization

Legal

Primarily in the area of

- O Civil litigation defense
- O Civil litigation plaintiff
- O Health Law/ Counsel to health care organizations

Risk Management/Patient Safety

- O Within Health Care Organization - estimate size/population _____
- O Position involves actual disclosure processes with patients/families? If yes, please describe your most frequent role:

_____

- o Position involves risk management or patient safety - some patient contact
- o Position involves risk management or patient safety - no patient contact

Does your organization utilize an open disclosure process?

_____ Always _____Most of the time _____.Rarely

Years in this position _____

Other: _____

SECTION II

In your opinion…..

1. **Is litigation (the commencement of a law suit) likely to be increased or decreased by open disclosure practices?**
   - o **Increased**
   - o **Decreased**
   - o **Not effected**

AND, has this changed in the recent past?

Please explain:

_____

2. **Are settlements, prior to the commencement of litigation occurring**
   - o **Frequently**
   - o **Somewhat**
   - o **Not at all**

AND, has this changed in the recent past?

Please explain: _____

3. **Are settlements post commencement of litigation occurring**
   - o **Frequently**
   - o **Somewhat**
   - o **Not at all**

AND, has this changed in the recent past?

Please explain: _____

4. **From your perspective, what changes to the Canadian healthcare and/or legal system would influence the relationship between disclosure and litigation?**

AND, has this changed in the recent past?

_____

SECTION III

Please answer from either your personal experience or, from your observations:

1. **Legal advice sought following patients being harmed by adverse events is**

   O Common
   O Uncommon

AND, has this changed in the recent past?

_____

2. **Factors affecting patient/family decisions to seek legal advice and/or commence legal action have been described in literature and include:**

   - **anger/frustration with health care provider or organization (including lack of communication);**
   - **need for additional information;**
   - **desire to ensure accountability;**
   - **degree of harm; desire for punishment;**
   - **concern about reoccurrence of adverse event**

Please describe what factors you believe to influence decisions to make a legal claim following and adverse event (which may or may not include any of the above listed factors):

_____

3. **What factors tend to prevent legal claims?**

WHAT - WHY? _____

<u>Patients and families</u> -If a legal claim was commenced, what was your experience with the legal process? For example, did you receive what you were seeking? If a legal claim was not commenced or pursued, was another process utilized that assisted you?

<u>For professionals -</u>What is the primary source of your information about the relationship between disclosure and litigation? For example: Professional experience; Educational opportunities; Literature?

_____

Additional Comments:

Please provide any additional information that you would like to offer in order to enhance the results of our population scan.

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