

PATIENT SAFETY, MEDICAL ERROR AND TORT LAW: AN INTERNATIONAL COMPARISON

FINAL REPORT

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The views expressed herein do not necessarily represent the official policy of Health Canada.

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EXECUTIVE SUMMARY

Background

Errors and adverse events in health care are now recognized to be far more widespread and more harmful to patients than was realized previously. Patients, already vulnerable when ill and in need of treatment, are left even more vulnerable when injured by the very system they turned to for help. A significant portion of adverse events are preventable. Medical error and patient injury have become serious concerns worldwide, resulting in numerous domestic initiatives and the launch of the World Alliance for Patient Safety by the World Health Organization. The National Audit Office in the United Kingdom observed that patient safety has become “the most important common issue in health care internationally”.¹ Regardless of differences in the organization and delivery of care, health and liability insurance, and legal environments among countries, the policy environment for patient safety is becoming increasingly globalized, and the need for action to reduce harm is urgent.

The debate about medical error and patient safety has been reframed to reflect a new understanding of how error and injury in health care occur. Rather than the traditional focus on the personal responsibility of health care providers, this new patient safety approach maintains that it is the institutional systems within which health care providers operate that cause harm more than individual practitioners. Reconfiguring the system and the way error is treated within it, it is contended, will result in safer care. Underlying systemic factors play a significant causal role in most adverse events and near misses in health care; it is thus inappropriate to blame individual health care providers when patients are injured. Analysis cannot be limited to occurrences at the “sharp end”, where practitioners interact with patients and each other in the process of delivering care, but must also include consideration of the role played by the “blunt” or remote end of the system, i.e. regulators, administrators, policy makers and technology suppliers, who shape the environment in which practitioners work.

However, the extent to which this approach to error reduction, and in particular, the de-emphasis on individual fault-finding, has been or can be incorporated into legal reasoning is not clear. It contrasts starkly with tort law, in which recovery of damages is largely premised on a finding of fault. The intersection of the two affects uptake of the patient safety approach, since law shapes the environment for the provision of health care, assessment of risks, and response to adverse events by all concerned. In important ways, law conditions the solutions that can be implemented, because people are guided in their conduct by the applicable legal frameworks and requirements.

This project involved a review and comparison of several countries, (1) examining incentives and disincentives to reducing medical error and enhancing patient safety inherent in existing legal frameworks (tort and procedural law); and (2) evaluating legal reforms undertaken or proposed, in order to assess their impact on patient safety initiatives, and distil lessons to be learned from these experiences. Canada, the United States, the United Kingdom, Australia, and New Zealand were studied, because they share similar legal systems (with the exception of Quebec in Canada), and because the systems-oriented patient safety approach has taken hold in

¹ England. National Audit Office, “A Safer Place for Patients: Learning to Improve Patient Safety”, HC 456Session 2005-2006 (London: Stationery Office, 2005), Appendix 4, 67.

much of the academic and policy literature. New Zealand's no-fault system for accident compensation offered a useful contrast to fault-based liability.

Findings

The study determined that, despite support for systemic analysis, the law has changed little in response. Tort law has been reformed, in some jurisdictions substantially, but the primary goal of most reforms has been to limit the risk and size of judgments, not to minimize error. In adopting these reforms, little attention was given to assessing whether they will affect the incidence of error, disclosure, or patient injury. Tort law's effect on accident prevention appears limited. Underclaiming for negligently caused injury is endemic, not just in jurisdictions with tort systems, but where alternative compensation systems exist as well. The absence of a tort system, as in New Zealand, has not been associated with significantly greater disclosure of error to patients, suggesting other factors exert a powerful influence in addition to the prospect of tort liability.

Accountability to patients and the public remains a pressing concern in all jurisdictions. Different mechanisms have been adopted to address this issue, and in some countries, to divert claims from the civil justice system; some of these show promise for consideration for adaptation to the Canadian environment. Wider acceptance of the patient safety movement's prescriptions for change will require patient safety advocates to become more attentive to injured patients' needs, including the need for compensation. Ensuring accountability and appropriate compensation for injury represent challenges to patient safety advocates' recommendations about how errors and injury should be addressed that have not yet been satisfactorily resolved.

There has been little attention to whether and how the tort reforms adopted in the various countries have affected patient safety or disclosure of harm. Similarly, there has been little empirical study of the effectiveness of patient safety initiatives, or at least those reviewed that affect the operation of the civil justice system, such as qualified privilege laws that shield reports of error from disclosure in legal proceedings.

Consideration of reform of the medical liability system in Canada must take account of two fundamental constraints. First, although there is scope for concerted action by governments in Canada on patient safety, proposals for legal reform must respect the realities of the Canadian federation, i.e. that jurisdiction over tort law, the administration of justice, and most aspects of health care is provincial. Second, as a practical matter, there is no evidence of the political or public will needed to undertake a program of radical tort reform (such as no-fault compensation) in the near future. Proposals for reform must respond to that reality, looking to the question of how best to create synergies between public and private law to achieve desired goals – in patient safety terms, gathering more information about errors, facilitating systemic analysis, and implementing systemic solutions to reduce future harm. Recommendations are aimed at making litigation count for patient safety.

Making Litigation Count for Patient Safety

Qualified Privilege, Error Reporting and Disclosure to Patients

Recommendation 1.1

Limited qualified privilege legislation that shields information gathered in connection with and the activities of quality assurance committees or designated patient safety initiatives from use in civil litigation should be adopted, including protection for external reporting and sharing of

information for patient safety purposes, but its continuation should be linked to evidence of compliance with requirements to report error and also to disclose harm to patients.

Recommendation 1.2

Effective oversight is required to ensure compliance with error reporting and investigative obligations, as well as with requirements for disclosure to patients

Recommendation 1.3

Patient safety initiatives such as error reporting systems must be monitored and evaluated to assess their results in improving care, communication and outcomes.

Reframing Liability to Advance Patient Safety Goals

Recommendation 2.1

Provinces should consider legislation extending hospital liability to include responsibility for the negligence of non-employed physicians treating patients on-site.

Recommendation 2.2

Implications for patient safety should be an important, explicit consideration in decision-making about and oversight of care, both in and outside hospitals.

Lawsuits as a Learning Resource

Recommendation 3

Provision should be made for systematic identification and dissemination of patient safety lessons to be learned from lawsuits, potentially under the aegis of or in conjunction with the Canadian Patient Safety Institute, or through external error reporting structures or provincial patient safety organizations where these exist. Possibilities for earlier and more comprehensive access to claims information for patient safety purposes should be explored with the affected stakeholders.

Liability Coverage, Government Subsidy and Access to Information

Recommendation 4

The substantial funding that governments contribute to the cost of physician and hospital liability coverage (thereby indirectly assuming a share of the risk of liability) should be tied to improved performance in specified, targeted patient safety initiatives.

Expanded Complaints Mechanisms as an Alternative to Litigation

Recommendation 5

More low key, accessible, inexpensive, conciliatory complaints resolution mechanisms, with power to consider complaints involving both institutions and different types of health care providers, should be made available.

Exploring No-Fault and Administrative Compensation Systems

Recommendation 6

Research should be sponsored to evaluate alternative compensation mechanisms, including no-fault compensation systems, with a view to determining their desirability in the Canadian environment.

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CHAPTER 1. FINAL REPORT

PATIENT SAFETY, MEDICAL ERROR AND TORT LAW: AN INTERNATIONAL COMPARISON

I. INTRODUCTION

Significance of this Study

Errors and adverse events in health care are now recognized to be far more widespread than had previously been realized. Even more importantly, we are better able to determine the extent of the harm they cause, and it is substantial. Many patients are seriously injured and even die as a result of adverse events during their care. A significant portion of those adverse events are preventable. With a problem of this magnitude causing such widespread harm, the need for effective response is urgent.

The debate about medical error and patient safety has been reframed since the release of the influential report, *To Err is Human*, by the Institute of Medicine in the United States in 1999.¹ That report, which concluded that much of the harm that patients suffer is the result of systemic factors, and advocated a systems-oriented approach to error reduction that de-emphasized individual fault-finding, has had a tremendous influence on policymakers and in much academic commentary. Its findings and recommendations have been repeated in other countries as well. In a very short time, “patient safety”, with its emphasis on the importance of systemic analysis in reducing error and injury to patients, has come to dominate discourse on the subject, and become a priority worldwide.

The extent of both awareness of the problem and the penetration of systemic approaches to understanding and responding to it is evident in the adoption of a Resolution by the World Health Assembly in 2002, urging members to pay the greatest possible attention to patient safety, and requesting the Director General of the World Health Organization (WHO) to carry out a series of actions to promote patient safety.² These included development of global norms and standards, promotion of evidence-based policies, promotion of mechanisms to recognize excellence in patient safety internationally, encouragement of research, and provision of

¹ Kohn, L., Corrigan, J., Donaldson, M. (eds), Institute of Medicine, *To Err is Human: Building a Safer Health System* (Washington DC: National Academy Press, 2000).

² World Health Ass’n., WHA55.18, online at: www.who.int/gb/ebwha/pdf_files/WHA55/ewha5518.pdf (last accessed May, 2005).

assistance to countries in key areas. In response, WHO launched the World Alliance for Patient Safety in 2004, which is committed to raising awareness and political commitment to improve the safety of care and facilitate development of patient safety policy and practice in WHO Member States.³ It is sponsoring work to understand the nature and causes of adverse outcomes and near misses, standardize nomenclature and taxonomy in order to facilitate the development and dissemination of solutions, and advance patient safety in specific areas such as blood safety, infection control, and medical devices.

The National Audit Office (NAO) in England noted in 2005 that the rate of development of patient safety initiatives “is increasing to the point that patient safety appears to be the most important common issue in health care internationally”.⁴ As an indication of the rapid expansion of interest and work in this area, it recounted that an internet search for “patient safety” in February 2004 showed just over 500,000 results, while the same search in March 2005 revealed 2,680,000 results.⁵ To update that figure, in March, 2006, entering the term “patient safety” on an internet search engine returned 91,500,000 results! Patient safety agencies and organizations, government offices and staff in health care institutions, research programs, articles in scholarly and popular publications and general interest in the subject have proliferated. In a very short time, patient safety has become a global issue.

Adverse Events and Patient Injury in Canada

Canada is no exception when it comes to patient injury – a significant number of Canadian patients are harmed by preventable adverse events while receiving treatment and care each year. In 2004, Baker and Norton *et al.* identified an incidence rate of adverse events (i.e. unintended injuries harming patients and caused by health care management) of 7.5% in acute care hospitals.⁶ Of these, 36.9% were considered highly preventable.⁷ In most cases (64.4%),

³ World Health Organization, “Patient safety”, online at : <http://www.who.int/patientsafety/en/> (last accessed July, 2005).

⁴ England. National Audit Office, “A Safer Place for Patients: Learning to Improve Patient Safety”, HC 456 Session 2005-2006, (London: Stationery Office, Nov., 2005), App. 4 “International comparisons of organizational learning for patient safety”, at 67 (hereafter NAO 2005); online at: http://www.nao.org.uk/publications/nao_reports/05-06/0506456.pdf (last accessed Dec. 2005) .

⁵ *Ibid.*

⁶ Baker, R., Norton, P. *et al.*, “The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada”, (2004) CMAJ 170(11) 1678-1689 (hereafter, Canadian Adverse Events Study).

⁷ *Ibid.*, at 1683.

the adverse event resulted in no or minimal to moderate impairment, with recovery within six months. However, 5.2% of adverse events resulted in permanent disability, and 15.9% in death.⁸ In addition to the toll on (and of) patients, adverse events often entailed longer periods of hospitalization, with associated increases in costs. Extrapolating from their study, they estimated that in 2000, of the almost 2.5 million annual admissions to similar hospitals in Canada, about 185,000 were associated with an adverse event, of which close to 70,000 were potentially preventable.⁹ This means that preventable adverse events cause more deaths than breast cancer, motor vehicle/transport and HIV combined.¹⁰

Patient Safety and the Law

The new understanding of how patient injury occurs gained widespread attention somewhat later in Canada than elsewhere. In the United States, the Institute of Medicine's work was preceded by the Harvard Medical Practice Study's 1991 report highlighting the extent of adverse events in hospital care in New York; many of these were preventable.¹¹ Other countries also recognized that their health care systems were prone to error and failure, and that solutions required a concentration on systemic improvements in the safety and quality of health care, and a concomitant move away from "shaming and blaming" the individual practitioners involved through civil liability, in-hospital processes and professional discipline.¹² The National Steering Committee on Patient Safety in Canada released its report, "Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care", in September, 2002.¹³ It, too, concluded that underlying systemic factors contribute to most adverse events, near misses and critical incidents, and underlined the importance of reporting problems without attaching blame. Pursuant to its recommendations, the Canadian Patient

⁸ *Ibid.* at 1681-2.

⁹ *Ibid.*, at 1678.

¹⁰ Canadian Institute for Health Information and Statistics Canada, "Health Care in Canada 2004" (Ottawa, CIHI, 2005) at 42-3, online at <http://www.cihi.ca> (last accessed July 2005).

¹¹ Brennan, T., Leape, L., Laird, N., Hebert, A., Localia, R., Lawthers, G., Newhouse, J., Weiler, P., Hiatt, H., "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I" (1991) 324 NEJM 370-6.

¹² See eg. England. Department of Health, *An organization with a memory: Report of an expert group on learning from adverse events in the NHS* (Chief Medical Officer, Chair), (London: Stationery Office, 2000); Wilson, R. *et al.*, "The Quality in Australian Health Care Study: Iatrogenic Injuries or adverse patient events in hospitalised patients" (1995) 163(9) Med.J.Aus. 458-71.

¹³ National Steering Committee on Patient Safety. Royal College of Physicians and Surgeons of Canada. Online at: <http://rcpsc.medical.org/publications/index.php> (last accessed October, 2002).

Safety Institute (CPSI) was established in December, 2003, with a national mandate to advance safer health systems for Canadians.¹⁴

The extent to which a “systems-oriented” approach, especially its de-emphasis on individual fault-finding, has been or can be incorporated into legal reasoning is not clear. The contrast with tort, and negligence law in particular, is stark: recovery of damages for negligence is premised on a finding of fault. The intersection of the two will affect uptake of the patient safety approach, since law forms a pervasive backdrop to decisions and actions of providers and patients, and shapes the environment for the provision of health care, assessment of risks, and responses to adverse events by all concerned. In important ways, law conditions the solutions that can be implemented, because people are guided in their conduct by the applicable legal frameworks and requirements.

The tension between the patient safety approach to error and injury, and tort law’s emphasis on finding fault is evident. Examining whether and how tort law has been adapted to take the new patient safety sensibility into account in jurisdictions with longer experience with the two can provide useful information. While there are important differences in the health care systems and social, political, economic and legal environments in the countries studied, there are also significant similarities, and a comparative study can be instructive. In each of the five countries (Canada, the United States, the United Kingdom, Australia and New Zealand), the utility of systemic analysis in addressing the problem of patient injury has been widely, although not universally accepted among policy makers and health care practitioners, but less so by the public. Some countries have implemented tort and other law reforms, although often not to advance a patient safety agenda. Analyzing developments elsewhere will assist in assessing how Canadian jurisdictions can best respond to the disjunction between tort law and patient safety approaches.

II. OVERVIEW OF THE PROJECT

Methods:

This project is an international comparison that uses synthesis research to examine the role of tort law and tort reform in facilitating and inhibiting efforts to reduce medical error and

¹⁴ Canadian Patient Safety Institute, online at: [http:// www.hc-sc.gc.ca/english/care/cpsi.html](http://www.hc-sc.gc.ca/english/care/cpsi.html)

improve patient safety. It focuses on four countries in addition to Canada: the United States, the United Kingdom, Australia and New Zealand. These countries were selected because they are common law jurisdictions and so, share similar legal systems,¹⁵ and because the systems-oriented patient safety approach has taken hold in much of their policy and academic literature on health safety, allowing assessment of whether changes in tort law or in statutory or regulatory frameworks governing civil liability have resulted. New Zealand's no-fault system for accident compensation (which includes injury caused by treatment), although retaining vestiges of a fault-based inquiry in cases of "medical error" until recently, offers a useful contrast to fault-based liability.

Despite sharing these characteristics, the countries also differ in important respects. Canada, the United States and Australia are federations. The United Kingdom and New Zealand are unitary states. With the exception of the United States, all the countries surveyed have systems of universal access to medically necessary services on the basis of need and not ability to pay, although the services covered are not uniform among the various plans. The legal status of physicians working in hospitals varies. For instance, in the United Kingdom, the National Health Service (NHS) employs most physicians providing NHS services in hospitals, while in the United States, physicians treating patients in hospitals are typically independent contractors. Arrangements for physicians' liability insurance differ as well, ranging from practitioner responsibility in the United States, through various forms and degrees of governmental subvention in Australia and Canada, to government responsibility in the U.K. for physicians providing NHS services.

Data Collection:

As synthesis research, the study identifies, reviews and analyzes existing knowledge. Site visits were conducted to each jurisdiction to gather additional material and conduct interviews with key informants in order to update information and better understand the full extent of the literature, the tort / accident compensation and patient safety systems, and their interaction in each country. However, primary research on the effects of various reforms was outside the scope of the project.

The following steps were taken:

¹⁵ With the exception of the province of Quebec in Canada, which is a civil law system.

- Identification and analysis of relevant literature, judicial decisions, statutory regimes and law reform initiatives in each of the five jurisdictions;
- Meetings with academics, policymakers and lawyers practicing in the area of medical malpractice in the jurisdictions being reviewed;
- Analysis of the goals of tort and procedural reforms in each jurisdiction, and assessment of congruence with a patient safety sensibility;
- Assessment of the state of relevant law in each country, including any evidence of the effects of reforms undertaken;
- Update literature reviews;
- Develop recommendations for consideration by policymakers and lawmakers.

The literature reviews undertaken were extensive, and included examination of the grey literature (policy documents, inquiry reports, position papers and other sources). Because the study has a dual focus on patient safety and tort, the review encompassed both bodies of literature, on patient safety and on tort law, with particular attention to their interaction. The material gathered was voluminous, and because the area is the focus of such intense interest and work, new sources and developments continued to appear over the course of the project, resulting in the need to update, add new material, and re-assess results frequently. After the various chapters on each country were drafted, they were reviewed by experts in those countries for accuracy and completeness.

Data Presentation:

The first chapter of this study contains the final report on this project. It introduces the problem of patient safety, the power of law, and the dissonance between patient safety advocates' understanding of how error occurs and that prevalent in negligence law. It reviews the basic concepts and reasoning employed in the patient safety literature and in tort law. The report focuses on the central issues at the interface of tort law and patient safety initiatives. It analyzes the most influential developments and trends in thinking, with examples from the countries reviewed. It makes recommendations for consideration for future action, reform and research. The chapters that follow examine developments in each of the countries reviewed – Canada, the United States, the United Kingdom, Australia and New Zealand – describing and analyzing tort reforms that have been undertaken, and the relationship among patient safety initiatives, tort law and the civil justice system (or, in the case of New Zealand, the accident

compensation system). The final chapter summarizes past and future dissemination activities, and identifies gaps remaining.

Given the volume of material reviewed, it would have been neither possible nor helpful to the reader to include reference to all of it in this report. Rather, I selected the sources that were of most assistance in tracking and understanding events, developments and their effects in the countries reviewed, and assessing initiatives and directions in law reform, with particular reference to the implications for patient safety. Definitions of key terms in patient safety and tort law can be found in the Glossary in Appendix A to this chapter. In order to increase the report's utility to different audiences, the elements of a negligence claim are explained in greater detail in Appendix B to this chapter.

Concepts in patient safety

The extent of adverse events and consequent harm to patients is so significant that, as the National Steering Committee on Patient Safety in Canada noted, "... it is no longer appropriate to think that previous and current processes to ensure safety are still effective in controlling adverse outcomes".¹⁶ Instead, patient safety advocates urge the adoption of a systems approach to patient safety, "based on the understanding that the individual practitioner is not a potential culprit to be blamed and punished, but rather that he or she is one participant interacting with many others in a highly complex environment. Adverse events are generally viewed as a consequence of the system; the goal is to improve the structure and/or process so the event is less likely to recur".¹⁷ Systems analysis recognizes that analysis cannot be limited to occurrences at the "sharp end", where practitioners interact with patients and each other in the process of delivering care, but must also include consideration of the role played by the "blunt" or remote end of the system i.e. regulators, administrators, policy makers and technology suppliers, who shape the environment in which practitioners work. As the National Steering Committee noted, "Human-factor engineers have consistently shown that the ability of sharp-end practitioners to avoid adverse events or near misses...depends directly or indirectly on a host of blunt-end factors, rather than on the isolated 'error' of human practitioners".¹⁸

¹⁶ *Supra*, n.13 at 14.

¹⁷ *Ibid.* at 17.

¹⁸ *Ibid.*, at 18.

The NAO identified five elements that most developed countries have identified in their strategies for improving patient safety:¹⁹

- “A ‘just’ or ‘fair’ culture that encourages a reporting and questioning culture;
- Systems for reporting and analysing incidents both locally and nationally;
- A good in-depth analysis process to establish root causes for selected individual incidents and aggregate incident reviews, thus enabling learning;
- A process to ensure that actions are implemented and corresponding improvements in patient safety and quality of care can be demonstrated; and
- Effective processes for sharing information at various levels – nationally, organizationally and clinically – for learning and improvement.”

Common themes are that error is inevitable but can be minimized, and that to do so, organizations must foster a culture that encourages reporting problems, analyzes incidents to determine all contributing causes, does not blame health care providers, implements effective responses, and disseminates lessons learned.

Concepts in Tort Law

The focus of this report is on one branch of tort law, the law of negligence, because that is the basis for most lawsuits against health care professionals, hospitals and their employees. As background, this section briefly outlines the purposes and uses of tort law, and the structure of negligence actions.

(a) Objectives of Tort Law

Compensation, corrective justice and deterrence are the three primary objectives of tort law. Many judges and scholars see compensation as tort law’s most important function. The Supreme Court of Canada has observed that “...the essential purpose of tort law...is to restore the plaintiff to the position he or she would have enjoyed but for the negligence of the defendant”.²⁰ However, liability for negligence is bounded by the requirement that there be an initial finding of fault. As Lewis Klar notes, “The essential characteristic of tort law’s primary area of operation is that it is a fault-based system of accident compensation”.²¹ Once that

¹⁹ *Supra*, n .3 at 67.

²⁰ *Athey v. Leonati* (1996), 140 D.L.R. (4th) 235 (S.C.C.).

²¹ Klar, L., *Tort Law* (3rd ed.) (Toronto: Thomson, 2003) at 9.

condition is satisfied, the damages awarded are meant to fully indemnify a plaintiff for all his or her losses, insofar as money can do so. The requirement to find fault rests on the principle that wrongdoers bear personal responsibility for the harm they have caused others, and so should restore the victim by paying damages.²² Thus, in addition to compensation, tort law also incorporates considerations of corrective justice, which place moral and ethical principles at the forefront, rather than instrumental justifications.²³ Accident prevention is the third important objective of tort law. A finding of liability and award of compensation are expected to deter other similar conduct (and resulting injuries) in the future. The Supreme Court of Canada recognizes that “One of the primary purposes of negligence law is to enforce reasonable standards of conduct so as to prevent the creation of reasonably foreseeable risks. In this way, tort law serves as a disincentive to risk-creating behaviour”.²⁴ Deterrence is meant to operate both specifically on the defendant, encouraging precautions to avoid a recurrence, and generally, as a guide to future conduct by others, so that they can govern their behaviour to avoid similar substandard conduct.

While academic criticism of each perspective abounds (and is beyond the scope of this paper to address), they co-exist as both objectives and justifications in many judicial decisions. Judges do not treat these goals as mutually exclusive or incompatible, nor do they resolve contradictions among them. Rather, they tend to appeal to one after the other, particularly compensation and deterrence, to explain policy considerations meant to be advanced by their judgments. Tort law also serves educative, symbolic and political functions.

(b) Tort Law and Regulatory Scholarship

Medical liability law has a dual character: it is part of the general tort and civil justice systems, and one of the mechanisms for health system governance as well. Some scholarship on patient safety and medical liability law argues that tort law should be understood as a form of regulation, defined broadly as the organized and deliberate leveraging of power or authority to effect changes in behaviour.²⁵ From that viewpoint, tort law can be considered as simply one

²² Cane, P., “Distributive Justice and Tort Law”, [2000] NZLR 401 at 403.

²³ In *Donoghue v. Stevenson*, the decision that marked the beginning of the modern law of negligence, Lord Atkin commented: “The liability for negligence, whether you style it such or treat it as in other systems as a species of ‘culpa’, is no doubt based on a general public sentiment of wrongdoing for which the offender must pay” – *M’Alister (or Donoghue) v. Stevenson*, [1932] A.C. 562 (H.L.).

²⁴ *Stewart v. Pettie*, [1983] 1 S.C.R. 131, 150, *per* Major, J.

²⁵ Mello, M., Brennan, T., “Fostering Rational Regulation of Patient Safety” (2005) 30 J.H.P.P.L. 375-416.

component of an overall regulatory strategy. This approach may be coupled with a preference for indirect, or “third party” governance that is subject to performance monitoring and oversight, rather than traditional command and control regulation as a governance mechanism.²⁶ While this argument has not been fully developed in the health law field, it has attracted some support in scholarship on tort law and patient safety, particularly from American commentators.²⁷ In many ways, it fits well with a predilection in American tort scholarship generally to focus on the deterrent potential in tort law, rather than its functions as a means of compensation / reparation to the victim of wrongdoing.²⁸

Commenting on efforts to theorize tort law as regulation in contexts other than medical liability, some Commonwealth scholars caution that analyzing tort law exclusively through a regulatory lens distorts understanding. Analysis is not as simple as concluding that, because courts set standards, monitor behaviour, and enforce standards through their decisions about tort liability, the tort system is a regulatory tool like any other. Academic commentary wary of “tort law as regulation” accepts that tort law certainly has instrumental and distributional effects, and that it is appropriate that these be taken into account by courts in their judgments. However, focusing only on the behaviour-modification potential in tort liability neglects its basic structure. As Peter Cane argues, tort law is not just about deterrence; it is “... a set of rules and principles of interpersonal responsibility for harm”, and that shapes what it can and cannot accomplish.²⁹ The interests that tort law advances, and that judges respond to in their decisions are diverse, and are not limited to forward-looking regulatory goals.³⁰ Resolving the larger debate on the applicability of regulatory scholarship to areas of private law is beyond the scope of this study. However, its existence reinforces arguments that when assessing the medical liability system and proposals for reform, it is insufficient to focus on only one of the tort system’s objectives,

²⁶ Eliades, P., Hill, M., Howlett, M. (eds), “Introduction”, *Designing Government: From Instruments to Governance* (Montreal: McGill-Queen’s U. Press, 2005), 3-20; Braithwaite, J., Healy, J., Dwan, K., “The Governance of Health Safety and Quality: A Discussion Paper”, Commonwealth of Australia, 2005, online at: <http://www.safetyandquality.org/governance0705.pdf> (last accessed Nov. 2005).

²⁷ Sage, W., “Medical liability and patient safety”, (2003) 22 *Health Affairs* 26-36: modern medical liability is best understood as “regulation by litigation”, Mello & Brennan, *supra*, n.25.

²⁸ Cane, P., “Tort Law as Regulation”, (2002) *CLW Rev.*

²⁹ *Ibid.*

³⁰ Stapleton, J., “Regulating Torts”, in Parker, C., Scott, C., Lacey, N., Braithwaite, J., *Regulating Law* (Oxford: Oxford U. Press, 2004), 122-143 at 136-7, 142.

detering substandard care. Reform must include improvement in the ways injured patients are compensated as well.

(c) Analysis of a Negligence Action

Turning to the structure of a negligence action, a plaintiff must prove on a balance of probabilities that:

1. The defendant owed him or her a legal duty of care;
2. The defendant breached the standard of care established by law;
3. The defendant's breach caused injury or loss to the plaintiff; and
4. The plaintiff's damages are not too remote to be recoverable in law.

Liability in negligence can arise from substandard care or treatment, and also from a failure to obtain the patient's informed consent to treatment. The elements of a negligence claims are explained in greater detail in Appendix B to this chapter.

(d) Constitutional Jurisdiction

Provinces have constitutional jurisdiction over tort law, the administration of justice, and most aspects of health care. That does not mean there is no role for the federal government, or for concerted action by all levels of government on issues of patient safety and tort law.³¹ However, the realities of the Canadian federation must be taken into account.

The preceding sketches the basic concepts and premises in patient safety, tort law and negligence. Of necessity, it omits or glosses over much of the complexity in these areas. However, it will serve as a starting point to inform consideration of developments in the law and the intersections with patient safety initiatives that follows, and will be expanded further as needed.

III. FINDINGS

The Patient Safety Environment

Patient safety and medical error have become global issues, and the policy environment has been globalized.

To Err Is Human, with its glaring analogy that the deaths caused by medical error in the United States were equivalent to a jumbo jet a day crashing, made patient safety a public issue.

³¹ For example, CPSI was established by the federal government

The data it presented was not new; it was based on studies that had been completed years previously.³² While the earlier studies had not captured public attention, they had spurred research examining the extent of medical error elsewhere. In 1996, the Quality in Australian Health Care Study, reported an adverse event rate of 16.6% in hospitalized patients in that country (later revised to 10.6%).³³ Publication of the IOM Report in 1999 prompted studies in other countries, with similarly grim findings about the rate of errors, extent of preventable adverse events and patient injury.³⁴

Prescriptions for reform from patient safety advocates in all the countries surveyed were similar as well. Not only has patient safety assumed prominence worldwide as a pressing issue in need of effective response, but analysis of causes of the problem, and how to respond -- i.e. systemic analysis and systemic solutions, rather than individual blame -- has “gone global”. Although this study is limited to a small number of developed countries with common law systems, inauguration of the WHO World Patient Safety Alliance, and the NAO’s observation that patient safety has become “the most important common issue in health care internationally”, clearly evidence the globalization of the policy environment, regardless of differences in the organization and delivery of care, health and liability insurance, and legal environments.³⁵ The chief features of the patient safety movement’s analysis of why errors occur, what action is needed, and the effects of legal liability on the ability of the health system to respond effectively are repeated across countries.

Patient safety analysis evidences common themes and tensions across countries.

The following distills the salient features of the patient safety movement’s analysis:

³² Wachter, R., Shojania, K., *Internal Bleeding: The Truth Behind America’s Terrifying Epidemic of Medical Mistakes* (N.Y.: Rugged Land Press, 2004) at 57.

³³ Wilson, R., *et al.*, “The Quality in Australian Health Care Study: Iatrogenic Injuries or adverse patient events in hospitalized patients”, (1995) 163 *Med. J. Aus* 458-471; Thomas, E. *et al.*, “A comparison of iatrogenic injury studies in Australia and the USA”, (2000) 12(5) *Internat’l. J. Qual. In Health Care* 371-378; Runciman, W., “A comparison of iatrogenic studies in Australia and the USA II: reviewer behaviour and quality of care”, (2000) 12(5) *Internat’l. J. Qual. In Health Care* 379-388.

³⁴ See eg. Canadian Adverse Events Study, *supra*, n. 6; Davis, P., *et al.*, “Adverse events in New Zealand hospitals I: occurrence and impact”, (2002) 115 *NZJM* 1167; Vincent, C., *et al.*, “Adverse events in British hospitals: preliminary retrospective record review” (2001) 322 *BMJ* 577-579, 1395.

³⁵ NAO 2005, *supra*, n.3.

1. Underlying systemic factors play a significant causal role in most adverse events and near misses in health care; it is thus inappropriate to blame individual health care providers when patients are injured.
2. Analysis cannot be limited to occurrences at the “sharp end”, where practitioners interact with patients and each other in the process of delivering care, but must also include consideration of the role played by the “blunt” or remote end of the system, i.e. regulators, administrators, policy makers and technology suppliers, who shape the environment in which practitioners work.
3. It is essential to find out about errors and injuries to patients, in order to (i) undertake systemic analysis of what has gone wrong, (ii) develop effective strategies to prevent, reduce and ameliorate harm, and (iii) disseminate lessons learned more widely through the health system so they can be implemented elsewhere as well.
4. The risk of negative repercussions if health care providers disclose errors chills disclosure.
5. The prospect of legal liability for negligence is a major impediment to openly disclosing errors and systemic analysis, because recovery of damages is conditional on a finding of fault. Further, the focus on whether individual care was substandard results in an inaccurate (because incomplete) understanding of why harm occurred, drives knowledge about errors underground, and consequently hampers development of responses that would reduce error and harm in the future. Practitioners’ exposure to legal liability should be reduced.
6. Information gathered and activities undertaken as part of quality assurance or patient safety initiatives should be insulated from disclosure or use in civil litigation and other types of legal proceedings, as well as more generally. It is also important that patients be given an explanation of what occurred and an apology when they have been harmed as a result of error, and apprised of plans to prevent a recurrence.
7. The culture of the health care system must be changed from a culture of “blame and shame” to a culture of openness, problem-solving and safety.

While patient safety advocates’ message calling for an end to individual blame has gained some acceptance, where and how to draw the line between blameless and blameworthy behaviour is far from settled, and major disagreements remain about what the repercussions of each should

be.³⁶ Tensions between systems and individual accountability are unresolved. Although patient safety advocates promote external oversight and pressure, such as third party error reporting systems, as useful tools to improve patient safety, they generally favour limiting the role of one of the traditional mechanisms of external oversight and accountability, the courts.

Michael Power suggests that the growing focus on implementing systems to control and manage risk (an ultimately unattainable goal) is an indication of intensified strategies on the part of management to avoid a secondary risk, i.e. being blamed when things go wrong (reputational risk). He is concerned that this tendency to “risk manage everything” will curtail development of creative solutions needed to address the primary risks.³⁷

The Tort System

Assessments of the performance of the medical liability system generally conclude that tort law does not achieve any of its central goals of compensation, deterrence or corrective justice well.

In the four countries surveyed that have tort systems in cases of personal injury (Canada, the United States, the United Kingdom and Australia), there are strong and persuasive critiques of its performance. While commentators and policymakers disagree among themselves about the purposes and functions of the tort system, and consequently in their analyses of its deficiencies and the goals toward which tort reform should be directed, there is wide agreement that the tort system falls short in achieving any one of its three main objectives: compensation, deterrence or corrective justice.³⁸ This is in part because its objectives are multiple, and so to some extent modify each other; each is also limited in scope.³⁹ However, conflicting and limited objectives

³⁶ See eg. New South Wales. Health Care Complaints Commission, “Investigation Report: Campbelltown and Camden Hospitals Macarthur Health Service” (December, 2003), at ii.

³⁷ Power, M., “The Risk Management of Everything”, (Demos, 2004), online at: <http://www.demos.co.uk> (last accessed July 2005).

³⁸ Compare eg., Abel, R., “A Critique of Torts”, (1990) 37 U.C.L.A. L.Rev. 785, and Epstein, R., “The Harm Principle – and How It Grew”, (1995) 45 U.T.L.J. 369.

³⁹ As noted Canadian torts scholar and judge Allen Linden observed, if the reparation function of modern tort law were its only task, “It [tort recovery] is welcome enough if there is nothing else available, but if full and swift compensation is the only task of tort law, it should be replaced by something less costly and dilatory”. However, as he notes, tort is not meant to provide universal compensation; entitlement is dependent on proving fault (Linden, A., *Canadian Tort Law* (7th ed.), (Toronto: Butterworths, 2001), at 5. Peter Cane points out that “there is an intrinsic mismatch between the responsibility-based compensation provided by tort law and welfarist principles, which focus on the needs of harm-sufferers”; it is therefore not surprising that, judged by the latter criterion, the tort system is considered to perform poorly -- Cane, P. “Tort Law as Regulation”, *supra*, n.29.

are only a partial explanation. Many commentators have concluded that the tort system simply falls short in doing what it is supposed to do.

Even when considering injuries that have been caused by fault, studies point out that the operation of the tort system is problematic as a means of compensation. A number of these examined the operation of the medical negligence system. In the United Kingdom, Lord Woolf singled out medical negligence cases for particularly intensive examination in his review of the civil justice system, because he considered it “...obvious that it was in the area of medical negligence that the civil justice system was failing most conspicuously to meet the needs of litigants”.⁴⁰ He noted that in medical negligence cases, costs were more often disproportionate in comparison with damages, and were in any event so high that they constituted a real barrier to access to the justice system, delays in resolving claims were greater, there was a lower success rate than in other areas of personal injury litigation, unmeritorious claims were often pursued and clear-cut claims defended for too long, and relations between the parties were marked by heightened suspicion and less co-operation than in many other areas of litigation.⁴¹ While explained in part by complexities in the substantive law of tort and particularly difficult issues of proof in medical negligence cases, he concluded that many of these problems resulted from structural factors in this type of claim. *Making Amends*, the 2003 report by the Chief Medical Officer of the United Kingdom on reforming the approach to clinical negligence in the National Health Service (NHS) concluded that, even after the civil justice reforms that followed on the Woolf Report, the system for resolving clinical negligence claims remained unsatisfactory because it was slow, complex, unfair, costly, time-consuming, damaging to morale and public confidence, unsatisfactory to patients left without explanations, apologies or reassurance about improvements, and impeded learning from mistakes, because it encouraged secrecy and defensiveness.⁴²

⁴⁰ United Kingdom, *Access to Justice* (Lord Woolf), (London: Department of Constitutional Affairs, 1996), online at: <http://www.dca.gov.uk/civil/final/contents.hrm> (last accessed December 2004).

⁴¹ *Ibid.*, ch. 15.

⁴² Chief Medical Officer, *Making Amends. A consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS* (London, Department of Health, 2003), at 13. (hereafter, *Making Amends*), online at: <http://www.doh.gov.uk/makingamends/cmreport.htm> (last accessed December 2004)..

In the United States, too, the tort system is considered to function poorly as a means of compensating for negligently caused injury.⁴³ Few people who have suffered injuries as a result of negligent health care sue, and far fewer still ever recover any compensation for their injuries. The Harvard Medical Practice Study concluded that only 1 in 8 patients who had been injured as a result of negligence commenced legal action, and of those, only 1 in 16 received any compensation.⁴⁴ Assessment is similar in the other countries surveyed: even when people have suffered legally compensable injuries in the course of treatment – i.e. they were harmed by substandard care -- they are unlikely to sue, and few medical negligence claims succeed.⁴⁵ Given the large numbers of preventable adverse events (a subset of which are caused by negligence), the small numbers of lawsuits for medical malpractice and the limited success in those, the evidence suggests that typically, the incidence of negligence in health care is significantly higher than the number of claims made, and much higher still than the number of people who recover any compensation.⁴⁶ The barriers to access to justice are formidable. They often affect those already least well off in society particularly harshly.⁴⁷

The tort system also falls short when evaluating its effectiveness in deterring unsafe conduct and thus, reducing future harm. After an extensive review of empirical evidence in the United States, Mello and Brennan could find only “limited evidence” that malpractice litigation has a deterrent effect.⁴⁸ In Canada, Elgie *et al.* concluded that tort law likely has only a

⁴³ See eg. Bovbjerg, R., “Liability Reform Should Make Patients Safer: ‘Avoidable Classes of Events’ are a Key Improvement”, (2005) 33 J.L.M.E. 478; Studdert, D., “On Selling ‘No-Fault’”, in Sharpe, V., (ed.), *Accountability: Patient Safety and Policy Research*. (Georgetown: Georgetown U. Press, 2004).

⁴⁴ Localio, A., *et al.*, “Relation Between Malpractice Claims and Adverse Events Due To Negligence: Results of the Harvard Medical Practice Study III”, (1991) 325 NEJM 245.

⁴⁵ See eg. Australian Health Ministers Advisory Council Legal Process Reform Group, “Responding to the Medical Indemnity Crisis: An Integrated Reform Package” (Marcia Neave, Chair) (Aug. 2002), at 13, para 3.2; online at: <http://www.health.act.gov.au/c/health?a=da&did=100111741&pid=1054039339> (last accessed July 2004).

⁴⁶ In Canada, see Prichard, J.R.S., *Liability and Compensation in Health Care. A Report to the Conference of Deputy Ministers of Health and Federal/Provincial/Territorial Review on Liability and Compensation Issues in Health Care* (Toronto: U. Toronto Press, 1990), at 17, estimating that less than 10% of viable claims attributable to negligence in health services resulted in payment (hereafter, the Prichard Report).

⁴⁷ In the U.S., see Studdert, D., “Selling No-Fault”, in Sharpe, V., (ed.), *supra*, n. at 208. In Canada, see Howse, R., Trebilcock, M., “The Role of the Civil Justice System in the Choice of Governing Instrument”, in Ontario Law Reform Commission, *Rethinking Civil Justice: Research Studies for the Civil Justice Review* (Toronto, Ontario Law Reform Comm’n., 1996), Vol. 1, 243-304, at 255.

⁴⁸ Mello, M., Brennan, T., “Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform”, (2002) 80 Texas L.Rev. 1595 at 1613, 1615; Weiler, P., *et al.*, *A Measure of Malpractice: Medical Injury, Malpractice Litigation, and Patient Compensation* (Cambridge: Harvard U. Press, 1993); Hyman, D., Silver, C., “The Poor State of Health Care Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution?”, (2005) 90 Cornell L. Rev. 893 at 917: evidence of deterrence is “surprisingly tenuous”.

“tangential effect” on the quality of health care, given the background presence of liability insurance that blunts the impact of damages awards on defendants, the small likelihood an action will be commenced, and the fact that the severity of the sanction and degree of culpability are often not commensurate.⁴⁹

However, as Mark Galanter points out, courts have a complicated, multi-faceted relationship to disputes. He argues that “The resolution of disputes, while important, is not the only (nor...the principle) link of courts and disputes...court not only resolve disputes: they prevent them, mobilize them and transform them”.⁵⁰ Parties not only bargain (and act) “in the shadow of the law”; courts also confer a kind of “regulatory endowment” on disputants, i.e. “what courts might do (and the difficulty of getting them to do it)” clothes the regulatory activities of others with authorizations and immunities.⁵¹ The very expense and remoteness of courts, and the overload, inertia and consequent inaction of public agencies bolsters the regulatory authority of other institutions (i.e. indigenous ordering). He concludes that courts impact disputes “...largely by the dissemination of information”, and that law is more significant for the cultural and symbolic meanings it conveys, than as “a set of operative controls”.⁵² These observations call for a broader assessment of the effects of law than can be captured by empirical studies trying to determine the extent to which tort liability increases defensive medicine, or the existence of direct links between changes in health professionals’ practice and medical malpractice litigation. They also support a more capacious view of the impact of law on individuals and institutions, and how they organize and conduct their affairs. When its more diffuse effects are taken into account, law, and tort law in particular, casts a long shadow.

The medical liability system nonetheless has strong support from a number of stakeholders.

Although positive assessments of the medical liability system are rare among academic commentators, it has strong support from a number of stakeholders – notably members of the

⁴⁹ Elgie, R., Caulfield, T., Christie, M., “Medical Injuries and Malpractice: Is It Time for No-Fault?”, (1993) 1 Health L.J. 97; Dewees, Duff and Trebilcock, *supra*, n. ; see generally Ison, T., *The Forensic Lottery: A Critique on Tort Liability as a System of Personal Injury Compensation* (London: Staples Press, 1967), 81-82.

⁵⁰ Galanter, M., “Justice in Many Rooms”, (1981), 19 J. Legal Pluralism 1-47.

⁵¹ *Ibid.*

⁵² *Ibid.*, 9-10.

public and the plaintiffs' bar, in the United States at least. Following release of the Institute of Medicine's (IOM) Report, *To Err Is Human*, detailing the widespread harm caused by preventable adverse events, members of the American public continued to believe that the major cause of bad care is bad physicians, and that they should be held to account and removed from practice.⁵³ Physician and lawyer William Sage comments that for the plaintiffs' bar in the United States, the IOM Report seemed "...mainly to confirm their belief in their own usefulness", rather than establish the need for public policies and frameworks that would reduce error.⁵⁴ Both groups took the high numbers of errors to mean that legal obligations should be strengthened, despite the IOM's message that most mistakes are the result of bad systems, not bad people.⁵⁵ The IOM's call to end blame and fault finding has not attracted wide public support. Empirical evidence of public attitudes on this issue is lacking in Canada. The Canadian Medical Protective Association, the physicians' mutual defence organization that provides liability coverage for 95% of physicians, considers the existing medical liability system to be "fundamentally sound", although in need of procedural reform to reduce the costs of judgments.⁵⁶

On occasion, the prospect of tort liability has clearly provided an incentive to physicians to improve practice, leading to reduced patient injury and death.

In the health care context, there are instances where the prospect of tort liability has spurred physicians to improve practice. Anaesthesia is the chief example. It is widely acknowledged that the American Society of Anaesthesiologists undertook its review of closed claims and developed guidelines to improve care in the 1980's because of professional unrest over large increases in malpractice insurance premiums, interest in reducing injuries that led to claims, and negative publicity.⁵⁷ The result has been a "resounding success" -- dramatic

⁵³ Blendon, et al., "Views of Practicing Physicians and the Public on Medical Errors", ((2002) 347 NEJM 1933-40; Leape, L., Berwick, D., "Five Years After *To Err Is Human*: What Have We Learned?", (2005) 293 JAMA 2384-2390, at 2384.

⁵⁴ Sage, W., "Understanding the First Malpractice Crisis of the 21st Century", in Gosfield A., (ed.), *Health Law Handbook 2003 Edition* (Westlaw), at 1.2. In Canada, there are some informal joint efforts by the plaintiff and defence bar to improve the process of clinical negligence litigation.

⁵⁵ Bovbjerg, R., *supra*, n. 43 at 478.

⁵⁶ Canadian Medical Protective Association, "Medical liability practices in Canada: Towards the right balance" (Ottawa: CMPA, Aug. 2005), at 22.

⁵⁷ Mello, M., Brennan, T., *supra*, n.25 at 377-378; Hyman & Silver, *supra*, n.48 at 920-1.

decreases in adverse events and deaths associated with anaesthesia.⁵⁸ Some American commentators argue that conditions have changed so substantially that the anaesthesia experience will not recur in that country.⁵⁹ Others argue that it shows there is an effective “feedback loop” between the tort system, improved practice and patient safety.⁶⁰ One reason the anaesthesia experience may be cited so often is that the connection between the potential for tort liability and improvements in the quality and safety of care can rarely be demonstrated so clearly.

Tort Reform

Apart from Canada, the countries surveyed have undertaken substantial legal reform. However, the triggers prompting reform differed. Given the heavy toll errors take on patients and the high costs they impose on society, one might have expected that changes to the tort system would be linked to initiatives to reduce medical error and improve patient safety. After all, reducing errors and the injuries that result would mean patients had less reason to sue.⁶¹ However, this was seldom the focus of reform.

In Australia and the United States, tort reforms were a response to liability insurance crises, and were aimed at reducing the frequency and severity of malpractice claims.

Australia and the United States implemented the most substantial tort reforms. In Australia, the catalyst for action was a crisis in the insurance industry, culminating in the collapse of two major insurers in 2001/02. Although even Mr. Justice Ipp, who chaired the panel the government appointed to review the law of negligence, noted that there was “never conclusive evidence that the state of the law of negligence bears any responsibility for this situation”,⁶² the tort system was the obvious candidate for government action – civil liability does affect insurance premiums, was being widely blamed as the culprit, and was a factor governments could regulate. The reforms, characterized by the Commonwealth government as

⁵⁸ Joint Committee on Accreditation of Healthcare Organizations, “Health Care at the Crossroads: Strategies for Improving the Medical Liability System and Preventing Patient Injury” White Paper (Feb., 2005), online at: http://www.jcaho.org/about+us/public+policy+initiatives/medical_liability.pdf (last accessed September, 2005).

⁵⁹ Mello & Brennan, *supra*, n.25.

⁶⁰ Hyman & Silver, *supra*, n.48.

⁶¹ Although as noted previously, lawsuits for medical malpractice are already infrequent.

⁶² Ipp, D., “Negligence – Where Lies the Future?”, (2003) *Aus. Bar Rev.* 158 at 159.

“unmatched in the common law world for their breadth and scope”, significantly altered both the substantive law of negligence and civil procedure.⁶³ They were meant to reduce the size and risk of judgments and the costs of negligence litigation, and while they were implemented too recently to comprehensively assess their effects, initial indications are that they have done so.⁶⁴

In the United States, tort reforms were undertaken in response to the most recent wave of increases in medical liability insurance premiums, not to address patient safety concerns.⁶⁵ Initiatives adopted continue the same approaches to liability reform that characterized responses to the last two malpractice insurance crises – as one writer notes, “more of the same, plus a heavy dose of patient safety rhetoric”.⁶⁶ This has meant damages caps, offset of payments from collateral sources, limits on lawyers’ fees, discretionary or mandatory periodic payments of damages, restrictions on joint and several liability for damages, heightened requirements for expert witnesses, shortened limitation periods and other measures.⁶⁷ Changes to the law have primarily been aimed at reducing the costs of malpractice litigation and judgments, and have made it more difficult for people to establish liability and entitlement to compensation. Mello reports strong evidence that caps on noneconomic damages reduce the average size of award by 20 to 30%, but not the frequency of claims. Other tort reforms have had little impact. Caps on noneconomic damages have disadvantages relating to patient safety and equity in the medical liability system.⁶⁸

⁶³ Commonwealth of Australia. “Reform of liability insurance law in Australia” (Canberra: Canprint Communications Pty, 2004), online at: <http://www.treasury.gov.au/contentitem.asp?pageId=035&ContentID=799> (last accessed July 2005), at 3.

⁶⁴ Australian Health and Welfare Institute, “Medical Indemnity National Data Collection Public Sector 2003 to 2004 covering the period July 2003- June 2004”; online at: http://www.apo.org.au/linkboard/results.chtm?filename_num=13683 (last accessed Jan. 2006); Pelly, M., “Harsh personal injury laws deny legitimate claims, says judge”, Sydney Morning Herald, Oct. 11, 2004.

⁶⁵ Bovbjerg, *supra*, n.43 at 480: reformers’ top priority was to limit the existing system of liability, not to build a better system; Mello, M., “Medical malpractice: Impact of the crisis and effect of state tort reforms”, Research Synthesis Report No. 10, Robert Wood Johnson Foundation (May, 2006), online at <http://www.policysynthesis.org> (last accessed May, 2006) at 6.

⁶⁶ Sage, W., “The Forgotten Third: Medical Insurance and the Medical Malpractice Crisis”, (2004) 23 Health Affairs 10-21, at 10.

⁶⁷ Furrow, B., *et al.*, *Health Law: Cases, Materials and Problems* (5th ed.) (St. Paul, MN: Thomson/West, 2004); Hyman & Silver, *supra*, n. 48 at 899. As at April, 2006, 26 states had some form of damages cap; most are applicable to the noneconomic component of awards- Mello, *supra*, n.65 at 7.

⁶⁸ *Ibid.* (Mello), 12.

In the United Kingdom, crises in trust in the NHS resulted in little tort reform until recently, but did lead to substantial legal and non-legal reform to improve the safety and quality of care.

Triggers for reform were different in the United Kingdom. The Woolf Report led to significant reform of the civil justice system. Those of particular relevance to medical malpractice cases include the introduction of pre-action protocols specific to clinical negligence claims, and provisions to rationalize procedures governing expert evidence.

In response to a series of scandals that plagued the National Health Service in the 1980's and 1990's, extensive public inquiries into deficient care and the resulting public outcry over misconduct in the NHS, and influential reports on the state of health care, the government implemented a number of regulatory initiatives and created a series of agencies focused on health quality and safety. These include the National Patient Safety Agency (NPSA) (created in 2001 to coordinate the efforts of the NHS regarding safety), the Healthcare Commission (its duties include investigating and assessing the performance of health facilities, addressing complaints about the NHS, and rating NHS performance), and the Council for Regulatory Excellence (to monitor the performance of self-regulating bodies). These reforms substantially increased internal and external monitoring and oversight in the health care system. However, tort law, and the basic requirement to prove fault in order to establish entitlement to compensation for negligent injury, remained largely untouched and intact until recently, despite the Chief Medical Officer's conclusion in *Making Amends* (2003) that the system for resolving clinical negligence claims was unsatisfactory, and that continued tort reform without other changes could not satisfactorily address deficiencies that remained.⁶⁹ Legislation is currently before Parliament that would provide an alternative compensation mechanism for lower value claims (the Redress Bill).

In Canada, although substantial reforms to the medical liability system have been proposed, they have not proceeded.

In Canada, the 1990 Prichard Report, which was commissioned in response to a perceived "malpractice crisis" in the late 1980's, recommended introduction of an alternative

⁶⁹ Supra, n.42 at 13

compensation system for people who suffered avoidable injuries in the course of treatment, while maintaining the option of suing in tort. It did not lead to changes in the tort system. As concerns about a “crisis” in liability coverage abated with changing economic times, and as provincial governments reached accommodations with physicians to subsidize the fees they paid for liability coverage, pressure for more substantial change dissipated, to be replaced with concerns about the sustainability of Canada’s publicly funded health care system and universal access to health care . Although the Prichard Report had concluded that less than 10% of viable claims attributable to negligence in health services resulted in payment,⁷⁰ the gap between the extent of negligent injury and compensation was not sufficient to galvanize politicians to change the way that people injured in the course of treatment were (or more often, were not) compensated.

Reforms to the civil justice system in various provinces have not targeted clinical negligence litigation. They have largely been focused on measures meant to reduce the cost of judgments, such as allowing courts to order periodic payment of damages awarded in personal injury cases, and reduce the cost of accessing the civil justice system, such as implementing simplified procedures for lower value claims, and expanding provisions to dispose of lawsuits without a full trial or the usual range of pre-trial procedures. The latter are likely of limited application in medical malpractice cases. Legislation has also been passed in a number of provinces strengthening qualified privilege for error reporting. While it may increase disclosure within the health care system, and thus advance patient safety initiatives (although empirical evidence of increased reporting is limited and equivocal), it can also affect access to justice, because restricting information about how and why a patient was harmed can make it more difficult to establish entitlement to compensation in legal proceedings.

No Fault Compensation Systems

Limited no-fault compensation systems have generally been implemented in response to crisis.

No-fault compensation systems have been adopted in a few limited instances in the United States. Virginia and Florida enacted administrative compensation systems for certain severely injured babies in 1987 and 1988, in response to rising malpractice insurance premiums

⁷⁰ Prichard Report, *supra* n.46 at 17.

that were thought to threaten patients' continued access to obstetric care.⁷¹ Conditions for eligibility are restrictive. The state programs are small, because they were meant to substitute for "particular tort claims that seemed to be causing a malpractice crisis", not to expand the class of injured patients compensated.⁷² Provider participation is voluntary. Claims have been too infrequent to give rise to generalizable findings for patient safety purposes.⁷³ "Leakage" to the tort system and adequacy of future funding are concerns.⁷⁴ The U.S. federal government created a no-fault compensation system for injuries resulting from childhood vaccination in 1986, also prompted by concerns that open-ended tort liability was causing manufacturers to withdraw from the market, threatening access. Evaluation of the program is limited but positive, though new and broader claims of injury are a challenge.⁷⁵

Contrasting no-fault systems as envisaged in theory with their reality when implemented in practice, Sloan notes that in Virginia and Florida, programs were enacted in times of crisis, primarily in response to stakeholder (physician and insurer) lobbying.⁷⁶ Consequently, programs adopted may not reflect wider public interests or sound public policy. He cautions that "A broad based program will never evolve from trying to relieve acute problems of insurance availability and affordability".⁷⁷

In Canada, the federal government implemented a limited no fault compensation system for people infected with HIV and Hepatitis C from blood transfusions, following recommendations to that effect made by the Commission of Inquiry on the Blood System.⁷⁸ It, too, was responding to a crisis: the financial collapse of the Canadian Red Cross Society that collected and supplied the tainted blood, and the inquiry's findings that government oversight and monitoring of the blood system had been deficient. Even then, at least as originally structured, compensation was limited to categories of claimants where the government would

⁷¹ Sloan, F., "Public Medical Malpractice Insurance", Pew Project on Medical Liability (2004), online at: <http://www.medliabilitypa.org> (last accessed May, 2006), at 55

⁷² *Ibid.*

⁷³ *Ibid.* at 63, 56: a total of 72 claimants had been paid to 2002 in Virginia, over a 15 year history of the program, and 151 claimants had been paid in Florida to 2002, over a 14 year history of the program.

⁷⁴ Bovbjerg, *supra*, n.43 at 484.

⁷⁵ *Ibid.*, n.98 and references cited therein; Furrow *et al.*, *supra*, n.67 at 492

⁷⁶ Sloan, *supra*, n.71 at 67-8

⁷⁷ *Ibid.* at 58.

⁷⁸ Some provinces supplemented and expanded the federal compensation.

have considered itself most at risk if lawsuits against it had proceeded to judgment. Eligibility has since been expanded.⁷⁹

Quebec has had a no-fault compensation system for people who suffer severe and permanent injuries from vaccines in place since 1986, following a Supreme Court of Canada judgment denying the claim of a young girl who experienced severe neurological disability after being vaccinated.⁸⁰ She had sued her physician, the vaccine manufacturer and the provincial government. Although finding that the government had no legal obligation to compensate her, the Court suggested that compensation would be appropriate, even if not required. The province implemented a no-fault compensation system shortly thereafter. Benefits are broad, but establishing eligibility is difficult. Claimants must prove a causal connection between the vaccine and the harm suffered. Success rates for claims are low (20 out of 117 claimants in a 15 year period).⁸¹

Broad-based no-fault compensation systems to replace tort liability for personal injury have been informed by and developed as a result of a considered policy process and widespread consultation.

In contrast to these limited schemes, New Zealand was not trying to resolve a crisis when it eliminated tort claims in personal injury cases in 1974 and implemented an administrative system to compensate for accidental injury (including injury caused by health care) in its stead. Its policy on accident compensation was developed pursuant to the recommendations of a Commission of Inquiry into Compensation for Personal Injury.⁸² The New Zealand system has not been immune to economic, social and political forces. Economic and political pressures since its inception led governments to tighten conditions for eligibility and decrease benefits. Of particular relevance to patient injury, the period 1992 to 2005 saw the re-introduction of a requirement to prove fault in cases of medical error, albeit in the context of administrative

⁷⁹ Dyer, O., “Canada’s legal system cheats patients and doctors alike”, Nat’l. Review of Medicine, Nov. 15, 2005.

⁸⁰ *P.G. du Quebec c. Lapierre*, [1985] 1 S.C.R. 241..

⁸¹ Kutlesa, N., “The Case for a Vaccine-Related Injury Compensation Scheme in Canada”, online at: http://www.law.utoronto.ca/documents/zhealthlaw04/kutlesa_handout.doc (last accessed Dec. 2005); Picard, A., “Only Quebec pays out for vaccine injuries”, Globe & Mail, 18 November, 2002, at A7. In the United Kingdom, too, the no-fault compensation system for vaccine-related injury requires proof of causation – Vaccine Damages Payment Act 1979.

⁸² New Zealand. Commission of Inquiry into Compensation for Personal Injury, *Compensation for Personal Injury in New Zealand: Report of the Royal Commission of Inquiry* (Gov’t. Printer, Wellington, 1967).

determinations rather than civil litigation. There was no need to prove fault to establish entitlement to compensation for other types of injury. This requirement was eliminated in 2005; claimants are now entitled to compensation if they have suffered “personal injury caused by treatment”, rather than having to establish that the care received was substandard.⁸³ Benefit levels have also risen, although coverage for noneconomic loss is still circumscribed. Low benefit levels, and the continued inequity in distinguishing between victims of accidents and people whose injuries or disabilities were not caused by accident (who do not qualify for accident compensation benefits, even though they may have equivalent or greater need) remain concerns. However, there is no movement to return to the tort system. Most people prefer the certainty and speed of the accident compensation system to the vagaries of the tort system.

In the United Kingdom, following on the Chief Medical Officer’s recommendations in *Making Amends*, legislation introduced in 2005 would enable patients to receive redress for lower value claims via an administrative system, without having to sue (the Redress Bill). Eligibility still tracks requirements for tort liability. This would be a system of general applicability. The Bill had not been passed at the time of writing. *Making Amends* had also proposed a no-fault Redress scheme for severely neurologically impaired babies, but at this point, the government has decided to proceed with a long-term plan to improve health, social and educational services for all children. It is expected that any proposals for legislation will support improved services for all children with disabilities, rather than benefit only children with birth-related injuries.⁸⁴

The Future of the Tort System

In Canada, radical reform of the tort system is unlikely in the near future.

The tort system, and negligence law principles in particular, have shown remarkable resilience. Despite sustained and cogent criticism of the tort system’s performance in achieving any of its central goals of compensation, deterrence and corrective justice, civil litigation has remained the primary means to resolve claims for medical error causing harm in all the countries reviewed except one. For more than thirty years, New Zealand, which replaced tort liability for

⁸³ *Injury Prevention, Rehabilitation and Compensation Act (No. 3) 2004*. See discussion *infra*, ch. , New Zealand.

⁸⁴ -----, “NHS Redress Bill”, Government Bills 2005/06 – In Progress, online at: <http://www.commonleader.gov.uk/print/page990.asp> (last accessed April, 2006).

personal injury with an administrative system of compensation, for accidental injury, has been the only exception. Where tort reform did become a priority, as in the United States and Australia, it was because of crises in the availability or affordability of liability coverage, and was aimed at reducing the frequency and severity of claims. Targeted no-fault compensation programs have been implemented infrequently, and are limited in scope. There has been little political will to replace or radically reform tort law.

In Canada, the reality of a well established tort system, stakeholders' vested interests in its continuation, a relatively stable claims environment, no liability insurance crisis, and the absence of significant, organized public or provider pressure for substantial tort reform translates into considerable inertia. Realistically, the existing tort and civil liability systems are here to stay, at least in the short and medium term. Patient safety initiatives must operate within this environment. A pragmatic assessment of the political and policy environments reveals nothing that would crystallize the political will needed for significant change. At the same time, the troubling performance of the medical liability system indicates a need for more substantial reform. Consequently, I have divided my recommendations into those that can be implemented within the existing tort system, and those that would require more radical reform.

IV. RECOMMENDATIONS

Short and Medium-Term Reform: Working With The Existing Tort System

What reforms in the short and medium term would assist in advancing a patient safety agenda within the confines of the tort system? The most obvious goal is to reduce error and harm to patients. The primary benefits would be safer health care and fewer injured patients; the secondary benefit, even though lawsuits for medical malpractice are already rare, would be a reduction in the need to sue.

1. Qualified Privilege, Error Reporting and Disclosure of Harm to Patients:

How can the civil justice system be changed to promote safer care? Patient safety advocates in all the countries surveyed have argued persuasively first, that there is an urgent need for accurate information about errors that have occurred, so that they can be investigated, their causes determined, and effective strategies developed to prevent or reduce harm in the future, and second, that confidentiality is essential to encourage disclosure. However, empirical

evidence that shielding information from disclosure in civil litigation increases error reporting is lacking. Consequently, only limited qualified privilege can be justified.

At the same time, disclosure of harm to patients is both a moral and legal obligation. Patients are entitled to know what happened and why. Too often, this does not occur. Incentives to encourage disclosure are important. Qualified privilege must be crafted as narrowly as possible to still ensure meaningful disclosure to patients.

In the United States, where QA activities have been protected by statutory privilege for longer than in Canada, evidence that statutory protection positively affects disclosure is limited and equivocal, and under-reporting is endemic.⁸⁵ Canada lacks robust empirical evidence of the effects of existing qualified privilege provisions on error reporting. The causes of under-reporting are broader and more complex than concerns about legal liability. Shielding information from use in legal proceedings will not necessarily mean that health care providers or healthcare institutions will become open and frank about errors that have occurred.⁸⁶ Qualified privilege legislation should include a sunset clause to ensure review of its effectiveness, and give providers and institutions a “use it or lose it” incentive to report error, and to disclose harm to patients. If under-reporting and non-disclosure persist, the positive effects of privilege may not be sufficient to justify the costs of non-disclosure to patients, the public and the justice system.

Recommendation 1.1

Limited qualified privilege legislation that shields information gathered in connection with and the activities of quality assurance committees or designated patient safety initiatives from use in civil litigation should be adopted, including protection for external reporting and sharing of information for patient safety purposes, but its continuation should be linked to evidence of compliance with requirements to report error and also to disclose harm to patients.

⁸⁵ Marchev, M., *Medical Malpractice and Medical Error Disclosure: Balancing Facts and Fears*, Nat'l. Academy for State Health Policy, #GNL53 (Dec., 2003); Furrow, B., “Medical Mistakes: Tiptoeing Toward Safety”, (2003) 3 *Hous. J. Health L. & Pol’y* 181-217. In Australia, see New South Wales, “Final Report of the Special Commission into Campbelltown and Camden Hospitals” (Bret Walker, Special Comm’r.) (July 30, 2004), at 132, online at: http://www.lawlink.nsw.gov.au/lawlink/Corporate/ll_corporate.nsf/pages/sci_final_report (last accessed Dec. 2004), suggesting that, because of the lack of empirical evidence to justify the privilege, his recommendation for statutory protection for root cause analysis and other QA activities be reviewed in a few years’ time to evaluate effectiveness.

⁸⁶ In the American context, Hyman & Silver, *supra*, n.48, argue that will not just happen from provider goodwill, absent the threat of litigation.

Error reporting systems are not a panacea, and adopting a systems approach to understanding the causes of injury will not guarantee an end to error suppression. Qualified privilege can be misused to avoid disclosure. As American bioethicist Edmund Pellegrino has noted, “The ‘system’ can be just as reluctant to admit error as the individual”.⁸⁷ For example, in Australia, the 2005 Bundaberg Hospital Inquiry found that successive state governments had improperly invoked qualified privilege to shield information about health system performance from disclosure following requests under the *Freedom of Information Act*, and that governments’ readiness to conceal information set the tone for Queensland Health staff, with similar results.⁸⁸

Recommendation 1.2

Effective oversight is required to ensure compliance with error reporting and investigative obligations, as well as with requirements for disclosure to patients

Evidence is required to establish that error reporting systems are effective, i.e. that the initiatives they support improve care and reduce harm to patients.⁸⁹ In addition to their cost to patients and the public in information foregone, error reporting systems impose additional burdens and costs of compliance on providers and institutions. If they do not lead to effective action in response, providers will not continue to report. In the United Kingdom, the National Audit Office has warned that, despite the sophisticated error reporting system the National Patient Safety Agency developed for the NHS, if it does not go beyond collecting data about errors to feed back useful lessons to health care providers and institutions, people will stop reporting.⁹⁰ In a number of inquiries into substandard hospital care and injury to patients in Australia, staff reported that they did not report incidents, let alone near misses, because there was no feedback about what would change – i.e. there was no indication their reports would make any difference.⁹¹

Recommendation 1.3

⁸⁷ Pellegrino, E., “Prevention of Medical Error: Where Professional and Organizational Ethics Meet”, in Sharpe, V., *supra*, n.43, 83 at 96.

⁸⁸ Queensland. “Queensland Public Hospitals Commission of Inquiry Report” (Davies, G., Com’r.) (Nov. 2005), online at <http://www.qphc.qld.gov.au> (last accessed Dec. 2005), at 476-7, paras. 6.530, 6.534, 6.553-4.

⁸⁹ Mello & Brennan, *supra*, n.25 at 380: “...the base of evidence about effective safety-enhancing measures is surprisingly thin”.– little evidence of what works.

⁹⁰ NAO 2005, *supra*, n.3, at 6-7, 9.

⁹¹ See eg. Forster, P., “Queensland Health Systems Review – Final Report” (Sept., 2005), online at: http://www.health.qld.au/health_sys_review/final/qhsr_final_report.pdf (last accessed Dec. 2005), at 185; Victoria Health Services Comm’n., “Royal Melbourne Hospital Inquiry Report” (Wilson, B., Comm’r.), (Aug., 2002), online at: http://www.health.vic.gov.au/hsc/rmh_report0802.pdf (last accessed Dec. 2005).

Patient safety initiatives such as error reporting systems must be monitored and evaluated to assess their results in improving care, communication and outcomes.

2. Make Litigation Count for Patient Safety I: Reframing Liability to Advance Patient Safety Goals

Legal frameworks governing negligence claims can be structured to advance patient safety goals of error reduction and harm prevention. Expanding hospital liability to include responsibility for non-employed physicians' negligence on-site could assist in doing so.

Systemic analysis of errors and patient injury highlights the problematic nature of the way in which the law attributes responsibility for negligence. Hospitals owe duties of care to their patients, and are directly liable for their own negligence (for instance, in monitoring staff competence or establishing systems needed to safely operate the hospital), and vicariously liable for wrongdoing by those for whom they are legally responsible -- most commonly, hospital employees, such as nurses. They are not generally liable for the negligence of independent contractors, most notably, non-employed physicians. It is not clear whether recent Supreme Court of Canada jurisprudence expanding the scope of vicarious liability and non-delegable duties of care in other contexts will be applied to health care, such that hospitals would be held liable for physicians' negligence.

In some countries, such as the United Kingdom, the issue does not arise in connection with hospital care for publicly insured services, because most physicians working in hospitals are employed by the National Health Service, and in any event, it has a policy of ignoring the distinction between employees and independent contractors in responding to claims, provided the claimant was injured in the course of receiving NHS treatment.⁹² In the United States, courts have increasingly held hospitals liable for the negligence of "independent" physicians on a variety of theories, although this is not always the case.⁹³ Canadian courts have been reluctant to interfere with hospitals' and physicians' settled expectations about physicians' independence,

⁹² Jones, M. *Medical Negligence* (London: Sweet and Maxwell, 2003) at 616, para. 7.035-6. In Australia, state governments assume responsibility for the negligence of physicians providing services in public hospitals – Australian Institute of Health and Welfare, "First Medical Indemnity National Data Collection Report: Public Sector, January to June 2003" (Canberra: AIHW, Dec. 2004), AIHW Cat. No HSE 34), online at: <http://www.aihw.gov.au/publications/index.cfm/title/10092> (last accessed Dec. 2005).

⁹³ In the United States, see Furrow et al, *supra*, n. at 413 ff, ch. 6, "Liability of Healthcare Institutions", reviewing developments in corporate negligence law, vicarious liability and non-delegable duties of care.

and with their arrangements about their respective spheres of liability.⁹⁴ However, the *status quo* is open to challenge as circumstances change.

The insights of the patient safety movement into the role of systemic factors in causing medical errors and patient injury, and in particular, about the ways in which constraints imposed at the “blunt end” of institutional decision-making shape decisions at the “sharp end” of practitioners and patients, lend considerable force to arguments for extending hospitals’ liability to include responsibility for the negligence of non-employed physicians. This is reinforced by changes in the organization and delivery of care: when physicians treat patients in hospitals, they do so as part of a team, and their practices are shaped by the confines of a particular institutional environment. The case for imposing enterprise liability that encompasses physician negligence is strengthened by the frequent observation that institutions are better able to undertake systemic analysis, and have far greater ability than individual practitioners to implement effective changes to reduce risk and prevent harm.⁹⁵ In the United States, where private funding is a significant feature of the health system, commentators argue that enterprise liability would both sharpen and better focus the deterrent signal sent by a finding of liability for negligence. As they point out, hospitals must bear the costs of most patient safety improvements, but the benefits flow largely to patients and providers, in the form of reduced injuries and decreased costs of error. Shifting to enterprise liability would align incentives for health care institutions to invest resources to make patient safety a priority – i.e. it would strengthen the “business case for safety”.⁹⁶ Even in systems such as Canada’s, where private funding and delivery of services is not a significant part of the hospital system, the prospect of organizational liability could function as an important external pressure for improvements in safety and quality.

Although not presently interpreted this way, the common law could incorporate this understanding of the extent of hospitals’ responsibility, and support a finding of liability for non-employed physicians’ negligence. Alternatively, enterprise liability could be imposed by legislation. In deciding whether such a development is warranted, it is important to determine

⁹⁴ *Yepremian v. Scarborough General Hospital* (1980), 110 D.L.R. (3d) 573 (Ont.C.A.), rev’g (1978) 88 D.L.R. (3d) 161 (Ont.H.C.).

⁹⁵ Dewees, D., Duff, D, Trebilcock, M., *Exploring the Domain of Accident Law: Taking the Facts Seriously* (N.Y.” Oxford U. Press, 1996); Mello and Brennan *supra*, n.48.

⁹⁶ Mello and Brennan, *ibid.*; Hyman & Silver, *supra*, n.48.

what would be gained by imposing responsibility for physician negligence on hospitals. The Supreme Court of Canada has identified two primary policy reasons for expanding vicarious liability in other contexts: ensuring effective compensation, and deterring future wrongdoing by imposing liability on the entity best able to take steps to prevent it.⁹⁷ Since both physicians and hospitals are insured, the concern is generally not to ensure plaintiffs will be able to recover damages awarded.⁹⁸ What should be key is whether extending hospital liability to include physician negligence will act as an incentive to hospitals to monitor and review systems and individual care providers, and to implement changes to reduce harm to patients, and whether the benefits of doing so outweigh the costs. Apart from liability insurance considerations, enterprise liability raises concerns among physicians that their autonomy in clinical decision-making would give way to institutional control. It also raises reputational concerns – that institutions (and their insurers) will lack incentives to vigorously defend physicians’ reputations, or conversely, will shield providers’ errors from disclosure,⁹⁹ or that physicians will lack motivation to defend the institution’s reputation and programs, once they are no longer individually at risk.

On the whole, enterprise liability has the potential to pressure hospitals to require health care providers to cooperate in making patient safety a priority, and could ease health care providers’ concerns about liability. It fixes hospitals with incentives to remedy unsafe systems in order to avoid future liability. However, enterprise liability would represent a significant departure from existing law on hospital liability. Cases that squarely raise the issue are rare, and hospitals and physicians have an incentive to settle cases prior to trial to avoid unfavourable precedents. There is no assurance courts will move in the direction of enterprise liability soon, uniformly, or at all. Legislation could be a more reliable way to ensure adoption of an “enterprise approach”

Hospital liability for physician negligence will not automatically translate into comprehensive, effective quality assurance activities and patient safety programs. The patterns of problematic care and harm to patients that led to numerous public inquiries into hospitals in the United Kingdom and Australia, although the state already assumes responsibility for the

⁹⁷ *Bazley v. Curry* (1999), 174 D.L.R. (4th) 45 (S.C.C.).

⁹⁸ Although class actions can threaten defendants’ solvency. As the tainted blood litigation made clear, aggregated liability in class actions can result in awards so substantial that even insured defendants, such as the Canadian Red Cross Society, cannot satisfy the judgments awarded.

⁹⁹ Sage, W., “Reputation, Malpractice Liability and Medical Error”, in Sharpe, *supra*, n.43, 159-184 at 182.

negligence of physicians providing care in the public system, is evidence of that.¹⁰⁰ More far-reaching changes in addition to enterprise liability will still be required.¹⁰¹

Recommendation 2.1

Provinces should consider legislation extending hospital liability to include responsibility for the negligence of non-employed physicians treating patients on-site.

The settings in which care is delivered are continuing to change. More health services, increasingly complex care and sicker patients are being moved outside hospitals to other types of health care institutions (such as long term care), clinics (increasingly the site of diagnostic procedures), physicians' offices and patients' own homes. Care is provided by formal and informal caregivers; the latter may lack training in the services to be provided. Little is known about the nature and extent of preventable adverse events in these settings, although they certainly do occur. As care provided intensifies, preventable adverse events will increase in number and severity as well, as will the potential for civil liability arising from negligent injury to patients. However, the "enterprise" providing care is no longer a hospital in these situations, and the "system" in which care is provided may be a single practitioner or loose cluster of locations and providers. The potential for error can be exacerbated by decisions about workplace organization, such as casualization of the labour force, reduced staffing or staff qualifications and other factors.¹⁰² This is true of (and occurring in) hospitals as well, but is even more of a risk in smaller settings. Proactively incorporating patient safety considerations in decisions about the location of and resources devoted to health care can reduce error and harm to patients.

Recommendation 2.2

Implications for patient safety should be an important, explicit consideration in decision-making about and oversight of care, both in and outside hospitals.

3. Make Litigation Count for Patient Safety II: Lawsuits as a Learning Resource

¹⁰⁰ See eg. Kennedy, I., *Learning from Bristol: the report of the inquiry into children's heart surgery at teh Bristol Royal Infirmary* (London: HMSO, 2001); online at: <http://www.bristol-inquiry.org.uk> (last accessed Dec. 2004); Bundaberg Inquiry, *supra*, n.88.

¹⁰¹ Faunce, T. *et al.*, "When silence threatens safety: lessons from the first Canberra Hospital neurosurgical inquiry", (2004) 12 J.L.Mwed. 112-118; Walsh, K., Shortell, S., "When Things Go Wrong: How Health Care Organizations Deal with Major Failures", (2004) 3 Health Affairs 103-111.

¹⁰² Storch, J., "Patient Safety: Is It Just Another Bandwagon?", (2005) 18 Nursing Leadership 39-55.

Lawsuits can provide important information about how patients are injured, and thus, can assist in improving safety and quality of care. The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) in the United States recognizes the utility of claims information for patient safety purposes, and has called for greater access to ongoing as well as closed claims, in order to increase the information available, and decrease the length of time that elapses before it can be accessed.¹⁰³ Similarly, the National Audit Office in the United Kingdom recommended that the Healthcare Commissioner make greater use of information from litigation and complaints as a learning resource, and work with other agencies to determine how best to share data. Confidentiality clauses often included in settlement agreements hamper access to this information for patient safety purposes. While insurers typically alert hospitals and health care providers to significant developments in judicial decisions as a risk management practice, it is not clear that such information is systematically or consistently incorporated into practice.

Recommendation 3

Provision should be made for systematic identification and dissemination of patient safety lessons to be learned from lawsuits, potentially under the aegis of or in conjunction with the Canadian Patient Safety Institute, or through external error reporting structures or provincial patient safety organizations where these exist. Possibilities for earlier and more comprehensive access to claims information for patient safety purposes should be explored with the affected stakeholders.

4. Liability Coverage, Government Subsidy and Access to Information

Malpractice litigation is relatively infrequent in Canada, particularly when compared to the extent of preventable adverse events (as noted previously, not all preventable adverse events indicate negligent care, but a subset do). Although the litigation environment can be volatile given the nature of claims made (such as those on behalf of infants seriously injured during birth), and the potential for aggregated liability in class actions, for physicians at least, claims experience has been relatively stable over the last several years.¹⁰⁴ Unlike recent experience in Australia, or current experience in the United States, Canada is not in the midst of a crisis in the availability or affordability of liability coverage.

¹⁰³ JCAHO, *supra*, n.58 at 37; NAO 2005, *supra*, n.3 at 10.

¹⁰⁴ Canadian Medical Protective Ass'n., "Annual Report 2004" (Ottawa: Author, 2005) at 8-11.

Most physicians are remunerated for the services they provide patients on a fee for service basis. Fees for services covered under Canada's universal health insurance system are negotiated between provincial medical associations and their respective provincial governments. Increased fees for liability coverage cannot be passed on to patients by charging more for insured services. Recognizing this, and wanting to ensure both continued access to health services and the availability of compensation when patients have been negligently injured and damages awarded, governments and provincial medical associations have negotiated agreements pursuant to which governments contribute to the cost of physicians' liability coverage. Arrangements vary among provinces, but the total amount of government contributions and the proportion of individual physicians' fees for liability coverage are substantial.¹⁰⁵ Hospitals' insurance arrangements resemble more traditional contracts of insurance. Many obtain liability coverage through participation in the Health Insurance Reciprocal of Canada (HIROC), a member-owned non-profit organization. Almost all hospitals in Canada are public, not private. While not generally owned by government, they receive the great majority of their funding from provincial governments, and the bulk of services they provide are publicly insured. Thus, hospitals, too, cover the cost of liability coverage with funds provided by government.

The patient safety movement repeatedly stresses the need for more information about errors and patient injury, and also the importance of open disclosure of harm to patients. The substantial financial assistance governments provide to defray the costs of liability coverage should give them leverage to require both physicians and hospitals to advance patient safety initiatives. This could be used to counter under-reporting of errors, or entail more extensive reporting of patient safety incidents, more detailed information on claims experience, changes in providers' practices, greater participation in patient safety initiatives, more disclosure of harm to patients, or other measures to advance patient safety.

Recommendation 4

The substantial funding that governments contribute to the cost of physician and hospital liability coverage (thereby indirectly assuming a share of the risk of liability) should be tied to improved performance in specified, targeted patient safety initiatives.

¹⁰⁵ See eg. Ontario, Ministry of Health and Long Term Care, "Malpractice Reimbursement Program Schedule – 2006", online at: http://www.health.gov.on.ca/english/providers/program/ohip/bulletins/4000/bul4431_att2.pdf (last accessed April, 2006).

5. Expanded Complaints Mechanisms as an Alternative to Litigation

The focus of this study is on the tort system, so a detailed consideration of complaints mechanisms is beyond its scope. However, they could be used to reduce litigation. Litigation can be a grueling, costly, uncertain and stressful experience for all involved, but especially for injured patients. Not everyone who has been injured in the course of treatment is seeking compensation, but it may be the only way to have their concerns heard. Patients and families may want information, an explanation and apology, or assurance that steps have been taken to prevent a recurrence. Litigation will not achieve those ends; remedies are limited to an award of damages. Conversely, lack of explanation does fuel lawsuits.¹⁰⁶ More routes to different forms of redress, such as in-house or independent complaints processes responsive to those needs could divert claims away from litigation and defuse the impetus to sue. Complaints resolution could be facilitated if integrated with mediation.¹⁰⁷

The United Kingdom has implemented a number of different ways to have complaints about care addressed that are independent of the court system. Explanatory notes to the Redress Bill, described earlier, indicate that where patients have been injured, the NHS is expected to “put the problem right, regardless of fault”, and that patients will be entitled to apologies and explanations, as well as financial compensation where appropriate.¹⁰⁸ In Australia, state Health Commissioners not only have the power to investigate complaints involving institutions and different types of health care providers, but in some instances can also order limited financial compensation. In New Zealand, the Health and Disabilities Commissioner can undertake both individual and systemic investigations, primarily in response to patient complaints, but also on his own initiative. These examples could provide models, and should be examined further to determine their suitability in the Canadian context.

Recommendation 5

¹⁰⁶ Bovbjerg, *supra*, n.43; Jones, *supra*, n.92 at 3.

¹⁰⁷ See eg. Liebman, C., Hyman, C., “Medical Error Disclosure, Mediation Skills, and Malpractice Litigation. A Demonstration Project in Pennsylvania”, Pew Project on Medical Liability, 2005, online at: <http://www.medliabilitypa.org> (last accessed April, 2006).

¹⁰⁸ Redress Bill Full Regulatory Impact Analysis Statement, online at: <http://www.dh.gov.uk/assetRoot/04/12/09/24/04120924.pdf> (last accessed March, 2006) at 12.

More low key, accessible, inexpensive, conciliatory complaints resolution mechanisms, with power to consider complaints involving both institutions and different types of health care providers, should be made available.

6. Long-term Reform: Should Canada Make Medical Malpractice Litigation History? Exploring No-Fault and Administrative Compensation Systems

Both the Canadian Patient Safety Institute and the Health Council of Canada have called for an examination of no-fault compensation.¹⁰⁹ The evidence that the medical liability system performs poorly in compensating patients and deterring unsafe care is strong. A number of commentators in the countries studied have called for adoption of “no-fault” injury compensation programs to replace the tort system. No-fault compensation has been proposed in Canada, either as a tort alternative (with eligibility premised on avoidability of injury rather than fault), or for all who suffer harm from medical procedures (regardless of error or avoidability), or for limited categories of designated compensable events (such as children severely injured during birth).¹¹⁰ However, outside New Zealand, no-fault compensation has only been adopted in very limited circumstances.

Should no-fault compensation be made more broadly available for injury occasioned by health care? Proponents argue that more victims of injury would be compensated more quickly and predictably, and that it has the potential to provide access to a wider range of benefits than are available through litigation. The administrative expenses of such a system would be dramatically reduced in comparison to the current medical liability system, because substantial resources would no longer be devoted to proving negligence and defending claims. Eligibility for compensation varies among the different proposals, but most are premised on avoidability of injury, an easier threshold to satisfy than proving fault, so more people could qualify for compensation. Some proposals for administrative compensation mechanisms incorporate

¹⁰⁹ Canadian Patient Safety Institute, *supra*, n.14; Health Council of Canada, “Health Care Renewal in Canada: Clearing the Road to Quality, Annual Report 2005” (Toronto: Author, Feb. 2006), at 4; online at: <http://www.healthcouncilcanada.ca> (last accessed February 2006).

¹¹⁰ As to the first option, see eg. the Prichard Report, *supra*, n.46; as to the second, see eg. the proposal made by Krever, J., reported in Dyer, O., “Canada’s legal system cheats patients and doctors alike”, *Nat’l. Review of Medicine*, 15 November 2005, online at: http://www.nationalreviewofmedicine.com/issue/2005/11_15/2_pulse_19.html. (last accessed Dec., 2005).; as to the third, see eg. CMPA, *supra*, n.56.

schedules of designated compensable injuries and events, which would reduce the costs of determining eligibility and entitlement to benefits and speed claims processing still further. Advocates of no fault also argue that it would improve injury deterrence through more systematic case identification, allow better monitoring and education, and (if combined with some form of experience rating and/or enterprise liability) could incorporate effective incentives for institutions and providers to implement programs to reduce error and provide safer care.¹¹¹

Opponents of no-fault compensation contend that it reduces incentives to take care. They argue that the tort system, even if inefficient, is still valuable because it pressures health care providers and institutions to improve care and reduce harm to patients. Even supporters of alternative compensation mechanisms acknowledge that “innovation that improves safety often happens in the shadow of liability”.¹¹² As the anaesthesia example described earlier demonstrates, the prospect of legal liability can in some instances lead to effective, concerted action to change patterns of care, reducing patient injury and death.

The projected costs of a broad no-fault compensation system give rise to the greatest disagreement. Supporters of no-fault compensation contend that the costs of such a system would be manageable, that benefit levels comparable to those available under the tort system could be provided, with the advantages that many more people could be compensated than at present, and that current inequities in who receives compensation could be alleviated.¹¹³ Opponents argue that savings are overstated, and costs are understated.¹¹⁴ If eligibility were easier to establish, then more people would be compensated, and either costs would be prohibitive, or the level of compensation provided, particularly to those most seriously injured, would be seriously inadequate. Even with a threshold of avoidability of injury rather than fault (the most common proposal), distinguishing the effects of the underlying disease or disability from those caused by health care would still be contentious. In their view, a no fault system

¹¹¹ Mello & Brennan, *supra*, n.48 at 1633; Bovbjerg, *supra*, n.43 at 485.

¹¹² Sage, W., “Understanding the First Malpractice Crisis of the 21st Century”, *supra*, n.54 at 1.4.

¹¹³ Bovbjerg, *supra*, n.43; Studdert, *supra*, n.43.

¹¹⁴ Mehlman, M., “Resolving the Medical Malpractice Crisis: Fairness Considerations”, (Pew Project on Medical Liability In Pennsylvania, 2003), online at: <http://www.medliabilitypa.org> (last accessed Nov. 2004). Sloan, *supra*, n.71 at 66, concludes that experience with no fault compensation in Virginia and Florida “does not support the view that a broader no-fault program would be less expensive than the tort system”. In his view, no fault systems implemented as a “crisis intervention” to relieve problems with the availability and affordability of insurance will never evolve into broad-based no fault programs; further, “...programs enacted during crises respond primarily to stakeholder lobbying and may not make sound policy” – *ibid* at 58, 67.

would require unacceptable compromises in eligibility for compensation, the extent of coverage and/or the benefit levels paid.¹¹⁵

In the United Kingdom, despite itemizing the serious and ongoing deficiencies in the tort system as a means of compensation, the Chief Medical Officer nonetheless recommended that it be replaced only for lower value claims and for claims on behalf of infants injured at birth, principally because of the expense of a broader alternative.¹¹⁶ The Redress Bill presently before Parliament is limited to lower value claims (less than 20,000 pounds), and still retains vestiges of a fault requirement in the administrative claims determination mechanism proposed, raising questions about how broadly monetary compensation will be available.¹¹⁷

New Zealand has had an administrative system for accident compensation since 1974. Claims can certainly be made more easily, are less costly, more certain, and resolved more quickly than through litigation. However, New Zealand's experience also illustrates that, as with other no-fault administrative compensation mechanisms such as workers' compensation, entitlements are subject to political, economic and social pressure, the vagaries of the political process, and neglect.¹¹⁸ Indeed, from 1992 until 2005, New Zealand effectively re-introduced a requirement that claimants establish fault in order to prove entitlement to compensation for injuries resulting from medical error. Benefit levels for certain types of damages were significantly curtailed during part of that period as well. As described earlier, eligibility for benefits was expanded in 2005. Claimants are now entitled to compensation for treatment injury, and no longer need to establish fault.

Rates of preventable adverse events among hospitalized patients are broadly similar in New Zealand as in the other countries reviewed.¹¹⁹ However, despite a simple, inexpensive, non-adversarial claims process, New Zealand, too, experiences significant under-claiming for

¹¹⁵ Evaluation of costs is complicated in the United States, because it does not have universal access to health care. Consequently, when Americans evaluate the cost of a no fault system, they must include the costs of future medical treatment as well as the more usual nonmedical consequences of injuries, such as lost employment income. In countries with universal health insurance, the costs of insured treatment necessitated by injury need not be compensable under a no fault system, provided subrogated claims by government for reimbursement of health care expenses are excluded from recovery.

¹¹⁶ *Making Amends, supra*, n. 42 at 110-115.

¹¹⁷ The government has decided that, in principle, improved compensation for children with disabilities should be made available on the basis of need, regardless of how the disability was caused, and so is not proceeding with the Redress scheme proposed for severely compromised infants.

¹¹⁸ Administrative no-fault compensation systems are not alone in this. The history of tort reform in the United States in particular clearly shows that it, too, is subject to political, economic and social pressure.

¹¹⁹ Davis, P., *et al, supra*, n.34.

compensation for injuries incurred in the course of health care. Davis *et al.* estimated the ratio of potentially compensable events to successful claims for compensation to be approximately thirty to one.¹²⁰ Nor do a high proportion of people who experienced preventable adverse events complain to the Health and Disability Commissioner (HDC). In a study by Bismark *et al.*, only .4% of adverse events, and 4% of serious preventable adverse events resulted in complaints to the HDC.¹²¹ The authors noted that patients who suffered more severe injuries were more likely to complain to the HDC, but that patients who were elderly, socioeconomically deprived, or of Pacific ethnicity were least likely to complain.¹²² In a multi-country survey of the experience of patients with health problems, 61% of New Zealand patients surveyed reported that their physicians had not told them a mistake had been made in their medical care or medication, although 54% had experienced a serious health problem as a result.¹²³ Although more patients reported being told about an error in their care in New Zealand than elsewhere, the extent of non-disclosure of harm is still significant.

The experience in New Zealand is surprising in light of the great emphasis that writers in countries with tort systems place on the barriers to access to justice that injured patients face when they must sue in order to obtain compensation for negligent injury. There are a number of possible explanations for low rates of complaints and claims for compensation, but it does seem clear that removing the prospect of civil liability and implementing no-fault compensation are not sufficient in themselves to ensure that health care providers disclose error to patients, or to ensure that patients who are entitled will obtain compensation for their injuries, or that the circumstances will be brought to the attention of authorities with a mandate and power to identify and develop strategies to address both individual and systemic shortcomings.

¹²⁰ Davis, P., Lay-Yee, R., Fitzjohn, J., Hider, P., Briant R., Schug, S., “Compensation for Medical Injury in New Zealand: Does ‘No-Fault’ Increase the Level of Claims Making and Reduce Social and Clinical Selectivity?” (2002) 27 J.H.P.P.L. 833-854.

¹²¹ Bismark, M., Brennan, T., Paterson, R., Davis, P., Studdert, D., “Relationship between complaints and quality of care in New Zealand: a descriptive analysis of complainants and non-complainants following adverse events”, (2006) 15 Qual. Saf. Health Care 17-22 at 21.

¹²² *Ibid.* at 22.

¹²³ Schoen *et al.*, “Taking the Pulse of Health Care Systems: Experiences of patients with Health Problems in Six Countries”, (Nov. 3, 2005), online at: http://www.cmwf.org/publications_show.htm?doc_id=313012 (last accessed Nov. 2005).

Ensuring providers and health care institutions remain accountable for the care they deliver (in the sense that they can be called to account to an authority for their actions¹²⁴) is an ongoing concern. Critiques of the tort system's ability to deter unsafe care have been reviewed previously. Among other factors, the sheer infrequency of claims weakens the deterrent signals tort sends.¹²⁵ Accountability is more of an issue with no-fault systems of compensation, because even the risk of tort liability is eliminated. Advocates of no-fault are quick to point out that "no-fault" does not mean "no accountability", and that indeed, the term "no-fault" is a misnomer, because not only would systems to ensure ongoing provider competence and quality of care be revised and strengthened, but no fault compensation systems can be structured to incorporate incentives to providers and institutions to improve the safety and quality of care.¹²⁶

The patient safety movement favours minimizing the role played by the tort system, believing it chills disclosure of harm to patients, suppresses error reporting, and thus, impedes the systemic analysis of error that is needed to improve care.¹²⁷ Commenting on the situation in the United States, Bovbjerg characterizes the safety-reform movement as "positioning itself to favor internal openness, largely surrounded by an external wall to shut out injured patients and their lawyers", a difficult position to justify, given the information it brought to light on the scale of error and harm to patients.¹²⁸ There is a lack of consensus on when individual, as opposed to systemic accountability is appropriate. While beyond the scope of this study, evidence is lacking that professional governance or other internal or external accountability mechanisms monitor and oversee practitioners and care well; indeed, these systems are often heavily criticized because they are perceived to protect provider over patient interests. Whether the tort system is replaced or not, patients and the public need and are entitled to effective external oversight and accountability mechanisms. Public trust that accountability can be effectively maintained will affect the willingness to countenance alternatives to the tort system. Additionally, reforms must address the availability and adequacy of compensation for patients who have been injured by medical error. As a pragmatic matter, patient safety advocates cannot expect wide acceptance of

¹²⁴ Mulgan, R., "Accountability: An Ever-Expanding Concept?" (2000) 78 *Pub. Admin.* 555-573 at 555, Scott, C., "Accountability in the Regulatory State", (2000) 27 *Law & Society* 38-60.

¹²⁵ Hyman & Silver, *supra*, n.48.

¹²⁶ See eg. Studdert, "On Selling No-Fault", *supra*, n.43 at 211.

¹²⁷ Bovbjerg, *supra*, n.43; Mello & Brennan, *supra*, n.48.

¹²⁸ *Ibid* (Bovbjerg), at 480.

their prescriptions for reform if they leave behind patients injured by error, or make it more difficult for them to recover compensation. More broadly, patients (and all of us who are prospective patients) deserve no less.

On the whole, a broad no-fault compensation system seems attractive because it could compensate more people harmed by health care, while at the same time, easing providers' and institutions' concerns about the risk of legal liability, and consequent tendency to suppress errors. However, the evidence base requires further examination and development. As Sloan points out, no-fault systems may be adopted for different reasons: coverage of losses caused by medical injuries, meeting needs of injured patients, efficient administration and loss management, ensuring continued availability and affordability of liability coverage, and improved deterrence of errors.¹²⁹ Consequently, assessments of their performance do not necessarily evaluate programs on the same basis. Disagreements about the costs of such programs are substantial. The range of possibilities in scope, benefit levels, conditions for eligibility, funding and other factors is wide. Concerns about ensuring accountability when the prospect of tort liability is removed persist. Targeted no-fault programs providing compensation to limited classes of beneficiaries in response to crisis situations, such as compensation for patients transfused with tainted blood, can be expected to re-appear periodically. They are *ad hoc* responses to crisis and as such, not satisfactory models for broad-based programs.

Research on the operation of the accident compensation and complaints systems in New Zealand has raised questions about the extent of patient uptake of either, even in the face of preventable adverse events. Other countries, such as Sweden and Denmark, have had no fault compensation systems for treatment injury in place for a considerable period of time as well. They were not studied as part of this project, and their experiences may differ. Because alternative compensation mechanisms, and no-fault compensation in particular, (i) seem to offer considerable promise, and (ii) the operation and effects of the medical liability system are so problematic, but (iii) much remains unknown about the impact of such systems, options to replace the tort system in the health care context should be studied further, with a view to determining the advisability of moving away from tort liability.

¹²⁹ *Supra*, n.114 at 54-5, 57.

Recommendation 6

Research should be sponsored to evaluate alternative compensation mechanisms, including no-fault compensation systems, with a view to determining their desirability in the Canadian environment.

APPENDIX A: Glossary

Adverse Event

An injury resulting from a medical intervention or medical management, rather than the underlying condition of the patient.¹³⁰

Error

“The failure of a planned action to be completed as intended, or the use of a wrong plan to achieve an aim.”¹³¹ Not all errors result in harm.

Negligence

The law of negligence is a branch of tort law. In law, negligence refers to a breach of a duty of care owed by one person or entity to another, which if breached, results in foreseeable and compensable harm to that other, or to some interest of his or hers.¹³² More narrowly, negligence can refer to one element of the cause of action for negligence, i.e. whether the defendant’s conduct met the standard of care.¹³³

Non-delegable duty of care

A non-delegable duty of care is not merely a duty to take care, but to ensure that care is taken. It is imposed when the nature of the defendant’s relationship with the plaintiff (for example, a special statutory undertaking of care or responsibility) is such that the defendant remains responsible for performance of the duty, no matter how or by whom it arranged to have the work done.¹³⁴

Patient safety

“The avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the processes of health care”.¹³⁵

Preventable adverse event

An error that results in injury to a patient.¹³⁶

¹³⁰ Kohn, L., Corrigan, J., Donaldson, M. (eds), Institute of Medicine, *To Err Is Human. Building a Safer Health System* (Washington: Nat’l. Academy Press, 2000), 18 (hereafter, IOM).

¹³¹ *Ibid.* at 4, 18, citing Reason, J., *Human Error* (Cambridge: Cambridge U. Press, 1990).

¹³² Sneiderman, B., Irvine, J., Osborne, P., *Canadian Medical Law* (2nd ed) (Toronto: Carswell, 1996), 85.

¹³³ Solomon, R., Kostal, R., McInnes, M., *Cases and Materials on the Law of Torts*, (6th ed.) (Toronto: Thomson Carswell, 2003), 227

¹³⁴ *Lewis v. B.C.*, [1997] 3 S.C.R. 1145.

¹³⁵ IOM, *supra*, n.1, at 57, citing the National Patient Safety Foundation, “Agenda for Research and Development in Patient Safety, online at: <http://www.ama-assn.org/med-sci/npsf/research/research.htm>. The Canadian Patient Safety Dictionary proposes an alternate definition of patient safety: “The reduction and mitigation of unsafe acts within the health-care system, as well as through the use of best practices shown to lead to optimal patient outcomes” - Davies, J., *et al.*, *The Canadian Patient Safety Dictionary* (Ottawa: Royal College of Physicians and Surgeons of Canada, 2003), 12.

¹³⁶ IOM, *supra*, n.1, at 18.

Tort

A civil wrong, other than a breach of contract, which the law will redress by way of an award of damages.¹³⁷

Vicarious Liability

A doctrine of law that imposes liability on certain persons or entities for injuries suffered by another, not because of any wrongdoing on their part, but because of the relationship the person or entity has with the wrongdoer. Vicarious liability is imposed most commonly in the employer/employee relationship: an employer is vicariously liable to third parties for torts committed by employees in the course of employment.

¹³⁷ Fleming, *The Law of Torts* (9th ed.), (Sydney: LBC Information Services, 1998) , 1.

APPENDIX B: Understanding Negligence Law

To establish liability for negligence, a plaintiff must prove on a balance of probabilities that:

1. The defendant owed him or her a legal duty of care;
2. The defendant breached the standard of care established by law;
3. The defendant's breach caused injury or loss to the plaintiff; and
4. The plaintiff's damages are not too remote to be recoverable in law.

Liability in negligence can arise from substandard care or treatment, and also from a failure to obtain the patient's informed consent to treatment.

Elements of a Negligence Claim

Duty of Care: It is well established that health professionals owe their patients a duty of care, as do hospitals and other health care institutions. Issues may arise with respect to the scope of the duty, but not its existence. Whether and in what circumstances statutory regulators or governments owe a private law duty of care to individuals with respect to health care is more problematic; case law on this points is divided and developing.

Standard of Care: As in negligence law generally, health care professionals must act in such a way as not to cause an unreasonable risk of harm to others. In determining the standard of care to be met, they are held to the standard of a reasonably competent member of their profession:¹³⁸ "Every medical practitioner must bring to his task a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. He is bound to exercise that degree of care and skill which could reasonably be expected of a normal, prudent practitioner of the same experience and standing, and if he holds himself out as a specialist, a higher degree of skill is required of him than of one who does not profess to be so qualified by special training and ability".

As a general rule in Canada, expert evidence of compliance with generally approved practice on questions of treatment and care is conclusive evidence of absence of negligence.¹³⁹ If the common practice is divided, a practice is acceptable if followed by at least a respectable minority of competent practitioners in the same field.¹⁴⁰ Professional judgment prevails in determining the standard of care, except in very limited circumstances.¹⁴¹ Error in judgment does not necessarily constitute negligence, or give rise to liability.¹⁴²

Causation:

(a) Substandard Care: The general, but not conclusive test for causation is the "but for" test, which requires the plaintiff to show that the injury would not have occurred but for the negligence of the defendant.¹⁴³ Causation can be difficult for a plaintiff to establish in a medical malpractice case, particularly given the risks often inherent in treatment, however skilfully performed, and the background presence of the plaintiff's illness. Medical experts "...ordinarily determine causation in terms of certainties", and when they cannot, are often reluctant to provide

¹³⁸ *Crits v. Sylvester* (1956), 1 D.L.R. (2d) 502,508 (Ont.C.A.), aff'd. [1956] S.C.R. 991.

¹³⁹ *ter Neuzen v. Korn*, [1995] 10 W.W.R. 1 (S.C.C.).

¹⁴⁰ *Lapointe v. Hopital Le Gardeur*(1992), 90 D.L.R. (4th) 7, 15 (S.C.C.).

¹⁴¹ When the standard practice is "fraught with obvious risks" such that "anyone is capable of finding it negligent without the need for clinical or diagnostic expertise" a court can find an approved practice, and the defendant who followed it, negligent – see generally Picard, E., Robertson, G., *Legal Liability of Doctors and Hospitals in Canada* (3rd ed.) (Toronto: Carswell, 1996) at 274.

¹⁴² *Wilson v. Swanson* (1956), 5 D.L.R. (2d) 113, 120 (S.C.C.).

¹⁴³ *Horsley v. MacLaren*, [1972] S.C.R. 441.

a firm opinion supporting the plaintiff's theory, making proof difficult.¹⁴⁴ Recognizing this, in some circumstances the stringency with which the plaintiff's evidence is assessed is relaxed; the court will draw a rebuttable inference of causation against a defendant on the basis of "very little affirmative evidence" on the part of the plaintiff.¹⁴⁵ Nonetheless, the barrier presented by the need to prove causation is often still formidable.

Once that hurdle has been passed, it is not essential that the defendant have been the sole cause of harm: "There will frequently be a myriad of other background events which were necessary preconditions to the injury occurring...As long as a defendant is *part* of the cause of an injury, the defendant is liable, even though his act alone was not enough to create the injury...most events are the result of a complex set of causes".¹⁴⁶ Once the causal connection is established, the defendant is held liable for any injuries caused *or contributed to* by his or her negligence.

This approach could allow for systemic analysis of the causes of injury, but most often, negligence actions are tightly focused on the individuals directly concerned in the events giving rise to the lawsuit. The court's task is to assess what occurred among the parties before it; they do not generally focus on the role more diffuse, systemic factors played in the plaintiff's injuries. Although institutional decisions about resources and constraints shape the environment in which health professionals treat patients and may have significantly contributed to the plaintiff's injuries, that causal connection may go unrecognized without a sophisticated understanding of organizational responsibility. Absent greater openness to theories of enterprise liability, this limits the utility of the tort system as a means to identify and deter systemic causes of injury.

The **burden of proof** that the plaintiff bears in a lawsuit can present additional difficulties. Medical error may materially increase the risk of injury (for example, that a particular disease or condition will develop). However, if the plaintiff cannot prove that her injury more probably than not resulted from the defendant's negligence (i.e. if non-negligent causes were equally or more likely to have been the cause), then she will not be able to meet the burden of proof, and her claim will fail.¹⁴⁷ Similarly, if the defendant misses the diagnosis of a serious illness through error, but the disease is unlikely to respond to treatment in any event, then the plaintiff would be unable to prove that the missed diagnosis more probably than not affected her prognosis. Some plaintiffs have tried to claim damages for loss of the opportunity to seek treatment as a compensable injury in itself, or to argue that materially increasing the risk of harm should be taken as proof that the defendant caused the injury, if that is the very kind of harm that the plaintiff suffered.¹⁴⁸ Neither argument has had notable success in Canada, unless the plaintiff can establish causation on a balance of probabilities.¹⁴⁹ Each of these theories, though, has been the basis for finding liability in the United Kingdom and elsewhere.¹⁵⁰ Lower courts in Canada are beginning to take note of these developments and consider their implications for

¹⁴⁴ *Snell v. Farrell* [1990] 2 S.C.R. 311; (1990), 72 D.L.R. (4th) 289 (S.C.C.).

¹⁴⁵ *Ibid.*

¹⁴⁶ *Athey v. Leonati* (1996), 140 D.L.R. (4th) 235; *Walker v. York Finch General Hospital*, [2001] 1 S.C.R. 647.

¹⁴⁷ *Cottrelle v. Gerrard* [2003] O.J. 4194 (C.A.).

¹⁴⁸ *Laferrriere v. Lawson* [1991] 1 S.C.R. 541.

¹⁴⁹ *Ibid.*; *St Jean v. Mercier*, [2002] 1 S.C.R. 491.

¹⁵⁰ *Fairchild v. Glenhaven Funeral Services*, [2002] 3 W.L.R. 89; [2002] 3 All E.R. 305 (H.L.); *Chappell v. Hart* (1998), 195 C.L.R. 232; *Chester v. Afshar* [2004] UKHL 41; *Gregg v. Scott*, [2005] UKHL 2; [2005] 2 W.L.R. 268 (H.L.).

Canadian law.¹⁵¹ It is not clear at this point whether and to what extent they will affect Canadian jurisprudence.

(b) Informed Consent:

The duty of care that health professionals owe patients includes an obligation to disclose information about treatment proposed, including any material, special or unusual risks, so that the patient can give informed consent. Courts have steadily broadened the information that must be given to the patient. In order to establish liability for breach of the duty to obtain informed consent, the plaintiff has to show that if properly informed, he or she would not have gone ahead with the treatment, i.e. the information would have made a difference to her decision, and therefore, the failure to inform was a cause of her injuries. What the plaintiff would have done is determined on a modified objective standard – i.e. what a reasonable person in the plaintiff’s position would have done if properly informed.¹⁵² It is difficult to discharge the burden of proof in this type of case; often, courts conclude that because of the plaintiff’s underlying condition and the need for treatment, he or she would have consented, even if told about all the risks, because the alternatives were so much worse.¹⁵³

Damages: Damages in negligence cases are compensatory. Awards of punitive damages are very rare. Once liability has been established, damages are meant to compensate the plaintiff for all losses incurred – i.e. to return him to the position he would have been in if the injury had not occurred, insofar as money can do so. While damages for pecuniary losses, such as the cost of future care and lost employment income, are fully recoverable, damages for nonpecuniary losses are calculated differently. In a trilogy of cases

revamping the law of damages in 1978, the Supreme Court of Canada imposed a cap of \$100,000 on damages for nonpecuniary loss for a “most extreme case”, reasoning that such losses are incalculable in any event, pecuniary losses are already fully covered by other heads of damage, this type of compensation should be viewed from a functional perspective and is meant to make life more endurable by providing for more general physical arrangements beyond those relating directly to the injuries, and the judgment’s broader effects (for instance on the cost of insurance) are relevant considerations when calculating this head of damages, and call for moderation.¹⁵⁴

Adjusted for inflation, by 2005 the upper limit for awards for nonpecuniary loss in personal injury cases was approximately \$295,000.¹⁵⁵ Periodic pressures to abandon or substantially increase the upper limit have not been successful to date.

Vicarious Liability: Vicarious liability is imposed when one person or entity is legally responsible for the torts of another because of the relationship between them. It does not require any wrongdoing by the party who is held vicariously liable. It is most common in the context of employment relationships: an employer is vicariously liable for the negligent acts or omissions of its employees committed within the course of employment. Thus, hospitals are vicariously liable for the negligence of employees, such as nurses and orderlies. Vicarious liability can also

¹⁵¹ In Canada, see eg. *B.M. v. B.C.(A.G.)*, [2004] B.C.J. No. 1506 (B.C.C.A.).

¹⁵² *Arndt v. Smith*, [1997] 2 S.C.R. 539.

¹⁵³ Robertson, G., “Informed Consent Twenty Years Later”, (2003) H.L.J. (Special Ed.) 153-60, on courts’ unsophisticated and problematic understanding of how individuals analyze and assess risk.

¹⁵⁴ *Andrews v. Grand and Toy* (1978) 83 D.L.R. (3d) 452 (S.C.C.).

¹⁵⁵ *Lee v. Dawson*, [2006] B.C.J. No. 679 (B.C.C.A.), confirming trial judge’s reduction of jury award of \$2 million for nonpecuniary loss in a personal injury case to the upper limit of \$294,600.

arise from the relationship between principal and agent.¹⁵⁶ However, vicarious liability is generally not imposed when the relationship between the parties is that of principal and independent contractor. Most often, doctors are considered to be independent contractors to whom the hospital has granted privileges enabling them to admit and treat patients. They are not hospital employees, and the hospital is not liable for their negligence.¹⁵⁷ The characterization of this relationship will depend on all the circumstances – interns and residents, for instance, are generally employed by the hospital as house staff.¹⁵⁸

Non-Delegable Duty of Care: In some instances, courts have held defendants liable on the basis that the nature of the defendant's relationship with the plaintiff (for example, a special statutory undertaking of care or responsibility), was such that it was under a non-delegable duty of care, i.e. a duty of care that could not be discharged by delegating performance to another, no matter how or by whom it arranged to have the work done.¹⁵⁹ The defendant is liable for a third party's negligence that injures the plaintiff, regardless of the character of its relationship with the negligent party. The defence of due diligence, i.e. that it took all reasonable steps to select competent people to carry out the tasks and monitor them, is not available

¹⁵⁶ In an agency relationship, “the principal empowers the agent to act on her behalf in such a way as to affect her legal relationship with others”, most commonly in connection with contracts and property – Osborne, P., *The Law of Torts* (Toronto: Irwin Law, 2000) at 316.

¹⁵⁷ *Yeapremian v. Scarborough General Hospital*, supra, n.94.

¹⁵⁸ *Ibid.*, 385-6.

¹⁵⁹ *Lewis v. B.C.*, [1997] 3 S.C.R. 1145.

CHAPTER 2: CANADA

Public awareness of the scale of medical error, the harm it causes patients, and the financial and other costs of adverse events came later in Canada than in other countries surveyed. That is not to say that the safety of patients was not a concern previously. Here as elsewhere, treating patients safely has long been one of the goals of health care. The release of *To Err is Human* in the United States, the Institute of Medicine's 1999 report on patient safety and medical error, gave new impetus to Canadian research on these issues, as well as to the efforts of health care providers, policymakers, professional associations and others to advance patient safety initiatives.¹ Publication of initial Canadian data, followed by the release of the National Steering Committee on Patient Safety's 2002 report, "Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care" and subsequent media attention to the issue, finally brought public recognition to the magnitude of injury to patients and the pressing need to develop effective responses.²

The first section of this chapter sets out a brief synopsis of developments since release of the National Steering Committee's Report, and summarizes data on the incidence of both preventable adverse events and negligent injury to patients. Section II describes arrangements for medical and hospital liability insurance. The third section reviews and assesses the implications of patient safety initiatives for the law of negligence and the reverse, with particular attention to the law governing hospital liability for physician negligence, statutory privilege for error reporting, and disclosure of harm. The final section considers proposals for reform of the tort system and their fate in Canada.

¹ Storch, J., "Patient Safety : Is It Just Another Bandwagon ?" (2005) 18 Nursing Leadership 39-55 at 42. See eg. Comité ministériel sur les accidents évitables dans la prestation des soins de santé. 2001 (Francoeur, J., Chair), "La gestion des risques, une priorité pour le réseau", (Quebec, QC: Ministère de la Santé et des Services Sociaux, 2001); online at <http://www.publications.msss.gouv.qc.ca/acrobat/f/documentation/2000/00-915.pdf> (last accessed October 2005).

² National Steering Committee on Patient Safety, "Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care" (Ottawa: Author, Sept. 2002), online at: <http://www.rcpsc.medical.org/publications/index.php> (last accessed Sept. 2002). The committee was established and supported by the Royal College of Physicians and Surgeons of Canada – Kondro, W., "Royal College moves on patient safety", (Sept 24, 2001), online at: http://www.cma.ca/cmaj/cmaj_today/2001/09_24.htm (last accessed March, 2003); see also Canadian Healthcare Ass'n., "Patient Safety and Quality Care: Action Required Now to Address Adverse Events – A Backgrounder" (Nov. 2002).

I. PATIENT SAFETY

The National Steering Committee on Patient Safety Report, “Building a Safer System”

Like its counterparts in other countries, the National Steering Committee concluded that underlying systemic factors contribute to most adverse events, critical incidents and near misses in health care, and underlined the importance of being able to report problems without blame attaching in order to inform systemic analysis of errors and develop solutions.³ A systemic approach recognizes that analysis cannot be limited to occurrences at the “sharp end”, where practitioners interact with patients and each other in the process of delivering care, but must also include consideration of the role played by the “blunt” or remote end of the system, i.e. regulators, administrators, policy makers and technology suppliers, who shape the environment in which practitioners work.⁴ It made two recommendations with respect to the legal system: first, that the statutory protection accorded data and opinions associated with patient safety and quality improvement discussions be strengthened to prevent their disclosure in legal proceedings, while preserving patients’ ability to access factual information about the adverse event. Second, it called for further consideration of the effects of the tort and health insurance systems on patient safety, with a view to formulating recommendations to promote a culture of safety.⁵

Canadian Patient Safety Institute

The Prime Minister and provincial Premiers included a provision in the 2003 First Ministers’ Accord on Health Care Renewal committing to take leadership in implementing the National Steering Committee’s recommendations.⁶ In December, 2003, the federal government established the Canadian Patient Safety Institute (CPSI), an independent nonprofit corporation with a mandate to advance safer health systems and facilitate collaboration among governments and stakeholders; it also included provision in the 2003 budget for \$50 million over five years to support patient safety initiatives, including \$8 million annually for CPSI, and \$2 million each year for development of a Canadian Medication Incident Reporting and Prevention System.⁷

³ *Ibid.* (Steering Cttee.) at 2.

⁴ *Ibid.* at 18, citing Reason, J., *Human Error* (NY: Cambridge U. Press, 1990), and Reason, J., *Managing the risks of organizational accidents* (Brookfield, VT: Ashfield Publishing, 1997).

⁵ *Ibid.*, at 4.

⁶ Canadian Patient Safety Institute, online at <http://www.cpsi-icsp.ca> (last accessed July 2005).

⁷ *Ibid.*

CPSI's role is facilitative and advisory; it has no power to require that action be taken. Of its key priorities, the most salient to the medical liability system are:⁸

- (1) examining the tort system and its effect on patient safety, and working with provincial/territorial governments and other stakeholders to make appropriate changes;
- (2) developing a legislative model for (i) protecting information shared from subpoena, (ii) no fault insurance, and (iii) mandatory reporting of adverse events, for consideration by provinces; and
- (3) developing and promoting national policy guidelines on disclosure of adverse events, and communication between health care professionals and patients when errors occur.

Of these, a no fault insurance system in particular could have radical implications, depending on its scope. The Health Council of Canada, which monitors progress on the 2003 First Ministers Accord on Health Care Renewal and the 2004 10-Year Plan to Strengthen Health Care, has also called for a re-examination of the issue of no-fault compensation for victims of adverse health care events as part of its strategy to improve quality of care, both so that health care providers will be more open to disclosing errors, and so that injured patients can be compensated without having to sue.⁹ Assessing these calls for action, the themes that recur most frequently vis a vis the medical liability system are (1) exploring tort reform / no-fault compensation; and (2) encouraging error reporting by preventing use of quality assurance information in legal proceedings.

Incidence of Adverse Events and Patient Injury

A study of the incidence of adverse events and patient injury in acute care hospitals in Canada published in 2004 (hereafter, the Canadian Adverse Events Study) identified an incidence rate of 7.5%; of these, the expert reviewers considered 36.9% highly preventable.¹⁰

⁸ *Ibid.*, "What We Do", at 15.

⁹ Health Council of Canada, "Health Care Renewal in Canada: Clearing the Road to Quality, Annual Report 2005" (Toronto: Author, Feb. 2006) at 4; online at <http://www.healthcouncilcanada.ca> (last accessed February 2006).

¹⁰ Baker, R., Norton, P., Flintoft, V., Blais, R., Brown, A., Cox, J., Etchells, E., Ghali, W., Hebert, P., Majumdar, S., O'Beirne, M., Palacios-Derflingher, L., Reid, R., Sheps, S., Tamblyn, R., "The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada", (2004) 170(11) CMAJ 1678-1689 (hereafter, Canadian Adverse Events Study). A Quebec study reported a 5.6% overall incidence rate of adverse events in Quebec healthcare facilities; of the almost 435,000 annual hospital admissions in the province that were similar to those in the Canada-wide study, about 24,000 were associated with an adverse event, of which almost 6,500 were considered preventable – Blais, R., Tamblyn, R., Bartlett, G., Tre, G., St-Germain, D., "Incidence d'événements indésirables dans les hôpitaux québécois", (Montreal: Université de Montréal, Groupe de recherche interdisciplinaire en santé (GRIS), 2004); see also Ste-Marie, M., "Patient Safety: Le Groupe Vigilance pour la

An adverse event was defined as “an unintended injury or complication that results in disability at the time of discharge, death or prolonged hospital stay and that is caused by health care management [including both individual hospital staff and broader systems and care processes] rather than by the patient’s underlying disease”.¹¹ Most (64.4%) resulted in no or minimal to moderate impairment, with recovery within six months. However, 5.2% of adverse events resulted in permanent disability, and 15.9% in death.¹² Extrapolating from their study, the authors estimated that in 2000, of the almost 2.5 million annual admissions to similar hospitals in Canada, about 185,000 were associated with an adverse event, of which 70,000 were potentially preventable, and that 9250 to 23750 deaths could have been prevented.¹³ The Canadian Institute for Health Information (CIHI) notes that this makes preventable adverse events one of the leading causes of death in Canada – more than deaths from breast cancer, motor vehicle/transport accidents and HIV combined.¹⁴

Turning to patients’ perceptions of medical error, a 2005 six country survey of patients with health problems found that, of the 751 Canadians surveyed, 15% reported a medical mistake having been made in their care, and 30% had experienced an error in their medical care, medication or laboratory tests during the past two years (the combined rate was exceeded only by the United States). Serious health problems resulted for 46% of patients who experienced a medical mistake or medication error.¹⁵ CIHI reported that in a 2003 survey, 5.2 million Canadians (approximately 24% of the population) responded that they or a family member had experienced a preventable adverse event in the course of treatment; 30% of these had occurred in the past year.¹⁶ More than half had serious health consequences.¹⁷

Securite des Soins: A Quebec Perspective”, (2005) 8 Healthcare Q. 119-121. A smaller study focused on the Ottawa Hospital identified an adverse event rate of 12.7%, of which 38% were preventable; 61% of the adverse events were experienced prior to hospitalization – Forster, A., Asmis, T. *et al.*, “Ottawa Hospital Patient Safety Study: incidence and timing of adverse events in patients admitted to a Canadian teaching hospital”, (2004) 170(8) CMAJ 1235-1240.

¹¹ *Ibid.* (Canadian Adverse Events Study) at 1679.

¹² *Ibid.* at 1681-2.

¹³ *Ibid.*, at 1683-4.

¹⁴ CIHI and Statistics Canada, “Health Care in Canada 2004” (Ottawa: CIHI, 2005), at 43, online at: <http://www.cihi.ca> (last accessed July 2005) at 42-43 (hereafter, CIHI)..

¹⁵ Schoen, C., Osborn, R., Huynh, P.T., Doty, M., Zapert, K., Peugh, J., Davis, K., “Taking the Pulse of Health Care Systems: Experiences of Patients with Health Problems in Six Countries”, Health Affairs Web Exclusive (Nov. 3, 2005), W5-509-W5-525, at 30, online at:

http://www.cmwf.org/publications/publications_show.htm?doc_id=313012 (last accessed Dec. 2005).

¹⁶ CIHI, *supra*, n. 14 at 43.

¹⁷ *Ibid.*

The extent of preventable adverse events and patient injury is even greater than indicated by the Canadian Adverse Events Study, which only measured patient injury in acute care hospitals. Patients receive health care in many settings, from formal and informal caregivers. Sometimes, care is self-administered. Preventable adverse events will occur in these situations as well.¹⁸ While the majority of claims for “medical misadventure” arise in hospital settings,¹⁹ the structure and location of health care delivery is changing. As more health services, increasingly complex care, and sicker patients are moved outside hospitals to other types of health care institutions (such as long term care), clinics (increasingly the site of diagnostic procedures), physicians’ offices (primary and specialist care) and their own homes, adverse events and the severity of the consequences for patients will increase in these locales as well, as will the risk of clinical negligence.

Incidence of Negligent Injury to Patients

While the Canadian Adverse Events Study provides recent measures of the incidence and effects of preventable adverse events, there are no studies of Canadian data that determine how frequently patients are harmed by negligent health care, or how many people recover compensation for their injuries. Most preventable adverse events are not caused by negligence (i.e. substandard care that harmed the patient), but a subset are. In a 1990 report commissioned by the Conference of Deputy Ministers of Health in response to a perceived malpractice “crisis” in the late 1980’s, Prichard extrapolated from American and Swedish data to conclude that in Canada, too, less than 10% of viable claims attributable to negligence in health services resulted in payment.²⁰ In the United States, the Harvard Medical Practice Study’s expert reviewers concluded that only 1 in 8 patients who had been injured by negligence sued, and of those, only 1

¹⁸ See eg. Leeder, J., Donovan, K., “Addicts at risk in drug scheme”, (Toronto) Star, 16 February, 2006, A1, 6, on death of patient in a methadone treatment program; Canadian Press, “Cinar co-founder dead”, Globe & Mail, 15 April, 2004, on death of woman during cosmetic surgery at private Montreal clinic; Carey, E., “1 in 4 patients get sick again after leaving hospital: study. Drug interactions most common error”, (Toronto) Star, 3 February, 2004, A16, on incidence and causes of complications after hospital discharge; see generally CIHI, *supra*, n. , 35-36.

¹⁹ Chapman, B., “Controlling the Costs of Medical Malpractice: An Argument for Enterprise Hospital Liability”, (1990) 28 OHLJ 523 at 539: 80% of all “medical misadventures” occurred in hospitals (citing American figures); see also Dewees, D., Trebilcock, M., “The Efficacy of the Tort System and Its Alternatives: A Review of the Empirical Evidence”, (1992) 30 OHLJ 57 at 86: 90% of all “large claims” occur in hospital settings.

²⁰ Prichard, J.R.S. (Chair), *Liability and Compensation in Health Care, A Report to the Conference of Deputy Ministers and Federal/Provincial/Territorial Review on Liability and Compensation Issues in Health Care* (Toronto: U. Toronto Press, 1990) (hereafter, the “Prichard Report”) at 17.

in 16 recovered any compensation.²¹ While the litigation environment in the two countries differs, there are not obvious reasons that a substantially smaller percentage of injuries would be caused by negligence in Canada, or that significantly more Canadians injured by negligent treatment sue and recover than in the United States.

The Canadian Adverse Events Study estimated that 70,000 hospital admissions were associated with preventable adverse events in 2000, and that thousands of deaths that occurred were potentially preventable. A portion of those would have been the result of negligence. The same is true of adverse events that were not included in that study, the ones that occur outside hospitals – some would have been caused by negligent care as well. Yet relatively few physicians are sued for negligence, especially when compared to the number of preventable adverse events. The Canadian Medical Protective Association (CMPA), the physicians' mutual defence organization that provides liability coverage for approximately 95% of Canada's physicians, consistently reports low rates of malpractice claims and lawsuits against its more than 66,000 members. It sets out its claims experience in its 2004 Annual Report: there were 1083 new legal actions commenced against its members in 2004 (continuing a decline in new legal actions evident over the past several years). A medical malpractice action lasts on average three to four years, and most are settled, dismissed, discontinued or abandoned. CMPA reports that 92% of cases concluded in 2004 were resolved prior to trial, with payment made to the plaintiff in 32% of these cases; the remaining 60% were withdrawn or abandoned by the plaintiff. Only 8% of cases concluded (104 cases) went to trial; of these, 86 cases resulted in judgment for the defendant physicians, and 18 cases in judgment for the plaintiffs.²² These outcomes are similar to its five year average (2000-2004).²³ Putting the two sets of data together, given the extent of preventable adverse events, it is likely that the incidence of negligence is significantly higher than the number of claims made, and much higher still than the even smaller number of people who actually recover any compensation.

II. MEDICAL AND HOSPITAL LIABILITY INSURANCE

²¹ Localio, A., *et al.*, "Relation Between Malpractice Claims and Adverse Events Due To Negligence: Results of the Harvard Medical Practice Study III", (1991) 325 NEJM 245.

²² Canadian Medical Protective Association, "Annual Report 2004", (Ottawa: Author, 2005) at 8-11.

²³ *Ibid.* (with the exception of 1 large class action settlement).

Almost all physicians in Canada are members of the Canadian Medical Protective Association (CMPA), a physicians' mutual defence organization that, while not an insurer *per se*, provides liability coverage and representation in medical malpractice actions to its members, as well as legal advice, counsel and assistance in other types of medico-legal proceedings.²⁴ There is no cap on the amount of financial assistance a member can receive, but there is also no obligation in the CMPA by-laws requiring it to provide assistance in respect of any particular medico-legal incident.²⁵ The CMPA operates on a fully funded model for current and past procedures.²⁶ Membership fees vary substantially by specialty and region of the country, but are not individually experience-rated.²⁷ Ontario physicians pay the highest fees, and Quebec the lowest, while the rest of the country falls in between.²⁸

Most physicians are remunerated for the services they provide to patients on a fee for service basis. Fees for insured services covered under Canada's universal health insurance system are negotiated between provincial medical associations and their respective provincial governments. Fees are meant to cover remuneration for physicians' services as well as overhead, including the cost of liability coverage (generally, the fees paid to CMPA). Increased CMPA membership fees cannot be passed on to patients by charging more for insured services. In recognition of this, since about the mid-1980's, provincial governments and medical associations have negotiated arrangements to provide for public contributions to physicians to reimburse them in whole or part for CMPA fees or similar medical liability insurance premiums. Arrangements vary in different provinces, but the total amount of government contributions and the proportion of individual physicians' CMPA fees governments pay are substantial.²⁹

²⁴ The CMPA has more than 66,000 members (CMPA Annual Report 2004, *ibid.*, at 2). This constitutes about 95% of doctors licensed to practice in Canada (CIHI, *supra*, n. 14 at 44).

²⁵ Dubin, C., "An Independent Review of the Canadian Medical Protective Association" (Ottawa: CMPA, 1996), (hereafter, "Dubin Report"); CMPA, *supra*, n.22 at 12..

²⁶ CMPA, *supra*, n.22 at 26; Borsellino, M., "Malpractice miracle", Medical Post, March 11, 2003, at 1, 65.

²⁷ CIHI, *supra*, n. 14 at 44.

²⁸ CMPA, *supra*, n.22 at 29.

²⁹ See eg. Ontario, Ministry of Health and Long Term Care, "Malpractice Reimbursement Program Schedule – 2006", online at: http://www.health.gov.on.ca/english/providers/program/ohip/bulletins/4000/bul4431_att2.pdf (last accessed April, 2006). The Ontario government reimburses physicians for the difference between the current year's CMPA fee and the fee in 1986 (the base rate). For instance, the reimbursement for family medicine practitioners for 2005 was \$2446 (\$650 base in 1986 to \$3096 fee in 2006), while for obstetricians, it was \$73,220 (\$4900 base to \$78,120 fee in 2006), and for orthopaedic surgery, \$20,864 (\$4900 base to \$25,764 fee in 2006). See also Borsellino, M., "Tort reform contributing to skyrocketing CMPA fees. But physicians don't bear most of rising costs directly, CMPA notes", Medical Post (30 November, 2004), at 2, 46.

Hospitals' insurance arrangements do not parallel those of physicians, but rather, resemble more traditional contracts of insurance. Many health care institutions participate in the Health Insurance Reciprocal of Canada (HIROC), a member-owned non-profit organization founded in 1987.³⁰ Unlike physician liability coverage, ratings used to determine individual facilities' premium levels are to some extent loss-sensitive, i.e. experience-rated.

III. DEVELOPMENTS IN TORT LAW

1. Constitutional Division of Powers

Any consideration of tort reform must take into account the division of powers between the federal and provincial governments. Provinces have constitutional jurisdiction over the administration of justice, and while "health" is not a single matter assigned exclusively to one level of government, the heads of provincial jurisdiction subsume so many aspects of health care (from general responsibility for property and civil rights in the province, through matters of a local or private nature, to specific authority to make laws concerning the establishment of hospitals) that the lion's share of responsibility for health care clearly rests with the provinces.³¹ Consequently, reform of tort law, rules of civil procedure, regulation of health professionals, and the legal governance of hospitals and other components of the health care system are matters for the provinces. That is not to say there is no role for the federal government, or for concerted action by all levels of government on issues of patient safety and tort law, but proposals for reform must take into account the realities of the Canadian federal system.³²

2. Common Law Developments in Negligence Law and Medical Liability

As explained in Chapter 1, in order to establish negligence, a plaintiff must prove on a balance of probabilities that: (i) the defendant owed him or her a duty of care; (ii) the defendant breached the standard of care established by law; (iii) the defendant's breach caused injury or loss to the plaintiff; and (iv) the plaintiff's injuries are not too remote to be recoverable in law. In the context of health care, liability for negligence can arise from substandard care or treatment, and also from a defendant's failure to obtain the patient's informed consent to

³⁰ Health Insurance Reciprocal of Canada, online at <http://www.hiroc.com> (last accessed June 2004).

³¹ *Constitution Act, 1867*, (U.K.), 30&31 Vict., c.3, s.92; Canadian Bar Association, *What's Law Got To Do With It? Health Care Reform in Canada* (Ottawa: Cdn. Bar Ass'n., 1994); Hogg, P., *Constitutional Law of Canada* (2004 student ed.) (Toronto: Thomson Carswell, 2004).

³² For example, CPSI was established by the federal government.

treatment. This section considers developments in the law of negligence that may be particularly affected by patient safety initiatives and the reverse.

(i) Guidelines, Policies and Accreditation Standards: Implications for Health Professionals' and Hospitals' Standard of Care

Clinical guidelines, patient safety policies and codes of conduct developed by health care organizations, professional associations, and NGO's such as health accreditation agencies can influence determinations of the standard of care in clinical negligence litigation. This type of "soft law", while not definitive in itself, may provide at least persuasive evidence of the standard of care.³³ Some provinces have approved health professions' codes of ethics through legislation, giving them the force of law.³⁴ If these include provisions requiring health professionals to inform patients of error, that requirement too is imported into the law.³⁵ As more patient safety standards are developed by accreditation bodies, self-regulating professions and other organizations, arguments may be raised that hospitals' or physicians' failure to comply is evidence that care was substandard, or that systems to prevent error and protect patients from harm were inadequate. Such claims may be met with the argument that the challenged practice was nonetheless followed by a respectable minority of competent practitioners, and so, is acceptable.³⁶ Patients would still have to prove the other elements of a negligence claim, including the causal link between the breach and the harm suffered.

Accreditation standards for health facilities may provide a case in point, although jurisprudence is scant. The Canadian Council on Health Services Accreditation (CCHSA) is a private non-profit accreditation agency that assesses health organizations against a set of national standards. It has representation from a number of organizations, including the Canadian Healthcare Association, the Canadian Medical Association, the Royal College of Physicians and Surgeons of Canada, the Canadian Nurses Association and the Canadian College of Health Services Executives.³⁷ It accredits a large majority of Canadian hospitals. Most accreditation

³³ *Spillane v. Wasserman*, [1992] O.J. No.2607; Cranley Glass, K., Campbell, A., "The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research", (2001) 46 McGill L.J. 73.

³⁴ Bailey, T., Ries, N., "Legal Issues in Patient Safety: The Example of Nosocomial Infection", (2005) 8 Healthcare Q. 140-145 at 142, citing Code of Ethics of Physicians, R.S.Q., c.C-26, s.87, 2001, c.78, s.56; Code of Ethics of Pharmacists, R.S.Q., c.P-10, c.C-26, s.87, c.P-10, r.5.

³⁵ *Ibid.*

³⁶ *Lapointe v. Hopital LeGardeur* (1992), 90 D.L.R. (4th) 7, 15 (S.C.C.).

³⁷ Morris, J., *Law for Canadian Health Care Administrators* (Toronto: Butterworths, 1996) at 13.

takes place on a voluntary basis, although in some provinces, it is mandatory – for example, Quebec requires private and public health care facilities to be accredited.³⁸ The Health Council of Canada has called for more health facilities to become accredited as a means to improve patient safety.³⁹ However, as it notes, few make their full assessment reports public.⁴⁰

To a great extent, the process relies on self-assessment.⁴¹ The CCHSA recently added patient safety goals to its accreditation standards, and will consider compliance with them as part of its accreditation program commencing in 2006.⁴² It has developed a list of sentinel events related to system or process deficiencies that can lead to death or major and enduring loss of function, and expects member organizations to implement a reporting system for adverse events, with provision for internal reporting, investigation and action on sentinel events, and external reporting as applicable.⁴³ Arguably, accreditation standards could inform the standard of care in malpractice proceedings, or provide evidence of shortcomings.⁴⁴

The same is true of standards developed by patient safety organizations, such as the “Safer Healthcare Now!” campaign that has adopted six targeted initiatives for implementation in hospital settings.⁴⁵ It now has more than 150 participant organizations. Such programs raise questions about the legal implications of (i) not participating when there is evidence these programs will reduce harm to patients, and (ii) joining, but not complying with program requirements. Will they be considered best practices, and so not legally required, or the new standard of care? While patient safety advocates generally favour minimizing the role of

³⁸ Health Council of Canada, 2005 Annual Report, *supra*, n.9, at 56.

³⁹ *Ibid.*

⁴⁰ *Ibid.*, at 55.

⁴¹ Morris, J., *Law for Canadian Health Care Administrators*, *supra*, n. 37 at 13.

⁴² Health Council of Canada, *supra*, n.9 at 55; CCHSA, online at <http://www.cchsa-ccass.ca> (last accessed July 2005).

⁴³ Canadian Patient Safety Institute, “Canadian Root Cause Analysis Framework. A tool for identifying and addressing the root causes of critical incidents”, at 9; online at: <http://www.cpsi-icspa.ca> (last accessed July 2005) (hereafter, CPSI RCA), citing Canadian Council on Health Services Accreditation, online at: www.cchsa.ca/pdf/GuideForSentinelEvents_e.pdf.

⁴⁴ See discussion *supra*, relative to health care providers and patient safety standards. In *Lahey v. Craig* (1992), 310 A.P.R. 91 (N.B.Q.B.); *aff'd* in part (1993) 351 A.P.R. 366 (N.B.C.A.); leave to appeal denied (1994), 368 A.P.R. (note) (S.C.C.), the trial judge used the CCHSA accreditation questionnaire and survey reports completed by the hospital and other evidence to establish the standard of care and its breach. The appellate court disapproved of the trial judge’s wide-ranging inquiry into the health care system generally and at the defendant hospital. However, material submitted by a hospital in connection with CCHSA accreditation could still be taken as evidence of the resources (personnel, facilities, equipment, material) it has or should have available, in the context of a more focused inquiry into breach of the standard of care.

⁴⁵ The evidence base for each indicates that implementation can lead to reduced morbidity and mortality – see Safer Healthcare Now!, online at: <http://www.saferhealthcarenow.ca/Default.aspx> (last accessed May 2006).

litigation, patient safety standards have the potential to affect determinations of the legal standard of care; such a development would in turn raise concerns about chilling organizations' willingness to participate.

(ii) Implications of Developments in Vicarious Liability and Non-Delegable Duties of Care: Extending Hospital Liability to Physician Negligence

As described in Chapter 1, physicians are generally considered independent contractors, and hospitals are not liable for their negligence.⁴⁶ The Supreme Court of Canada recently expanded the application of vicarious liability and non-delegable duties of care and thus, expanded liability for the negligence of third parties in some circumstances.⁴⁷ However, none of these decisions arose in the context of health care. What will these developments signify for hospitals? Some commentators have suggested that the logic underlying these cases would apply to hospitals as well, such that they should be subject to a non-delegable duty of care to ensure care and skill are taken in the treatment of patients, based on their special relationship with a vulnerable population and public reliance on the hospital to ensure quality care is delivered, as well as their statutory duties.⁴⁸ Others argue that hospitals could be held vicariously liable for non-employed physicians' negligence.⁴⁹ Recent jurisprudence (again in contexts other than health care) evidences a somewhat more restrictive approach to imposing vicarious liability or a non-delegable duty of care.⁵⁰

When the question of imposing liability for third parties' wrongdoing has been raised in the health care context, some lower courts have continued to reject arguments that health facilities can be held liable for the negligence of non-employed physicians.⁵¹ Others, however,

⁴⁶ *Yepremian v. Scarborough General Hospital* (1980), 110 D.L.R. (3d) 573 (Ont.C.A.); rev'g. (1978), 88 D.L.R. (3d) 161 (Ont.H.C.).

⁴⁷ The concepts of vicarious liability and non-delegable duties of care are explained in Appendix B to Chapter 1.

⁴⁸ Osborne, P., *The Law of Torts* (2d ed.) (Toronto: Irwin Law, 2003) at 324; Fridman, G., *Introduction to the Canadian Law of Torts* (2d ed.) (Markham, ON: LexisNexis Butterworths, 2003), 336.

⁴⁹ Picard, E., "The Liability of Hospitals in Common Law Canada", (1981) 26 McGill L.J. 997 at 1018, suggested that if properly applied, the organization test could result in a finding of vicarious liability.

⁵⁰ See, eg. *B.(K.L.) v. B.C.*, [2002] 2 S.C.R. 403; *M.B. v. B.C.*, [2003] 2 S.C.R. 477; *G.(E.D.) v. Hammer*, [2003] 2 S.C.R. 459; *Blackwater v. Plint*, [2005] S.C.J. No. 59, 2005 SCC 58; *E.B. v. Order of the Oblates of Mary Immaculate*, 2005 SCC 60. See also *B.(J.-P.) v. Jacob*, (1998) 166 D.L.R. (4th) 125 (N.B.C.A.) (hospital not vicariously liable for sexual assault of patient by nurse it employed,; since patient was not under this nurse's care, the assault did not occur in the course of employment).

⁵¹ See eg. *H.(J.E.) v. Lay* [2001] A.J. No.296 (Alta. Q.B.); *Locke v. Smith*, [2002] O.J. No. 2173 (C.A.); *Lafond v. Fabian*, [2004] O.J. No. 2787, para. 18 (Ont. Master).

have refused to dismiss the issue summarily.⁵² *Yeprémian v. Scarborough General Hospital*, in which a divided Ontario Court of Appeal held that a hospital could not be found liable for a non-employed physician's negligence, has remained the controlling precedent for more than 25 years.⁵³ The Supreme Court of Canada granted leave to appeal in *Yeprémian*, but the hospital agreed to pay the patient a guaranteed minimum of \$2 million to settle the case before the appeal was heard, and the matter ended there.⁵⁴ Commentators question whether the logic of *Yeprémian* should continue to prevail, given changes in the organization and delivery of care.⁵⁵ Courts in other countries increasingly hold hospitals liable for the negligence of "independent" physicians, on a variety of theories.⁵⁶

Courts have been reluctant to disturb physicians' and hospitals' settled expectations and arrangements about their respective spheres of liability.⁵⁷ However, deference to existing insurance arrangements made by hospitals and physicians is open to challenge.⁵⁸ The insights of the patient safety movement into the role of systemic factors in causing medical error and patient injury – i.e. the ways in which constraints imposed at the "blunt end" of institutional decision-making shape decisions and events at the "sharp end" of practitioners and patients -- lend considerable force to arguments for extending hospitals' liability to include responsibility for the negligence of non-employed physicians. The case for doing so is strengthened when coupled with the Court's rationale for expanded recognition of vicarious liability, i.e. that deterrence can best be promoted by fixing liability at an organizational level, where there is the power to implement effective changes to reduce risk and prevent harm.⁵⁹ Expanding hospital liability would also reflect changes in the organization and delivery of care more accurately. In many

⁵² In both *Jaman Estate v. Hussain*, [2002] 11 W.W.R. 241, 2002 MBCA 81, [2002] M.J. No. 283 (Man. C.A.) and *Richardson v. Tory*, [2004] NBQB 324, para. 16, the courts refused to grant summary judgment in favour of the hospitals on this issue.

⁵³ *Supra*, n. 46. Although the decision is only of persuasive effect outside Ontario, decisions in other provinces are consistent.

⁵⁴ Picard, E., Robertson, G., *Legal Liability of Doctors and Hospitals in Canada* (3rd ed) (Toronto: Carswell, 1996) at 390.

⁵⁵ See eg., Morris, J., "Malpractice and Institutional Liability", in Dykeman, M.J. (ed.), *Canadian Health Law Practice Manual* (Toronto: Butterworths, 2000) (looseleaf ed.), para. 6.58: "Whether physicians who are granted privileges at hospitals in Canada will continue to be considered independent practitioners for whom the hospital is not, in law, responsible, remains an unanswered question"; see also Picard, E., *supra*, n.44.

⁵⁶ See eg. ch.3, *infra*, on the United States.

⁵⁷ See eg. *Yeprémian v. Scarborough General Hospital*, *supra*, n.46, per MacKinnon, A.C.J., and Arnup, J.

⁵⁸ See eg. Picard, *supra*, n.49 at 1006, querying whether the need to take out overlapping insurance should "...be compelling enough to destroy or sterilize the duty that would otherwise be owed by the hospital to the patient?"

⁵⁹ *Bazely v. Curry* (1999), 174 D.L.R. (4th) 45 (S.C.C.).

instances, physicians' services cannot be evaluated properly in isolation from treatment provided by the rest of the health care team, and the institutional environment in which they are provided.

The inquest into the deaths of twelve children while undergoing or shortly after cardiac surgery at the Winnipeg Health Sciences Centre in 1994 shed considerable light on the inextricably intertwined roles of the various actors and levels of activity when considering the reality of how health care is delivered in the setting of a modern hospital.⁶⁰ One of the striking features of the inquest report is the careful detailing of the many levels and systems in which there were shortcomings, as well as the variety of decision-makers who did not discharge their responsibilities properly, and the ways in which these deficiencies combined to contribute to the children's deaths. For instance, hospital decisions about staffing levels, monitoring of problems, recruitment procedures and other matters significantly affected the ability of the team caring for the children to provide proper care.⁶¹ In light of this reality, the exercise of partitioning responsibility when poor care is provided in circumstances such as this seems particularly contrived.

(iii) Liability of Statutory Regulators and Government

Dissatisfaction with the oversight exercised by statutory regulators and an inability to recover from individual tortfeasors has led some victims harmed by members of self-regulating professions to sue statutory regulators in tort, alleging that their failure to effectively control the member after being alerted to misconduct allowed him or her to continue practicing and cause them harm. Initially, the Supreme Court of Canada held that claims in negligence would not lie against statutory regulators, based on its analysis of the statutory immunities and the law regarding the duty of care owed by such entities.⁶² It has since modified that position, and held that in some circumstances, regulators may be liable for gross negligence despite good faith immunity provisions in the enabling statute.⁶³

⁶⁰ Sinclair, M. (Assoc. C.J.), *The Report of the Manitoba Pediatric Cardiac Surgery Inquest: An Inquiry Into Twelve Deaths at the Winnipeg Health Sciences Centre* (Winnipeg, MA: Provincial Court of Manitoba, 2000), online at: www.pediatriccardiacinquest.mb.ca (last accessed June 2002).

⁶¹ *Ibid.*

⁶² *Cooper v. Hobart*, [2001] 3 S.C.R. 537; *Edwards v. Law Society of Upper Canada*, [2001] 3 S.C.R. 562. These decisions were followed in the health care context in Ontario in *Rogers v. Faught*, [2002] O.J. No. 1451 (C.A), dismissing an action against a self-governing body of a health profession.

⁶³ *Finney c. Barreau du Quebec*, [2004] S.C.J. No. 31.

Governments have generally been immune from liability for negligence in their decision-making about the organization and funding of the health care system, on the basis that such decisions did not give rise to a private law duty of care, and were not amenable to a finding of negligence because they were policy and not operational decisions.⁶⁴ More recently, creative pleading by plaintiffs has successfully invoked governments' responsibility to take reasonable care in implementing policy decisions, for which it can be found negligent.⁶⁵ Many of these cases involve allegations that governments failed to maintain safe systems – for instance, in response to outbreaks of SARS or West Nile virus.⁶⁶ In patient safety terms, these claims seek to hold the ultimate “blunt end” actor responsible – government. Most such claims have only faced preliminary challenges at this point, and it is not clear whether they will ultimately succeed. Jurisprudence establishing the lines between policy and operational decisions, and the boundaries of private law duties of care that governments owe members of the public with respect to health care is not yet well developed. Plaintiffs face formidable challenges.⁶⁷

3. Disclosing Information, Reporting Errors and Qualified Privilege

Patient safety advocates urge that information about medical errors and near misses disclosed or gathered in the course of patient safety and quality assurance processes must be kept confidential. Because information about what has gone wrong is so important to systemic analysis of patient injury and in developing strategies to reduce injury, and because health care providers are reluctant to make such disclosure if doing so carries the risk of negative repercussions (i.e. “blame and shame”), they argue that the public interest in facilitating initiatives to make health care safer justifies non-disclosure. In advancing this position, patient safety advocates' arguments are aligned with those of organized medicine and medical liability insurers, who have long resisted allowing access to or use of quality assurance information in medical malpractice litigation, although for somewhat different reasons.⁶⁸

There is another important public interest at stake. Access to information assists those concerned to learn about and evaluate what occurred. There are legitimate reasons to do so

⁶⁴ *Just v. B.C.* (1989), 64 D.L.R. (4th) 689 (S.C.C.); *Mitchell Estate v. Ontario*, [2004] O.J. No. 3084 (Div. Ct.).

⁶⁵ *Williams v. Canada (A.G.)*, [2005] O.J. No. 3508; (2005) 76 O.R. (3d) 763 (Sup. Ct.).

⁶⁶ See eg. *Baric v. Tolmak*, [2006] O.J. No. 890 (Sup. Ct.); *Williams v. Canada*, *ibid* ; but see *Cilinger c. Quebec*, [2004] J.Q. No. 11627 (C.A.), leave to appeal denied (2005) eCarswell Que 5795 (eC); *Mitchell Estate*, *supra*, n. 59.

⁶⁷ *Odhavji Estate v. Woodhouse*, [2003] 3 S.C.R. 263; *Cooper v. Hobart*, *supra*, n.57.

⁶⁸ See, eg. CMPA, “Medical liability practices in Canada: Towards the right balance” (Ottawa: Author, 2005), at 11.

beyond the confines of error reporting systems. An injured patient certainly has a powerful claim to know what happened and why. More generally, disclosing errors helps maintain trust in the integrity of the health care system and practitioners. In the event that a patient does sue, the ability to access all relevant information and put it in evidence before a court is considered key to resolving disputes accurately. Professional governing bodies and human resources departments also have an interest in access to information about what occurred, to ensure accountability and safety and quality of care. When access is restricted, their ability to discharge their responsibilities can be diminished as well. Decision-making about access to information and confidentiality must take both public interests into account.

(i) Internal and External Error Reporting

Hospitals implemented formal and informal processes to review the safety and quality of care long before the advent of the patient safety movement. Although most often partial and piecemeal, they provided some opportunity to analyze errors and adverse events. Because confidentiality was considered important to encourage participation, a number of provinces shielded at least some internal quality assurance (QA) processes from disclosure by means of qualified privilege legislation.⁶⁹ Statutory protection for QA activities has expanded steadily, such that all provinces and territories now provide some legislative protection for quality of care information.⁷⁰ The availability, scope and extent of qualified privilege varies.⁷¹ Generally, factual information is still accessible to the patient, at least to the extent it is not already included in the patient's health record.⁷²

Where statutory protection is not available, production in connection with civil proceedings can sometimes be resisted on the basis that the information is protected by common law privilege. Determinations are made case by case. The basis for such a claim is generally either legal professional privilege, i.e. that the information was obtained or prepared for the dominant purpose of assisting in litigation, or that privilege is justified because the public

⁶⁹ Rozovsky, L., Inions, N., *Canadian Health Information: A Practical Legal and Risk Management Guide* (Markham: Butterworths, 2002).

⁷⁰ CPSI, RCA, *supra*, n.43 at 10-12, and 33, Appendix A, "Legislative Protection for Quality of Care Information", listing applicable legislation by province and territory.

⁷¹ Qualified privilege regimes vary in the types of healthcare organization whose QA activities are protected, what committees are protected, how protection is claimed, whose communications and what information are protected, exceptions, and other matters.

⁷² See eg. *Quality of Care Information Protection Act*, SO. 2004, c.3, Sch. B.

interest in fostering the confidentiality of such communications outweighs what the information would add in assisting the court to correctly dispose of the litigation (the “Wigmore criteria”).⁷³ The public interest argument has met with mixed success in the health care context.⁷⁴

Systems for reporting errors and near misses are becoming increasingly formalized and expansive within institutions, and are being extended to require both reporting by more types of health facilities, and reporting to third parties, such as regional health authorities or government.

⁷⁵ Third party reporting may be mandated by statute, or imposed by policy. For example, in Quebec, the executive director of an institution or designate is required by law to report all accidents or incidents (essentially, near misses) in non-nominate form to the regional board.⁷⁶ Quebec also requires creation of risk and quality management committees to identify incident or accident risks, ensure support to the victim, and establish monitoring systems to undertake causal analysis and prevent recurrence.⁷⁷ Alberta mandates reporting of “significant mishaps” at non-hospital surgical facilities to the relevant regional health authority and the ministry of health.⁷⁸

Wider reporting requirements have raised questions about whether external reporting and new internal reporting procedures are protected by privilege. Statutory regimes that expand reporting have generally expanded protection for information and new third party QA activities as well. For instance, Saskatchewan requires health districts to report specified types of critical incidents to the ministry of health on a non-nominate basis, and health facilities to similarly report to the regional health authority. The authority must investigate the incident and determine how to prevent its recurrence. Its report, too, is submitted to the minister, who can then share it with other regional health authorities and health facilities in order to disseminate lessons learned.⁷⁹ These activities and documents are protected from disclosure by statutory privilege.⁸⁰

⁷³ *R. v. Gruenke*, [1991] 3 S.C.R. 263; *Slavutych v. Baker*, [1976] 1 S.C.R. 254.

⁷⁴ Picard & Robertson, *supra*, n.54 at 413-417; compare, eg. *Smith v. Royal Columbian Hospital* (1981), 123 D.L.R. (3d) 723 (hospital complaints committee documents privileged) with *Feige v. Cornwall* (1980), 30 O.R. (2d) 61 (S.C.). (rejecting claim of privilege for hospital incident report).

⁷⁵ Error reporting systems vary in the types of events that must be reported, to whom, for what purposes, action required following an event, requirements to and limits on sharing information, purposes of permitted disclosure, the nature of information protected, the types of legal proceedings in which there is protection from disclosure, and other matters. See generally CPSI, RCA, *supra*, n.43 at 10-13.

⁷⁶ CPSI, RCA, *supra*, n.43 at 8; see generally *An Act Respecting Health Services and Social Services*, R.S.Q., c.S-4.2.

⁷⁷ *Ibid.*

⁷⁸ Bailey & Ries, *supra*, n.34 at 144, referencing Alberta’s *Health Care Protection Act* and regulations.

⁷⁹ *Regional Health Services Act*, S.S. 2002, c.R-8.2, The Critical Incident Regulations, c.R-8.2 Reg. 3 (effective Sept. 15, 2004), Saskatchewan Critical Incident Reporting Guidelines, 2004, online at <http://www.health->

Other provinces are also creating protected zones to enable information about adverse events and responses to be shared beyond the bounds of the institution for patient safety purposes.⁸¹

Error reporting and adverse event investigation are insulated from disclosure on the assumption that reporting will not occur otherwise. The case for doing so is based on anecdotal evidence. Canada lacks empirical studies to determine whether, in provinces where statutory protection for error disclosure in the context of QA activities has been in place for some time, the existence of the privilege has made any difference to reporting. Does it in fact encourage more health care providers to come forward, more reports of error, and/or more forthright explanations of what occurred? In the United States, where QA activities have been protected by statutory privilege for longer, evidence that it positively affects disclosure is limited and equivocal.⁸² The causes of under-reporting are broader and more complex than concerns about legal liability. Consequently, shielding information generated as part of QA processes will not necessarily boost reporting.

When statutory privilege is expanded, it is important to remember that doing so comes at a cost – (i) to injured patients, in accessing information so they can find out what happened, as well as obtain information needed to establish legal entitlement to compensation when harmed by negligence, (ii) to the public, in learning about and assessing health care delivery, and (iii) to accurate dispute resolution by courts and other decision-making bodies.⁸³ We know little about

gov.sk.ca/mc_sk_ci_rep_guideline_2004.pdf; CPSI RCA, *supra*, n. at 16. At present, 6 types of critical incidents (serious adverse health events, as defined) must be reported: serious surgical errors, crippling mistakes in medication; patient disappearance or suicide in a health facility; errors resulting in death or disability to a mother or child during labour or delivery; and serious injury due to delays in transportation or emergency care (Critical Incident Reporting Guidelines, *ibid.*). Since implementation, reports of errors have continued to increase, which is considered a positive development – personal communication, J. White, Provincial Quality of Care Coordinator, Saskatchewan Ministry of Health, January, 2006.

⁸⁰ *Regional Health Services Act*, *ibid.*, s. 58; *Evidence Act*, S.S. 1989-90, c.57, s.35.1

⁸¹ See eg. *Regional Health Authorities Amendment and Manitoba Evidence Amendment Act*, S.M. 2005, c. 24 (Royal Assent June 16, 2005; proclamation pending), imposing a duty on health authorities and institutions to inform individuals if they have experienced a critical incident, and requiring investigation, action and reporting by the facility to the regional health authority, and by the RHA to the minister of health. Information generated is protected from disclosure.

⁸² Marchev, M., “Medical Malpractice and Medical Error Disclosure: Balancing Facts and Fears”, Nat’l. Academy for State Health Policy, #GNL53 (Dec. 2003), at 13, online at: <http://www.nashp.org>; Furrow, B., “Medical Mistakes: Tiptoeing Towards Safety”, (2003) 3 Hous. J. Health L. & Pol’y 181-217 at 203 notes that in the only study to that time on whether increasing protection from disclosure for data about errors and patient injury led to an increase in reporting, there was “little difference” in reporting between systems that provided confidentiality and those that did not.

⁸³ In the Manitoba inquest into pediatric cardiac deaths, parents of the children who had died put forward recommendations for consideration by Sinclair, J., including removal of the provision in the provincial *Evidence Act*

whether QA processes and/or error reporting systems actually reduce error and injury. In a 1989 study of privilege and quality assurance, Inions assessed Canadian QA programs at that time as:

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“...unable to ensure or guarantee quality of care. Terms such as ‘quality assistance’ ...are preferable as these terms more accurately describe the goal to improve quality of care...The term quality assurance is presumptuous and misleading as this process does not currently have the capability of guaranteeing high quality care to patients in hospitals. The assessment of problems necessarily involves conjecture and speculation. Methods used to measure and describe quality are unreliable”.

Her point was that in light of this, QA information can be easily misconstrued by patients and courts, and so ought not be disclosed. While it is to be expected that quality assurance activities have improved over the years since she wrote, her analysis also supports the conclusion that shielding QA activities from disclosure via qualified privilege in order to support programs meant to keep people safer may be protecting an aspiration rather than a reality.

Because confidentiality is considered essential to encourage disclosure, and the need for accurate information about errors is urgent, qualified privilege legislation can be justified. However, given the lack of robust evidence of its efficacy, such legislation should include a sunset clause. This would enable review to ensure it is effective. If under-reporting persists, the positive effects of privilege for patient safety programs may not be sufficient to justify the costs of non-disclosure. In the American context, Marchev noted that when powerful stakeholders achieve strong statutory protections for confidentiality in error reporting, they are difficult to repeal, whether they achieve their goals or not.⁸⁵ Incorporating a sunset clause into qualified privilege legislation would take this reality into account, and give providers a “use it or lose it” incentive to report error. Legislation in the various provinces, however, has not made qualified privilege conditional on acceptable results.

(ii) Disclosure to Patients

that allowed standards committees to withhold information regarding problems involving hospital-based physicians, and more thorough disclosure about risks to parents can make informed decisions – Sibbald, B., “Twelve deaths in Winnipeg: judge must ponder 48 000 pages of inquest testimony”, (1998) 159(10) CMAJ 1285-1287, at 1287.

⁸⁴ Inions, N., *Privilege and Quality Assurance: The Issues for Canadian Hospitals* (Ottawa: Cdn. Hospital Ass’n., 1989), 6-7.

⁸⁵ Marchev, *supra*, n.82.

When a patient has been harmed in the course of treatment, the ethical obligation to disclose what has occurred to the patient is clear.⁸⁶ There is a legal obligation to disclose harm to patients as well, although the precise parameters of the legal duty – what must be disclosed, by whom, and in what circumstances – are not entirely settled.⁸⁷ In many instances, disclosure is also required by professional standards of practice.⁸⁸ In some provinces, disclosure to patients harmed by adverse events is required by law, either directly, or by means of statutory approval of professional codes of ethics that in turn mandate disclosure of harm.⁸⁹ In Quebec, for instance, patients receiving care in hospitals have a statutory right to be informed of accidents (defined as “an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user...”).⁹⁰ Hospitals and other types of health care facilities have begun to adopt policies requiring disclosure of adverse events to patients. The CMPA, which provides liability coverage for most physicians, encourages members to disclose the occurrence of adverse events to patients, as well as the nature of adverse clinical outcomes.⁹¹ However, policies are often couched in limited and guarded terms. The College of Physicians and Surgeons of Ontario, for instance, states that a patient has a right to disclosure about harm that may have occurred to him, but that its policy is not meant to address “...issues concerning the cause of the harm” or reporting to third parties.⁹² The CMPA cautions that disclosure to patients “...relates to the prompt, factual and non-judgmental disclosure of the clinical information about the particular adverse event...”, but cautions against being more expansive.⁹³

Widespread support for disclosing harm to patients has not translated into widespread action; practice still falls short. In a 2005 survey of the experiences of patients with health problems in six countries, 19% of Canadian patients surveyed reported experiencing a medication error or a mistake in their treatment or care; 46% experienced serious health

⁸⁶ Hebert, P., Levin, A., Robertson, G., “Bioethics for clinicians: 23. Disclosure of medical error”, (2001) 164(4) CMAJ 509.

⁸⁷ Picard & Robertson, *supra*, n.54 at 171. An outstanding issue is whether hospitals are also under a legal duty to disclose harm to patients -- the implications that would flow from such a duty would be significant. I am grateful to Gerald Robertson for this point.

⁸⁸ See eg College of Physicians and Surgeons of Ontario, “Disclosure of Harm”, CPSO Policy #1-03 (Feb. 2003), online at: <http://www.cpso.on.ca> (last accessed June 2003).

⁸⁹ Bailey & Ries, *supra*, n.34 at 142

⁹⁰ *Ibid.*, citing *An Act Respecting Health Services and Social Services*, R.S.Q., c.S-4.2.

⁹¹ CMPA, “Disclosing adverse clinical outcomes” (Oct. 2001); “Disclosure to Quality Assurance Committees in Hospitals” (June 2004).

⁹² CPSO, *supra*, n.88.

⁹³ *Supra*, n. 91.

problems as a result. However, 74% of those patients had not been told about the error by doctors involved in their care.⁹⁴

4. Expanding Access to Information

(i) Profiling

In contrast to statutes shielding an increasing range of QA activities from disclosure, a recent initiative to expand public access to information about physicians' professional history does incorporate a sunset clause. Manitoba's Physician Profile Regulation, which took effect in 2005, makes information about physicians' professional history publicly available, including disciplinary actions and judgments in medical malpractice cases in the 10 preceding years.⁹⁵ It resulted from recommendations made by a committee reviewing results of the Manitoba Pediatric Cardiac Surgery Inquest, and is meant to support better informed decision making by the public.⁹⁶ It applies only to physicians. The regulation's effectiveness must be reviewed within five years.⁹⁷ There is no equivalent elsewhere in Canada, although some provinces provide limited public access to information about professionals' disciplinary history.⁹⁸

(ii) Apologies

No Canadian jurisdiction currently has legislation protecting apologies from use in civil proceedings. While it may be no more than a theoretical possibility, there is concern that an apology could be construed as an admission of liability, or adversely affect entitlement to liability insurance coverage as an admission against interest.⁹⁹ Believing apologies are important to patients, and that they can benefit providers and potentially reduce litigation as well, British

⁹⁴ Schoen *et al.*, *supra*, n.15 at W5-514 (the survey identified a combined rate of 30% of patients who experienced a mistake in medical care, medication or laboratory error).

⁹⁵ Physician Profile Regulation, Reg. 104/2005, made under the *Medical Act*, C.C.S.M. c.M90, s.4.

⁹⁶ This initiative was the result of recommendations made by the Review and Implementation Committee for the Report of the Manitoba Pediatric Cardiac Surgery Inquest (the Thomas Committee), (Winnipeg, Manitoba, 2001), online at: <http://www.gov.mb.ca/health/cardiac.html> (last accessed June 2002); see generally Pope, W., Physician profiling – Does it help make doctors accountable?", powerpoint presentation at "Physician Accountability and Patient Compensation: Alternatives to Tort" Conference, Physician Insurers Ass'n of America, Ottawa, Sept. 8-10, 2005.

⁹⁷ *Ibid.*, s.12.

⁹⁸ See eg. *Regulated Health Professions Act*, S.O. 1991, c.18, Sch. 2, *Health Professions Procedural Code*, s.23.

⁹⁹ British Columbia. Ministry of the Attorney General, "Discussion Paper on Apology Legislation" (Jan. 30, 2006), at 2-3, online at: <http://www.bc.ca> (last accessed April 2006); see also Canada. Commission of Inquiry on the Blood System in Canada, *Final Report*, Vol. 3 (Krever, H., Comm'r.) (Ottawa: Ministry of Public Works and Gov't Services of Canada, 1997) at 1038: one of the reasons the C.E.O. of the Canadian Red Cross Society offered to explain why the Red Cross declined to apologize to people who had contracted HIV and Hepatitis C through blood transfusions was a prohibition in its liability insurance contract against admitting liability.

Columbia became the first province to introduce legislation in 2006 that would prevent use of apologies (including admissions of fault) in determining fault or liability in civil proceedings, or to affect insurance coverage, regardless of contractual provisions to the contrary.¹⁰⁰ In doing so, it is following the lead of a number of American states that have passed what are colloquially termed “I’m Sorry” laws. The British Columbia statute had not been passed at the time of writing.

5. Procedural Reform

(i) Class Actions

Most instances of patient injury involve harm only to individuals, so class actions are not often available on the facts in medical malpractice cases. However, the potential to aggregate claims through a class action, although a relatively recent arrival in Canada, can make litigation a realistic possibility when it would not have been on an individual basis.¹⁰¹ Flaws in drugs, medical devices, use of equipment and other technology, testing the safety of blood and other products, substandard infection control, institutional and government policies and procedures, and others have all given rise to class actions in the health care context. While not large in number, potential liability for damages can be very great indeed. The CMPA reports that it settled a single class action for \$29.5 million in 2001.¹⁰² Recovery of this magnitude is not common, but as the types of acts and omissions alleged to constitute wrongdoing, the parties owing duties of care, and the frequency of claims continue to grow, so will findings of aggregated liability.¹⁰³

(ii) Simplified Procedure; Summary Proceedings

Beyond liberalizing rules for class actions, procedural reforms affecting the tort system have been limited. A number of provinces have adopted simplified rules of court applicable to lower value claims. Rules of procedure, maximum recovery, and costs recoverable are all

¹⁰⁰ British Columbia. *Apology Act*, Bill 16 (First Reading March 28, 2006).

¹⁰¹ See generally Cassels, J., Jones, C., *The Law of Large-Scale Claims. Product Liability, Mass Torts and Complex Litigation in Canada*, Toronto: Irwin Law, 2005), and Jones, C., *Theory of Class Actions*, (Toronto: Irwin Law, 2003).

¹⁰² CMPA, *supra*, n.22 at 16. The claim arose from improper sterilization of equipment at a diagnostic clinic, resulting in a number of patients contracting Hepatitis B (*Anderson v. Wilson*(1999), 44 O.R. (3d) 673)..

¹⁰³ For instance, lawsuits against governments by victims of West Nile virus, and by people who contracted SARS, for alleged deficiencies in its public health planning and responses have withstood initial challenges – see eg. *Eliopoulos v. Ontario (Minister of Health and Long Term Care)*, (2005) 76 O.R. (3d) 36; [2005] O.J. No. 2225 (Div. Ct.); and *Williams v. Canada (A.G.)*, *supra*, n.65.

limited; the aim is to increase access to the civil justice system by reducing the costs of lawsuits. Rules of court have also been amended to expand circumstances in which actions can be disposed of by summary proceedings – i.e. without a full trial. These types of initiative are not likely to be of much utility in medical malpractice claims, given the complex legal issues and disputed facts often involved, and the need for expert evidence and significant investment of lawyers’ time to properly prepare and present a case. Even at the time of the Prichard Review in the late 1980’s, the evidence was that medical negligence claims involving less than \$100,000 were routinely discouraged by legal counsel.¹⁰⁴

(iii) Periodic Payment of Damages

Some provinces have granted courts discretion to order damages to be paid by way of periodic payments without the consent of both parties.¹⁰⁵ Others are considering moving to discretionary or mandatory periodic payments when damages awarded exceed a minimum amount. The underlying reasoning is that periodic payments, while complying with the principle that damages awarded should return the plaintiff to the position she would have been in had she not been negligently injured, will achieve that end for substantially less money. Scheduled periodic payments raise concerns that plaintiffs’ decisions about how to spend the damages awarded would be restricted.

IV. PROPOSALS FOR TORT REFORM

Reform proposals have included no-fault compensation, hybrid systems, alternate dispute resolution, and changes to the tort system. Trebilcock has pointed out the need for caution when considering radical reform: “Whatever the empirical frailties in the evidence on the deterrent effects of tort law, tort theorists who propose...alternatives have rarely bothered to acquaint themselves with the empirical evidence on the efficacy of alternative control mechanisms”.¹⁰⁶ He concluded that, at least with respect to automobiles and industrial accidents, the evidence has often been inconclusive or disappointing.¹⁰⁷

¹⁰⁴ Picard & Robertson, *supra*, n.49 at 429, citing Prichard Report, *supra*, n.20, Appendix A at 104.

¹⁰⁵ Manitoba and Nova Scotia permit orders for periodic payment of damages without the consent of both parties.

¹⁰⁶ Trebilcock, M., “The Future of Tort Law: Mapping the Contours of the Debate”, (1989) 15 Can.Bus.L.J. 471, 483.

¹⁰⁷ *Ibid.*

The 1990 Prichard Report, *Liability and Compensation in Health Care*, which was commissioned by the Conference of Deputy Ministers of Health in response to a perceived malpractice crisis in the late 1980's, recommended that the tort system be maintained for clinical negligence claims, although with the addition of a companion enriched no-fault compensation option for injuries resulting from avoidable events.¹⁰⁸ It concluded that the threat of tort litigation was useful in improving the quality of health care, and further, that the ability to seek compensation through civil litigation was likely to force governments to ensure that benefit levels paid under a no-fault system were not allowed to become so low that they were no longer an attractive option compared to suing for negligence. However, no changes to the tort system resulted. Even though the Report concluded that less than 10% of viable claims attributable to negligence in health services resulted in payment,¹⁰⁹ the extent of uncompensated negligent injury was not enough to prompt politicians to change the way patients were (or more often, were not) compensated.

Mr. Justice Krever, who conducted the Commission of Inquiry on the Blood System after many people became infected with HIV and Hepatitis C from blood transfusions, considered the tort system a failure as a compensation mechanism, and recommended the creation of a no-fault system for blood-related injury. He rejected the option of maintaining tort liability as an alternative, because of the public costs involved in operating both a tort-based and no-fault system, the negative aspects of what could become a two-tier justice system, and the lack of certainty in compensation.¹¹⁰ He also advocates implementing no-fault compensation more generally for patients injured in the course of treatment, in order to address the needs of the many people left without recourse under the current medical liability system.¹¹¹

Pursuant to the Commission's recommendations, the federal government implemented a limited no fault compensation system for people infected with HIV and Hepatitis C from blood

¹⁰⁸ *Supra*, n.20.

¹⁰⁹ *Ibid* at 17.

¹¹⁰ Canada. Commission of Inquiry on the Blood System in Canada (Krever, H., Comm'r.), *Final Report*, Vol. 3, (Ottawa, 1997) at 1029-1045..

¹¹¹ *Ferguson v. Hamilton Civic Hospitals* (1983), 40 O.R. (2d) 577, aff'd. (1985) 50 O.R. (2d) 75. Other judges have criticized the operation of the tort system as well --see eg *Rothwell v Raes* (1988), 66 O.R. (2d) 449 (H.C.), aff'd. (1990), 76 D.L.R. (4th) 280 (Ont.C.A.); see also Dyer, O., "Canada's legal system cheats patients and doctors alike", Nat'l. Review of Medicine, Nov. 15, 2005.

transfusions.¹¹² In doing so, it was responding to a crisis: the financial collapse of the Canadian Red Cross Society that collected and supplied the tainted blood, and the inquiry's findings that government oversight and monitoring of the blood system had been deficient. Even then, at least as originally structured, compensation was limited to categories of claimants where the government would have considered itself most at risk if lawsuits against it had proceeded to judgment. Eligibility has since been expanded.¹¹³

Quebec has had a no-fault compensation system for people who suffer severe and permanent injuries from vaccines in place since 1986, following a Supreme Court of Canada judgment denying the claim of a young girl who experienced severe neurological disability after being vaccinated.¹¹⁴ She had sued her physician, the vaccine manufacturer and the provincial government. The Court suggested that government compensation would be appropriate, although not legally required. The province implemented a no-fault compensation system shortly thereafter. Benefits are broad, but establishing eligibility is difficult. Claimants must prove a causal connection between the vaccine and the harm suffered. Success rates for claims are low (20 out of 117 claimants in a 15 year period).¹¹⁵

The Dubin Report commissioned by the CMPA supported retaining existing approaches to determining medical liability. It did suggest further study of designating compensable events in limited instances, such as in the case of birth-related injuries.¹¹⁶

The CMPA commissioned an international review of selected compensation and liability systems, and released a policy paper on medical liability in 2005.¹¹⁷ It identified its goals as (i) reduction of adverse events, (ii) compensation (“ensuring patients suffering harm as a result of physician negligence are compensated quickly, appropriately and equitably”), (iii) due process, (iv) accountability, and (v) affordability.¹¹⁸ Both the review and the CMPA policy paper argued for retaining the existing medical liability system; in the CMPA’s view, “The current medical

¹¹² Some provinces supplemented and expanded the federal compensation.

¹¹³ Dyer, O., *supra*, n.111.

¹¹⁴ *P.G. du Quebec c. Lapierre*, [1985] 1 S.C.R. 241..

¹¹⁵ Kutlesa, N., “The Case for a Vaccine-Related Injury Compensation Scheme in Canada”, online at: http://www.law.utoronto.ca/documents/zhealthlaw04/kutlesa_handout.doc (last accessed Dec. 2005); Picard, A., “Only Quebec pays out for vaccine injuries”, *Globe & Mail*, 18 November, 2002, at A7.

¹¹⁶ *Supra*, n.25.

¹¹⁷ Secor Consulting, “Alternative Patient Compensation Models in Canada. Summary Report”, Ottawa: CMPA, Sept. 8, 2005); CMPA, “Medical liability practices in Canada: Towards the right balance” (Ottawa: CMPA, Aug., 2005).

¹¹⁸ CMPA, *ibid.*, at 4.

liability system in Canada is fundamentally sound and is very likely the best possible model for our circumstances”.¹¹⁹

This conclusion is weakened by the striking absence of any consideration in either document of the great disparity between the extent of patient injury in Canada caused by preventable adverse events, and the very small number of cases in which patients receive compensation for the injuries they have suffered. Not all preventable adverse events equate with negligence, but a subset do. The estimates available indicate that the number of negligent adverse events is much larger than the number of people who sue or recover for negligence.¹²⁰ The CMPA’s conclusion about the medical liability system seems based on outmoded perceptions of the health care system – i.e. that errors are rare, and that few true quality and safety problems exist. The Canadian Adverse Events Study and other research in Canada and internationally have shown that view to be without basis. The failure to take into account either the scale of patient injury or the preventable nature of many adverse events (and the implications of both for the incidence of negligence) makes it difficult to accept the CMPA’s contention that the existing medical liability system is the best possible in the Canadian context, particularly when one of its own goals is that patients harmed by physician negligence obtain prompt, fair compensation.

Much of the academic work on medical liability was produced in response to the last medical malpractice “crisis”, when fees charged to CMPA members for liability coverage and health care institutions’ liability insurance premiums increased dramatically.¹²¹ Commentators pointed out that, if there was a crisis, it was in how poorly the tort system functioned to compensate patients injured by negligence – i.e. how few people harmed by health care sued, and the even smaller number that succeeded.¹²² Picard and Robertson note that one of the principal reasons for low rates of claiming is “...problems of access to the justice system”.¹²³ Given information asymmetries between patients, providers and institutions, there is no assurance a patient will know or be able to obtain and appreciate the information needed to understand that

¹¹⁹ *Ibid.*, at 22.

¹²⁰ Prichard Report, *supra*, n.20.

¹²¹ See eg. Elgie, R., Caulfield, T., Christie, M., « Medical Injuries and Malpractice : Is It Time For No-Fault ? » (1993) 1 Health L.J. 97; Prichard Report, *supra*, n. .

¹²² *Ibid.*(Elgie).

¹²³ *Supra*, n.54 at 428.

he or she has been a victim of a medical error. Lawsuits are slow, complex, costly despite greater availability of contingency fees, unpredictable, and in the case of medical liability claims, usually unsuccessful. These factors are felt particularly acutely by those with the fewest resources, who are already the most vulnerable. The result is that those least advantaged in society (sometimes as a result of injuries from treatment received) are also least able to access the civil justice system.¹²⁴ Access is not improving. Recent years have seen a steady decline in claims frequency against physicians; with the exception of the impact of a single large class action settlement in 2001, average awards and settlements paid by the CMPA have remained fairly stable over the past 5 years.¹²⁵

Proposals for procedural reform have generally been directed towards controlling costs, not towards reducing medical error. The CMPA has lobbied for several procedural reforms for years: greater use of structured settlements and periodic payments in judgments, an end to subrogated claims by provincial health insurers for the cost of providing health and social services (on the basis that such awards essentially transfer money from one government pocket to another), and greater opportunities for settlement pre-trial, such as mediation.¹²⁶ Reducing the cost of lawsuits make sense, as long as it can be done in ways that are fair to all concerned. It has also suggested that the possibility of a segregated compensation system for compromised infants be explored further; these are the most costly type of individual claims it faces.¹²⁷ Depending on the structure of any system adopted, particularly conditions for eligibility and scope and level of benefits, such a scheme has the potential to be a better means of compensation in this type of case. Provincial governments, too, have an interest in re-structuring damages awards, particularly in cases of clinical negligence. Doing so would reduce their costs, since the subsidies governments provide for the cost of liability coverage now constitute a significant portion of the total amounts paid. Changes to federal legislation have also been suggested, to end taxation of personal injury awards so that damages would no longer need to include amounts to “gross up” the award to take into account liability to pay tax on future investment income

¹²⁴ Howse, R., Trebilcock, M., “The Role of the Civil Justice System in the Choice of Governing Instrument”, in Ontario Law Reform Comm’n., *Rethinking Civil Justice: Research Studies for the Civil Justice Review* (Toronto: Ontario Law Reform Comm’n., 1996), Vol. 1, 243-304, at 255.

¹²⁵ CMPA Annual Report 2004, *supra*, n. 22 at 16.

¹²⁶ CMPA “Medical liability practices”, *supra*, n.68 at 20.

¹²⁷ *Ibid.*

earned on lump sum compensation. This type of proposal, too, is directed towards reducing costs. Beyond this type of procedural reform and legislation strengthening qualified privilege for error reporting, however, there seems little will – public or political – for more radical change, and consequently, little likelihood of substantial tort reform in the near future.

V. CONCLUSION

Procedural reforms affecting the tort system have been directed at reducing costs – costs to the losing party of damages awarded (for example, by ordering periodic payment of damages), and costs to the parties and the civil justice system (for instance, establishing simplified procedures for lower value claims, or expanding summary proceedings). A few law reform initiatives have had a patient safety focus, at least in their most recent incarnation. Strengthened statutory protection from disclosure for QA activities is one example. Its effects are broader, though: restricting access to information also makes it more difficult for patients to prove negligence and entitlement to compensation when they have been injured. To date, governments have not taken advantage of the opportunity to link strengthened protection from disclosure to progress on error reporting, disclosure of harm to patients, or other policy goals.

Courts, for their part, have steadily expanded common law liability for negligence, particularly in personal injury cases.¹²⁸ They have extended circumstances when a duty of care is owed, become more demanding in determining whether the standard of care was breached, and adopted alternative approaches that make it easier to prove causation. Writing extra-judicially about developments in the law of causation in negligence cases, McLachlin, J. (now Chief Justice of the Supreme Court of Canada) observed that judges’ willingness to relax the traditional “but for” test stemmed from the growing “imbalance between the perception of a wrong and the inability to bring the wrongdoer to account and compensate the victim”, as well as the need to ensure effective deterrence of harmful activity.¹²⁹ She warned that the frequent result of “no recovery” even when people have suffered harm and there has been wrongdoing is “inconsistent with modern expectations”, and may lead people to turn elsewhere “...if the tort system is unable

¹²⁸ Klar, L., “Downsizing Torts”, in Mullaney, N., Linden, A. (eds), *Torts Tomorrow: A Tribute to John Fleming*, (Sydney: LBC Information Services, 1998), 305-320, at 307-8. Some recent decisions have taken a more conservative approach to the existence of a duty of care – see eg. *Cooper v. Hobart*, *supra*, n.57; *Child v Desormeaux*, 2006 SCC 18; but see now *Young v. Bella*, 2006 SCC 3..

¹²⁹ McLachlin, B., “Negligence Law – Proving the Connection”, in Mullaney, N., Linden, A., *ibid.*, 16-35, at 17, 32.

to meet public perceptions of justice”.¹³⁰ Alternatives may not be a realistic possibility for people injured by treatment, given the limited powers and mandates of complaints resolution mechanisms at present. Not only courts, but policymakers, too, grapple with whether the role of tort law should be altered to reflect new understandings of responsibility, and the appropriate balance between distributive and corrective justice. Other countries face similar conundrums. Their experiences, both positive and negative, can provide valuable insights to inform consideration of these issues in Canada. The remaining chapters in this study review developments at the juxtaposition of medical malpractice law and patient safety initiatives in jurisdictions that share similar legal systems and patient safety sensibilities with Canada, with a view to assessing lessons to be learned.

¹³⁰ *Ibid.*, at 34.

CHAPTER 3. UNITED STATES

Introduction

The patient safety movement had its origins in the United States. The subject has been researched, theorized, critiqued, assessed and analyzed longer and more extensively there than anywhere else. The federal and state governments, non-governmental organizations and the private sector have all devoted substantial funds and other resources to patient safety initiatives. At the same time, tort reform has been an American preoccupation for many years. The literature on both in the United States is vast. Consequently, despite significant differences in the structure and funding of health care, medical liability insurance, and legal climate between the United States and Canada, American experience with the interface between patient safety and tort reform can be instructive. Developments must be understood, however, in the context of that country's health care and legal systems. *Vis a vis* health care, even though public funding accounts for more than half of national health expenditures, the private for-profit sector plays a much greater role in the funding and delivery of health care than in Canada.¹ With no system of universal health insurance, access to health care differs as well. While most Americans do have health insurance, many are significantly underinsured, and a significant percentage do not have any health insurance to cover the cost of needed health services. As for medical liability insurance, the availability of adequate and affordable insurance to physicians is far less certain than in Canada.² These differences affect both analysis of the problems presented by the troubled relationship between patient safety and the tort system, and prescriptions for reform. The legal environments in the two countries differ as well. Leaving aside variations in substantive law, American litigation is characterized by the potential for markedly higher damages awards, greater reliance on contingency fees, more extensive use of juries in civil trials, different rules to determine damages for pain and suffering, and different costs rules (costs do not "follow the event" -- i.e. responsibility for the costs of litigation does not shift depending on

¹ Public funding includes tax expenditures -- Sage, W., "Unfinished Business: How Litigation Relates to Health Care Regulation", (2003) 28 J.H.P.P.L. 387-419 at 408; Levit, K., Smith, C., Cowan, C., Sensenig, A., Catlin, A., "Health Spending Rebound Continues in 2002", (2004) 23 Health Affairs 147.

² Studdert, D., Mello, M., Sage, W., DesRoches, C., Peugh, J., Zapert, K., Brennan, T., "Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment", (2005) 293 JAMA 2609-2617.

success).³ On the whole, Americans are more litigious than their Canadian counterparts, and this holds true for medical malpractice claims as well.

This chapter outlines and analyzes the interrelation of the tort system and the patient safety movement. It explains the background to the Institute of Medicine (IOM) report that made the problem of medical error a public issue, and recounts what has occurred in its aftermath. It reviews scholarship assessing the performance of the tort system, the history of the present malpractice “crisis”, and the tort reforms adopted as a result. It describes proposals for more radical law reform, including some that would supplant the tort system entirely, and others meant as “workaround” solutions to political inertia and deadlock. Finally, it considers the role of patients and the public at the interface of patient safety and malpractice litigation, and the place of tort law in regulatory scholarship.

The Institute of Medicine Report, *To Err Is Human*

The release of the Institute of Medicine’s landmark report, *To Err is Human*, in 1999 made the extent of medical error and the grievous harm it causes to patients a national issue.⁴ It concluded that between 44,000 and 98,000 deaths each year in the United States were the result of medical errors, making it the eighth leading cause of death. More people died from medical errors than from motor vehicle accidents or workplace accidents; total national costs of preventable adverse events were between \$17 billion and \$29 billion, of which health care costs represented over half.⁵ Both the scale of the problem and its devastating results made the need for effective action apparent.

To that end, the report also examined how errors occur in health care. It pointed out that most errors are the result of slips, lapses and other human shortcomings within complex systems of care that were not designed to prevent errors. The usual response of blaming and punishing individuals considered to be “at fault” not only misstated the problem, but also misdirected efforts to prevent future harm, and hampered initiatives to learn from errors so that improvements could be implemented. Accordingly, it recommended that the systems within which errors occurred be studied, “...to make it easier to do the right thing, to reduce the likelihood that any residual errors will reach patients, and to intervene promptly with remediation

³ Gilmour, J., “Overview of Medical Malpractice Law in Canada”, (1994) 3 Ann. H. L. 179.

⁴ Kohn, L., Corrigan, J., Donaldson, M. (eds.), *To Err Is Human: Building a Safer Health System* (Washington: National Academic Press, 2000) (hereafter, the IOM Report).

⁵ *Ibid.*, 1-2.

should injuries nonetheless occur;... a transformation in the response to errors, which it called moving to a culture of safety. This means fixing problems rather than fixing blame...”⁶ The new approach, with its focus on systemic analysis, ending the “culture of blame” and de-emphasizing individual fault-finding, quickly became highly influential. It is a philosophy that has become the mainstay of the patient safety movement, not just in the United States, but around the world.⁷ However, as the American experience indicates, putting it into practice in the context of a pre-existing and complex landscape of rights, relationships, obligations, interests and needs is far from easy.

Background to the IOM Report

The Institute of Medicine was not the first to identify patient safety as a pressing issue; much of the intellectual foundation had been laid by scholars and practitioners over the preceding decade.⁸ The IOM’s work was based on a series of earlier reports on medical errors. In the mid-1970’s, a study of the costs of medical injuries sponsored by the California Medical Association revealed significant levels of adverse events, many of which were considered likely to have resulted in a finding of physician liability had patients sued.⁹ This was followed by the Harvard Medical Practice Study in the 1980’s, which undertook an extensive review of medical records of hospitalized patients, adverse events and malpractice claims in New York. It estimated that nearly 7000 New Yorkers died as a result of negligent injury in hospitals in 1984.¹⁰ In the early 1990’s, a study of Utah and Colorado found rates of adverse events similar to New York’s, although fewer deaths resulting from negligence.¹¹ While all of these earlier studies were undertaken with a view to bringing about tort reform, in the IOM report itself, one

⁶ Bovbjerg, R., Raymond, B., “Patient Safety, Just Compensation and Medical Liability Reform”, Kaiser Permanente Institute for Health Policy (Jan. 2003), online at: http://www.khip.org/publications/briefs/patient_safety.pdf (last accessed July, 2005), at 6 (hereafter, Bovbjerg 03).

⁷ See eg. World Health Organization, “Patient Safety”, online at: <http://www.who.int/patientsafety/en/> (last accessed July, 2005).

⁸ Wachter, R., “The End of the Beginning: Patient Safety Five Years After ‘To Err Is Human’”, *Health Affairs* Web Exclusive (Nov. 30, 2004), W4-534, at W4-535, online at: <http://www.cmwf.org> (last accessed Dec. 2004), referencing Leape, L., “Error in Medicine”, (1994) 272(3) *JAMA* 1851-7; Reason, J., *Human Error* (N.Y: Cambridge U. Press, 1990).

⁹ Mello, M., Brennan, T., “Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform”, (2002) 80 *Texas L.R.* 1595 at 1599 (hereafter, Mello & Brennan 02).

¹⁰ Brennan, T., *et al.*, “Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I”, (1991) 324 *NEJM* 370.

¹¹ Studdert, D., *et al.*, “Negligent Care and Malpractice Claiming Behavior in Utah and Colorado”, 38 *Med Care* 250-260; E. Thomas *et al.*, “Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado”, (2000) *Med Care* 261-271.

finds surprisingly little discussion of medical malpractice law.¹² Commenting on this omission, Mello and Brennan note that the IOM’s decision was strategic: “Having seen that medical malpractice reform was difficult and contentious, they hoped to keep the patient safety movement out of that quagmire”, and instead, went “direct to the public”, bypassing the medical profession and hospitals, and using public relations techniques to make the case for urgent action.¹³ The IOM called for substantial improvements in error prevention – a 50% reduction in 5 years.¹⁴ The hope was that pressure from external environments on health care providers and organizations would make errors so costly that the case for safety would become compelling.¹⁵ Combined with their calls for an end to legal, cultural and other impediments to safety initiatives, and more research to identify and develop effective responses, they expected they were setting the stage for major change.

Five Years After the IOM Report

Despite the attention generated by the IOM Report, error and patient injury remain a serious problem in the United States. In a 2005 study of patients with health problems in six countries, one third (34%) of American patients reported experiencing medical, medication or laboratory errors in the previous two years, the highest of all the countries surveyed.¹⁶ Of these, 77% occurred outside hospital. For 45% of those who reported a mistake in care or medication, the error caused serious health problems.¹⁷

Patient safety advocates confirm that the situation remains grave. This study coincided with the fifth anniversary of the release of *To Err Is Human*, an occasion which provided an opportunity for taking stock. The assessment of some of the most influential leaders in the patient safety movement was that progress had been frustratingly slow, and that, while the IOM Report had “changed the conversation”, there was “little evidence that systematic improvements in safety are widely available”; despite considerable activity, efforts are “affecting patient safety

¹² The goals of these studies differed: sponsors of the California study wanted to reduce the amount of malpractice litigation, and submerged the study results for fear it would spark more malpractice litigation if there were greater awareness of the incidence of preventable adverse events, while the Harvard and Utah/Colorado investigators were interested in replacing the tort system with no-fault compensation - Mello & Brennan 02, *supra*, n.9 at 1599-1600.

¹³ *Ibid.*, at 1601.

¹⁴ IOM, *supra*, n.4, at 4.

¹⁵ *Ibid.*, 21.

¹⁶ Schoen, C., Osborn, R., Huynh, P.T., Doty, M., Zapert, K., Peugh, J., “Taking the Pulse of Health Care Systems: Experiences of Patients with Health Problems in Six Countries”, Health Affairs Web Exclusive, Nov. 3, 2005, W5-509-509 at 514, online at: .

¹⁷ *Ibid.*

at the margin”.¹⁸ The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) commented in 2005 that “error remains ubiquitous in health care delivery”.¹⁹ Leape and Davis summarize the situation: “When it comes to improving patient safety, we have plenty of recognition of the problem but no real commitment to solving it. As a result, hospitals are still dangerous places to be if you are sick”.²⁰

Why So Slow?

Leape and Berwick, leaders in the patient safety movement from the beginning, concluded that structural factors had posed formidable barriers: professional fragmentation, deeply rooted traditions of professional autonomy and individualism in medicine, entrenched hierarchical authority structures, and diffuse accountability.²¹ A number of other factors contributed as well: physicians’ fear – of loss of autonomy, external control, untried analytical approaches, and malpractice liability – as well as lack of leadership prioritizing patient safety in health care institutions, the absence of robust measures to assess improvement, and a perverse reimbursement structure that in some instances subsidizes unsafe care, since physicians and hospitals can bill for services required to treat patients injured through their errors.²²

There has also been a degree of “push-back” against viewing safety as a problem of system design.²³ As Bovbjerg *et al.* point out, the patient safety movement is “...grounded in institutions and associations rather than a grass-roots response to liability-disciplinary fears among those practitioners affected by the accidents”.²⁴ Among physicians, not all are convinced that the best explanation for medical error is systems failure, nor that the best way to respond is

¹⁸ Leape, L., Berwick, D., “Five Years After *To Err Is Human*: What Have We Learned?”, (2005) 293(10) JAMA 2384, online at <http://www.jama.com> (last accessed May, 2005); see also Wachter, *supra*, n.8.

¹⁹ JCAHO, “Health Care at the Crossroads: Strategies for Improving the Medical Liability System and Preventing Patient Injury” White Paper, (Feb. 2005), http://www.jcaho.org/about+us/public+policy+initiatives/medical_liability.pdf (last accessed Sept. 2005).

²⁰ Leape, L., Davis, K., “To Err Is Human; To Fail to Improve Is Unconscionable” (Commonwealth Foundation, Aug., 2005), online at: http://www.cmwf.org/aboutus_show.htm?doc_id=2873032&#doc287032 (last accessed Aug. 2005).

²¹ *Supra*, n.18.

²² *Ibid.* at 2388; Crane, R., Raymond, B., Neisner, J., “In Pursuit of Safety: Challenges, Progress and Policy Implications for the U.S. Patient Safety Movement” (Kaiser, 2003).

²³ *Supra*, n.17 at 2384; see also Liang, B., Ren., L., “Medical Liability Insurance and Damages: Getting Beyond BandAids to Substantive Systems Treatment to Improve Quality and Safety in Health Care”, (2004) 33 Am.J.L.Med. 501 at 531.

²⁴ Bovbjerg, R., Miller, R., Shapiro, D., “Paths to Reducing Medical Injury: Liability and Discipline vs. Patient Safety – and the Need for a Third Way”, (2001) 29 J.L.M.E. 369-380, at 372; see also Liang, B., Ren, L., *supra*, n.23 at 531..

by ending blame.²⁵ Turning to patients and the public, patient safety advocates’ message that individual liability and fault-finding will actually impede progress in making health care safer has not found wide acceptance. As William Sage wryly observed, tort reform that shields health care providers from legal liability “is not an intuitive solution to rampant medical error”.²⁶ In a system which many characterized as “insiders protecting insiders”, people may simply consider systemic analysis to be another way to achieve exactly the same end.²⁷ That conclusion is even more understandable given that patient safety advocates themselves acknowledge that, despite all the activity meant to reduce errors and make care safer, there has been little improvement.

Responses to the IOM Report

That is not to say that nothing was done in response to the IOM Report – quite the contrary. The focus of this study is on the interactions between patient safety and the tort system, so other than a brief reference to some of the more significant developments, consideration of the many government, NGO and private sector initiatives that resulted will be limited to how they impact on or are affected by the operation of tort law.²⁸

(i) Federal:

The U.S. Congress appropriated \$50 million annually for patient safety research in 2001, launching hundreds of new investigators and studies in patient safety research; it also confirmed the Agency for Healthcare Research and Quality as the lead federal agency to coordinate patient safety research.²⁹ However, despite the IOM’s recommendation, there is no comprehensive national monitoring system, and while a number of federal agencies have mandates and priorities focused on patient safety, oversight is fragmented by clinical area or among agencies.³⁰

²⁵ *Supra*, n. 18 at 2387.

²⁶ Sage, W., “Medical liability and patient safety”, (2003) 22 *Health Affairs* 26-36, at 30.

²⁷ *Ibid.*

²⁸ At the federal level, the Quality Interagency Coordination Task Force (QuIC), a collaborative effort among federal agencies, issued a report, “Doing What Counts for Patient Safety, Federal Action to Reduce Medical Errors and Their Impact”, Report of QuIC to the President (2000) that laid out a strategy of more than 100 actions designed to create a national focus on reducing errors, strengthening the patient safety knowledge base, ensuring accountability for safe health care delivery, and implementing patient safety practice.

²⁹ However, in 2004, Congress earmarked almost all of those funds for IT studies, narrowing the field of study substantially (Leape & Berwick, *supra*, n.18 at 2385). See also White, S., “Patient Safety Issues”, and “National Patient Safety Initiatives”, in Byers, J., White, S. (eds.), *Patient Safety: Principles and Practice* (N.Y: Springer, 2004), at 10, 49.

³⁰ Leape and Berwick, *supra*, n.18 at 2384; White, *supra*, n. 29 at 47-59; Farley, O., Morton, S., Damberg, C., Fremont, A., Berry, S., Greenberg, M., Sorbero, M., Teleki, S., Ricci, K., Pollock, N., “Assessment of the National Patient Safety Initiative: Context and Baseline Evaluation Report” (Santa Monica: RAND Corp., 2005), at 12, 23-24 (hereafter, RAND Report).

Although there is no unified mechanism to collect data on adverse events or medical errors, or to aggregate data across multiple health settings, the passage of the federal *Patient Safety and Quality Improvement Act* in 2005 should facilitate sharing of data among patient safety organizations.³¹

(ii) State:

Mello and Brennan identify common themes from the many legislative and administrative initiatives that states undertook: they (1) established organizations to study patient safety, (2) provided for central repositories of data about adverse events, with mandatory or voluntary reporting systems, (3) adopted or strengthened confidentiality for information reported, (4) protected whistleblowers, (5) directly regulated structural elements significant for safety, such as staffing levels, (6) some created financial incentives such as discounts on hospital liability insurance for reductions in serious adverse events, (7) required disclosure of adverse events to patients, and (8) used their licensure authority to require facilities to improve safety.³² Yet despite what seem to be wide-ranging responses, Mello and Brennan consider the state action to have been largely “...augmenting the information base for regulation, rather than deploying specific error-reducing interventions”.³³

Further, as they point out, “...the base of evidence about effective safety-enhancing interventions is surprisingly thin”.³⁴ There is little empirical evidence to inform decisions about what types of initiatives or regulation to pursue, and much of what is available measures effectiveness (i.e. what produces affirmative benefit), rather than safety (i.e. what prevents inadvertent harm to patients). At present, there is neither a common understanding of what issues come within the concepts of medical error and patient safety, nor scientifically sound methods to measure errors and their causes.³⁵ Nor is there agreement in the health care community on a standard set of patient safety measures.³⁶ However, preventable adverse events are so widespread, and the harm they cause so great, that stakeholders often respond to the

³¹ White, *ibid.* at 47; *Patient Safety and Quality Improvement Act of 2005*, Public Law 109-41; RAND Report, *supra*, n. 29 at 13.

³² Mello, M., Brennan, T., “Fostering Rational Regulation of Patient Safety”, (2005) 30 J.H.P.P.L. 375-426 at 385 (hereafter Mello & Brennan 05), and <http://www.jhpl.yale.edu/appendix/30.3Appendix-1.pdf> (last accessed Dec. 2005), cataloguing state legislative initiatives.

³³ *Ibid.*, 386.

³⁴ *Ibid.*, 380.

³⁵ RAND Report, *supra*, n.30 at 33.

³⁶ *Ibid* at 25.

imperative to take some action that could reasonably be expected to improve safety, even in the absence of robust evidence.

(iii) Private Sector

The private sector, including both for-profit entities and non-profit NGO's, plays a stronger role in patient safety initiatives in the United States than in other countries, acting in a number of capacities. There are numerous research, policy and technical initiatives to support patient safety, led by an array of organizations and coalitions across the country. I comment on three instances of private sector involvement with implications for the medical liability system: as regulator, as purchaser of health care services (including indirectly, through provision of health benefit plans to employees), and as contractor. Each of these is discussed in more detail below.

(a) Private Regulation:

Non-profit organizations play a leading role in the accreditation of health care facilities. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accredits hospitals, nursing homes, home health and other facilities, and the National Committee on Quality Assurance (NCQA) accredits managed care plans and other providers.³⁷ JCAHO remains heavily dominated by hospital and physician representatives.³⁸ While facility accreditation is nominally voluntary, federal and state governments rely on JCAHO accreditation in their hospital licensure and Medicare/Medicaid certification programs, making it effectively mandatory.³⁹ Government reliance on private accreditation rather than its own routine monitoring is explained on pragmatic grounds: the cost of the accreditation program is borne by the facilities rather than government, and private accreditation working with institutions in a consultative fashion is expected to achieve greater voluntary compliance.⁴⁰

Even prior to the IOM Report, JCAHO had been active in patient safety initiatives, adopting a Sentinel Events reporting policy in 1996 to encourage facilities to report errors and root cause analyses to it.⁴¹ While loss of accreditation is a possibility if JCAHO learns of non-

³⁷ RAND Report, *supra*, n.30 at 27.

³⁸ Mello & Brennan 05, *supra*, n.32 at 382.

³⁹ Furrow, B., Greaney, T., Johnson, S., Jost, T., Schwarz, R., *Health Law: Cases, Materials and Problems* (5th ed.) (St. Paul, MN: Thomson/ West, 2004) at 182-3.

⁴⁰ *Ibid.* at 182

⁴¹ JCAHO, "Sentinel Event Policy and Procedures", online at: <http://www.jcaho.org> (last accessed Dec. 2004).

reporting, it is rare.⁴² The same can be said of reporting – it, too, is a rare occurrence, with only 400 reports of sentinel events a year.⁴³ JCAHO added a standard requiring disclosure of harm to affected patients in 2001, and in recent years, has continued to focus more of its accreditation standards on improving safety and quality.⁴⁴ There has been no systematic evaluation of the effectiveness of its oversight.⁴⁵ JCAHO itself notes that hospitals have identified its accreditation requirements as the major driver of their patient safety initiatives.⁴⁶ However, JCAHO’s collaborative approach to the institutions it regulates has been criticized for being too accepting, “...slow to develop meaningful standards and reluctant to develop meaningful enforcement mechanisms”.⁴⁷

Public and private regulation were integrated still further, as the Centers for Medicare and Medicaid Services (CMS) (the federal agency responsible for managing health care quality for Medicare and Medicaid beneficiaries) instituted a rule in 2003 requiring hospitals to develop quality assessment and performance improvement (QAPI) programs.⁴⁸ To a great extent, CMS is relying on JCAHO’s accreditation process for evaluation of these programs; it has indicated that JCAHO surveys could provide grounds for CMS enforcement.⁴⁹

What do the actions of private regulators have to do with the medical liability system? First, because of role they play in the health care system, they wield substantial influence in debates about tort reform. Second, they represent important accountability mechanisms at the interface of the public/private divide. Third, some commentators have suggested that clinical guidelines and patient safety policies developed by health care organizations, professional associations and NGO’s such as JCAHO could influence determinations of the standard of care in clinical negligence litigation. Arguments that compliance with guidelines and policies should serve as at least persuasive, if not definitive evidence that the standard of care was met are

⁴² Furrow *et al.*, *supra*, n. 39 at 58.

⁴³ JCAHO 05, *supra*, n.19.

⁴⁴ RAND Report, *supra*, n.30 at 27 (almost half JCAHO’s accreditation standards are directly related to safety); Furrow *et al.*, *supra*, n.42.

⁴⁵ Mello & Brennan 05, *supra* n.32 at 382, note that the AHRQ concluded it was “reasonable to assume” JCAHO’s contribution was positive.

⁴⁶ JCAHO, *supra* n.19 at 9, citing Devers, K., Pham, H., Liu, G., “What is driving hospitals’ patient-safety efforts?”, (2004) 23(2) Health Affairs .

⁴⁷ Furrow, B., “Medical Mistakes: Tiptoeing Towards Safety”, (2003) 3 Hous. J. Health L. & Pol’y 181-217 at 209.

⁴⁸ White, *supra*, n.29 at 51; RAND Report, *supra*, n.30 at 28: QAPI’s are to include systemic examination of hospitals’ programs, and quality improvement projects

⁴⁹ *Ibid.*, 60-62;

familiar in malpractice litigation.⁵⁰ However, as the patient safety movement's findings about the extent of error become widely disseminated and more patient safety standards are developed by JCAHO and other organizations, arguments may also be raised that hospitals' or physicians' failure to comply is evidence that care was substandard, or that systems to prevent error and protect patients from harm were inadequate.⁵¹ Private regulators' patient safety standards could be accepted by courts as the legal norm for institutions and practitioners.

(b) Private Purchasing:

American commentators and policymakers see great potential in the ability of health care purchasers and payers (including government) to exert pressure to bring about change.⁵² While individual consumers/patients cannot realistically do so, larger entities can, essentially enforcing accountability for standards they set via market mechanisms, i.e. the negative threat to take their business elsewhere, or the positive incentive of increased remuneration for meeting safety targets. Capitalizing on their greater role in the United States, buyers have started to become more assertive in demanding improvements in patient safety. The most notable example of concerted action by purchasers of health care was the creation of the Leapfrog Group in 2000. It is a coalition of major employers and other large private and public healthcare purchasers that provide health care benefits to more than 37 million people, and was formed to mobilize employer purchasing power to reduce preventable medical errors.⁵³ It chose 3 main goals for hospitals to achieve, based on their expected effects on preventing error and saving lives: implementing computerized physician order entry; concentrating highly technical surgery services in high volume centres; and specialized staffing in intensive care units.⁵⁴ Some of these goals have been controversial because of the high costs of implementation, shortages of specialists, and limited access to care in areas without the specified volume of procedures;

⁵⁰ Furrow *et al.*, *supra*, n. 39 at 486 – 7; Mehlman, M., “Resolving the Medical Malpractice Crisis: Fairness Considerations”, Pew Project on Medical Liability in Pennsylvania (2003) at 66-67; online at: <http://www.medliabilitypa.org> (last accessed Nov. 2004).

⁵¹ Furrow, *ibid.* at 447; Bovbjerg, R., “Liability Reform Should Make Patients Safer”, (2005) 33 J.L.M.E. 478 at 480-481 (hereafter, Bovbjerg 05).

⁵² Leape and Berwick, *supra*, n.18 at 2389; Furrow, *supra*, n. 47 at 195; Crane *et al.*, *supra*, n.21 at 8; IOM Report, *supra*, n.4.

⁵³ White, *supra*, n.29 at 10, 70-71; see generally Leapfrog Group, online at: http://www.leapfroggroup.org/about_us/leapfrog_factsheet (last accessed April 2006).

⁵⁴ *Ibid.* (White).

Leapfrog has since revised its standards somewhat as a result.⁵⁵ Mello and Brennan, while generally supportive of initiatives such as Leapfrog, question whether the standards it set, albeit easy to measure, are the most effective approaches to improving safety; this in turn raises questions about whether the costs of compliance are justified.⁵⁶

(c) Private Contracting:

With radical tort reform stymied by lack of political will and powerful stakeholder interests, some commentators have proposed that private organizations such as hospitals supplant the tort system by simply adopting alternative compensation systems as part of their contracts with employers/patient groups to provide health care.⁵⁷ Contracting out of the tort system entails complex issues that are beyond the scope of this study. However, the proposal does raise intriguing possibilities, not just for private entities, but also for government in the United States, since government funded Medicare and Medicaid programs are major components of health care spending in the United States.

Assessing the Tort System

American courts and commentators identify the same three purposes of the tort system as elsewhere in the common law world: deterrence, compensation, and corrective justice. Assessment of the tort system's performance is also similar across jurisdictions: it is not considered to perform any of these functions particularly well.⁵⁸ This assessment is explained in more detail below. American academic commentary emphasizes the deterrent role of tort law more than other common law jurisdictions, an approach influenced not just by law and economics scholars, but also by scholarship that focuses more broadly on the role of law in regulating human conduct and safety.⁵⁹ That orientation has influenced recommendations for reform.

⁵⁵ *Ibid.* at 10.

⁵⁶ Mello & Brennan 05, *supra*, n.32 at 394.

⁵⁷ Bovbjerg 05, *supra*, n.51 at 490.

⁵⁸ See, eg. Weiler, P., *A Measure of Malpractice: Medical Injury, Malpractice Litigation and Patient Compensation* (Cambridge, Harvard U. Press, 1993); Ison, T., *The Forensic Lottery* (London: Staples Press, 1967).

⁵⁹ Cane, P., "Tort Law as Regulation", (2002) 31(4) CLWR 305. See eg. Mello & Brennan 05, *supra*, n.31; Bovbjerg 05, *supra*, n.51 at 479 on the "central rationale of liability – keeping patients safe". That is not to say that considerations of corrective justice are disregarded in tort scholarship, but that they do not figure prominently in health law scholars' writings.

(i) Compensation

Few people who have valid claims arising from their medical care sue, and fewer still actually receive compensation.⁶⁰ The graphic analogies in the IOM Report – that the death toll from medical error was equivalent to a jumbo jet crashing each day -- made the extent of medical error and the gravity of the harm it causes very clear. While most errors are not caused by negligence in the legal sense, a significant portion are – many more than give rise to lawsuits, and substantially more again than ever result in awards of damages. The Harvard Medical Practice Study estimated that 8 times as many patients suffered an injury from negligence as filed a malpractice claim in New York state, and about 16 times as many patients suffered an injury from negligence as received compensation from the tort liability system.⁶¹ The barriers to litigation are formidable – cost, delay, uncertainty, information asymmetries that leave some patients unaware their injuries were caused by errors rather than their underlying illness, and difficulties in meeting legal tests for causation and fault.⁶² The tort system is criticized not just because it is poor at compensating people injured in the course of treatment (which is not its goal), but because it is not well equipped even to compensate people who have been injured by negligence. This is especially troubling in light of the scale of negligent error that occurs.

(ii) Corrective Justice

Liability for negligence is premised on personal responsibility to make good the harm caused by one's wrongdoing. Liang and Ren contend that in the context of medical liability, this has translated into one prevalent philosophy: "punish the last person to touch the patient".⁶³ The underlying premise in clinical negligence litigation is the traditional one that "practitioners are in charge, need to be held personally responsible, and should take the primary blame for injuries".⁶⁴ However, that model no longer accurately reflects the organization of health care, given

⁶⁰ Bovbjerg 03, *supra*, n.6 at 7-8; JCAHO, *supra*, n.19 at 13, citing Studdert, D., Mello, M., Brennan, T., "Medical malpractice", (2004) 350(3) NEJM; Baker, T., "Reconsidering the Harvard Medical Practice Study Conclusions about the Validity of Medical Practice Study Conclusions", (2005) 33 J.L.M.E. 501.

⁶¹ Localio, A., Russell, A., Brennan, T., Laird, N., Hebert, L., Peterson, L., Newhouse, J., Weiler, P., Hiatt, H., "Relation between Malpractice Claims and Adverse Events Due to Negligence, (1991) 325 NEJM 245-251.

⁶² Bovbjerg 03, *supra*, n.6 at 7-8, notes that only 43% of claimants won some compensation in physician malpractice claims closed in 1984, the last nationally representative study (citing United States. General Accounting Office, "Medical Malpractice: Characteristics of Claims Closed in 1984" (Washington: GAO, Apr. 22, 1987) (publication no. GAO/HRd-87-55). The American Medical Association reports that, using 2003 figures, more than 70% of medical liability claims do not result in any payments to patients – AMA, "Medical Liability Reform – NOW!" (AMA, June, 2005) at 7.

⁶³ *Supra*, n.24 at 503.

⁶⁴ Bovbjerg *et al*, *supra*, n.24 at 369; Leape, L., "Error in Medicine", (1994) 272 JAMA 1851.

advances in technological capabilities, changes in care delivery, effects of cost constraints on clinical decision-making, pressure to maintain revenues, and other factors. The individual focus in much malpractice litigation misses the mark in important ways, particularly in light of the IOM's compelling argument that the causes of error in health care are most often systemic, and not individual. Tort law, however, is not concerned with identifying all, or even the most significant causes of injury. Its concern is with the defendant before the court; analysis need only start and end there. In order to establish liability, a plaintiff need only demonstrate that he or she caused or contributed to the plaintiff's injury.

(iii) Deterrence

Commentators agree that the tort system underperforms in deterring future harm. After an extensive review of the empirical evidence, Mello and Brennan could only find "limited evidence" that malpractice litigation has a deterrent effect.⁶⁵ Several features of the medical liability system contribute.

(a) Misaligned Incentives

Even solid supporters of the tort system concur with this assessment, although they argue that it could be made more effective if its incentives for behavioural change were altered to shift the risk of liability from individual health care providers to health care institutions.⁶⁶ They consider tort's deterrent signals to be not only piecemeal, but misdirected, because responsibility for the costs of making improvements in safety is generally borne by hospitals and other health care institutions, but the benefits (in terms of reduced injuries and reduced liability costs) are reaped by patients and providers.⁶⁷ Aligning the incentives to make care safer would strengthen the "business case for safety".⁶⁸

(b) Under and Overdeterrence

Tort law is criticized for both underdetering unsafe care and for overdeterrence. Tort is said to underdeter because so few instances of clinical negligence actually result in litigation; as a result, the deterrent signals tort gives are weak and not always consistent. On the other hand,

⁶⁵ *Supra*, n.9 at 1613, 1615; Hyman, D., Silver, C., "The Poor State of Health Care Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution?", (2005) 90 *Cornell L.Rev.* 893 at 917: evidence of deterrence is "surprisingly tenuous".

⁶⁶ *Ibid.*

⁶⁷ Mello & Brennan 05, *supra*, n.32; Furrow, *supra*, n.47 at 191; Mello & Brennan 02, *supra*, n.9 at 1620.

⁶⁸ Mello & Brennan 02, *ibid.* at 1595; Bovbjerg 05, *supra*, n. 51 at 480, 489; Hyman & Silver, *supra*, n.65 at 958.

many physicians overestimate the risk of being sued, and may alter their practices in ways that are unnecessary and inappropriate.⁶⁹ Although “chronic defendants” often rely on the latter argument to bolster calls for tort reform, robust evidence of such practices has been lacking.⁷⁰ It is difficult to isolate defensive medicine; practitioners may order tests and procedures for complex and intertwined reasons, including not only fear of litigation, but also legitimate risk reduction for the patient, response to patient demand, reimbursement incentives, habit, and others.⁷¹ However, recent research suggests that defensive medicine is widespread, especially in high-risk specialties.⁷² To the extent it occurs – for instance, ordering tests or performing diagnostic procedures of low predictive value, or aggressively treating low-risk conditions – defensive medicine may have the perverse effect of raising the legal standard of care, by making this level of response the new norm.⁷³

(c) Inaccurate Results?

Critics also argue that the tort system not only fails to compensate people who were injured by negligent care, but that it awards compensation to people even though they were not negligently injured. The Harvard Medical Practice Study (HMPS) is often cited in support of this conclusion.⁷⁴ If the charge is accurate, the deterrent signals in judgments finding care negligent would be an unreliable guide to future conduct. Physicians in particular view the outcomes in medical malpractice litigation as haphazard, rather than reflecting accurate judgments about whether care was substandard.⁷⁵ Their conclusions are likely reinforced when legal scholars and organizations such as JCAHO do the same.⁷⁶ For instance, writing in 2005, Mello and Brennan acknowledge that studies confirm that patients who are injured by negligence

⁶⁹ Mello & Brennan 02, *supra*, n.9 at 1609; Bovbjerg 03, *supra*, n.6 at 6; Kachalia, A., Choudhry, N., Studdert, D., “Physician Responses to Malpractice Crisis: From Defense to Offense”, (2005) 33 J.L.M.E. 416 at 417.

⁷⁰ Mello & Brennan 02, *supra*, n.9 at 1607.

⁷¹ Sage, W., “Understanding the First Malpractice Crisis of the 21st Century”, in Gosfield, A., (ed.), *Health Law Handbook, 2003 Edition* (Westlaw) at 1.5 (hereafter, “Crisis”). Defensive medicine is “a deviation from sound medical practice that is induced primarily by a threat of liability”; it may reduce or improve quality, depending on the circumstances – Studdert *et al.*, *supra*, n. 2; it can indicate “assurance behaviour” or “avoidance behaviour”.

⁷² *Ibid.*, (Studdert *et al*) although as the authors note, self-reporting may skew results; see also Kessler, D., McClellan, K., “Malpractice Pressure, Managed Care, and Physician Behaviour”, in Viscusi, K. (ed.), *Regulation Through Litigation*, (Washington DC: AEI-Brookings Joint Center for Regulatory Studies, 2002), 183-200, at 185.

⁷³ Studdert *et al*, *supra*, n.2.

⁷⁴ Baker, T. “Reconsidering the Harvard Medical Practice Study Conclusions about the Validity of Medical Practice Study Conclusions”, (2005) 33 J.L.M.E. 501

⁷⁵ Mello & Brennan 05, *supra*, n.32 at 388.

⁷⁶ See eg. JCAHO, *supra*, n.18 at 4.

are more likely than others to sue, and also that the tort system does a “fairly good job” of compensating meritorious claims.⁷⁷ However, later in the same article, they comment that providers perceive malpractice litigation as punitive, and critique it for the “well demonstrated mismatch of claims and negligent adverse events”.⁷⁸ They do not explain that the mismatch is between the many negligently caused injuries and the small number of successful lawsuits, rather than between findings of negligence and treatment that met the standard of care. A recent review of closed claims confirmed that, although claims with no evidence of error are not uncommon, most of these are denied compensation. Further, most claims that involved injuries due to error did result in compensation.⁷⁹ However, the claims process was lengthy (5 years on average), and costly – for every dollar spent on compensation, 54 cents went to administrative expenses.

Criticizing the tendency to overstate how frequently incorrect attributions of negligence are made in malpractice litigation, Baker demonstrates that the HMPS finding that many medical malpractice claims do not involve negligence “rests on a small and precarious empirical base”. He cites a number of more recent studies that contradict the HMPS conclusion; they establish that medical malpractice claims handling “appropriately filters out most non-meritorious cases”, and that the presence or absence of negligence most strongly explains both the likelihood and size of payment to the plaintiff.⁸⁰ Hyman and Silver, too, undertake to rehabilitate tort law, arguing that the prospect of liability restrains providers and institutions, keeping them from acting primarily out of self-interest by threat of payment and sanctions. While the civil justice system is a very inefficient way to bring about behavioural change, they conclude that liability does make a “modest positive contribution to patient safety”.⁸¹ It could be improved by (i) shifting more liability to institutions, since they have greater capacity to implement the systemic improvements needed to reduce errors, and to monitor and control practitioners so they adhere to

⁷⁷ Mello & Brennan 05, *supra*, n.32 at 388.

⁷⁸ *Ibid.*, 411-412.

⁷⁹ Studdert, D., Mello, M., Gawande, A., Gandhi, T., Kachalia, A., Yoon, C., Puopolo, A., Brennan, T., “Claims, Errors and Compensation Payments in Medical Malpractice”, (2006) 354(19) NEJM 2024-2033. Disturbingly, payment of claims not associated with error occurred less frequently than did the converse, form of inaccuracy, i.e. non-payment of claims where there had been error.

⁸⁰ Baker, T, *supra*, n.74 at 501, 509-511.

⁸¹ Hyman & Silver, *supra*, n.65 at 917.

safe practices; and (ii) linking providers' compensation to measurable improvements in keeping patients safer, and better informed when things have gone wrong – i.e. pay for performance.⁸²

(iv) Anaesthesia – a Tort Success Story

There is general agreement that the prospect of tort liability has clearly spurred physicians to make their practices safer in a few instances. Anaesthesia is one. In the mid-1980's, the American Society of Anaesthesiologists (ASA), motivated by professional unrest over large increases in malpractice insurance premiums, interest in reducing injuries that led to claims, and negative publicity, began a review of closed claims.⁸³ Mello and Brennan recount that the objective of the study was not to address the incidence of adverse events *per se*, but to identify the major types of injuries that resulted in claims, and design strategies to improve patient safety.⁸⁴ The result was a “resounding success”, dramatically decreasing adverse events and deaths associated with anaesthesia.⁸⁵

Hyman and Silver argue that this demonstrates both that external pressure plays an important role in compelling practitioners to protect patients (since the profession had long known these types of injuries were preventable, but did not mount a concerted response until compelled by liability and negative publicity), and that an effective “feedback loop” can exist between litigation and health care quality.⁸⁶ Sage, too, concludes that “innovation that improves safety often happens in the shadow of liability”.⁸⁷ Mello and Brennan, however, argue that, although practitioners “considered patient safety a good risk management strategy” before the HMPS study raised doubts about the accuracy of negligence determinations, the context has changed; now, providers “seek merely to limit their liability”.⁸⁸ Consequently, they believe the anaesthesia experience, in which tort liability did spur significant improvements in patient safety, is not likely to be repeated.

Background to Current Tort Reforms

(i) Context

⁸² *Ibid.*, 974-984.

⁸³ Mello & Brennan 05, *supra*, n.32 at 377-8; Hyman & Silver, *supra*, n.65 at 920-1.

⁸⁴ *Ibid.*

⁸⁵ .JCAHO, *supra*, n.19 at 6, 19

⁸⁶ *Supra*, n. 65 at 921.

⁸⁷ Crisis, *supra*, n. 71 at 1.4.

⁸⁸ *Supra*, n.32 at 388.

While progress in improving patient safety has been limited, there has been a great deal of action on tort reform. Medical malpractice law operates at the state and not federal level, so tort regimes are not uniform nation-wide. Given the heavy toll errors take on patients and the high costs they impose on society, one might have expected that medical liability reform would be linked to initiatives to improve the safety of health care. Civil litigation has, after all, remained the primary means to address claims of medical error in the United States for many years.⁸⁹ Most obviously, reducing errors and the injuries that result would mean patients had less reason to sue, but this was not the focus of legislative reform or lobbying.⁹⁰ Although “[l]egal reform and improved patient safety seem inextricably intertwined...none of the traditional approaches to liability reform...aim to break this cycle. Instead, they all primarily seek to help medical professionals and their liability insurers rather than patients and patient safety improvement efforts”.⁹¹ Tort reform was undertaken in response to the most recent wave of increases in medical liability insurance premiums, not to address patient safety concerns.⁹² The American Medical Association declared malpractice reform its top legislative priority, with at least 20 states in a malpractice “crisis”, and another 24 at risk.⁹³ As with the preceding two malpractice insurance crises, changes to the law were primarily aimed at reducing the frequency and severity of claims.⁹⁴

⁸⁹ Liang & Ren, *supra*, n.23 at 527; Sage, W., “Putting the Patient Back in Patient Safety: Linking Patient Complaints and Malpractice”, (2002) 287(22) JAMA 3003-5, at 3003.

⁹⁰ Schoenbaum, S., Bovbjerg, R., “Malpractice Reform Must Include Steps to Prevent Medical Injury”, (2004) 140(1) Ann. Int. Med. 51-3, online at: <http://www.annals.org/cgi/content/full/140/1/51?ijkey=1KzXomem6UqrE&keytype=ref...> (last accessed Oct 2004)..

⁹¹ *Ibid.* at 1.

⁹² Bovbjerg 05, *supra*, n.51 at 480: reformers’ top priority was to limit the existing system of liability, not to build a better system.

⁹³ Reported in Kachalia *et al*, *supra*, n. 69 at 416-7.

⁹⁴ Marchev, M., “Medical Malpractice and Medical Error Disclosure: Balancing Facts and Fears”, National Academy for State Health Policy, #GNL53 (Dec., 2003), at 11, online at <http://www.nashp.org>; Bovbjerg 03, *supra*, n.5 at 14; Furrow *et al.*, *supra*, n.39 at 482; Hyman, D., Silver, C., *supra*, n.65 at 899 conclude: “The most popular proposals [for tort reform] – damages caps, credits for payments from collateral sources, heightened requirement for expert witnesses, and limits on contingency fees – have more to do with provider and insurer self-interest than with health care quality. Their purpose is to reduce insurance costs in the short run, not to improve delivery systems in ways that address low-quality care or decrease the frequency of harmful errors.”

Recounting that history, Sage notes that in the 1960's, what had been a stable malpractice climate and insurance environment changed, as litigation against physicians increased.⁹⁵ The 1970's were characterized by a "crisis of availability" in medical liability insurance as claims frequency and severity rose rapidly; state legislatures responded with "generous" tort reform, and also took direct measures to ensure access to insurance, such as establishing joint underwriting associations. The 1980's saw a "crisis of affordability", marked by steep increases in the price of insurance, rather than unavailability *per se*; in response, the medical profession successfully obtained tort reform in most states that had not previously enacted it. In the relatively long periods of stability between malpractice insurance crises, both courts and legislatures steadily expanded liability, as they tended to do with other industries.⁹⁶ Another malpractice insurance crisis emerged in the late 1990's and continues to the present time.⁹⁷ Commentators argue that it is more severe, and is certainly different in character than its predecessors.⁹⁸ A number of factors have combined to distinguish this insurance crisis from those that preceded it, including advances in medical technology (increasing medicine's capacity both to treat and to err, and raising patients expectations); industrialization in health care driving structural changes in care delivery; the impact of cost containment; and the real possibility that access to care will be affected as the cost of insurance increases. The responses, though, have been familiar; Sage characterizes these as "more of the same, plus a heavy dose of patient safety rhetoric".⁹⁹

(ii) Medical Malpractice, Liability Insurance and Health Policy:

Sage argues that for too long, both the debate over medical liability reform and the political process in the United States have been characterized by what he terms "malpractice exceptionalism", i.e. a sense of a sharp divide between medical liability and other issues in health

⁹⁵ Sage, "Crisis", *supra*, n.71 at 1.3-1.4; Sage, W., "The Forgotten Third: Medical Insurance and the Medical Malpractice Crisis", (2004) 23 Health Affairs 10-21 at 15 (hereafter, "Medical Insurance"); see also Bovbjerg 03, *supra*, n.6 at 15: "...erosion of reforms often occurs after symptoms of crisis subside".

⁹⁶ Sage, "Crisis", *ibid.* at 1.3-1.4; Sage, "Medical Insurance", *ibid.*; see also Bovbjerg 03, *supra*, n.6 at 15: "...erosion of reforms often occurs after symptoms of crisis subside".

⁹⁷ Kachalia, A., et al., *supra*, n.69; Mello, M., "Medical malpractice: impact of the crisis and effect of state tort reforms", Research Synthesis Report No. 10, Robert Wood Johnson Foundation (May 2006) at 15, online at: <http://www.policysynthesis.org> (last accessed May 2006): the liability crisis is beginning to show signs of abating in some states.

⁹⁸ Sage, W., 2004, "Medical Insurance", *supra*, n.95 at 12-13; see also Sage, "Crisis", *supra*, n.7 at 1.3-1.4; Kachalia et al., *ibid.*, United States. General Accounting Office, "Medical Malpractice Insurance: Multiple Factors Have Contributed to Increased Premium Rates" (Washington, 2003).

⁹⁹ Sage, "Medical Insurance", *supra*, n.95 at 10.

system design.¹⁰⁰ This has seriously affected the ability to link patient safety to risk management within health care organizations. As he says, “Physician defendants are happiest if few claims arise, fewer claims are validated by verdict or settlement, still fewer claims are publicized. Accordingly, the prudent insurer and its counsel urge secrecy, dispute fault, deflect responsibility and make it as slow, and expensive as possible for plaintiffs to continue the fight”.¹⁰¹ There is little summary information available about the actions of health insurers to address patient safety issues and performance as part of their contracts with providers.¹⁰² However, Sage argues that liability insurance must be understood as a component of the health system, and re-configured in that light.

I. Tort Reform: Limiting the Size and Risk of Judgment

The tort reforms most sought by medical interest groups are caps on damages, collateral source offset provisions, shorter limitation periods, and limits on plaintiffs’ attorneys’ compensation.¹⁰³ Furrow *et al.* divide the measures adopted in various states into four groups:¹⁰⁴

- (1) reducing claims, via shortened limitation periods, controls on legal fees, and other means;
- (2) limiting compensation paid to plaintiffs, most powerfully by (i) caps on damages awards applicable to either the non-pecuniary portion of compensation or the total recovery (as at April, 2006, 26 states had some form of damages cap, primarily on the non-economic component of loss¹⁰⁵), but also including (ii) collateral offset provisions that require or allow reduction of damages awards by the amount of other compensation; (iii) allowing or requiring courts to order damages payable by periodic payments rather than a lump sum; (iv) ending joint and several liability;
- (3) altering the plaintiff’s burden of proof, such as heightened requirements for expert witnesses; and

¹⁰⁰ Sage, “Crisis”, *supra*, n.71 at 1.6.

¹⁰¹ “Medical Insurance”, *supra*, n.95 at 10.

¹⁰² RAND Report, *supra*, n.30 at 28.

¹⁰³ Bovbjerg, 03, *supra*, n.6 at 14, and Appendix A, at 25-6, “Notable Conventional Tort Reforms”, Appendix B, 27-8 “Conventional Tort Reform Measures by State”.

¹⁰⁴ Mello, *supra*, n. 97; Furrow, B. *et al.*, *supra*, n.39 at 482-484; see Kelly, C., Mello, M., “Are Medical Malpractice Damages Caps Constitutional?”, (2005) 33 J.L.M.E. 515 at 528-533 for a chart of state damages caps laws and the results of constitutional challenges; Marchev, M., *supra*, n.94, App. A, “Selected State Tort Reform Measures”, and App. B, “Recent State Malpractice Legislative Activity”.

¹⁰⁵ Mello, *supra*, n.97, at 7-8.

(4) altering the role of the courts, for instance by mandating pre-trial screening devices or mediation.¹⁰⁶

Despite the many reforms, their effect on the rapid increases in medical liability insurance premiums has been limited.¹⁰⁷ In a 2006 study, Mello reports strong evidence that caps on noneconomic damages reduced the average size of awards by 20 to 30%, but not the frequency of claims. They have disadvantages for patient safety and equity considerations. Other tort reforms have shown little impact.¹⁰⁸

Legislative initiatives that limit liability have in some instances been countered by initiatives that could impose greater sanctions on practitioners. For instance, in what appears to be a legislative tug-of-war, voters in Florida passed a constitutional amendment in 2004 that would prohibit physicians found to have committed three or more incidents of medical malpractice (based on “clear and convincing evidence” before a court or administrative agency such as the state board of medicine) from being licensed to practice medicine in the state.¹⁰⁹ This initiative was reportedly championed by Florida trial lawyers in response to an aggressive tort reform campaign by the Florida Medical Association to cap non-economic damages in medical malpractice cases at \$250,000.¹¹⁰ Commentators expect the new provision to increase pressure to settle cases prior to any final determination (whether well-founded or not), to avoid application of the “three strikes and you’re out” law. Tort reform in the United States is highly politicized, with well organized and sophisticated pressure groups on all sides.

Some reforms are meant to align incentives between malpractice and patient safety regimes. In Pennsylvania, medical malpractice reforms were accompanied by the first state-wide system requiring reports of adverse events that harmed patients, near-misses and infrastructure failures to a central authority, as well as written disclosure of serious adverse events to patients,

¹⁰⁶ See generally Struve, C., “Expertise in Medical Malpractice Litigation: Special Courts, Screening Panels, and Other Options”, Project on Medical Liability Reform in Pennsylvania (Pew Charitable Trusts, 2003), online at <http://www.medliabilitypa.org> (last accessed April, 2006); Liebman, C., Hyman, C., “Medical Error Disclosure, Mediation Skills, and Malpractice Litigation: A Demonstration Project in Pennsylvania”, Project on Medical Liability Reform in Pennsylvania (Pew Charitable Trusts, 2005), online at: <http://www.medliabilitypa.org> (last accessed April 2006).

¹⁰⁷ Kachalia *et al*, *supra*, n.69 at 418.

¹⁰⁸ *Supra*, n.97 at 12.

¹⁰⁹ Zedeker, D., “Medical malpractice bills” (Apr. 22, 2005), online at: <http://www.winktv.com/x14975.xml?ss=print> (last accessed Jan. 2006).

¹¹⁰ Barach, P., “The Unintended Consequences of Florida Medical Liability Legislation”, Perspectives on Safety, Agency for Health Research and Quality (n.d.), online at: <http://www.webmm.ahrq.gov/perspective.aspx?perspectiveID=14> (last accessed Jan. 2006).

and imposing penalties for failure to do so.¹¹¹ Provisions shielding error reports from use in civil litigation depend on compliance with the state reporting system.¹¹²

II. Tort Reform: No-Fault Administrative Compensation

Replacing tort liability with administrative systems to determine compensation on a no-fault basis had been proposed even before the IOM's 1999 Report. Proponents argue that they provide a fairer way to compensate injured patients, avoid the damaging effects of adversarial civil litigation, and reduce malpractice insurance premiums.¹¹³ However, no-fault compensation schemes have been implemented in only a few instances for narrowly defined categories of injuries. In 1987 and 1988, Virginia and Florida enacted administrative compensation systems for certain severely injured newborn babies.¹¹⁴ They did so out of concern about rising malpractice insurance premiums for obstetricians in particular, which were thought to threaten patients' access to obstetric care.¹¹⁵ When litigated, these types of cases typically involve high claims for compensation, take a long time to resolve, and are unpredictable in outcome. Both states narrowly limit eligibility for compensation, and while both provide broad benefits, they are more limited than those potentially available in a successful tort claim.¹¹⁶ Bovbjerg nonetheless maintains that compensation levels claimants actually receive are comparable to those in the tort system.¹¹⁷ Eligibility is determined administratively; benefits are paid as expenses accrue, and are secondary to other sources of compensation. Virginia requires referral of practitioners who have been the subject of a claim to the state medical board, but claims are not reported to the National Practitioner Databank.¹¹⁸ Physician participation is voluntary; funding is raised by levies on hospitals and physicians; participating physicians pay higher levies.¹¹⁹ Evaluation of the programs is hampered by the small number of claims that qualify, and claims have been too infrequent to draw lessons for patient safety

¹¹¹ Furrow, *supra*, n.47 at 212-217.

¹¹² *Ibid.*

¹¹³ See eg. Weiler, P. *et al.*, *A Measure of Malpractice: Medical Injury, Malpractice Litigation and Patient Compensation* (Cambridge: Harvard U. Press, 1993).

¹¹⁴ Furrow *et al.*, *supra*, n. 39 at 488-9.

¹¹⁵ Mehlman, M., *supra*, n.50 at 78; Struve, F., "Public Medical Malpractice Insurance", Project on Medical Liability in Pennsylvania (Pew Charitable Trusts, 2004), online at: <http://www.medliabilitypa.org> (last accessed April 2006), at 55.

¹¹⁶ Bovbjerg, R., "Liability Reform Should Make Patients Safer", (2005) 33JLME 478-500, at 484.

¹¹⁷ Mehlman, *supra*, n.50 at 77.

¹¹⁸ Furrow *et al.*, *supra*, n. 39 at 489; Sloan, *supra*, n.115 at 64..

¹¹⁹ *Ibid.*(Furrow).

purposes.¹²⁰ “Leakage” of cases to the tort system, adequacy of future funding, and provider and hospital reluctance to tell parents about the programs have been identified as concerns.¹²¹

A federal no-fault compensation system, the *National Childhood Vaccine Injury Act of 1986*, was also created because of concerns that open-ended tort liability was causing too many manufacturers to stop producing vaccines, threatening access.¹²² Claimants are automatically compensated if the injury they suffer is one of the listed side effects in the Vaccine Injury Table; otherwise, they must prove that the vaccine caused or significantly aggravated their condition, but need not establish fault. Again, benefits are broad, but more limited than those recoverable in a successful tort claim. Claims are determined before a federal court officer. Claimants who are unsuccessful, or who do not accept the compensation offered, can still sue in tort, but must proceed in federal court.¹²³ Evaluation has been largely positive with respect to both the process and the scheme’s effect on stabilizing the vaccine market.¹²⁴

III. Tort Reform: Shielding Information from Disclosure in Litigation

Some commentators go beyond criticizing the medical liability system’s shortcomings on the compensation, deterrence and corrective justice fronts to castigate it as inimical to and in conflict with basic patient safety premises. Patient safety advocates consider it essential that errors be reported, so that providers can investigate mistakes and learn how to prevent them in the future. JCAHO concludes that the “tort system inspires suppression”.¹²⁵ Brennan, a physician, lawyer, and lead investigator on the HMPS investigative team, writes of the “dead weight of the legal system” holding hospitals back from embarking on error prevention programs.¹²⁶ Don Berwick, a leading patient safety advocate and the force behind the 100,000 Lives Campaign, reportedly refers to the tort system as “poison” to openness and honesty.¹²⁷ Similar sentiments abound among patient safety advocates – that fears of legal liability sparked

¹²⁰ Sloan, *supra*, n. 115 at 56, 63: 72 claimants paid in 15 years in Virginia; 161 claimants paid in 14 years in Florida, as at 2002.

¹²¹ *Ibid.*, at 58; Bovbjerg 05, *supra*, n.51 at 484.

¹²² *National Childhood Vaccine Injury Act of 1986*, Title III of Public Law 99-660, 42 USC Sec. 300a-1 et seq.; Bovbjerg, 05, *supra*, n.51 at 483.

¹²³ *Ibid.* (Bovbjerg) at 484; Furrow *et al.*, *supra*, n.39 at 492.

¹²⁴ *Ibid.* (Bovbjerg) at n.98 and references cited therein.

¹²⁵ JCAHO, *supra*, n.19 at 11.

¹²⁶ Brennan, T., “The IOM Report: Could It Do Harm?”, (2000) 342 NEJM 1123; see also Bov 05, 479, commenting that it is difficult to implement patient safety fully in the shadow of liability

¹²⁷ Bovbjerg 05, *supra*, n.51 at 479.

by the tort system drive errors underground and impede efforts to improve patient safety.

Physician and lawyer William Sage captures the irony in this position well:

“For decades, the medical profession denounced malpractice suits on the ground that few true quality problems existed.... patient safety gurus prov[ed] the profession wrong. Nonetheless, these reformers echo the ‘no lawyers’ refrain of the very physicians whose overconfidence they exposed, although they argue against liability not because the health care system is perfect, but because it can only become so if sheltered from outside scrutiny”.¹²⁸

Protecting reports about errors and quality assurance (QA) information from disclosure in legal proceedings and to patients became the second major focus of tort reform, vigorously lobbied for by patient safety advocates as well as its traditional supporters, organized medicine and malpractice insurers.¹²⁹ This section analyzes developments in the law governing reporting (providing information to oversight bodies) and disclosure (providing information to patients and families).

(i) Error Reporting Systems

Many states have implemented voluntary or mandatory reporting systems for adverse events, and also adopted or expanded peer review protection for information disclosed or gathered in connection with quality assurance activities, preventing its use in medical malpractice lawsuits, and sometimes more broadly. Following the IOM Report and the most recent round of increases in malpractice insurance premiums, more states imposed mandatory reporting systems (23 states by 2005), while acceding to renewed pressure by providers for stronger protection of reported data from disclosure in legal proceedings.¹³⁰ The Institute of Medicine had proposed a system for mandatory reporting of serious adverse events with significant public access, stating that “requests for confidentiality and protection from liability seem inappropriate in this context”.¹³¹ It also recommended confidential, voluntary reporting systems for near misses and errors that caused minor or moderate injuries.¹³² Most states have enacted protections from disclosure that provide more expansive protection than this.¹³³ A 2003

¹²⁸ Sage, W., “Principles, Pragmatism and Medical Injury”, (2001) 286(2) JAMA 226-228 at 226.

¹²⁹ Bovbjerg 05, *supra*, n.51.

¹³⁰ Rosenthal, J., Booth, M., “Maximizing Adverse Event Data to Improve Patient Safety”, Nat’l. Academy for State Health Policy (Oct. 2005) at 3, online at: <http://www.nashp.org>; see also RAND Report, *supra*, n.29 at 28-29.

¹³¹ IOM Report, *supra*, n.4 at 102.

¹³² From an ethical point of view, the guarantee of confidentiality is justified only by the principle of utility, i.e. that health care providers will not participate otherwise: Sharpe, V., “Introduction: Accountability and Justice in Patient Safety Reform”, in Sharpe, V. (ed.), *Accountability: Patient Safety and Policy Reform* (Washington DC: Georgetown U. Press, 2004) at 8.

¹³³ Marchev, *supra*, n.94 at.2.

study prepared for the National Academy for State Health Policy reviews various types of state confidentiality provisions in place, ranging from peer review protection (the most vulnerable to challenge) to inclusion as an integral part of a reporting system established by statute (the most reliable protection).¹³⁴ It points out that, despite provider concerns, it is unclear whether reporting actually does lead to increased litigation.¹³⁵

Neither voluntary nor mandatory reporting systems have been particularly effective at surfacing errors. The Joint Commission on Accreditation of Healthcare Organizations, for instance, has had a voluntary Sentinel Events Reporting policy in place since 1996. However, it receives only about 400 new reports of sentinel events (i.e. serious adverse events) each year – nowhere near the 44,000-98,000 error-related deaths (let alone the far more numerous injuries) that the IOM estimated occurred annually.¹³⁶ State systems that require mandatory error reporting are also plagued by under-reporting, facilitated by ease of avoidance and failure to sanction non-compliance.¹³⁷ The newest generation of mandatory reporting systems attempts to rectify this: some broaden reporting requirements to include near misses as well as adverse events that caused harm, and impose penalties for non-compliance. While they also shield information from use in legal proceedings, protection may not be absolute, but conditional on compliance with the statutory reporting system in order to encourage compliance.¹³⁸ The extent of protection afforded by the state systems varies and can give rise to tension. Providers and institutions want broad protection; state governments may be prepared to protect information from disclosure in civil litigation, but may want to use it in the course of regulatory proceedings or in connection with licensure or facility accreditation.¹³⁹ There are also conflicts between the need for data specificity in order to make reports useful, and legal requirements to aggregate data to protect privacy.¹⁴⁰ This, too, can affect compliance.

¹³⁴ *Ibid.* (Marchev), at 5-8; Table 1 describes different state systems.

¹³⁵ Hyman & Silver, *supra*, n.65 at n.94, quoting Leape 2003 347 NEJM 1633, 1635: no link between reporting and litigation has ever been demonstrated.

¹³⁶ JCAHO, *supra*, n.19 at 28.

¹³⁷ Furrow, *supra*, n.47 at 204, 182; Marchev, *supra*, n.94 at 2.

¹³⁸ Furrow, *supra*, n. 47 at 212-7.

¹³⁹ Marchev, *supra*, n.94 at 10; but see Liang & Ren contra, *supra*, n.23 at 525: institutions fear loss of accreditation from reporting to JCAHO.

¹⁴⁰ RAND Report, *supra*, n.30 at 28-29; see generally Flowers, L., Riley, T., “State-Based Mandatory Reporting of Medical Errors: An Analysis of Legal and Policy Issues” (Portland ME: Nat’l. Academy for State Health Policy, 2001), online at <http://www.nashp.org>.

Reports alone will not prevent errors. In order to be effective, reporting systems must be adequately resourced to analyze data properly, disseminate lessons learned, and ensure compliance.¹⁴¹ Health care institutions also need sufficient resources to respond adequately to advice received. Wachter and Shojania note that at one point, JCAHO was pressured to declare a temporary moratorium on new sentinel event alerts (identifying clear and present dangers) until the old ones had been cleared away, because hospitals did not have the resources to respond.¹⁴² State systems' focus on improving performance following events reported has been weak, and the reporting systems themselves are vulnerable to financial pressure occasioned by shrinking budgets and political opposition.¹⁴³

The federal *Patient Safety and Quality Improvement Act*, which came into force in 2005, is meant to address concerns about whether errors and analyses reported to a third party, such as a state agency or JCAHO, are entitled to legal privilege protections.¹⁴⁴ Citing the IOM Report, the importance of supporting a non-punitive culture of learning, and the superiority of voluntary reporting systems to do so, the statute provides broad protections from use in civil, criminal and administrative proceedings at the federal, state and local levels for reports of patient safety information to and among patient safety organizations.

It is unclear whether increasing protection from disclosure for data about errors and patient injury will actually lead to an increase in reporting.¹⁴⁵ The causes of under-reporting are broader and more complex than concerns about legal liability. Once powerful stakeholders achieve strong statutory protections, they are difficult to repeal.¹⁴⁶ Consequently, Marchev suggests that states enacting such provisions would be wise to include sunset provisions in the legislation to ensure review of their effectiveness. If under-reporting persists, it may be necessary to change strategies to boost compliance.¹⁴⁷

(ii) Disclosure to Patients

¹⁴¹ Wachter, *supra*, n.8 at W4-538.

¹⁴² Wachter, R, Shojania, K., *Internal Bleeding: The Truth Behind America's Terrifying Epidemic of Medical Mistakes* (N.Y: Rugged Land Press, 2004), at 288.

¹⁴³ RAND Report, *supra*, n.30, at 28-9.

¹⁴⁴ *Supra*, n.31. The statute includes limited whistleblower protection as well.

¹⁴⁵ Marchev, *supra*, n.94 at 13; Furrow, *supra*, n.47 at 203 reports that in the only study to that time of the issue, there was "little difference" in reporting between systems that provided confidentiality and those that did not.

¹⁴⁶ *Ibid.* (Marchev).

¹⁴⁷ *Ibid.*, 10, 13.

It is widely recognized that there is an ethical obligation to disclose harm to patients.¹⁴⁸ Disclosure is urged on the grounds of moral obligation, and also as an important component of the culture of openness needed to establish safe systems. JCAHO's accreditation standards have required disclosure of sentinel events and other unanticipated outcomes of care to patients since 2001.¹⁴⁹ Nonetheless, disclosure by either institutions or providers is not widespread.¹⁵⁰ JCAHO reports that in a recent study, half the hospitals surveyed were reluctant to comply with this standard because of fear of medical liability lawsuits.¹⁵¹ Even with many states enacting laws that prohibit relying on apologies as an admission of liability in legal proceedings, JCAHO reports that if disclosure is extended to include the offer of an apology, hospitals and physicians "...are even more likely to gravitate to traditional 'defend and deny' behaviors".¹⁵² Evaluating progress 5 years after the IOM Report, patient safety leaders Leape and Berwick expressed the hope that the "ethically embarrassing debate over disclosure of injuries to patients" is fading, but acknowledged that "actual practice still lags far behind rhetoric".¹⁵³ While JCAHO certainly has a model of what *should* occur, Sage notes that no models have yet been developed to successfully *implement* disclosure of adverse events to patients.¹⁵⁴

Some states have made disclosure of adverse events to patients mandatory.¹⁵⁵ However, both the structure of patient safety programs and laws cloaking QA activities in secrecy can make it even more difficult for patients to get information about what happened to them and why. As Bovbjerg notes, the safety-reform movement "favors internal openness, largely surrounded by an external wall to shut out injured patients and their lawyers".¹⁵⁶ A 2005 study of patients with health problems in six countries confirms that patients are still often kept in the dark about medical error. Of the patients surveyed in the U.S., 22% reported having experienced

¹⁴⁸ Bovbjerg 05, *supra*, n.51 at 482, citing the American Medical Association; see also Pellegrino, E., "Prevention of Medical Error: Where Professional and Organizational Ethics Meet", in Sharpe, *supra*, n.126 at 83-98.

¹⁴⁹ *Supra*, n.30 at 27.

¹⁵⁰ Bovbjerg 05, *supra*, n.51 at 480.

¹⁵¹ JCAHO, *supra*, n.19 at 27-28.

¹⁵² *Ibid.*

¹⁵³ *Supra*, n.18 at 2388.

¹⁵⁴ "Medical liability and patient safety", *supra*, n.26 at 31. The "Sorry Works" campaign seems to be taking positive steps to develop uniform processes for disclosure and apology – see <http://www.sorryworks.net> (last accessed April 2006).

¹⁵⁵ Pennsylvania was the first state to require written disclosure of adverse events to patients in 2002, with Nevada and Florida following suit shortly thereafter – JCAHO, *supra*, n.19 at 14.

¹⁵⁶ Bovbjerg 05, *supra*, n. 51 at 480.

an error in their medical care or medication, and of those, 75% had not been told about the mistake by doctors involved in their care, although for many, serious health problems resulted.¹⁵⁷

Disclosure is also promoted as a form of risk management, on the basis that open communication when things have gone wrong reduces the likelihood of litigation.¹⁵⁸ While there is evidence that non-disclosure predisposes people to sue, Bovbjerg reports being able to find only one published study on the converse, i.e. that disclosure is associated with either reduced litigation or lower payments to injured patients.¹⁵⁹ Beyond anecdotal experience that the effects of full disclosure are salutary, evidence that it bears a direct relationship to reducing the frequency and severity of claims is very limited. Particularly when patients have suffered serious harm, they may need to sue regardless of disclosure and apology, in order to offset the financial burden of their injuries. This is especially likely in the United States, where there is no system of universal coverage for the costs of health care.

Increasing restrictions on the various avenues to access information about health care and the results of treatment can spark a backlash, as increasingly dissatisfied injured patients and consumers become more assertive in demands for disclosure of medical errors.¹⁶⁰ Evidence of this can be seen in some recent state legislative initiatives. For example, in Florida, a constitutional amendment passed in 2004 allows patients who suffered adverse events in the course of their care to access documentation about the incident and/ or similar incidents affecting other patients, including records of provider deliberations such as QA reviews.¹⁶¹ This is unlikely to be an isolated instance of efforts to circumvent increasingly stringent restrictions on access to information.

(iii) Using Medical Malpractice Information To Improve Patient Safety

Despite its antipathy towards the tort system, JCAHO recognizes that claims information can provide important information about how patients are injured, and thus, could assist in improving quality and safety.¹⁶² However, access is limited, because most cases are settled on

¹⁵⁷ Schoen *et al.*, *supra*, n.16 at W5-514.

¹⁵⁸ See eg. JCAHO, *supra*, n.19 at 27.

¹⁵⁹ Bovbjerg 05, *supra*, n.51 at 482.

¹⁶⁰ Marchev, *supra*, n.94 at 11.

¹⁶¹ Greene, L., "Patients' rights law narrowed", St. Petersburg Times State (Apr. 29, 2005), online at: http://www.sptimes.com/2005/04/29/State/Patients_rights_law_.shtml (last accessed Jan. 2006); Barach, *supra*, n.106.

¹⁶² JCAHO 05, *supra*, n.19 at 37; see also Marchev, *supra*, n.94 at 11.

terms that require confidentiality. Even when cases go to trial, access is available only for closed claims, entailing long delays. JCAHO and others have called for changes to these rules to provide greater access to this data for patient safety purposes.

Physicians named in medical liability judgments and settlements, as well as disciplinary actions must be reported to the National Practitioner Databank (NPDB).¹⁶³ Access to this information is limited: hospitals and licensing boards can access it in order to track physician performance issues, but it is not available more widely – for instance, for use in medical malpractice litigation.

Not surprisingly, there is disagreement about what use should be made of NPDB data. Patient advocates note that a small percentage of physicians are involved in a high proportion of payouts reported to the NPDB, and criticize the disparity between the incidence of payments in malpractice claims and the lack of disciplinary action or review by state licensing boards.¹⁶⁴ They consider this evidence that authorities are not being sufficiently vigilant in monitoring for problematic practitioners. Critics of the NPDB consider this a simplistic and misleading analysis.¹⁶⁵ JCAHO has called for the system to be redesigned or replaced, both because the information it contains is substantially incomplete, and because its focus on individual practitioners is incompatible with the patient safety movement’s focus on systemic analysis.¹⁶⁶

Many physicians argue that claims history is not useful in judging performance, and argue that the NDPB is effectively disseminating misinformation. For instance, an insurer may settle a claim for economic reasons (the high costs of proceeding to trial), or because the plaintiff’s circumstances (age, extent of injuries, and other factors) were considered particularly sympathetic, even though the physician involved was not negligent. Yet as Wachter recounts, that case will be reported to the NPDB, “which is checked every time the physician applies for a new job—much like sex offenders are obliged to register with the local police every time they move”.¹⁶⁷ The analogy is flawed, but clearly conveys physicians’ resentment that NPDB data

¹⁶³ JCAHO, *supra*, n.19 at 15.

¹⁶⁴ Wachter, R., Shojania, K., *Internal Bleeding: The Truth Behind America’s Terrifying Epidemic of Medical Mistakes* (N.Y: Rugged Land, 2004), at 324.

¹⁶⁵ *Ibid.*

¹⁶⁶ JCAHO, *supra*, n.19 at 15, 37-38 citing United States. General Accounting Office, “National Practitioner Data Bank: Major improvements are needed to enhance Data Bank’s reliability”, GAO-01-130 (Washington: GAO, 2000).

¹⁶⁷ Wachter & Shojania, *supra*, n.142 at 309.

informs external accountability mechanisms. They consider it unfair, inaccurate, inappropriate and unnecessary. Tying regulatory oversight to the medical liability system intensifies practitioners' determination to resist findings of legal liability.¹⁶⁸

IV. Proposals for More Radical Law Reform

Proposals have also been made for more radical restructuring of the medical liability system. These involve substantial reform of one or more of the central attributes of the tort system, i.e. what constitutes a compensable event and eligibility; the measure of compensation; mechanisms for and sources of payment; and the forum for dispute resolution.¹⁶⁹ The different approaches centre on (i) creating alternative mechanisms to compensate patients; (ii) resolving disputes through a "no fault" administrative system; and (iii) shifting liability from individuals to organizations.¹⁷⁰ Elements of all three may be combined.

(i) The Institute of Medicine: Demonstration Projects

The Institute of Medicine called for a series of demonstration projects to test no-fault systems for injury compensation.¹⁷¹ It suggested that four or five states create non-judicial injury compensation systems that would be patient-centred and focused on enhancing safety. The aim was to develop systems that provided fair, reasonable, timely compensation for avoidable injuries to a greater number of patients, while stabilizing the malpractice insurance market by limiting health care providers' financial exposure. Two administrative models were proposed:¹⁷²

(1) Provider-based early payment, with limits on damages for self-insured or experience-rated provider groups that agreed to identify and promptly compensate patients for avoidable injuries, with state-set limits on compensation for pain and suffering, and backed by federal re-insurance; and

(2) Statewide administrative resolution: States would grant all health care providers immunity from most tort liability in exchange for mandatory participation in a state-sponsored administrative system to compensate patients for avoidable injuries.

¹⁶⁸ Sage, W., "Reputation, Malpractice Liability, and Medical Error", in Sharpe, V., *supra*, n.126, 159-184, at 175.

¹⁶⁹ Furrow *et al.*, *supra*, n.39 at 485-6.

¹⁷⁰ JCAHO 05, *supra*, n.19 at 31.

¹⁷¹ Institute of Medicine, *Fostering Rapid Advances in Health Care: Learning from System Demonstrations* (2002), online at: <http://www.nap.edu/books/0309087074.htm> (last accessed July 2005).

¹⁷² Furrow *et al.*, *supra*, n.39 at 487-8, Mehlman, *supra*, n.50 at 78-79.

These systems would incorporate incentives for health care providers to report and analyze medical mistakes, and involve patients in efforts to reduce errors.¹⁷³ The demonstration projects recommended have not been implemented to date.

(ii) Voluntary Reform:

In the absence of progress on state-wide demonstration projects, academic commentators and policy makers have continued to develop and promote reforms meant to integrate error prevention with better ways to compensate injured patients who have been harmed, adding “workarounds” that take into account constraints in the political environment that make substantial law reform highly unlikely.¹⁷⁴ Some represent radical departures from tort law; others could be adapted to fit within the existing medical liability system. Bovbjerg divides the alternatives into four categories: those that (i) voluntarily increase disclosure within the existing tort system; (ii) encourage disclosure by allowing defendants who make “early offers” to pay limited damages; (iii) replace tort with an administrative system of compensation; and (iv) use pre-determined lists of “avoidable classes of events” (ACE’s) as the basis for awards of compensation.¹⁷⁵ JCAHO has also canvassed the alternative system reforms most frequently proposed: strict liability / no-fault administrative systems, preventable events (ACE’s), mediation-early offer, health courts, and enterprise liability.¹⁷⁶ Its summary and assessment is included in Appendix A to this chapter. Of the various options, the two that attract the most support are enterprise liability and administrative systems of compensation meant to replace the tort system.¹⁷⁷

(a) Enterprise Liability:

Enterprise liability can co-exist with tort and no-fault systems. It changes the locus of liability for patient injuries from individual physicians to hospitals or other health care institutions, without requiring major changes to other rules for proving liability and damages. As in Canada, hospitals can already be held directly liable in negligence for breaches of the standard of care they owe patients, and vicariously liable for the negligence of employees. Developments

¹⁷³ Marchev, *supra*, n.94 at 12.

¹⁷⁴ Bovbjerg 05, *supra*, n.51 at 481.

¹⁷⁵ *Ibid.*

¹⁷⁶ JCAHO, *supra*, n.19 at 35-36, Table I, reproduced in Appendix A to this chapter.

¹⁷⁷ See, eg. Mello & Brennan 02, *supra*, n.9 at 1597-8; Mello & Brennan 05, *supra*, n.32 at 398; Studdert, D., Brennan, “Toward a Workable Model of ‘No-Fault’ Compensation for Medical Injury in the United States”, (2001) 27 *Am J.L. & Med.* 225.

in the law regarding corporate negligence, vicarious liability, and non-delegable duties of care in the United States increasingly shift the locus of liability from non-employed physicians to hospitals.¹⁷⁸ Consequently, moving to enterprise liability would not be such a radical departure from existing trends in American medical liability law.

Enterprise liability fits with the philosophy of patient safety -- i.e. that the causes of most error are systemic, and solutions need to be as well. Institutions, not individual practitioners, control systems of care and can effect such changes. As a practical matter, institutions are better able to undertake systemic analysis, and also have the ability to plan and institute effective system-wide responses. Enterprise liability is also favoured because it would both sharpen and better focus the deterrent signals sent by a finding of liability. As explained previously, American commentators consider the lack of a compelling “business case for safety”(since hospitals must bear the costs of most patient safety improvements, but patients and providers reap the benefits in reduced injuries and decreased costs of error) a significant drawback to the current medical liability system. Shifting to enterprise liability would align responsibility for the costs of safer systems with the prospect of benefiting from reduced liability, increasing the incentives for health care institutions to invest resources to make patient safety a priority.¹⁷⁹ Supporters of enterprise liability fine-tune their proposals further, with provision for measures such as experience-rated contributions to increase incentives for safety,¹⁸⁰ and “channeling”, which aggregates physicians into larger enterprises such as hospitals, and consolidates malpractice coverage in a single carrier.¹⁸¹

Despite the appeal of being relieved of the prospect of individual liability, earlier proposals to move to a system of enterprise liability encountered strong opposition from organized medicine.¹⁸² Physicians are concerned about the loss of autonomy entailed in such a shift; they foresee professional control over clinical decision-making becoming subject to

¹⁷⁸ For an overview of developments in hospital liability, see generally Furrow *et al.*, *supra*, n.39 at 413ff, Ch. 6, Liability of Healthcare Institutions.

¹⁷⁹ See eg. Mello & Brennan 02, *supra*, n.9.

¹⁸⁰ *Ibid*; Sage, *supra*, n.128 at 227.

¹⁸¹ Mello & Brennan 02, *supra*, n.9 at 1624; Hyman & Silver, *supra*, n.65 at 974-5; Mello and Brennan consider this a more politically feasible solution than replacing individual physician liability with full-fledged enterprise liability.

¹⁸² Furrow *et al.*, *supra*, n.39 at 491.

institutional control.¹⁸³ In reality, moves in that direction are already well advanced in the United States, with the rise of managed care organizations and their influence on the practice of medicine, the purchase of group medical practices by hospitals, and other developments that substantially affect the conduct of clinical practice.¹⁸⁴ In any event, enterprise liability focused on shifting liability to hospitals was largely overtaken by events in the U.S., as managed care organizations rather than hospitals became the new locus of control over financing and delivery of care.¹⁸⁵ Proposals for enterprise liability remain alive and well in debates over patient safety and tort reform.

(b) No-Fault Administrative Systems:

Experience with administrative compensation systems for injuries caused by medical care in the United States has been very limited. However, proponents envisage a broadly available alternative to the current fault-based system. The threshold for eligibility for compensation proposed would be avoidability of the injury, rather than negligence.¹⁸⁶ Eligibility would be determined through administrative procedures; some proposals incorporate schedules of compensable injuries and events, and/or determination by specialized panels as well.¹⁸⁷ Administrative systems are compatible with enterprise liability, and can include provisions to encourage injury prevention, such as experience-rated contributions to the compensation fund and incentives for reporting error.¹⁸⁸ Supporters recognize that, in order to ensure that “no-fault” does not mean no accountability, systems to ensure ongoing provider competence and quality would have to be revised and strengthened as well.¹⁸⁹

Critics of no-fault systems have raised concerns about cost. At present, many people who have suffered even serious injuries caused by clinical negligence do not sue. Under a no-fault system, eligibility would be easier to establish, and more people would be compensated.

¹⁸³ Sage, W., “Unfinished Business: How Litigation Relates to Health Care Regulation”, (2003) 28 J.H.P.PL. 387 at 410.

¹⁸⁴ Furrow *et al.*, *supra*, n.39 at 491.

¹⁸⁵ Morreim, H., “Medical Errors: Pinning the Blame Versus Blaming the System”, in Sharpe, *supra*, n.126, 213-232, at 218. Consideration of the operation of managed care or the vast literature to which it has given rise in the United States is beyond the scope of this study.

¹⁸⁶ JCAHO, *supra*, n.19 at 35; Mehlman, *supra*, n.50 at 74.

¹⁸⁷ With respect to the latter, commentators warn that specialized “health courts” pose risks of politicization, narrowed judicial perspective, greater costs to litigants (Struve, *supra*, n.106 at 4), and “capture” by or inappropriate alignment with health providers (Mehlman, *supra*, n.50).

¹⁸⁸ Bovbjerg 05, *supra*, n.51 at 485; Mello & Brennan 02, *supra*, n.32 at 1633..

¹⁸⁹ See, eg. Studdert, D., “On Selling ‘No-Fault’”, in Sharpe, V., *supra*, n.132, 203-212, at 211.

Opponents argue that either the cost of such a system would be prohibitive, or the level of compensation provided, particularly to those most seriously injured, would be seriously inadequate.¹⁹⁰ Mehlman notes that the only examples of no-fault systems currently operative in the health care context in the United States involve situations where ensuring continued access had become a concern. As noted previously, supporters nonetheless argue that on the whole, experience has been sufficiently positive to warrant closer consideration.

(c) Reform Without Law Reform

Increasingly, reformers are proposing ways to work around legislative inaction by developing alternative systems that could be implemented without substantial law reform. They no longer seem to expect that any comprehensive alternative to the medical liability system can be enacted successfully in the current political environment.¹⁹¹ The entrenched interests arrayed on all sides of the debate on tort reform are simply too powerful and too divided. Bovbjerg, for example, suggests that health care organizations implement one of the alternatives by contracting with patients (organized in groups to equalize bargaining power or through employer-provided health benefits plans, and protected by revamped consumer protection laws).¹⁹² Alternatively, “virtual” demonstration projects could be conducted, shadowing the experience of patients and determining what would have occurred had one of the alternatives been in place, in order to evaluate their performance.¹⁹³ Taking a different approach to the idea of demonstration projects, Sage points out that the federal government could implement alternatives with a comprehensive restructuring of medical malpractice claims involving Medicare and Medicaid patients.¹⁹⁴ This approach would enlist government support in its capacity as funder of health care services, rather than as lawmaker.

Patients, Patient Safety and Medical Malpractice Litigation

Although patient safety advocates routinely acknowledge that patients are important partners in making care safer, such avowals are difficult to reconcile with lobbying for legislative change to keep more information confidential and inaccessible to patients. The actual involvement proposed for patients is quite limited; they are usually directed to ask more

¹⁹⁰ Mehlman, *supra*, n.50 at 75-6.

¹⁹¹ Bovbjerg 05, *supra*, n.51 at 490.

¹⁹² *Ibid.* at 491.

¹⁹³ *Ibid.*

¹⁹⁴ Sage, “Medical Insurance”, *supra*, n.95 at 20.

questions and report unusual occurrences in their care.¹⁹⁵ However, patients may not know what to expect, or that they have been harmed by an adverse event. Commentators caution against unrealistic and inappropriate plans to shift too much responsibility to sick patients to ensure there is no error in their care.¹⁹⁶ Not only do they lack the practical support needed to assume this role, but recent research suggests that patients who are seen as more assertive and demanding run the risk of being met with defensive behaviour by physicians, perhaps extending beyond suspicion to confrontation and abandonment.¹⁹⁷

Patients who have been injured in the course of treatment need compensation, especially when they are also responsible for the costs of the health care they require as a result of medical error. Entitlement to compensation under the current system is fault-based, i.e. it requires proof that the injuries were the caused by negligence. Most people will not be able to sue, given the high costs and unpredictability involved, and those that do face a difficult road, not made any easier by some of the legislative reforms sought in the name of patient safety. As Bovbjerg notes, "...the public face of patient safety has not been friendly to injured patients".¹⁹⁸ This reality adds weight to the case for integrating efforts to improve both patient safety and compensation for injured patients.

The Public, Patient Safety and Medical Malpractice Litigation

The IOM bypassed organized medicine and health administration by taking its message about the toll exacted by medical error directly to the public when it released *To Err is Human*. However, five years later, leading patient safety advocates Leape and Berwick concluded that public concern had proved "too evanescent" to sustain sufficient external pressure on the health care system to bring about change.¹⁹⁹ Others disagree, and believe public and media attention to particularly egregious incidents has had a positive effect on patient safety.²⁰⁰ Returning to the example of anaesthesia described previously, one of the factors that prompted the ASA to undertake its analysis of patient injury was the intense media and public attention to a few cases

¹⁹⁵ Liang & Ren, *supra*, n.23; JCAHO 05, *supra*, n.19 at 10: patients should be "members of the team" and "educated advocates" in their own care.

¹⁹⁶ Entwistle, V., Mello, M., Brennan, T., "Advising Patients About Patient Safety: Current Initiatives Risk Shifting Responsibility", (2005) 31 J. Qual. & Pt. Safety 483-494.

¹⁹⁷ Studdert, D., *et al.*, *supra*, n.2.

¹⁹⁸ Bovbjerg 05, *supra*, n.51 at 478.

¹⁹⁹ *Supra*, n.18, at 2389.

²⁰⁰ Wachter, *supra*, n.142 at 270.

where error was apparent. This suggests that public pressure can play a significant, if sporadic, role.²⁰¹

Sage comments that, without a climate of trust and effective internal and external controls, efforts to reduce practitioners' legal liability will be strenuously resisted.²⁰² The public wants to "retain avenues of self-help", including litigation, even if realistically, the high costs and uncertainty preclude a lawsuit in all but a few cases.²⁰³ The threat of legal liability is still widely perceived as an important, even if theoretical pressure.

Tort Law as Regulation:

As noted previously, American legal scholars tend to emphasize the deterrent functions of tort law. Some take that position further, arguing that tort law should be understood as a form of regulation, defined broadly as the organized and deliberate leveraging of power or authority to effect changes in behaviour.²⁰⁴ From that viewpoint, tort is "part of an overall regulatory strategy" that sets standards of behaviour, monitors compliance and enforces those standards; its effectiveness is evaluated by how well it performs those functions.²⁰⁵ The focus then becomes determining how best to create synergies between public and private law to achieve desired goals. While this argument has not yet been fully developed in the health law field, it has attracted some support in scholarship on tort reform and patient safety.²⁰⁶ Commenting on efforts to theorize tort law as regulation in regulatory scholarship generally, some Commonwealth writers caution that analyzing tort law exclusively through a regulatory lens distorts understanding.²⁰⁷ They accept that tort law certainly has instrumental and distributional effects (despite that not being its explicit orientation), and also that it is useful to assess tort law instrumentally.²⁰⁸ However, they argue that it is important to take account of tort law's other purposes as well – both compensating those who have suffered harm, and imposing liability on the basis of interpersonal responsibility. While resolving the larger debate on the applicability of

²⁰¹ Bovbjerg *et al.*, *supra*, n.24 at 372; JCAHO, *supra*, n.19.

²⁰² Sage, *supra*, n.26.

²⁰³ *Ibid.*

²⁰⁴ See, eg. Mello & Brennan 05, *supra*, n.32 at 376.

²⁰⁵ Sage, *supra*, n.26; Cane, *supra*, n.59.

²⁰⁶ See eg. Sage, *ibid.*: modern medical liability is best understood as "regulation by litigation"; Mello & Brennan 05, *supra*, n.32.

²⁰⁷ Sage, *ibid.*; see generally, Viscusi, K., *Regulation Through Litigation* (Washington DC: AEI-Brookings Joint Center for Regulatory Studies, 2002).

²⁰⁸ Cane, *supra*, n.59; Stapleton, J., "Regulating Torts", in Parker, C., Scott, C., Lacey, N., Braithwaite, J., *Regulating Law* (Oxford: Oxford U. Press, 2004), 122-143

regulatory scholarship to areas of private law is outside the scope of this study, it is an important issue to bear in mind in decision-making about regulatory reform.

Conclusion:

Although the Institute of Medicine intentionally set out to downplay the role of malpractice law in *To Err Is Human*,²⁰⁹ experience over the six years since the release of that Report has made it clear that advancing the patient safety agenda requires careful attention to its interface with the medical liability system. Law shapes the environment for the provision of health care, assessment of risks, and responses to adverse events by all concerned. As such, it conditions the solutions that can be implemented. Taking law into account means more than assessing the legal implications of different patient safety initiatives. Bovbjerg and other writers are correct when they urge the patient safety movement to promote better compensation for patients who have been injured by medical error.²¹⁰ Not only is it the right thing to do, but it is becoming apparent that without getting patients and the public behind reforms, there is little chance they will be implemented. What patients and the public have seen instead are efforts to reduce compensation payable to injured patients and make it more difficult to recover, and to block access to information about their injuries that could assist in establishing entitlement. They will not support reforms that are, or are perceived to be, harmful to their interests.

The explicit attention to the ability of health care purchasers to influence health care providers to improve safety that is evident in much of the American literature presents intriguing possibilities in the Canadian environment, because of the existence of universal health insurance. Canadian governments are by far the largest funders of health care in the country, and their power is magnified by their position as single payer. They also contribute substantial sums to the cost of physicians' and hospitals' liability coverage. It would be useful to explore the possibility of linking targets for specific patient safety improvements in some way with funding health care or government subventions. The ramifications of linking pay for performance in this way would be complex, and unintended consequences are likely to abound. Further study would be essential prior to embarking on such a program.

The assessment of physicians' attitudes in much of the American literature is discouraging – for doctors too, I expect. Sage describes it as follows:

²⁰⁹ See n. 14, *supra*, and accompanying text.

²¹⁰ Bovbjerg 05, *supra*, n.51 at 478.

“Doctors hate malpractice suits. They hate them passionately and continuously. Being sued becomes a recurring nightmare for many physicians, and occasionally an obsession. Eliminating malpractice suits takes precedence over every other political objective – whether public-interested or self-serving—for the American Medical Association and state medical societies. No contradictory belief, however well-reasoned, empirically based, or sincerely held, succeeds in crowding out antipathy toward malpractice from physicians’ minds. Not the large number of patients who die unnecessarily each year from medical errors; not the desirability of allowing patients to sue HMOs for improper care”.²¹¹

Such attitudes, staunchly maintained despite countervailing arguments, make the gulf between the medical profession and what patient safety advocates hope for and patients need immense. It is difficult to craft solutions to bridge a gap of these dimensions.

Would the situation improve if the prospect of malpractice liability were removed?

Medical liability is such a force on the American scene that it understandably becomes the focal point of legal scholarship on patient safety and tort reform. For supporters of radical tort reform, a no-fault or administrative compensation system can seem the answer to all their problems.

However, unintended consequences need to be anticipated and taken into account as well.

Proposals to move to a system of no-fault compensation have attracted a great deal of support from scholars and leaders in the patient safety field over the years. All are quick to agree that any such move would have to be accompanied by strengthened provisions for professional oversight and discipline, in order to ensure that practitioners can still be held accountable. This will not be as straightforward as seems to be assumed. Much American writing has been so focused on criticizing the tort system and hammering home its shortcomings that relatively little attention has been directed to how alternative systems to ensure continuing individual accountability would operate. Most seem to assume some variation on a discipline system that would cull the really bad apples, i.e. cases of “true” incompetence, incapacity, or repeated and unjustified refusal to follow safe procedures. Even less attention has been devoted to the likely effects of a reduced and re-oriented discipline system on providers’ willingness to disclose errors and otherwise participate in a more open system.

I suggest that, based on experience in other countries, both these issues require considerably more attention. The question of when providers’ conduct crosses the line and should be referred to professional discipline proceedings or have employment repercussions is

²¹¹ Sage, *supra*, n.168, at 159.

highly contentious.²¹² Nor will removing tort liability automatically result in changed behaviour by practitioners and institutions, such that they openly disclose and discuss errors that have occurred. Provider resistance should not be underestimated. In New Zealand, which abandoned tort liability for personal injury more than 30 years ago, health care practitioners have still felt threatened by the prospect of professional disciplinary or employment sanctions, and have not been forthcoming about patients harmed by medical error.²¹³ The reasons for non-disclosure are far more complex and multi-faceted than simple fear of legal liability. If a no-fault system is not seen to impose meaningful accountability on institutions and providers, then it will not attract public support; at the same time, if it cannot reassure practitioners that accountability will not revive blame, shame and punishment in another forum, it will meet with significant opposition from them.

²¹² See Chapter 4 in this study, “Australia”, Appendix 2, Camden and Campbelltown Hospitals Inquiry.

²¹³ See Chapter 5 in this study, “New Zealand”.

APPENDIX A

Health Care at the Crossroads: Strategies for Improving the Medical Liability System and Preventing Patient Injury
(Joint Commission on Accreditation of Healthcare Organizations, 2005)

TABLE I: ALTERNATIVE SYSTEM REFORMS AND THEIR IMPACT

	STRICT LIABILITY (NO-FAULT) ADMIN. SYSTEM	PREVENTABLE-EVENTS (ACES)	MEDIATION-EARLY OFFER	HEALTH COURTS	ENTERPR. LIABILITY
TERRENCE EFFECT – PATIENT SAFETY IMPACT	<ul style="list-style-type: none"> - supports creation of a just patient safety culture - encourages reporting of adverse events 	<ul style="list-style-type: none"> - represented consensus on what constitutes an avoidable event - encourages prevention of avoidable events 	<ul style="list-style-type: none"> - alternative dispute resolution mechanism to litigation can potentially “warm” reporting of adverse events 	<ul style="list-style-type: none"> - more reliable judgments have the potential to send clearer messages for deterrence 	<ul style="list-style-type: none"> - provides incentives for prioritization of enterprise-wide safety
SWIFT COMPENSATION	<ul style="list-style-type: none"> - no-trial, administrative process - compatible with “early offer” compensation system 	<ul style="list-style-type: none"> - can trigger eligibility for early compensation offer 	<ul style="list-style-type: none"> - provides prompt settlement and compensation 	<ul style="list-style-type: none"> - swifter address of claims - could provide more reliable and standardized compensation 	
OPEN DISCLOSURE	<ul style="list-style-type: none"> - removal of litigation threat supports open disclosure 	<ul style="list-style-type: none"> - makes “avoidability” and therefore, eligibility for compensation, transparent to providers and patients alike 	<ul style="list-style-type: none"> - offers non-judicial dispute resolution that encourages communication between parties 		
CORRECTIVE JUSTICE	<ul style="list-style-type: none"> - provider is accountable for all avoidable medically related losses 	<ul style="list-style-type: none"> - restitution can be sought in conventional tort system or alternative system - potential to compensate greater number of injured patients 	<ul style="list-style-type: none"> - health care provider or organization is accountable - settlements are often sequestered 	<ul style="list-style-type: none"> - provides the potential for more reliable and credible adjudication of claims - makes fault determinations 	<ul style="list-style-type: none"> - holds enterprise accountable for the safety and quality of health care practice and practitioners

TABLE 2: AN OVERVIEW OF ALTERNATIVES

	STRICT LIABILITY (NO-FAULT) ADMIN. SYSTEM	PREVENTABLE-EVENTS (ACES)	MEDIATION-EARLY OFFER	HEALTH COURTS	ENTERPR. LIABILITY
KEY FEATURES	<ul style="list-style-type: none"> -eligibility based on avoidability rather than negligence - no trial, holds providers strictly responsible for medically related losses 	<ul style="list-style-type: none"> - pre-determination of events that should not occur in quality health care delivery - triggers eligibility for compensation 	<ul style="list-style-type: none"> - prompt, private settlement offers 	<ul style="list-style-type: none"> - appointment of special expert courts to hear medical cases or administer compensation based on avoidable events 	<ul style="list-style-type: none"> - shifts liability from individual provider to provider organization
PROS	<ul style="list-style-type: none"> - promotes prevention & transparency - widens eligibility for compensation - faster resolution of claims 	<ul style="list-style-type: none"> - standardizes eligibility for compensation - quicker identification of meritorious cases 	<ul style="list-style-type: none"> - can avoid litigation - lowers costs - swift & assured compensation for patients - promotes transparency 	<ul style="list-style-type: none"> - could improve the reliability of judgments - quicker resolution of claims - provides public access to settlement and adjudication findings 	<ul style="list-style-type: none"> - promotes institutional safety - potential to stabilize liability insurance fees
CONS	<ul style="list-style-type: none"> - preception that “no-fault” means “no accountability” 	<ul style="list-style-type: none"> - comprehensive ACE list currently non-existent - development of the list requires an array of expert consensus 	<ul style="list-style-type: none"> - intensifies pressure on patients to settle 	<ul style="list-style-type: none"> - requires judges who have special knowledge or training 	<ul style="list-style-type: none"> - legal provisions (Stark laws) may prohibit liability insurance coverage of non-employee physicians
COMPABILITY	<ul style="list-style-type: none"> - compatable with current system if based on “earn-in” model- providers meet criteria for admin. system; others are in conventional system 	<ul style="list-style-type: none"> - a basis to determine eligibility for alternative and conventional compensation systems - can be paired with standardized compensation fee schedule 	<ul style="list-style-type: none"> - used with current tort system - can be used with admin. system, AECs 	<ul style="list-style-type: none"> - is paired with ACEs and standardized compensation schedule - adds trial option to an administrative system 	<ul style="list-style-type: none"> - works with alternatives and current tort system
REAL-WORLD APPS.	<ul style="list-style-type: none"> - worker’s compensation laws - Fla. & Va. injury-specific demonstrations 		<ul style="list-style-type: none"> - Liability insurer models - Health plan models - Provider models 	<ul style="list-style-type: none"> - Special court precedents – tax and patent courts – and worker’s compensation laws 	<ul style="list-style-type: none"> - precedents in product liability law

CHAPTER 4. UNITED KINGDOM

I. THE TORT SYSTEM AND REFORM

The principles of negligence law are broadly the same in the United Kingdom as in Canada, although their interpretation and application differ somewhat. The focus of this chapter is on the laws of England. Continuing dissatisfaction with the system for resolving claims of clinical negligence, particularly in medical malpractice cases, has prompted a number of reviews of the civil justice system, and reform to procedural law in particular. These are reviewed in more detail below, in order to understand their import for the conduct of negligence claims and for patient safety initiatives.

Structure of Medical Malpractice Claims

While doctrinal tort law is similar in the two countries, there are differences in the structure and funding of malpractice litigation. First, with respect to structure: most medical treatment in the U.K. is carried out by the National Health Service (NHS) and is publicly funded. Since the introduction of NHS Indemnity in 1990, the NHS has been legally responsible for claims of medical negligence made against its employees, including physicians.¹ The NHS does not seek contribution from the employee.² Hospitals are vicariously liable for the negligence of their employees, and directly liable for their own negligence, but the incentive to shift blame and therefore, responsibility for paying damages, to an independent contractor physician or the reverse (as in Canada) is absent, at least relative to NHS services. Physicians' status as hospital employees, together with the NHS policy of ignoring the distinction between employees and independent contractors provided the claimant was injured in the course of receiving NHS treatment, also mean that arguments that the hospital owes the patient a non-delegable duty of care (which can be breached by a physician's negligence) are of much less practical importance.³ As Strickland notes, with the expansion of the NHS' legal liability, the indemnity aspect of clinical risk was transferred from physicians' mutual defence organizations to the NHS, and that, together with the increasing threat of clinical negligence claims, widened ownership of clinical

¹ Grubb, A., Laing, J. (eds.), *Principles of Medical Law* (2nd ed) (Oxford: Oxford U. Press, 2004), at 542-3, para. 8.90ff; Jones M., *Medical Negligence* (London: Sweet and Maxwell, 2003) at 627.

² Grubb & Laing, *ibid.*, at 543, para 8.91.

³ Jones, *supra*, n.1, at 616, para 7.035-6. Jones points out that the question may still have practical significance if a patient is sent by the NHS facility to a non-NHS facility for needed treatment.

risk beyond physicians.⁴ While the legal status of general practitioners can be complex, those who are not NHS employees would be sued directly, as would physicians providing private treatment to patients.⁵ Physicians who are not the NHS' responsibility obtain coverage for malpractice claims through participation in mutual defence organizations, which assume responsibility for representing their physician members in civil actions and other types of proceedings.⁶

Funding and Managing Claims

Since 1995, any actions against the NHS Trusts for clinical negligence, including employees' negligence, are dealt with on behalf of the NHS by the National Health Service Litigation Authority (NHSLA).⁷ The NHSLA administers five "schemes": two main clinical schemes, the Clinical Negligence Scheme for Trusts (CNST) (post-April 1995 events), established to fund the costs of litigation through annual contributions by NHS bodies and the pooling of funds, and the Existing Liabilities Scheme, which covers claims against NHS bodies arising from events prior to April 1995, a third that covers a small number of claims remaining from a previous administrative structure, and two non-clinical schemes covering claims relating to liability to third parties and property expenses incurred post-April, 1999.⁸ The contributions that NHS Trusts make towards the costs of clinical negligence are determined by the NHSLA based on its assessment of the risk management standards in place and claims history in each Trust.⁹ From its inception, part of the NHSLA's remit was to improve the way that clinical negligence claims were handled in the NHS, and it has taken steps to do so, for instance by encouraging mediation, explanations and apologies, piloting a small "fast track" project for lower value claims ("Resolve"), controlling costs of its own solicitors, and other measures.¹⁰

⁴ Strickland, C., "The ownership of clinical risk in acute hospitals in England – an historical perspective", in Garwood-Gowers, A., Tingle, J., Wheat, K. (eds.), *Contemporary Issues in Healthcare Law and Ethics* (Edinburgh Elsevier, 2005), at 61.

⁵ Jones, *supra*, n.1, at 600-601, para 7-010, 7-011.

⁶ Personal communication, Frances Szekely, Medical Defence Union, May 6, 2005; see generally Medical Defence Union, GP & Primary Care Homepage, online at: <http://www.the-mdu.com/gp/index/asp> (last accessed June, 2005).

⁷ See generally Strickland *supra*, n. 4, at 65: The NHSLA is a Special Authority established by the Secretary of State by virtue of the NHS Litigation (Establishment and Constitution Order (SI 1995 2800).

⁸ Wheat, Kay, "Is There a Medical Malpractice Crisis in the UK?", (2005) 33 J.L.M.E. 444 at 445.; NHSLA Annual Report 2004, at 7 (hereafter, NHSLA 2004), online at <http://www.nhsla.com> (last accessed March 2005).

⁹ Chief Medical Officer, *Making Amends. A consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS* (London: Department of Health, 2003), at 11 (hereafter, *Making Amends*), available online at: www.doh.gov.uk/makingamends/cmreport.htm (last accessed Dec. 2004).

¹⁰ *Ibid.* at 92.

Turning to how plaintiffs fund litigation, clinical negligence claims are the only major area of personal injury claims for which legal aid is still available. It is both means and merit tested, i.e. claimants must meet financial eligibility criteria, and the Legal Services Commission must be satisfied that the case justifies granting public funding, taking into account prospects of success and possible benefits of litigation.¹¹ Solicitors representing legally aided clients in clinical negligence claims must have expertise in the area, ensuring assessments for the Commission and advice to clients are informed. The Commission may direct lower value claims (less than £10,000) to the NHS complaints procedure.¹² In his 2003 report, *Making Amends*, the Chief Medical Officer observed that: (1) nearly 90% of clinical negligence cases received Legal Aid; (2) while full funding was only available to those on Income Support, just under half the population was eligible on income grounds for some Legal Aid; (3) of the clinical negligence cases that concluded in 2001/2002, 53% of cases were not funded beyond initial investigation, but of those that proceeded to litigation, 57% were successful; and (4) the highest proportion of people pursuing a claim were in relatively high or low income households.¹³ In 2003/04, 6,064 new legal aid certificates were issued for clinical negligence claims.¹⁴ In 2004/05, results where certificates had been granted in clinical negligence cases were mixed: in cases where proceedings were issued but the case concluded without a hearing, benefits to the client were reported in 58% of cases, while a beneficial outcome to clients was reported in 51% of cases that proceeded to a final hearing.¹⁵

The introduction of conditional fee arrangements (CFA) in 1995 offered another alternative for funding litigation. Under a CFA, the lawyer agrees not to charge if unsuccessful, but if successful, the client agrees to pay the lawyer's fee plus a percentage markup ("success fee"). If the client loses, she will be liable to pay the defendants' costs, under the "costs follow the event" rule that applies in Canadian litigation as well. To fund this liability, a claimant who does not have "before the event" insurance (sometimes available as an adjunct to other policies,

¹¹ *Ibid.*, at 67.

¹² See eg National Audit Office (NAO), "Handling clinical negligence claims in England", HC 403 (London: The Stationery Office, 2001) at 4.

¹³ *Supra*, n.9 at 70.

¹⁴ Wheat, *supra*, n.8 at 445, 449 (noting a reduction in certificates after the release of *Making Amends*).

¹⁵ Legal Services Commission, Annual Report 2004/2005, online at <http://www.legalservices.gov.uk> (last accessed Jan. 2006).

such as home insurance) can take out “after the event” insurance to cover the cost of losing.¹⁶ *Making Amends* reported little take-up of either CFAs or after the event insurance in clinical negligence cases, because of both high cost and limited availability.¹⁷

The Woolf Report, *Access to Justice*

There have been a number of reviews of the litigation process, sparked by concerns about how the legal system handles claims for compensation for personal injury in general, and clinical negligence in particular. Lord Woolf’s review of the civil justice system, begun in 1994 and resulting in his 1996 report, *Access to Justice*, is of particular note, both for its analysis and because it resulted in significant procedural reform.¹⁸ Lord Woolf concluded that the current system was too expensive, too slow, too unequal as between litigants who were well-resourced and those who were not, too uncertain as to cost and time, too adversarial, and too fragmented, with unclear responsibility for the administration of civil justice, and inattention to the rules of court by the parties.¹⁹ He singled out medical negligence cases for particularly intensive examination, because it was “...obvious that it was in the area of medical negligence that the civil justice system was failing most conspicuously to meet the needs of litigants...”.²⁰ He noted the following problems in particular:

- Disproportionate costs in comparison with damages, especially in lower value cases;
- Delay in resolving claims is more often unacceptable;
- Unmeritorious claims were often pursued, and clear-cut claims defended, for too long;
- Lower success rate than in other areas of personal injury litigation;
- Heightened suspicion and less co-operation between parties than in many other areas of litigation.

He observed that smaller medical malpractice claims can seldom be litigated because of cost, and that even larger claims can rarely be litigated without assistance from Legal Aid.²¹ The result

¹⁶ Wheat, *supra*, n.8 at 445.

¹⁷ *Supra*, n.9 at 71.

¹⁸ Online at <http://www.dca.gov.uk/civil/final> (last accessed December, 2004). Lord Woolf was appointed Master of the Rolls, the most senior civil judge in England, prior to publication of the Final Report.

¹⁹ *Ibid.*, Overview, para. 2.

²⁰ *Ibid.*, ch. 15.

²¹ Indeed, the National Audit Office reported in 2001 that the legal and administrative costs of settling claims exceeded the money actually paid to the claimant in the majority of claims under £45,000 - National Audit Office, “Handling clinical negligence claims in England”, *supra*, n. 12, cited in *Making Amends*, *supra*, n.9 at 69-70. Some

was that “...in the vast majority of cases, both sides are funded from the public purse”, money that could be better spent compensating victims or improving standards of care to avoid future injuries.²²

While noting that the substantive law of tort plays a role in the higher costs of these claims because the difficulty of proving causation and negligence is “more acute” in medical negligence cases, he concluded that the failure of the civil justice system in this area was fundamentally the result of the climate of mutual suspicion and defensiveness that prevailed in medical malpractice lawsuits. Improved case management could go some way towards addressing problems identified, but it alone could not bring about the changes needed. He called for a more conciliatory and co-operative approach, adding that in order to address patients’ mistrust,

“...the medical profession and the NHS administration must demonstrate their commitment to patients’ wellbeing by adopting a constructive approach to claims handling. It must be clearly accepted that patients are entitled to redress, and that professional solidarity or individual self-esteem are not sufficient reasons for resisting or obstructing valid claims”.²³

Patients should also be entitled to expect explanations and where appropriate, apologies.²⁴ He made wide-ranging recommendations for reform applicable to both civil litigation generally, and clinical negligence cases in particular. His underlying premises were that litigation should be a last resort and avoided wherever possible, and that the civil justice system should be fair to litigants, just in its results, understandable to those who use it, and have procedures and costs proportionate to the issues involved.²⁵

Civil Justice Reform

Most of Lord Woolf’s proposals were accepted by government, and extensive civil justice reforms followed. These included implementation of Pre-Action Protocols to provide a clear sequence of steps for both parties to follow beginning prior to the commencement of litigation

of the figures in the NAO Report have been questioned because they relied on older cases and may not have accurately represented current costs of settlements.

²² *Supra*, n.18, ch. 15, para, 3.

²³ *Ibid.*, ch. 15, para. 22.

²⁴ *Ibid.*, para. 29.

²⁵ *Ibid.*, Overview, para 9; for a summary, see *Making Amends*, *supra*, n.9 at 91.

and backed by timelines and penalties, provisions for offers to settle, increased use of joint experts, strengthened case management powers for judges, and encouragement of alternative dispute resolution.²⁶ One of the first protocols adopted dealt with clinical negligence. It includes provision for substantive letters of claim and response prior to commencing proceedings, meetings of experts and other matters.²⁷

Other reforms have been implemented as well. The Judicial Studies Board now develops guidelines to provide more standardized valuations for many injuries, to facilitate greater consistency in award levels.²⁸ More recently, amendments to the *Courts Act* allow courts to order that damages be paid by periodical payments without requiring consent of the parties, meaning that the courts can impose structured settlements.²⁹ Commentators agree that, while it is still early to assess the full impact of the Woolf Reforms, they appear to have had positive results.³⁰

An additional consideration in reforming the civil justice and tort systems in England is the effect of the *Human Rights Act*, 1998, which incorporates the requirements of the European Convention on Human Rights into English law, including Article 6, which ensures the right to a fair hearing.³¹ While not generally affecting the conduct of clinical negligence litigation, it would have to be taken into account in the formulation of alternative compensation regimes.

Incidence of Adverse Events and Clinical Negligence Litigation

Comprehensive studies of the numbers of adverse events patients experience in hospitals or from health care generally in the United Kingdom are lacking. In a small study, Vincent *et al.* found an overall rate of 11.7% of hospital patients experienced adverse events, with about half being judged preventable, and a third leading to moderate or great disability or death.³² *Making Amends*, extrapolating from American and English studies, accepted that 850,000 adverse events were occurring to hospital in-patients in England each year, in the context of an estimated 50

²⁶ Wheat, *supra*, n.8 at 449.

²⁷ Jones, *supra*, n.1, at 873, App. 2, “Pre-Action Protocol for the Resolution of Clinical Disputes”.

²⁸ *Making Amends*, *supra*, n.9 at 92; see generally <http://www.jsboard.co.uk> (last accessed June, 2005).

²⁹ *Courts Act 2003*; NHSLA Annual Report 2003/2004 at 12, online at <http://www.nhsla.com/home.htm> (last accessed Jan. 2006); Grubb & Laing, *supra*, n.1 at 548, para. 8.100.

³⁰ Wheat, *supra*, n.8 at 449; *Making Amends*, *supra* n.9 at 91-92; Department for Constitutional Affairs, “Emerging Findings. An early evaluation of the Civil Justice Reforms” (March, 2001).

³¹ *Making Amends*, *supra*, n.9 at 113.

³² Vincent, C., Neale, G., Woloshynowych, M., “Adverse events in British hospitals: preliminary retrospective record review”, 2001 *BMJ* 322: 517-519, 1395.

million clinical decisions for every million population in the NHS.³³ In 2005, the National Audit Office, relying on Department of Health estimates, noted that the incidence of adverse events experienced by NHS patients admitted to hospital was one in ten, of which half were preventable.³⁴

These figures do not include the numbers of adverse events in non-hospital settings, such as primary care. Research carried out as part of the *Making Amends* review found that of 8000 people interviewed, approximately 400 considered they had suffered injury or other adverse effects as a direct result of medical care, and of these, 30% reported a permanent impact on their health. Just over half of the adverse events occurred in NHS hospitals, and 25% in primary care.³⁵ A 2005 comparison of the experiences of patients with health problems using the health care systems in six countries found that, of the 1770 people surveyed in the United Kingdom, 17% reported that a medical mistake or medication error had been made in their treatment or care, causing a serious health problem for 42%, and 22% reported a medical, medication or laboratory error in their care in the last two years..³⁶ For 67% of U.K. patients, the mistake or error in medication occurred outside the hospital. 72% had not been told about the error by physicians involved in their care.³⁷

Litigation Experience

Not all adverse events, even those that are preventable, are the result of negligence. Some, however, are. Data on the incidence of clinical negligence litigation indicates that few people who have suffered even preventable adverse events sue. At the same time, people may sue even though the care involved was entirely appropriate – i.e. there was no negligence involved.

The NHSLA reported that in 2004-05, it received 5,609 claims of clinical negligence and 3,766 claims of non-clinical negligence against NHS bodies.³⁸ It noted that this continued a

³³ *Supra*, n.9 at 31-32.

³⁴ National Audit Office, “A Safer Place for Patients: Learning to Improve Patient Safety” (Nov. 2005), at 1, (hereafter, NAO 2005), online at http://www.nao.org.uk/publications/nao_reports/05-06/0506456.pdf (last accessed Jan. 2006).

³⁵ *Supra*, n.9 at 33, para. 8.

³⁶ Schoen, C., Osborn, R., Huynh, P.T., Doyt, M., Zapert, K., Peugh, J., Davis, K., “Taking the Pulse of Health Care Systems: Experience of Patients with Health Problems in Six Countries”, Health Affairs Web Exclusive (Nov., 2005), W5-509-W5-525; online at http://www.cmwf.org/publications/publications_show.htm?doc_id=31302 (last accessed Dec. 2005).

³⁷ *Ibid.*

³⁸ NHSLA, “About the NHS Litigation Authority”, online at: <http://www.nhsla.com/home.htm> (last accessed Jan. 2006).

downward trend in new claims evident over the last few years – for instance, in 2004-05, it received 439 CNST claims per month, compared to 481 claims per month under CNST in 2003-04.³⁹ An analysis of all clinical claims the NHSLA has handled since its inception in 1995 shows that 38.01% were abandoned by the claimant, 43.1% settled out of court, 1.97% settled in court in favour of the patient (including court approval of settlements negotiated for children), 0.5% settled in court in favour of the NHS, and 16.42% remain outstanding.⁴⁰

The average time taken to deal with a clinical claim under the CNST from the time when the NHSLA is notified of the claim to the time damages are paid or it is discontinued is 1.44 years.⁴¹ Individual claims experience can vary widely; many do not proceed past preliminary stages and conclude quickly, while others take many years to resolve, especially if the extent of injury or causation is difficult to determine.

Cost of Adverse Events

Patient injuries are very costly, most obviously and acutely to the person concerned, but also to the health care system. In 2005, the National Audit Office reported that patient safety incidents (the term preferred by the National Patient Safety Agency, rather than adverse event or clinical error) cost the NHS an estimated £2 billion a year in extra bed days; hospital acquired infections added an additional £1 billion to these costs.⁴² The NHSLA paid £502.9 million in connection with clinical negligence claims in 2004-05, including both damages paid to patients and the legal costs borne by the NHS. This compares to £422.5 million paid in 2003-04.⁴³ Patients and their families bear substantial financial and non-financial costs when injured by health care whether they sue or not, meaning that the total direct and indirect costs of patient injury are far greater than these amounts.

II. PATIENT SAFETY

The place of quality improvement and patient safety initiatives in England has changed substantially, becoming more prominent since the mid-1980's. The Bristol Inquiry was a

³⁹ NHSLA Annual Report 2004-05 at 13, online at <http://www.nhsla.com/home.htm> (last accessed Jan. 2006).

⁴⁰ NHSLA, "About the NHSLA", *supra*, n.38.

⁴¹ *Ibid.*

⁴² NAO 2005, *supra*, n.34 at 1.

⁴³ NHSLA, "About the NHSLA", *supra*, n.38. The figures for non-clinical claims are £25.1 million for 2004-05, and £10.1 million for 2003-04.

particularly powerful catalyst. Walshe and Shortell summarize the facts as follows: “Between 1990 and 1995, despite repeated warnings about poor surgical quality outcomes, cardiac surgeons at the hospital [the Bristol Royal Infirmary] continued to operate on newborns until the U.K. Department of Health forced them to stop. A subsequent public inquiry concluded that thirty-five deaths had been avoidable. Three doctors were disciplined by the General Medical Council [2 cardiac surgeons, and a radiologist who was the chief executive of the hospital at the time], and two ... lost their licenses to practice medicine”.⁴⁴ The full public inquiry established by the Secretary of State and chaired by Sir Ian Kennedy began hearing evidence in October 1998 and published its report with almost 200 recommendations in July, 2001.⁴⁵

The events at Bristol and their aftermath, including the Inquiry as well as the public and media outcry, had a huge impact. It is said to have created “shockwaves”, and caused a “sea change in medical and wider British society attitudes to professional self-regulation, clinical competence, and healthcare quality improvement”.⁴⁶ Commenting on events at Bristol, the Chief Medical Officer observed in *Making Amends* that it and other highly publicized failures in the standard of care in hospitals

“...epitomized the gap which had opened up between the perception of the public and that of the medical profession in what was acceptable or unacceptable freedom in clinical decision-making...These events can be seen as a turning point in the development of a new culture and relationship between practitioner and patient based on partnership, communication and provision of information”.⁴⁷

Health care professionals and organizations became more willing to accept national standards of conduct and regulation in health care, and to recognize that professional self-regulation alone was not sufficient.⁴⁸ At the same time, the series of medical scandals – Bristol, Shipman, Alder

⁴⁴ Walshe, K., Shortell, S., “When Things Go Wrong: How Health Care Organizations Deal With Major Failures”, (2004) 23 Health Affairs 103-111, at 104.

⁴⁵ Kennedy, I., *Learning from Bristol: the report of the public inquiry into children’s heart surgery at the Bristol Royal Infirmary 1984-1995*, (London: HMSO, 2001), online at <http://www.bristol-inquiry.org.uk> (last accessed November 2004). The Inquiry is reported to have cost approximately £14 million – Walshe, K., Offen, N., “A very public failure: lessons for quality improvement in healthcare organizations from the Bristol Royal Infirmary” (2001) 10 Quality in Health Care 250-256.

⁴⁶ Dyer, C., “Kennedy refused to read General Medical Council’s reports”, BMJ 2001; 323: 183; Walshe, K., Offen, N., “A very public failure: lessons for quality improvement in healthcare organizations from the Bristol Royal Infirmary”, (2001) 10 Quality in Health Care 250-56, quoting Smith, R., “All changed, changed utterly. British medicine will be transformed by the Bristol case”, BMJ 1998; 316: 1917-8.

⁴⁷ *Supra*, n.9 at 44.

⁴⁸ Personal communication, Sir Ian Kennedy, May 16, 2005.

Hey and Dr. Ledward – changed patients’ attitudes, making them more inquiring, more demanding, and less deferential.⁴⁹ Strickland credits the loss of public confidence occasioned by the scandals in the late 1980’s and early 1990’s with marking the beginning of “greater public ownership of clinical risk”.⁵⁰ As Kay Wheat has observed, whether the inquiries were about clinical negligence *per se* or not, the outcry over misconduct in the NHS was concerned with “...what the public might well perceive to be great swathes of ‘malpractice’”.⁵¹

Reports prepared for the government on the state of healthcare (two were particularly significant -- *An Organization With a Memory*, and *Building a Safer NHS for Patients*⁵²), as well as the inquiry reports highlighting serious failings in systems or clinical standards led the government to undertake a number of regulatory initiatives and create a series of agencies focused on health quality and safety. They are meant to improve the management of clinical risk and introduce best practice in care and management.⁵³ The focus of this paper is on the interaction of the tort system and tort reform with patient safety initiatives. Consequently, a detailed consideration of either the implications of the inquiries and the events that led up to them for quality and safety initiatives, or the many quality and safety programs and agencies that were created is beyond the scope of this paper. However, since they have implications for the tort system, and are also important to an understanding of how complicated and crowded the landscape of healthcare oversight has become (in addition to courts adjudicating negligence claims), I will outline the major initiatives briefly, and then review some of the ways that these developments may affect the conduct of litigation and vice versa.

Patient Safety and Quality Agencies

New organizations were created, and existing mandates revamped to emphasize responsibilities for safety and quality. These include the National Patient Safety Agency, the Commission for Healthcare Audit and Inspection (replacing the Commission for Health Improvement), the National Institute for Clinical Excellence, new emphasis on the role of the

⁴⁹ Tingle, John, “Clinical Risk Management: Law, Policy and Context”, in V. Mayett (ed.), *Tolley’s Managing Risk in Health Care* (2nd ed.), (Lexis Nexis Reed Elsevier, 2004), 95 at 100.

⁵⁰ *Supra*, n.4 at 68.

⁵¹ *Supra*, n.8 at 450.

⁵² Department of Health, *An organization with a memory: Report of an expert group on learning from adverse events in the NHS* (Chief Medical Officer, Chair) (London: Stationery Office, 2000); Department of Health, *Building a safer NHS for patients, implementing an organization with a memory* (London: Department of Health, 2001).

⁵³ Tingle, *supra*, n.49 at 97, para. 5.4.

Parliamentary and Health Service Ombudsman, National Audit Office review of clinical negligence and clinical governance, and others. The self-regulating bodies of professions continue to govern the professional standards and practices of their members.⁵⁴ They are now overseen by the Council for Regulatory Excellence, which was established in 2003 to ensure consistency and good practice among regulators – i.e. to monitor the monitors.⁵⁵ It can refer certain cases to the courts for disposition where it considers that regulators have been too lenient.⁵⁶ The central management of litigation by the NHSLA was described previously. The NHSLA also plays a role in setting risk management standards for NHS Trusts.

National Patient Safety Agency

The National Patient Safety Agency (NPSA) was created in 2001 to coordinate the efforts of the NHS regarding patient safety. Emphasizing systems analysis, it has developed a number of patient safety tools and a national reporting and learning system (a patient safety data collection system), and is proceeding with work on implementing “Being Open”, a program to encourage disclosure to patients/families when patients have suffered moderate or severe harm or death as a result of error, together with an apology, and explanation of steps that will be taken to prevent a recurrent.⁵⁷

National Audit Office

The National Audit Office (NAO) has undertaken an extensive study of the handling of clinical negligence claims, as well as reporting on the implementation of clinical governance and results of patient safety initiatives.⁵⁸

National Institute for Health and Clinical Excellence (NICE)

⁵⁴ See eg., General Medical Council, “Good Medical Practice”, and “Developing medical regulation: a vision for the future: the GMS’s response to the call for ideas by the review of clinical performance and medical regulation” (General Medical Council, April, 2005), and generally the Council’s website, <http://www.gmc-uk.org> (last accessed June, 2005).

⁵⁵ The Council was established by the *NHS Reform and Health Care Professions Act 2002*. See the Council for Regulatory Excellence, online at <http://www.chre.org.uk> (last accessed August 2005).

⁵⁶ *Ibid.*

⁵⁷ See especially NPSA, “Seven Steps to Patient Safety – an overview guide for NHS staff”, and “Root Cause Analysis: Exploring Incidents, Improving Safety” (NPSA, 2003), online at www.npsa.nhs.uk/sevensteps (last accessed May 2005); see also http://www.npsa.nhs.uk/site/media/document/247_boardminutesOctober03.pdf (last accessed May 2005); “Being open- communicating patient safety incidents to patients and their carers”, online at: <http://www.npsa.nhs.uk/health/reources/beingopen> (last accessed March, 2006).

⁵⁸ *Supra*, n’s. 12, 34.

NICE is part of the NHS, and promotes clinical excellence and the effective use of resources by providing national guidance on treatments and care in the areas of technology appraisals, clinical guidelines, and interventional procedures.⁵⁹

Commission for Healthcare Audit and Inspection

The Commission for Healthcare Audit and Inspection (Healthcare Commission) replaces the Commission for Health Improvement, and began operation in 2004. Its statutory mandate includes duties to investigate and assess the performance of healthcare organizations, consider complaints about the NHS that cannot be resolved through internal complaints processes, report on the state of healthcare in England (NHS and private sector), rate performance in the NHS, regulate the independent healthcare sector through annual registration and inspection, publish surveys of patient and staff views, and coordinate reviews of healthcare by others.⁶⁰

Parliamentary and Health Services Ombudsman

The Parliamentary and Health Services Ombudsman (Health Service Ombudsman) is charged with undertaking independent investigations into complaints that government bodies, other public bodies and the NHS in England acted improperly or unfairly, or provided a poor service.⁶¹ It recently completed a review of the reformed NHS complaints procedures in England, concluding that fragmentation in complaints systems, combined with shortcomings in complaints handling capacity and leadership, and a failure to focus on patients' needs, resulted in "just remedies not being secured for just complaints".⁶² It added that overall, the system makes it difficult for patients to have things put right when they have gone wrong.⁶³

⁵⁹ See generally National Institute for Health and Clinical Excellence, online at <http://www.nice.org.uk> (last accessed Dec. 2005).

⁶⁰ See generally the Healthcare Commission, online at; <http://www.healthcarecommission.org.uk> (last accessed Jan., 2006). The Healthcare Commission was created by the *Health and Social Care (Community and Health Standards Act) 2003*.

⁶¹ Parliamentary and Health Service Ombudsman, "Role and purpose statement", online at http://www.ombudsman.org.uk/about_us/role_purpose.html (last accessed December, 2005).

⁶² Health Service Ombudsman for England, "Making things better? A report on reform of the NHS complaints procedure in England", Second Report, Session 2004-05, HC 413 (March, 2005), at 5. In 2004-05, the number of people dissatisfied with local NHS complaints resolution and seeking an independent review of their complaints from the Healthcare Commissioner doubled. As at October, 2005, it was investigating 4500 complaints – Healthcare Comm'r., "NHS sees doubling of people demanding their NHS complaint be independently reviewed" (Oct. 31, 2005), online at: <http://www.healthcarecommission.org.uk/NewsAndEvents/PressReleases/PressReleasesDetail'f...> (last accessed March 2006).

⁶³ *Ibid.*

Even this partial list of agencies and their responsibilities gives an indication of how complicated the monitoring and oversight of healthcare have become. John Tingle points out the tremendous impact that the various accountability mechanisms have had, not just on patients' experience, but on the NHS and the working lives of its staff: NHS hospitals are answerable to many separate regulators with different missions, agendas and requirements, resulting in duplication and "...forcing them to spend millions of pounds on even more administrators to navigate their way through the system".⁶⁴ Recognizing this, some efforts are being made at streamlining and consolidation.⁶⁵ For instance, the Healthcare Commission and the other main healthcare inspection, review and audit bodies have entered into an agreement, the Concordat, which commits each to minimize duplication and encourage joint inspections beginning in 2005.⁶⁶ Nonetheless, the interrelationships among the various initiatives and bodies are not always clear, and overlap and duplication remain.

Reviewing progress to date, the National Audit Office concluded that, while much remains to be done, overall, the safety culture within NHS Trusts and encouragement for reporting and learning from mistakes have improved with the introduction of initiatives focused on clinical governance and patient safety, although it warned that feedback to institutions and providers must be improved, or people will stop reporting. It also observed that trusts are still predominantly reactive in their response to patient safety issues, and a blame culture persists in parts of some organizations.⁶⁷ This is evident in provider attitudes. A survey of 2500 physicians found that only 15% reported colleagues' serious errors (respondents were not asked about near misses).⁶⁸ The great majority (97%) thought a reporting system would improve care, but believed it should be independently operated, because of past experience with blame and "witch hunts". Respondents were guardedly optimistic about the potential for the NPSA's anonymous system for reporting.⁶⁹

⁶⁴ *Supra*, n.49 at 98. See also NAO 2005, *supra*, n.34 at.3, charting the many stakeholders in patient safety at the trust, local and national levels, and at 8, on duplicate reporting of patient safety incidents.

⁶⁵ Department of Health, "Reconfiguring the Department of Health's Arm's Length Bodies" (London, 2004), online at: <http://www.dh.gov.uk/PublicationsPolicyandGuidanceArticle/fs/en?> (last accessed Jan. 2006).

⁶⁶ Healthcare Commission, "Welcome to the Healthcare Commission", online at: <http://www.healthcarcommission.org.uk/Homepage/fs/en> (last accessed Jan. 2006).

⁶⁷ NAO, 2005, *supra*, n.34 at 2.

⁶⁸ White, C., "Doctors mistrust systems for reporting medical mistakes", *BMJ* 2004; 329: 12.

⁶⁹ *Ibid.*

Clinical Governance and Clinical Negligence

The primary purpose of these reforms was to improve patient safety and quality of care. However, returning to the focus of this paper, their secondary effects, particularly their interaction with clinical negligence litigation, are significant as well.

1. The most obvious effect if the reforms achieve their aims would be a reduction in medical error and resulting harm to patients, in turn reducing the number of lawsuits. As the Chief Medical Officer of Health noted in *Making Amends*, "...the relevance to medical litigation is obvious – if more of the healthcare risks that currently cause harm to patients are identified, anticipated and reduced, then the number of avoidable injuries to patients should be reduced. So too should their severity. This must be the primary aim".⁷⁰

That is certainly the ultimate goal, but what of more immediate effects on litigation and vice versa? Several have been suggested.

2. Protocols and guidelines can affect the standard of care in clinical negligence claims.

With respect to determinations of negligence, if risk management processes such as those instituted by the safety and quality agencies lead to greater standardization through the adoption of protocols or the promulgation of clinical guidelines, then departing from those procedures might be characterized as carelessness.⁷¹ While unlikely to be considered conclusive on the issue of negligence, such evidence could be highly persuasive, giving the protocols more weight and providers and organizations greater incentive to follow them, resulting in enhanced safety.

3. Improved communication with patients is expected to reduce complaints and claims.

Sometimes the crux of a claim is a failure to obtain informed consent prior to treatment (i.e. to tell the patient about the treatment and its risks in a careful and comprehensible way). After an adverse event, some patients sue because they cannot find out what happened and why.⁷²

Explanation and dialogue can assist.

4. The NHSLA- instituted clinical risk management standards can reinforce incentives to improve care, in turn containing the incidence and costs of negligence.⁷³ NHS Trusts pay a

⁷⁰ *Supra*, n. 9 at 8.

⁷¹ Jones, *supra*, n.1, at 2;

⁷² *Ibid.* at 3.

⁷³ Heasell, S., "Cost implications and ethics of healthcare quality regulation", in Tingle, J., Foster, C., Wheat, K., *Regulating Healthcare Quality: Legal and Professional Issues* (Edinburgh: Butterworth-Heinemann, 2004), 43 at 48.

contribution towards the costs of litigation annually, but can obtain a discount by complying with the Clinical Negligence Scheme for Trusts (CNST) risk management standards.⁷⁴ There are three CNST levels trusts can reach, and a 10% discount for attaining each level, for a total 30% discount at level three. Since each level presumably indicates a safer organization, one would expect improved quality of care, resulting in fewer injuries to patients and therefore, less litigation. The flow-through of benefits may not be significant in practice, however. Tingle has noted that many trusts remain at CNST level one, i.e. the basic level of a clinical risk management framework, so the anticipated improvement in standards and safe systems may not occur.⁷⁵

5. Additional ways to have complaints resolved can better meet the needs of claimants.

The multiplication of agencies concerned with safety and quality has been accompanied by a multiplication in the avenues for making complaints about care received. Many people dissatisfied with their treatment do not seek compensation, but rather, want information, or an explanation and apology. Litigation will not achieve those ends. Conversely, lack of explanations does fuel lawsuits.⁷⁶ More routes to different forms of redress, such as complaints processes responsive to the needs for apology and explanation, could divert claims away from litigation and better satisfy claimants. The Health Ombudsman's recent review of the NHS complaints processes offers a caveat to this optimistic view, however. She noted that a survey of complainants to her office revealed that few seek monetary compensation on beginning the complaints process, but that "...the process itself makes them more likely to ask for financial redress because of the time and effort they have expended in trying to get their complaint resolved"; additionally, when compensation is offered, a small amount can antagonize the complainant further.⁷⁷ The complaints process, then, can make people more or less likely to sue.

6. Availability of additional routes to obtain financial redress could reduce the need to litigate, but would require further development. The Healthcare Ombudsman is of the view that, although the existing NHS complaints system is silent about financial redress, NHS bodies

⁷⁴ NHSLA 2004-05 Annual Report, online at: <http://www.nhsla.com/home.htm> (last accessed Jan. 2006).

⁷⁵ Tingle, *supra*, n.49 at 106. See also Strickland, *supra*, n. 4, at 65, suggesting that because level 1 is easily attainable, the financial incentives may not be significant enough to encourage progression to the more demanding higher levels.

⁷⁶ Jones, *supra*, n.1 at 3, citing evidence from Action for the Victims of Medical Accidents (now, Action Against Medical Accidents) (AvMA).

⁷⁷ *Supra*, n.62 at, 10.

can make special payments where there has been financial loss as a result of the actions or omissions of an NHS body. Her office has increasingly been securing financial redress from NHS bodies for complainants on this basis. However, at present, "...other than by submitting a complaint to the Ombudsman, financial redress has generally only been available through legal action for medical negligence", and complainants who indicated they were taking legal action were excluded from NHS complaints procedures.⁷⁸ She recommended that regardless of whether negligence in the legal sense had been established, NHS bodies should be receptive to paying some recompense to complainants for their severe difficulties (whether only in carrying the complaint forward, or also in connection with healthcare received is unclear), and that all levels of complaints should be able to provide a full range of remedies, including financial compensation.⁷⁹ The basis, conditions and terms for compensation appear undeveloped.

7. Civil litigation can discourage disclosure, and hence, can be counter-productive to the operation of patient safety programs, which rely on sharing information to identify mistakes and learn from errors.

8. Conversely, lawsuits can provide information that can be used to improve patient safety. The National Audit Office recommended that the Healthcare Commission make greater use of information from litigation and complaints as a learning resource, and work with the NHSLA and the NPSA to determine how best to share data.⁸⁰ The NHSLA already alerts NHS Trusts to significant developments in judicial decisions with a view to improving clinical practice,⁸¹ but it is unclear whether the cautions it issues are incorporated into NHS and clinician practice in systematic ways. The utility of data about clinical negligence claims is likely to be limited by the reality that most cases settle before a definitive determination of what occurred and why, and settlements are often subject to non-disclosure agreements.

8. Mediation and other forms of alternative dispute resolution can offer broader remedies than courts, and can also divert cases away from civil litigation.⁸² The Better Regulation Task

⁷⁸ *Ibid.*, 14.

⁷⁹ *Ibid.*, 15-16.

⁸⁰ NAO 2005, *supra*, n.34 at 10. See also Vincent, C., Walshe, K., Davy, C., Esmail, A., "Learning from litigation: the role of claims analysis in patient safety", in Walshe, K., Boaden, R., *Patient safety. Research into Practice* (Maidenhead, Open U. Press, 2006), 144-160.

⁸¹ See eg., Jones, M., "A Risky Business", (2005) 13 Tort L.Rev. 40 at 50.

⁸² *Making Amends, supra*, n.9 at 118.

Force recommended that the Pre-Action Protocols be strengthened to require parties to explain why they rejected mediation, and that this be a consideration in costs awards.⁸³

9. No-Fault Compensation. The most radical proposal to emerge from all of the activity aimed at improving the situation of injured patients and reducing the incidence of future harm was the Bristol Inquiry's recommendation that the clinical negligence system be abolished and replaced with alternative systems for compensating patients and overseeing health care delivery and providers. In *Learning from Bristol*, Sir Ian Kennedy, who chaired the inquiry, wrote:⁸⁴

The system [of clinical negligence litigation] is now out of alignment with other policy initiatives on quality and safety: in fact it serves to undermine those policies and inhibits the safety of care received by patients... We believe that the way forward lies in the abolition of clinical negligence litigation, taking clinical error out of the courts and the tort system.

He recommended that the system for compensating people who suffer harm from medical care be reviewed, with a view to introducing an administrative system that would respond promptly to patients' needs in place of tort, and take account of other administrative systems for meeting the financial needs of the public.⁸⁵ This was not the only such proposal, and in response, in 2001 the Department of Health initiated a review of the system for handling compensation claims and complaints in the NHS, chaired by the Chief Medical Officer. His report, *Making Amends: A consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS*, was published in 2003.⁸⁶ It was meant to address ways to improve patient safety, the difficulties injured patients face in obtaining redress, and the high costs of the tort system.⁸⁷

III. MAKING AMENDS

The recommendations in *Making Amends* are concerned with improving standards and not just preventing litigation. However, several commentators have noted that the measures recommended place at least equal importance on preventing litigation and containing costs to the NHS as on risk management and restoring trust in the NHS.⁸⁸ The report concluded that even with recent reforms to personal injury litigation, the present system was still unsatisfactory

⁸³ Better Regulation Task Force, "Better Routes to Redress" (May, 2004), at 28.

⁸⁴ *Supra*, n.45 .

⁸⁵ *Ibid.*

⁸⁶ *Supra*, n. 9.

⁸⁷ *Ibid.*

⁸⁸ Jones, *supra*, n.1 at 40, 52; Wheat, *supra*, n.8 at 448.

because it remained complex, unfair, slow, costly, time-consuming, damaging to morale and public confidence, unsatisfactory to patients left without explanations, apologies or reassurance about improvements, and a barrier to learning from mistakes because of its encouragement of secrecy and defensiveness.⁸⁹ It identified four options for reform: (1) continue to reform the tort system; (2) introduce no-fault compensation; (3) introduce fixed tariffs for particular types of injury administered by a national tribunal; and (4) a composite package of reform.⁹⁰

While acknowledging that reforms undertaken previously and the work of the NHSLA had led to improvements, the CMO rejected change based solely on continued tort reform, because:⁹¹

- Who can and cannot prove negligence remains a “lottery”;
- There is little support for patients making complaints and claims;
- The current legal system provides little or no incentive to report, learn from and reduce errors;
- The adversarial system undermines the relationship between patients and healthcare professionals, reduces trust in the NHS, and diverts staff from clinical care;
- A more entrenched “litigation culture” could result in greatly increased costs and increased defensive medicine, as in the United States;
- Independent evaluation of a small claims pilot (Resolve) that had been supported by the Department of Health and the NHSLA found that even patients who receive compensation often remain dissatisfied if they do not also receive explanations, apologies, and reassurance about preventative action in the future;
- While difficult to determine definitively, the tort system appears to have provided little incentive for the prevention of mistakes, or putting right mistakes that have been made.

He concluded that further modifications to court-based processes without more could not resolve these issues.

Given the many shortcomings in the tort system as a means of compensation identified in this report and others, and the advantages of no-fault compensation, no-fault seems an appealing alternative. However, it, too, was rejected, principally because of expense. Overall costs would be higher because of a lower threshold for claims (i.e. no need to prove negligence)

⁸⁹ *Supra*, n.9 at.13.

⁹⁰ *Ibid.*, at 109-118.

⁹¹ *Ibid.*, at 110, para. 5; 108, para. 61.

and a greater number of claims; compensation levels would be lower in order to keep the system affordable, leaving some patients with unmet needs; and difficulties would arise in distinguishing the effects of disease from those caused by health care. The implications of the right to a fair hearing guaranteed by the *Human Rights Act of 1998* were also a consideration.

A system of fixed tariffs administered through a national tribunal was also rejected, because of the generally low levels of awards under other such systems, their lack of relationship to victims' actual losses, and the inflexibility in both awards and timing.⁹²

Making Amends recommended a composite package of compensation, with three parallel compensation schemes. One would provide "NHS Redress" for low value claims, a second would provide redress for cases involving brain damaged babies, but on a much greater order of magnitude and with less exacting eligibility criteria, and all other claims would still be resolved through the tort system, although because of changes to the calculation of damages, at reduced cost to the NHS. NHS Redress would include an investigation and explanation of adverse events, as well as information about action planned to prevent a recurrence, development and delivery of a package of care where needed (including remedial treatment or continuing care as necessary), and payments for the costs of care or treatment that the NHS could not provide, and for pain and suffering.⁹³ Accepting a package of compensation would preclude litigation. Both of the first two compensation schemes are outlined in general terms, meaning that there are a number of uncertainties about how they would operate.

The proposal for low value claims provides that eligibility for payment would depend on the harm having been avoidable, and "serious shortcomings" in the standards of care (also referred to as "seriously substandard NHS hospital care").⁹⁴ That standard seems to require that fault and causation be established, as in a claim for clinical negligence. Difficulties in establishing causation and breach of the standard of care could be eased by provisions making the process less legalistic and more administrative, simplifying procedures and timing in straightforward cases, and defining the qualifying circumstances in a more expansive fashion than is the case in negligence claims. Nonetheless, some form of that determination would still have to be made.

⁹² *Ibid.*, at 114, 115.

⁹³ *Ibid.* at 115, para. 22.

⁹⁴ *Ibid.*, at 115, para.22; 120.

Eligibility for compensation for babies who have suffered brain damage is not so limited; claimants need only establish the presence of severe neurological impairment, and that it is related to or resulting from the birth.⁹⁵ Consequently, causation would be easier to establish. It is estimated that under the tort system, claims on behalf of babies with brain damage currently account for approximately 60% of costs, and even then, many claims are unsuccessful.⁹⁶ If adopted, this would be a true no-fault system.

Finally, those who chose not to apply for or accept packages of compensation or who did not fit the criteria for either stream could still litigate, although the availability of redress could be taken into account in decisions about funding lower value claims. *Making Amends* includes other recommendations about how the NHS should respond to patients who have been injured by an adverse event, and about the civil justice system. Relative to the latter, it recommends that mediation should be seriously considered before litigation, and that the rule requiring that complaints be halted when there is a legal claim be rescinded, so that regardless of financial compensation, patients can still obtain apologies, explanations, and information about plans to prevent future harm.⁹⁷ It also proposed the introduction of a statutory “duty of candour” (Lord Woolf had suggested a similar duty already existed at common law). Health care professionals and managers would be required to inform patients when they become aware of a possible negligent act or omission, with an exemption from disciplinary action for those who reported adverse events, unless the health professional had committed a criminal offence or it would be unsafe to allow the person to continue to treat patients.⁹⁸ In order to reduce disincentives to reporting errors, it recommended that documents and information collected to identify adverse events be protected from disclosure in court, provided that full information on the event was also included in the medical records (and therefore, presumably, available to the patient).⁹⁹

Two additional recommendations are meant to reduce the cost to the NHS of compensating tort claims that remain outside the Redress schemes: first, that in paying damages for future care and losses, the expectation should be that periodical payments will be used, and

⁹⁵ *Ibid.*, at 121.

⁹⁶ Jones, *supra*, n.1, at 46.

⁹⁷ *Ibid.*, Recommendations 15, 8.

⁹⁸ *Ibid.* at 125, Recommendation 12.

⁹⁹ *Ibid.* at 126, Recommendation 13.

second, that the costs of future care should no longer reflect the costs of private treatment.¹⁰⁰ Michael Jones points out that the second of these is controversial, because “...there is no guarantee that the care claimants need will be provided by the NHS when it is needed”.¹⁰¹ The Better Regulation Task Force confirmed that despite the importance of rehabilitation, “a demand is being generated that cannot be met”; while the private sector has responded, the NHS is hampered by a lack of resources and competing priorities.¹⁰²

Given the persuasive critiques of the tort system set out in *Making Amends*, and its conclusion that

“...it is impossible to escape from the fact that tort sits so uncomfortably in an NHS with an ethos of equity and a wish to bring about the greatest good to the greatest numbers. Even a reformed tort system is unfair in compensating only the select few. It offers no dynamic for higher quality and safer care for the large number of patients...It creates few incentives for providers of health care to reduce risk”,

it is in some ways surprising that the Report nonetheless recommended retaining tort in clinical negligence cases.¹⁰³ It situated its proposals as a way to “...move the role of tort from its current central position to the outer perimeter of the NHS”.¹⁰⁴ Even if fully implemented, that goal is still likely to be only partially realized. Claims on behalf of brain-damaged babies, which account for a majority of costs incurred in clinical negligence claims, would be resolved through a no-fault system. Lower value claims and their disproportionate expenses would be moved to an alternate recovery system; although still requiring some proof of fault and causation, this would likely increase recovery in lower value cases, including some that cannot presently meet the legal definition of negligence (although the rigor of the tests to be applied remains unclear and will affect recovery). However, others who have suffered an injury from treatment or care would be limited to tort claims, with all the difficulties that the report itself identifies so clearly, and with more limited entitlement to damages. In the end, the proposals are a pragmatic response to the CMO’s conclusion that a comprehensive no-fault

¹⁰⁰ *Ibid.*, Recommendations 16 and 17.

¹⁰¹ *Supra*, n.1 at 51. The *Law Reform (Personal Injuries) Act 1948*, s. 2(4) provides that in an action for personal injuries, in determining the reasonableness of expenses, the possibility of avoiding the expenses by taking advantage of facilities available under the NHS is to be disregarded.

¹⁰² Better Regulation Task Force, *supra*, n.83 at 33-34.

¹⁰³ *Supra*, n.9 at 118.

¹⁰⁴ *Ibid.* at 119.

system that would provide levels of compensation acceptable to the public was simply unaffordable for the NHS.¹⁰⁵

IV. THE NHS REDRESS BILL, 2005

In October, 2005, the government introduced the NHS Redress Bill.¹⁰⁶ It is aimed at lower value claims; the government is not proceeding with reforms to the compensation system for babies who have suffered brain damage related to birth at this time, having decided to pursue measures to improve the standards of care for all children with disabilities, however incurred. The Bill is intended to reform the clinical negligence system, enabling patients with claims arising in connection with certain health services in England to receive redress without having to resort to the legal system. It is expected to increase spending on compensation in the short term, because it will bring new claims into the system, but to realize savings in the longer term because of a reduction in expenditures on legal costs, with estimates of the Bill's impact ranging from £7 million in savings to £48 million in costs.¹⁰⁷ It would be funded by contributions from scheme members (primarily NHS Trusts), supplemented with funding from the Department of Health. It would be available for claims arising from hospital care and other listed qualifying services provided as part of the NHS.¹⁰⁸ The initial upper limit on claims is expected to be £20,000.¹⁰⁹

Incidents will be investigated by patient redress investigators, who are to comply with rules of natural justice, and whose practice will be monitored by the Healthcare Commission.¹¹⁰ It is anticipated that the NHSLA will be responsible for determining eligibility and managing financial compensation, although the scheme will be administered locally.¹¹¹ In order to establish eligibility for redress, there must be "qualifying liability in tort" that is (1) consequent on personal injury or loss arising out of breach of a duty of care owed in connection with the diagnosis of illness, or the care or treatment of a patient; and (2) in consequence of an act or omission of a healthcare professional (whether regulated or unregulated). At the same time, in a

¹⁰⁵ *Making Amends*, *supra*, n.9 at 112, para 13.

¹⁰⁶ The NHS Redress Bill, 2005, as amended (Bill 137), online at: <http://www.publication.parliament.uk/pa/cm200506/cmbills/137/2006137.htm> (last accessed March 2006).

¹⁰⁷ Full Regulatory Impact Assessment Statement (hereafter, RIAS), online at: <http://www.dh.gov.uk/assetRoot/04/12/09/24/04120924.pdf> (last accessed March, 2006), at 15.

¹⁰⁸ NHS Redress Bill, *supra*, n.106 .

¹⁰⁹ RIAS, *supra*, n.107.

¹¹⁰ *Supra*, n.106.

¹¹¹ RIAS, *supra*, n.107.

somewhat contrary instruction, the NHS is expected to “put the problem right, regardless of fault”.¹¹² Since it is enabling legislation, details of the redress scheme are scant, although it must provide for offers of compensation (financial and/or otherwise), as well as apologies and explanations. Civil litigation is precluded if an offer of compensation is accepted. The scheme can be triggered by claims by or on behalf of a patient, and by service providers identifying eligible cases. Organizations and individuals investigating or reviewing care and the Health Care Commission can be required to consider whether there may be liability under the scheme, and respond accordingly. The Health Service Commissioner will be authorized to investigate complaints arising from the administration of the scheme.¹¹³

There is widespread support for the aim of the Bill, i.e. providing an alternative to lawsuits for clinical negligence.¹¹⁴ However, a number of patient and consumer groups have strongly criticized it because (1) the NHS itself would decide the merits of any case for redress, (2) patients would not have access to specialist medico-legal advice essential to influence decisions about their claims, and (3) robust mechanisms to ensure patient safety lessons are learnt are lacking.¹¹⁵

In February, 2006, the government was narrowly defeated in the House of Lords on an opposition amendment that introduced independence into investigations under the scheme (via patient redress investigators). The Bill as amended will now be debated in the House of Commons.¹¹⁶

While the qualifying criteria simply track the tort framework for establishing negligence and hence, require proof of both causation and fault, the extent to which the scheme will provide an effective response to concerns about unfairness in the clinical negligence system will be greatly affected by decisions about how and by whom these determinations will be made. At this point, one cannot ascertain the extent to which the legislation will achieve its goal of not only

¹¹² *Supra*, n.107 at 12.

¹¹³ *Supra*, n.106.

¹¹⁴ See eg. British Medical Association, “NHS Redress Bill – England and Wales”, online at <http://www.bma.org.uk/ap.nsf/Content/NHSRedressBill> (last accessed March, 2006); Patient Advocacy Liaison Service (PALS), “NHS Bill causes concern. AvMA and other groups are lobbying for improvements in government plan” online at <http://www.pals.nhs.uk/CmsContentView.aspx?ItemId=1281> (last accessed March 2006).

¹¹⁵ See generally Action against medical accidents (AvMA), online at <http://www.avma.org.uk> (last accessed March, 2006).

¹¹⁶ Action against medical accidents (AvMA), “Progress in Parliament”, online at http://www.avma.org.uk/index_main.asp?SectionID=&Status= (last accessed March, 2006).

providing redress to patients, but also de-emphasizing blame (which by its terms the scheme seems to require), and replacing it with a focus on learning from mistakes, preventing harm and reducing risk.

V. REFLECTIONS ON TORT REFORM AND PATIENT SAFETY IN ENGLAND

Despite cogent criticisms of tort, and even with the imminent introduction of one part of the Redress system for lower value claims, tort principles and the tort system show remarkable persistence. While it is possible to remove some types of claim from the purview of clinical negligence, as was done in the United Kingdom with the *Vaccine Damages Payment Act 1979*, moves in that direction are cautious and partial. Even that system requires proof of causation, i.e. a determination on the balance of probabilities that serious mental or physical disability was caused by the administration of specified vaccines.¹¹⁷ Replacing tort raises concerns about cost, equity (how to justify a special scheme for medical malpractice cases when people who are disabled or suffer personal injury from other causes, whether tortious or not, do not have access to an equivalent compensation system), and accountability (particularly in an environment where public trust in the NHS, regulatory agencies and government has been severely shaken by repeated public exposure of instances and patterns of seriously substandard clinical care, clinical and managerial governance, and oversight mechanisms).

No-fault compensation systems, while appealing in theory, were rejected by the CMO in *Making Amends*, by the English government which has only gone as far as to propose a Redress scheme for lower value claims, and in Scotland, where it was considered that no-fault (1) did not encourage improvements in the quality of care, and (2) because vestiges of fault remain, required a bureaucratic system that still had to tackle complex issues of negligence and causation, but without legal expertise.¹¹⁸ Even one of the major English non-government organizations that provides advice and support to people affected by medical accidents and negligence, Action Against Medical Accidents (AvMA), while not enamoured of the tort system given the reality of its effects on people injured by health care, is hesitant to support a move to an entirely no-fault compensation system. It is concerned that no-fault recovery would be arbitrarily limited.

¹¹⁷ *Making Amends*, *supra*, n.9 at 104.

¹¹⁸ Scotland. Report of the Expert Group on Financial and Other Support, “2. Summary of Conclusions and Recommendations, Conclusions, No-Fault Compensation”, (Dec. 2, 2004), online at <http://www.scotland.gov.uk/library5/finance/egfs-03.asp> (last accessed Dec. 2004).

Additionally, the pressures for positive change in organizational culture and safety that result from negligence claims and judgments (even if the focus is on preventing claims rather than preventing accidents) would be lost. While AvMA sees considerable potential in the Redress schemes proposed in *Making Amends*, it believes emphasis should be on a fair and open system with proportionate repercussions for what has occurred, rather than an illusory and ultimately inappropriate wish for “no blame”. Given that in important ways, the patient safety agenda arose from patients and from litigation, AvMA considers the tort system useful as a last resort to ensure accountability.¹¹⁹

Looking to the tort system as a means to compensate for personal injury resulting from treatment remains problematic. Suggestions that groundless negligence claims are overwhelming the system are not founded, although the perception that there is a “culture of compensation” has its own dynamic and damaging effects.¹²⁰ While there may be some need to control an attitude encouraging claimants to “have a go” at litigation, that problem is not widespread; it is more important to have systems in place that ensure people with legitimate claims can bring them forward and obtain redress.¹²¹ The introduction of enterprise fault liability with the NHS Indemnity Scheme, together with the increase in clinical negligence claims, the aftermath of the series of scandals that plagued the NHS, and extensive analyses of improvements needed in the health care system have all contributed to support broader efforts to address clinical risk. Still, for more than a decade, reviews of the civil justice system have repeatedly criticized tort’s shortcomings, and faulted the operation of the clinical negligence system in particular for failing to achieve justice. These criticisms gain force as more becomes known about the large number of adverse events patients suffer that could be prevented. A smaller, but still significant portion of those would involve negligence, yet relatively few result in litigation or compensation. Despite this, moving tort from the centre to the periphery, as the Chief Medical Officer envisaged, has not occurred, nor has it been entirely accepted as a policy goal.

At the same time, many other entities now play a role in safety and quality efforts and are working to influence the actions of clinicians and administrators to improve care. What is

¹¹⁹ Personal communication with Peter Walsh, Liz Thomas, and Kitty Williams, Action against medical accidents (AvMA), May 4, 2005.

¹²⁰ Better Regulation Task Force, *supra*, n.83 at 11-12.

¹²¹ *Ibid.*, at 37.

particularly striking to an outsider analyzing developments in patient safety in England is the massive scale of the response on the administrative side -- there are new agencies, new mandates, new resources, new responsibilities, new studies, new evaluations, and new money. In that sense, tort's central role may be overtaken or at least shared with other players, and perhaps sometimes upstaged. While initial experience with the operation of these new agencies indicates a need to clarify, refine and simplify their mandates, reporting requirements and interrelationships, efforts are being made to lighten the load of compliance and simplify access for the public, while maintaining the momentum to ensure better, safer care.

CHAPTER 5. AUSTRALIA

Australia is of particular interest to this study because of the extent of activity on both the tort reform and patient safety fronts over the last several years. Governments across the country have enacted substantial changes to tort law. At the same time, many safety and quality programs were introduced, while at some hospitals, patterns of problematic care, patient injury and ineffectual responses triggered the concentrated scrutiny of public inquiries and reviews examining the operation of care delivery and safety and quality systems in practice. The sweeping tort reforms have given rise to extensive analysis and commentary. Numerous policy documents, inquiry reports and other reviews, as well as recent evaluations of the work of the national safety and quality organization provide a great deal of information about developments in patient safety and issues that remain outstanding. Taken together, the two bodies of literature, on tort law and patient safety, provide a rich resource for this study. Both are important to an understanding of the ways in which the civil liability system and patient safety initiatives affect each other.

The first section of this chapter outlines the background, aims and outcomes of the recent tort reforms. Section II reviews developments in patient safety initiatives and analyzes those most germane to civil liability. The final section assesses the implications of tort reform for patient safety programs, and in turn, the import of patient safety initiatives for the civil liability system.

I. Tort Reform

The law of negligence is broadly similar in Canada (with the exception of Quebec) and Australia.¹ Australia's extensive reforms to tort law are significant to this study for several reasons. First, one of the drivers of change was concern about the consequences of medical malpractice litigation, not just tort litigation in general. Second, tort reform coincided with the implementation of many safety and quality initiatives, allowing examination of the interaction between the two. Third, Australia is a federal jurisdiction and, like the provinces in Canada, the states and territories have power over and responsibility for the health care system,

¹ On Australian medical law, see Skene, L., *Law and Medical Practice: Rights, Duties, Claims and Defences* (2nd ed.) (Sydney: Lexis Nexis, 2004).

administration of the court system, and many of the laws regulating civil liability, including tort.² While the tort reforms enacted were not entirely uniform, the state, territorial and Commonwealth governments did agree on a common approach to evaluating the law and the direction reform should take, and in broad terms, a common response.³ Whether or not one agrees with the solutions adopted, or even the initial analysis of the problem, analyzing the conditions for and implementation of common action on tort reform in a federal state with important similarities to ours in its constitutional division of powers can assist in determining lessons to be learned from this experience for Canada.

This Section outlines the factors that led to review of the law of negligence and the reforms recommended. It summarizes the legislative responses, characterized by the Commonwealth government as “unmatched in the common law world for their breadth and scope”.⁴ While necessarily preliminary because the changes were implemented only recently, it assesses the likely effects of the aggressive programs of law reform undertaken.

Factors Triggering Tort Reform

The immediate catalyst for action was a crisis in the insurance industry, which came to a head with the collapse of Australia’s largest public liability insurer (HIH) in 2001 and its largest medical indemnity organization (UMP) in 2002.⁵ Changes to the tort system were not prompted by a concern to improve patient safety or reduce medical error. As the Commonwealth government noted: “These reforms were specifically designed to promote predictability to improve the cost and availability of liability classes of insurance and alleviate a crisis that had engulfed the Australian community”.⁶ Although precipitated by the collapse of the two major insurers, the debate about what had caused things to come to this pass and how to respond had been brewing for some time.

² Commonwealth of Australia. “Reform of liability insurance law in Australia” (Canberra: Canprint Communications Pty, 2004) (hereafter, Commonwealth 2004 Report), online at: <http://www.treasury.gov.au/contentitem.asp?pageId=035&ContentID=799>, (last accessed July 2005), at 3.

³ *Ibid.*, at 6.

⁴ *Ibid.*, at 3.

⁵ Tito-Wheatland, F., “Medical Indemnity Reform in Australia: ‘First Do No Harm’” (2005) 33 J L.Med. Ethics 429 at 433-434.

⁶ Commonwealth 2004 Report, *supra*, n.2 at 3.

There is considerable disagreement among Australian writers about the reasons for the insurers' collapse.⁷ Various factors are cited: on the business side, mismanagement, lack of prudential regulation and commercial realities (insurers' poor business practices, the cyclical nature of the insurance industry, falling stock markets worldwide reducing insurers' return on investments, ripple effects following the terrorist attacks of September 11, 2001, and others).⁸ As for the civil justice system, the litigation environment was increasingly characterized as too lenient and too generous (the Ipp Report summarized widely held views at the time: negligence law was considered to be unpredictable and unclear, cases were too easy for plaintiffs to win, and damages awards in personal injury cases were often too high⁹). This type of criticism of the outcomes in negligence actions increasingly permeated public discourse.

An influential speech delivered by the Chief Justice of New South Wales in 2002, titled "Negligence: The Last Outpost of the Welfare State", captured a number of themes in the debate.¹⁰ Australian judges seem less circumspect than their Canadian counterparts about commenting publicly on legal developments, and this speech was no exception. Spigelman, CJ, argued that negligence law had become too favourable to claimants, both as a result of what Patrick Atiyah had termed "stretching the law", and also, he suggested, because of a parallel trend in courts to "stretch the facts" in order to justify recovery.¹¹ Unspoken assumptions about the background presence of insurance and (quoting a colleague) "...a compensation-conscious community [in which] citizens look for others to blame" had led to expansions in the scope of negligence law and the damages recoverable, to the point where judgments were out of step with public expectations and threatened to impose too heavy a burden on the community.¹² While noting that the trend appeared to have been reversed in recent judgments, he was doubtful that legislators would "have enough patience to allow this development to work itself out", particularly since the government had effectively "accepted the position of re-insurer of last

⁷ Compare Tito-Wheatland, *supra*, n.5 and Commonwealth 2004 Report, *supra*, n.2; see also Luntz, H., "The Australian Picture", (2004) 35 VUWLR 879; Underwood, P., "Is Ms. Donoghue's Snail in Mortal Peril?" (2004) 12 TLJ 39-60.

⁸ See eg. Tito-Wheatland, *supra*, n.5; Underwood, *supra*, n.7.

⁹ Commonwealth of Australia, "Review of the Law of Negligence Report" (David Ipp, Chair), (Sept. 2002) (Canberra: Australian Gov't Publishing Services, 2002) at p.25-6, online at: <http://revofneg.treasury.gov.au/content/reports.asp> (last accessed July 2004) (hereafter, Ipp Report). Refuting this view, see eg. Luntz, *supra*, n.7; Underwood, *supra*, n.7.

¹⁰ Spigelman, J.J., "Negligence: the Last Outpost of the Welfare State" (2002) 76 Aus. L.J. 432.

¹¹ *Ibid.*, at 433.

¹² *Ibid.*

resort”, with the financial responsibilities that entailed.¹³ In his view, when the common law of negligence had been modified by statute previously, the changes had reflected the interests of “...the persons driving the reform process...insurers or public instrumentalities with equivalent interests”, such that “...the primary source of ideas about what changes are required have come from the perspective of insurance underwriters seeking to limit claims (and therefore premiums), or their functional equivalents in a government backed scheme seeking to restrict the call on public funds...”.¹⁴ While he, too, favoured reform to restrict liability and damages and curtail “...the imperial march of the tort of negligence”, he argued that reforms that were principle driven would better achieve these goals than the prevailing “underwriter driven reform”.¹⁵ This was strong language, and much quoted.¹⁶

Whatever the precise combination of causes and the respective contribution of each, fallout from the collapse of the two insurers was significant: enforcement of existing claims by victims of wrongdoing became uncertain, public liability and medical indemnity insurance premiums increased substantially, community events were cancelled when insurance was unavailable or unaffordable, some physicians withdrew services, and the possibility of longer term unavailability of physician services in certain areas of the country loomed.¹⁷ Governments considered the situation had “the potential to cause major social disruption”.¹⁸ They responded to protect people who had existing claims, protect organizations and medical practitioners who faced claims from past events, and to ensure insurance would be available and affordable in the future.¹⁹ The shared sense of crisis galvanized politicians to deliver substantial change quickly.²⁰

The Ipp Report: Review of the Law of Negligence

The tort system was an obvious candidate for attention. The civil liability system does affect insurance premiums, was being widely blamed as the chief culprit, and was a factor

¹³ *Ibid.*, at 434.

¹⁴ *Ibid.*, at 439-440.

¹⁵ *Ibid.*, at p.441, 440, 436. It should be noted that characterization of reform is often in the eye of the beholder!

¹⁶ Cane, P. “Reforming Tort Law in Australia: A Personal Perspective”, (2003) 27 *Melb.U.L.Rev.* 649, at 664.

¹⁷ Cane, *ibid.*, at 665; Luntz, *supra*, n.7 at 888-9. As Ipp, J. put it, while “There is no conclusive evidence that the state of the law of negligence bears any responsibility for this situation”, insurers acted as though it did, and made insurance unavailable or unaffordable, such that “the basic fabric of community life is being harmed” – Ipp, D., “Negligence – Where Lies the Future?” (2003) *Aus. Bar Rev.* 158 at 159 (hereafter, “Ipp 2003”).

¹⁸ Cane, *supra*, n.16 at 665.

¹⁹ Luntz *supra*, n.7 at 889.

²⁰ Clark, S. and McInnes, R., “Unprecedented Reform: The New Tort Law” (2004) 15 *ILJ.*

governments could regulate. Not surprisingly, that is where they focused their response. The Commonwealth, state and territorial governments established a “principles-based” review of the law of negligence, conducted by a judge, an academic torts scholar, a medical professional, and a member of a local authority, collectively known as the “Panel of Eminent Persons”.²¹ It began work in July, 2002, and was given two months to report initially, and three months to deliver a final report (the “Ipp Report”).²² The governments’ directions to the Panel were explicit: “The award of damages for personal injury has become unaffordable and unsustainable as the principal source of compensation for those injured through the fault of another. It is desirable to examine a method for the reform of the common law with the objective of limiting liability and quantum of damages arising from personal injury and death”.²³ The panel was to inquire into the common law of negligence, its underlying principles and operation in the case of personal injury or death, how to limit liability and quantum of damages (with particular reference to public authorities, non-profit organizations, and medical negligence), and how to harmonize recovery available under other statutes to ensure reform efforts were not stymied.²⁴ The process was driven by the Treasury ministries, which influenced both the statement of the problem and the solutions. As Peter Cane, one of the members of the panel, commented, “...the underlying problem was seen as being primarily economic rather than legal”.²⁵ The crisis identified was the high costs of negligence claims, and not, for instance, an unacceptable incidence of medical error, or the disparity between the large numbers of patients injured by healthcare, and the relatively small numbers of patients compensated through the legal system. The solutions developed aimed to lower and shift those costs, by reducing the scope of liability and the quantum of damages.

²¹ Cane, *supra*, n.16 at 667.

²² *Ibid.* at 666.

²³ Commonwealth of Australia. “Review of the Law of Negligence Report (David Ipp, Chair), (Sept., 2002), online at: <http://revofneg.treasury.gov.au/content/reports.asp> (last accessed July 2004), at ix (hereafter, the Ipp Report).

²⁴ *Ibid.*, ix-xi.

²⁵ Cane, *supra*, n.16 at 667. Cane identifies himself as a “radical” on tort reform, believing that the tort system is poor at compensating for injury, deterring future harm, and accurately assigning responsibility for “moral” fault (tort’s three classic justifications). He supports a social security type of replacement. The Ipp Review was given a very different agenda: it was to craft reforms based on the premise that too much is spent on compensating injured people through tort law, and that tort strikes the wrong balance between injurers and injured in terms of responsibilities to care for oneself and others – *ibid.*, at 651.

The panel recommended significant changes to the law of negligence, most of which governments adopted. Of the Ipp Report's 61 recommendations, those most relevant to medical malpractice litigation are as follows:²⁶

- altered tests for foreseeability of a risk of harm, as well as the duty to take precautions with regard to obvious risks;
- modification of test for standard of care to re-instate deference to expert medical opinion, unless “irrational”;
- re-statement of test for causation, to require proof of (i) factual causation (i.e. that negligence played a part in bringing about the harm), falling within (ii) an appropriate scope of liability (a normative determination about allocating the cost of injury);
- affirmation of subjective test to determine what a plaintiff would have done if the defendant had not been negligent, but excluding the plaintiff's testimony on that issue (relevant to failure to warn / inform of risks of treatment);
- equation of liability for breach of non-delegable duty of care with vicarious liability;
- statutory restrictions on circumstances in which damages for pure mental harm can be awarded;
- imposition of caps on damages for personal injury claims (past and future economic loss and non-economic loss), and additional restrictions on recovery, such as for gratuitous services;
- development of guidelines regarding quantum of damages;
- establishment of thresholds (for general damages, “15% of a most extreme case”);²⁷
- introduction of mandatory mediation with a view to securing structured settlements;
- retention of existing law regarding civil liability for wrongful acts and omissions done in good faith by Good Samaritans and volunteers;
- imposition of standard, shorter limitation period, commencing from discoverability;
- deduction of collateral benefits from damages awards on “like against like” basis;

²⁶ Ipp Report, *supra*, n.23.

²⁷ *Ibid.*, at 192, para. 13.4, 13.5. In Australia, “general damages” refer to non-economic loss. The Panel believed this threshold would exclude claims for relatively minor injuries (typically soft tissue injuries that heal quickly), with relatively insignificant economic loss (if any), and total compensation in the range of \$50,000 (Aus.), of which a significant proportion would be made up of general damages and legal fees.

- elimination of pre-judgment interest on damages for non-economic loss;
- abolition of exemplary and punitive damages;
- elimination and reduction of costs awards in smaller claims;
- retention of existing law governing joint and several liability in cases of personal injury or death, rather than proportional liability.

It recommended that the changes be incorporated in a single statute in each jurisdiction, applicable to claims for damages for personal injury or death, regardless of whether brought in tort, contract, equity, pursuant to statute or otherwise. While acknowledging that its recommendations would reduce or eliminate some compensation payable under the laws then in effect, thus shifting the costs of those injuries from injurers to injured parties, it left decisions about how to respond to that issue to governments.²⁸ It also pointed out that, although beyond its mandate, reductions in the secondary costs of compensation – i.e. legal fees and insurers’ administrative costs incurred in delivering compensation – could significantly contribute to reducing the overall costs of compensation.²⁹

The Neave Report: Responding to the Medical Indemnity Crisis

As the Ipp panel began work, the Australian Health Ministers Advisory Council (AHMAC) also appointed a group to develop recommendations for reforms to legal processes in health care claims. Its objectives were to improve patient safety, reduce the need to litigate and encourage earlier finalization of claims; provide fair compensation, and ensure affordable and sustainable premiums so medical services could be maintained.³⁰ The AHMAC Legal Process Reform Group was to develop proposals for governments’ consideration that would:³¹

- Reduce the need for litigation, encourage early resolution of claims before litigation, and streamline litigation processes to reduce delay;
- Improve handling of adverse events; and

²⁸ *Ibid.*, at 28, para 1.21.

²⁹ *Ibid.*, at 28, para 1.18. Little information is available on administrative and legal costs of claims, although it has been reported that legal defence costs paid by Australian medical defence organizations in the decade to 2001 were between 25% and 50% of damages paid (including plaintiffs’ costs borne by MDO’s) – Traverse, R., “Litigation and the medical indemnity crisis”, (2004) 12 JLM 178 at 180.

³⁰ Tito-Wheatland, *supra*, n.5 at 436.

³¹ Australian Health Ministers Advisory Council (AHMAC) Legal Process Reform Group, “Responding to the Medical Indemnity Crisis: An Integrated Reform Package”, (Marcia Neave, Chair) (Aug. 2002), online at: <http://www.health.act.gov.au/c/health?a=da&did=10011741&pid=1054039339> (last accessed July 2004), (hereafter, the Neave Report), at 8.

- Assess reforms needed to medical negligence law to ensure a proper balance among the interests of health care consumers, doctors and the community.

It was headed by Marcia Neave, Chair of the Victorian Law Reform Commission, and included representatives from government, medicine, and the plaintiff and defense bar. It, too, began work in July, 2002, and reported in August, 2002.

Given that its remit was from the health ministries rather than Treasury, and the different emphasis in its mandate, the premise guiding its work differed as well: reforms must balance the public interest in fair compensation with the public interest in ensuring premiums are affordable and sustainable, so that appropriate medical service levels can be maintained.³² It was focused not just on litigation reform, but also on broader systems issues such as the handling of adverse events, and was more attentive to balancing the interests of those concerned, rather than just limiting liability and damages. Some of its recommendations were similar to the Ipp Report's, including capping certain heads of damage, improving use of expert witnesses, changing limitation periods, imposing thresholds for compensable injuries, and facilitating structured settlements. Others differed, such as protecting apologies from constituting admissions of liability, enhancing alternatives such as ADR and conciliation by Health Care Complaints Commissions to divert claims from litigation, and addressing the need for a systematic response to long-term care costs.³³ The Neave Report explicitly considered the links between patient safety and litigation, and recommended measures to both encourage openness and enhance abilities to monitor where needed.³⁴ These included statutory protection from disclosure for risk management activities to facilitate greater openness about adverse events, support for open disclosure to patients to reduce the need to litigate simply to obtain information, and requirements to notify appropriate authorities when payments were made to resolve claims, to allow for investigation, if warranted.³⁵

³² *Ibid.* at 9.

³³ Mendelsohn, D., "Australian Tort Reform: Statutory Principles of Causation and the Common Law" (2004) JLM. 492; see eg. Neave Report, *supra*, n.31 at 88.

³⁴ Neave Report, *ibid.* at 26ff.

³⁵ *Ibid.*, at 37.

Both Reviews acknowledged being hampered in their work by the lack of good quality data on the incidence, causes and costs of medical litigation, and reliable and convincing empirical evidence about changes that should be made and their effects.³⁶

Statutory Reform

The Ipp Report overshadowed the Neave Report in its immediate uptake, although more recently, attention has returned to issues such as legislative support for open disclosure and investigating adverse events.³⁷ By November, 2002, governments had agreed to both a package of liability reforms based on key recommendations of the Ipp Report, and to work towards harmonizing the law of damages.³⁸ Changes to the law were quickly implemented in two or three waves of statutory reform in the states, territories and Commonwealth.³⁹ In terms of the distinction Spigelman, CJ had drawn between “underwriter driven” reform and “principle driven” reform, the statutory enactments included both.

Although the Ipp Report’s recommendation for nationally uniform legislation did not prevail, legislation in the various jurisdictions shares important features.⁴⁰ In some instances, reforms adopted went further than the Ipp Report had recommended, for instance by excluding “Good Samaritans” and volunteers from civil liability for wrongful acts and omissions done in good faith, and protecting apologies from constituting admissions of liability.⁴¹ Governments also set a higher discount rate than the Ipp Report recommended, despite the hardship that doing so would cause. As Mr. Justice Ipp pointed out, setting an unrealistically high discount rate is “...an unfair and entirely arbitrary way of reducing damages”, that most disadvantages “... those who are the most in need – namely, the most seriously injured”.⁴² Some jurisdictions adopted additional measures aimed at reducing litigation further, such as restricting legal advertising, and requiring lawyers to certify that cases have a reasonable chance of success before acting for a client on a claim or defence.⁴³ Federal legislation was passed in support, including amendments

³⁶ *Ibid.*, at 13, para 3.1ff; Ipp Report, *supra*, n.23 at 32, para 1.38-39.

³⁷ Underwood, *supra*, n.7; Tito-Wheatland, *supra*, n.5 at 436-7. Madden, W., “Tort reform and medical liability” (Dec. 2002) 54 *Plaintiff* 14, compares the Ipp and Neave Reports with legislation enacted in New South Wales.

³⁸ Commonwealth 2004 Report, *supra*, n.2 at 6; although see Ipp, 2003, *supra*, n.17 at 161-2.

³⁹ Some states – New South Wales in particular -- had already embarked on a program of changes to personal injury law before the Ipp Review (Luntz, *supra*, n.7 at 890, 895; Cane, *supra*, n.16 at 668).

⁴⁰ Mendelsohn, *supra*, n.33 at 494; Ipp (2003), *supra*, n.17 at 161, 162.

⁴¹ See eg. Mendelsohn, *ibid.*, and references cited at n. 23 therein; Luntz, *supra*, n.7 at 897, 891.

⁴² Ipp 2003, *supra*, n.17 at 170; see also Luntz, *supra*, n.7 at 898.

⁴³ See, eg. Commonwealth 2004 Report, *supra*, n.2 at 6, 116 (NSW legislation).

to tax laws to remove barriers to structured settlements, and to trade practices law, to foreclose efforts to circumvent state law reform by relying on causes of action other than negligence.⁴⁴ Reports issued by the Commonwealth government post-reform summarize the extensive changes made in each jurisdiction.⁴⁵

Statutory reform has continued, although at a slower pace. Some changes to civil procedure have been adopted in response to recommendations made by inquiries into deficient care and patient injury.⁴⁶ They are meant to improve patient safety and reduce error by encouraging greater openness among health care providers about adverse events. For instance, New South Wales recently extended statutory protection from compelled disclosure to teams engaged in root cause analysis and their work. These changes are discussed in greater detail in Sections II and III of this chapter.

Long-Term Care

Meanwhile, discussion of a statutory long-term care scheme outside the tort system for people who have been catastrophically injured re-emerges periodically. It was proposed (not for the first time) in the Neave Report;⁴⁷ more recently, the Australian Medical Association renewed its call for government support of such an initiative, arguing that it would both benefit people severely injured in accidents (including medical accidents), and make medical indemnity arrangements more certain and secure.⁴⁸ If adopted, it would have the potential to significantly affect tort liability, but without additional information about benefit levels, scope, eligibility and funding, its effects cannot be predicted with certainty.

The Medical Indemnity Support Scheme

Concomitant with the sweeping legislative reforms, the Commonwealth government put in place a medical indemnity support scheme. The cost of claims against public hospitals and

⁴⁴ Commonwealth of Australia, "Reform of liability insurance: Progress as at 8 April 2005", online at: <http://www.treasury.gov.au> (last accessed Nov. 2005), at 3 (hereafter, Commonwealth 2005 Report).

⁴⁵ *Ibid.*, and Commonwealth 2004 Report, *supra*, n.2 at 11-12.

⁴⁶ See, eg. New South Wales. "NSW Government Response to the Legislative Council General Purpose Standing Committee No. 2 Inquiry into Complaints Handling Within NSW Health" (March, 2005), online at: <http://www.health.gov.au/safetyandqualitydocs/NSW%20Report%20on%20comphandling.pdf> (last accessed Dec. 2005).

⁴⁷ Neave Report, *supra*, n.31 at 86.

⁴⁸ Australian Medical Association, "Carr in the Driver's Seat on Long-Term Care for the Severely Injured – AMA" (Feb. 10, 2005), online at: <http://www.ama.com.au/web.nsf/doc/WEEN-69G5QQ> (last accessed Dec. 2005).

their employees, including physicians, were already borne by state and territory governments.⁴⁹ Fiona Tito-Wheatland has summarized the elements of the package: (1) premium support (subsidizing physicians' premiums); (2) high cost claims scheme (a subsidy to meet half of damages payable over \$300,000); (3) run-off cover scheme (coverage after physicians die or leave the workforce); (4) exceptional claims scheme (all damages payable in excess of \$20 million); and (5) contribution by members of one insurer to its unfunded tail.⁵⁰ The Commonwealth government estimated that the cost of its commitments was approximately \$150 million (Aus.) per year.⁵¹ The effectiveness of these provisions is currently under review.⁵²

The Litigation Landscape Prior to Tort Reform

Any assessment of the effects of the reforms to tort law will require a comparison with what was replaced. In that regard, questions have been raised about whether there actually was an unsustainable "litigation explosion" fueled by medical negligence claims, or an unprincipled "pro-plaintiff" tilt to results, necessitating the large and sudden increases in insurance premiums that occurred.⁵³ A study by Wright and Melville reviewing empirical evidence about changes in rates of litigation in New South Wales concluded that there was no evidence of a general

⁴⁹ Australian Institute of Health and Welfare, "First Medical Indemnity National Data Collection Report: Public Sector, January to June 2003" (Canberra: AIHW, Dec. 2004), AIHW Cat. No HSE 34), online at: <http://www.aihw.gov.au/publications/index.cfm/title/10092> (last accessed Dec. 2005).

⁵⁰ Tito Wheatland, *supra*, n.5 at 437; see also Australia. Minister for Health and Ageing, "Final element of medical indemnity legislation introduced" (May 13, 2004), online at: <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2004> (last accessed Dec. 2005); Australia. Department of Health and Ageing, "High Cost Claims Scheme- Frequently Asked Questions" (June 22, 2005), online at <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-medicalindemnity-fa> (last accessed Dec. 2005); Australia. Department of Health and Ageing, "Exceptional Claims Scheme (formerly known as Blue Sky Scheme) (June 21, 2005), online at <http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/health-medicalindemnity-bl> (last accessed Dec. 2005).

⁵¹ Australia. Department of Health and Ageing, "Medical indemnity insurance: improvements", online at: http://www.health.gov.au/internet/wcms/publishing.nsf/Content/factsheet-medical_indemnit.. (last accessed Dec. 2005).

⁵² Australia. Minister for Health and Ageing, "Medical Indemnity Policy Review 2005" (Nov. 25, 2005), online at: <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2005> (last accessed Dec. 2005).

⁵³ See eg. Underwood, *supra*, n.7: "there appeared to be scant, or no, evidence to support" the conclusion that unpredictability in interpreting the law of negligence was a factor in driving up premiums; see also Luntz, *supra*, n.7 at 899; Luntz, H., "Reform of the law of negligence wrong questions – wrong answers" (2002) 8(2) U.N.S.W.L.J. Forum 18, refuting the suggestion that negligence law was developing in ways that inappropriately favoured plaintiffs

litigation explosion during the relevant time period.⁵⁴ Others strongly disagree.⁵⁵ The two views are largely irreconcilable, given that they depend not only on evaluations of factual data about lawsuits, but importantly, on different judgments about the aims of law, and who should bear responsibility for the costs of injury.

Focusing on medical negligence claims, it is widely accepted that people injured by health care seldom sue. Even when people have suffered significant disability as a result of highly preventable adverse events in the course of medical treatment, litigation is infrequent.⁵⁶ Conversely, not all lawsuits are evidence of negligence – there may have been no fault or injury at all. While precise figures are difficult to ascertain, there is a significant disparity between the number of lawsuits claiming medical negligence and the much larger number of adverse events. The 1995 Professional Indemnity Review Report compared the estimated number of adverse events (in excess of 400,000, with 230,000 clearly preventable) with the estimated incidence of litigation (fewer than 2000 per year alleging negligence, of which few go to court, and many never result in payment).⁵⁷ The 2002 Neave Report accepted that the volume and size of claims based on allegations of medical negligence had grown, but pointed out that a number of factors contributed to this development beyond simply an increase in the number of lawsuits, including growth in the number of services provided, medical developments, and medical advances resulting in decreased mortality from health care but increased periods of life with significant disability.⁵⁸

Recent Public Sector Litigation Claims Experience

⁵⁴ Wright, T., Melville A., “Hey, but who’s counting? The metrics and politics of trends in civil litigation”, in Priest, W., and Aneu, S. (eds.), *Litigation Past and Present* (Sydney, University of New South Wales Press, 2004), 96-122, at 109, 117.

⁵⁵ See eg. Spigelman, JJ. “Negligence and Insurance Premiums: Recent Changes in Australian Law”, (2003) 11 T.L.J. 61: “I am quite satisfied that the underlying cause [of rapid increases in insurance premiums] was the practical application of the fault-based tort system in the context of adversary litigation. This had produced outcomes which the community was no longer prepared to bear. What brought the issue to a head...were developments in the insurance industry”.

⁵⁶ Corrs, Chambers, Westgarth, “Open Disclosure Project: Legal Review” (Jan. 22, 2002), online at: <http://www.nsh.nsw.gov.au/teachresearch/cpiu/CPIUwebdocs/FinalLR858178v1.pdf> (last accessed July 2004), at 25.

⁵⁷ Referenced in the Neave Report, *supra*, n.31 at 13, para 3.2.

⁵⁸ *Ibid.* at 15, para 3.9, and generally, ch. 3.

Australia's new Medical Indemnity National Data Collections for the public sector provide more recent data about levels of litigation and the size of claims.⁵⁹ It includes both legal actions that are underway, and those considered sufficiently likely to materialize into a claim that a reserve has been set. As at June, 2003, 2,394 current claims had been reported, and 272 claims had been finalized during the preceding six months.⁶⁰ Most of these would have arisen from events and lawsuits that pre-dated the tort reforms. Almost 45% of claims had a reserve range of \$30,000 (Aus) or less; 5.6% of claims had a reserve range in excess of \$500,000 (including 16% of obstetrics claims).⁶¹ While it is estimated that the first report included only 50% of claims within its scope because of initial difficulties coordinating information from disparate systems, that had increased to 80% of claims by its second report, and further improvements in reporting are expected.⁶²

The Second Indemnity Data Report indicates that 1641 new claims were received and 827 claims finalized during the period July 1, 2003 to June 30, 2004. The database included 4956 claims in total during that time. Of claims finalized, 40% (340 claims) were decided out of court (82% of those with a claim size in excess of \$100,000 – 50 claims). Overall, only 6% (48 claims) were decided in court (16% of those with a claim size greater than \$100,000). Almost half (43%) of finalized claims were discontinued; 56% of these (207 claims) had a total claim size of less than \$10,000, and 33% (122 claims) resulted in no payment. Of claims finalized through a court decision, almost half resulted in no payment.⁶³ It is not yet clear whether the tort reforms, essentially making many smaller claims non-economic, will diminish insurers' willingness to make some payment in order to settle, because the threat of litigation will often have been eliminated (although such payments would have been atypical of medical insurers in any event).

⁵⁹ Australian Institute of Health and Welfare, "First Medical Indemnity National Data Collection Report: Public Sector, January – June 2003" (Canberra: AIHW, Dec. 2004), AIHW Cat. No. HSE 34, online at: <http://www.aihw.gov.au/publications/index.cfm/title/10092> (last accessed Dec. 2005) (hereafter, First Indemnity Data Report); and Australian Institute of Health and Welfare, "Medical Indemnity National Data Collection Public Sector 2003 to 2004, covering the period July 2003 – June 2004; online at: http://www.apo.org.au/linkboard/results.shtml?filename_num=13683 (last accessed Jan. 2006) (hereafter, Second Indemnity Data Report).

⁶⁰ *Ibid.*, First Indemnity Data Report at 17-18.

⁶¹ *Ibid.* at 18.

⁶² *Ibid.*, at 3; Second Indemnity Data Report, *supra*, n.59.

⁶³ *Ibid.* (Second Indemnity Data Report) at 12, 38. Information on results of finalized claims was lacking in 11% of cases.

Data on private sector medical indemnity claims may eventually be included in these reports as well.⁶⁴ As the reports become more comprehensive, they will provide the data needed to analyze trends in medical indemnity claims and litigation. Even with current limitations, the picture is not one of rampant and uncontrolled medical malpractice litigation. Further, the majority of claims are for smaller amounts, and the bulk of costs are associated with a relatively small number of large claims.

The Effects of Tort Reform

It is too early to assess the full impact of the tort reforms. Indications are that smaller claims have been significantly affected, a predictable result of the thresholds for damages, limitations on recovery of legal costs in smaller claims and other measures that were introduced.⁶⁵ Chief Justice Spigelman has criticized the operation of the threshold for general damages in particular (15% of a most extreme case).⁶⁶ He noted that general damages (i.e. non-economic losses) used to comprise about half the total damages in claims up to \$100,000, and that claims for non-economic loss in these cases had effectively been abolished, adding that while insurance companies might consider such payments small, “the matters are not small from the perspective of the injured person”.⁶⁷ It is not clear whether and to what extent complaints-based processes in the states and territories that have limited power to order payments will provide an alternative for claims where court is no longer an option. Larger claims will also be seriously affected by capped damages, limitations on certain heads of damage, increases in the discount rate, and other restrictions on assessing damages.

None of this is unexpected; reducing the risk of liability and size of judgments was, after all, the aim of the reforms. There has been some speculation that the new restrictions may lead lawyers to look further afield for other types of claims or different defendants.⁶⁸ The

⁶⁴ Some data is becoming available, but with a focus on satisfying prudential regulatory requirements – First Indemnity Data Report, *supra*, n.49.

⁶⁵ Spigelman, CJ reported a reduction in District Court cases, which handles most personal injury work, from about 20,000 in 2001 to 8000 in 2003 – *infra*, n.66. Anecdotally, Clark and McInnes reported that several law firms specializing in personal injury work reduced staff because of decreased work.-- Clark and McInnes, *supra*, n.20.

⁶⁶ Pelly, M., “Harsh personal injury laws deny legitimate claims, says judge”, Sydney Morning Herald, Oct. 11, 2004. In Australian law, general damages refer to non-economic loss, such as pain and suffering and loss of enjoyment and expectation of life.

⁶⁷ *Ibid.*

⁶⁸ See, eg. Spigelman, J.J., “Negligence and Insurance Premiums: Recent Changes in Australian Law” (2003) 11 T.L.J.61, and Clark, *supra*, n.20, mentioning intentional torts and class actions as candidates; see also Cashman, P.

Commonwealth government is certainly positive about the results. It reported that the insurance climate in Australia had “vastly improved” as a result of the reforms and government support, that capacity was returning to the insurance industry, price increases had stabilized, and international underwriters were interested in what was now considered an “attractively priced and profitable business”.⁶⁹

There are different views about how significantly statutory reforms will affect the substantive law of negligence.⁷⁰ Commentators also differ on what direction the law will take – for instance, whether it will be more or less difficult for plaintiffs to establish causation.⁷¹ Overall, as Mr. Justice Underwood and others have pointed out, the extent of changes to the law will depend on interpretation and application by the courts.⁷² However, in commenting on the legislative aftermath to the Ipp Report, Peter Cane, one of the members of the panel, argues that judges should follow the legislatures’ lead, since political processes of law reform are preferable to judicial as a mechanism for legalizing norms, “given the fact of genuine...disagreement about values and about the functions and effects of law”, and that “processes of legislative legalisation are more pluralistic and open”.⁷³

What The Law Reform Process Omitted

Resolving the insurance crisis was the prime consideration in Australian tort reform. It seems to have overwhelmed consideration for the interests of those to whom the financial costs of injury were shifted and the support they would require, i.e. the distributional consequences of these reforms. The speed of its adoption also precluded careful assessment of the terms of the

“Tort reform and the medical indemnity ‘crisis’”, (2002) 8(2) U.N.S.W.L.J. Forum 51 at 54, suggesting switching “forensic focus” from physicians to drug companies.

⁶⁹ Commonwealth 2004 Report, *supra*, n.2 at 11-12.

⁷⁰ Contrast Parker, M., “Reforming the law of negligence: solutions in search of a problem”, (2003) 11 T.L.J. 136. “...there is little reason to think that the changes recommended by the IR [Ipp Report] will produce significant changes to findings of negligence against Australia’s doctors and health institutions” with Commonwealth 2004 Report, *supra*, n.2, characterizing the scope of changes to common law as unprecedented.

⁷¹ See, eg. Mendelsohn, D., *supra*, n.33 at 509, who argues that, while the tort reforms have made it more difficult for plaintiffs to establish a duty of care and breach of the standard of care, they may have made it easier to prove causation; Spigelman, CJ (2003), *supra*, n.55 at 27, contented himself with observing that “...One can anticipate a considerable body of litigation about the scope, meaning and application of [the causation] provision”; Madden, W., “Causation developments and the Civil Liability Act”, Law Society J. (March, 2004), 66 at 67, suggests early indications are that there may not be major changes from how courts made decisions at common law about causation in cases of failure to warn; see also Crofts, P., “The more things change, the more they stay the same or the Civil Liability Act 2003 (Qld) – opportunity lost?”, (2003) 11(10) Health L. Bulletin 113.

⁷² Underwood, *supra*, n.7; Clark & McInnes, *supra*, n.20.

⁷³ Cane, P. “Taking Disagreement Seriously: Courts, Legislatures and the Reform of Tort Law” (2005) 25 OJLS 393-417.

support package government provided to the insurance industry, and what opportunities government subvention presented for requiring reforms in clinical governance and practice that could advance other policy goals, such as enhancing patient safety.

II. Patient Safety

Improving patient safety has been an important focus in Australia as it has elsewhere, particularly after publication of the Quality in Australian Health Care Study in 1995.⁷⁴ It found an adverse event rate of 16.6% in hospitalized patients, later revised to 10.6% following a comparison of methods with a similar American study.⁷⁵ Half were considered to be preventable.⁷⁶ The magnitude of these findings was a significant driver of the numerous safety and quality programs that have been developed at all levels, from government to service providers. The focus of this paper is on the interaction of tort law and patient safety initiatives, and so it does not attempt to detail these. Rather, the remainder of the chapter outlines the genesis and work of the first national organization established to lead and coordinate patient safety and quality of care efforts, the Australian Council on Safety and Quality in Health Care (the Council), reviews recent developments, and assesses the potential impact of the civil liability system and tort reform on patient safety initiatives and vice versa. Two patient safety programs in particular, open disclosure and root cause analysis, have been heavily promoted in Australia, and because of their potential interaction with the civil liability system and each other, are considered in greater depth. Similar programs have been adopted in other countries – root cause analysis has become a mainstay of the patient safety toolkit. Australia’s experience is unique, however, because substantial changes were being made to both patient safety programs

⁷⁴ Wilson, R., Runciman, W.B., Gibberd, R.W., Harrison, B.T., Newby, L. & Hamilton, J.D., “The Quality in Australian Health Care Study: Iatrogenic Injuries or adverse patient events in hospitalised patients”, (1995) 163(9) *Med. J. Aus.* 458-471. The QAHCS was commissioned by the Professional Indemnity Review, Commonwealth Dep’t. of Health, “Review of Professional Indemnity Arrangements for Health Care Professionals, Compensation and Professional Indemnity in Health Care – Final Report”, (Tito, Fiona, Chair), online at: <http://www.safetyandquality.org/articles/Publications/fitopir.pdf> (last accessed Nov. 2004).

⁷⁵ Thomas, E.J., Studdert, D., Runciman, W.B., Webb, R.K., Wilson, R.M. et al, “A comparison of iatrogenic injury studies in Australia and the USA”, (2000) 12(5) *Internat’l. J. Quality in Health Care* 371-378; Runciman, W., Webb, R., Helps, A., Thomas, E., Sexton, E., Studdert, D., Brennan, T., “A comparison of iatrogenic studies in Australia and the USA II: reviewer behaviour and quality of care”, (2000) 12(5) *Internat’l. J. Quality in Health Care* 379-388

⁷⁶ Wilson *et al.*, *supra*, n.74.

and the tort system simultaneously (albeit for different reasons), and because of its early focus on developing formalized process for open disclosure .

The Australian Council for Safety and Quality in Health Care

Spurred by the release of the Quality in Australian Health Care Study and on the recommendation of expert advisory groups, the Australian Health Ministers established the Australian Council for Safety and Quality in Health Care in January, 2000, with a mandate to lead national efforts to improve the safety and quality of health care provision.⁷⁷ It had a term of five years (later extended to June, 2006), a total funding allocation of \$55 million (of which half was provided by the Commonwealth and half by the states and territories), and reported annually to the Australian Health Ministers' Conference (AHMC).⁷⁸ As the Council's term drew to a close, the AHMC appointed a committee to review its work and develop proposals for the governance of safety and quality initiatives in the future, which reported in 2005 (the "Review").⁷⁹ Pursuant to the Review's recommendation, the AHMC established a new, smaller body in place of the Council, the Australian Commission on Safety and Quality in Health Care.⁸⁰ Its term began January 1, 2006. It, too, will be funded by all levels of government. While enhancing patient safety in hospitals continues to be an important goal, the Commission's mandate has been broadened to focus on quality improvement in the health care system more generally, including primary health care and the private sector. It will also be responsible for publishing national reports on the state of safety and quality, recommending national standards and datasets, identifying issues and policy directions in health care safety and quality, and advising Health Ministers on "best practice" thinking.

⁷⁷ Barraclough, B., "Advancing the Patient Safety Agenda: An Australian Perspective" (Commonwealth Fund, 2004), Publication No. 696, Appendix A, at 18, available online at: <http://www.cmwf.org> (last accessed Nov., 2004). Both the Taskforce on Quality in Australian Healthcare, which the Health Ministers established in 1995, and the National Expert Advisory Group on Safety and Quality in Australian Health Care, which reported in 1999, recommended formation of a national body.

⁷⁸ Australia. "National Arrangements for Safety and Quality of Health Care in Australia: The Report of the Review of Future Governance Arrangements for Safety and Quality in Health Care" (Paterson, R., Chair), (July, 2005), available online at: <http://www.health.gov.au/safetyandqualityreview> (last accessed Nov. 2005). The Australian Health Ministers' Conference (AHMC) is a mechanism for consultation between commonwealth, state and territorial health ministers; it is assisted by the Australian Health Ministers' Advisory Council (AHMAC), which includes the heads of commonwealth, state and territorial health departments in its membership – *ibid.* at 4, n.2.

⁷⁹ *Ibid.*

⁸⁰ Australia, Department of Health and Aging, "Australian Commission on Safety and Quality in Health Care – Consumer Information", available online at: <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/acsqhc-eoi-cons> (last accessed Dec. 2005).

From its inception in 2000, the Council focused on safety.⁸¹ Like patient safety advocates in other countries, its fundamental premises were first, that a systems approach was essential to improving patient safety, and second, that the culture of health care delivery had to change, shifting away from blaming individual practitioners when things went wrong to recognizing and addressing the underlying systemic causes of adverse events, so that health care providers could learn from accidents and mistakes.⁸² Although the Council could only recommend and not require action, it was influential in gaining wider acceptance and understanding of that agenda across the country. It played an important role as a policy advisory body; as its Chair, Bruce Barraclough, noted, it successfully influenced change through a “collaborative ‘third party broker’ approach, [while] also identifying, coordinating and funding action at all levels of the health care system”.⁸³ Examples include work on developing national standards, system re-design such as medication safety programs, supporting health practitioners, in part through educational strategies for achieving safer systems and responding to error, funding local initiatives to improve health care safety, and promoting greater awareness and understanding of a systems-based approach.⁸⁴ It also commissioned work assessing the implications of legal frameworks for particular patient safety initiatives, such as open disclosure and qualified privilege. In the Review’s assessment, the Council’s successes included “...raising awareness of safety and quality issues and how to tackle them, particularly among clinicians and administrators involved in quality improvement activities”, as well as “elevat[ing] the importance of taking a systems approach to safety and quality improvement”.⁸⁵

It was hampered by limitations on its ability to implement change. Some were the result of structures imposed on it. As Barraclough noted, the Council had no way to require that initiatives be “entrenched and assured” within the health care system, as it had neither statutory authority nor operational capacity to do so, while responsibility and accountability for patient safety across the health system generally were often unclear, and capacity to take steps needed to achieve quality improvement was inadequate.⁸⁶ Conversely, some limits resulted from the

⁸¹ The Review, *supra*, n.78 at 6.

⁸² *Ibid.*, 7; Barraclough, *supra*, n.77 at 10.

⁸³ Barraclough, *ibid.*, 5.

⁸⁴ Review, *supra*, n.78 at 57-58.

⁸⁵ *Ibid.*, at 8-9

⁸⁶ Barraclough, *supra*, n.77 at 9, 12.

structures it developed – the Review, for instance, concluded that it could have achieved greater uptake had it developed more extensive partnerships with stakeholders, including consumer networks.⁸⁷ The Review also considered Council’s decision at the outset to emphasize safety rather than a broader quality agenda to have hindered its effectiveness.⁸⁸ However, given the centrality of the Quality in Australian Health Care study to the Australian patient safety movement, with its startling revelations about the numbers of adverse events and harm to patients,⁸⁹ and given that safety is so clearly crucial to quality in health care, it is difficult to fault the Council for that decision.

I have outlined the Council’s mandate and operation briefly as background to a consideration of how legal frameworks, and the civil liability system in particular, may affect patient safety initiatives. I concentrate on two that the Council championed: open disclosure and root cause analysis. Both of these programs sparked concerns on the part of health care providers and institutions about their potential legal implications. In response, the Council commissioned several papers to explore the issues and review their legal ramifications, as well as to consider ways in which law could be used as an incentive to encourage their implementation.

Open Disclosure

Open disclosure is “... the process of open discussion of adverse events that result in unintended harm to a patient while receiving health care and the associated investigation and recommendations for improvement”.⁹⁰ The elements of open disclosure are an expression of regret, a factual explanation of what happened, the potential consequences of the event, and the steps being taken to manage the event and prevent its recurrence.⁹¹ The Open Disclosure process is described in greater detail in Appendix A to this chapter. In Council’s view, open, honest, and immediate communication, acknowledging that things had gone wrong and providing reassurance to patients and their carers that lessons learned will help prevent a recurrence, are key steps in improving patient safety, as well as being consistent with health care

⁸⁷ Review, *supra*, n.78 at 10, 12.

⁸⁸ *Ibid.*, at 10 .

⁸⁹ Barraclough, *supra*, n.77 at 4.

⁹⁰ ACSQHC, “List of Terms and Definitions for Safety and Quality”, available online at <http://www.safetyandquality.org/index.cfm?page=Action> (last accessed Dec. 2005),

⁹¹ ACSQHC, National Open Disclosure Standard Fact Sheet, available online at <http://www.safetyandquality.org/articles/Action/opendisclact.pdf> (last accessed Dec. 2005).

providers' ethical obligations, and reducing the likelihood of lawsuits.⁹² It developed the *Open Disclosure Standard, a National Standard for open communication in public and private hospitals* (hereafter, the Standard), which was endorsed by the Ministers of Health as a national standard in 2003.⁹³

While communication is one theme of open disclosure, caution is the other. Participants are instructed not to blame, to restrict themselves to facts not opinions, and to avoid singling individuals out. For instance, the person responsible for preliminary follow-up with the patient “must not criticise others or comment on matters outside their own expertise”, although he or she should respond to patient queries and concerns. This approach is consistent with the underlying premise that most adverse events in health care are the result of systems deficiencies and failures, and is also meant to assuage health care providers' concerns about participating. Organizations are directed to develop policies and practices to ensure that the open disclosure process focuses on safety and not attributing blame, and avoids adverse findings against individual professionals. Policies and procedures should take patients', carers', and staff privacy and confidentiality into consideration.⁹⁴ Issues relating to individuals are to be left to disciplinary processes where appropriate.⁹⁵ Circumstances suitable for referral to disciplinary processes are limited to those where a patient may have been harmed by “a criminal or intentionally unsafe act”.⁹⁶ This is narrower than statutory frameworks governing the discipline of doctors or nurses, and seems a conscious move meant to signal a new, less punitive approach. While urging that open

⁹² *Ibid.*, 1. As the Legal Review commissioned by the Council's Open Disclosure Project noted, “A common cause of complaint by patients and carers, and one that potentially exacerbates patient harm, anxiety and the likelihood of legal action, is that information about the causes of and circumstances surrounding adverse events is often withheld from patients and their carers”. - Corrs, Chambers and Westgarth, “Open Disclosure Project: Legal Review” (Jan. 2002), available online at: <http://www.nsh.nsw.gov.au/teachresearch/cpiu/CPIUwebdocs/FinalLR858178v1.pdf> (last accessed Dec. 2005), at 1 (hereafter, Legal Review). Council's approach is consistent with the results of a literature review it had commissioned, which found that across categories of analysis, no author advocated non-disclosure as “a principle worthy of maintaining”; on the contrary, disclosure was important for reasons of quality management, risk management, ethical obligations, legal considerations, and patients' autonomy / right to know - see Walton, M., “Open Disclosure to Patients or Families After an Adverse Event: A Literature Review”, (Nov. 2001), available online at http://www.nsh.nsw.gov.au/teachresearch/cpiu/open_disclosure.shtml#Literature20Review (last accessed Nov. 2005).

⁹³ ACSQHC, “Open Disclosure Standard: A National Standard for Open Communication in Public and Private Hospitals Following an Adverse Event in Health Care”, available online at http://www.safetyandquality.org/articles/Publications/OpenDisclosure_web.pdf (last accessed August 2004) (hereafter, the Standard); Review, *supra*, n.78 at 58.

⁹⁴ *Ibid.*, at 2-3.

⁹⁵ *Ibid.*, 9.

⁹⁶ Standard, *supra*, n. 93 at 9.5.

disclosure investigation be continued even when disciplinary processes are ongoing, since “useful information for system improvement may emerge”, the Standard recognizes the need to avoid conflict between disciplinary and open disclosure investigations, and to ensure that the rights of the person being investigated are respected.⁹⁷

The tensions inherent in introducing open disclosure into an existing landscape of complex legal relations, rights, obligations, regulation and liabilities will affect its chances of success. It is difficult to see how the distinctions between fact and opinion, or between stating what occurred and why but not criticizing, however attractive in theory, can be sustained in practice. It will be especially difficult because of the often fraught nature of the encounter with a patient who has been injured, and the reality that disclosure will involve dialogue and not just a pre-scripted speech delivered by the health care provider. Patients who have been harmed will want to know who did or failed to do what, and while systemic analysis will give a more complete and more sophisticated answer to the question of what went wrong, “who did it” is a part of the answer.

Legal Ramifications of Open Disclosure

The direction to avoid blame arises in part from Council’s underlying model of how adverse events occur – i.e. that causes are most often systemic, so blaming individuals misstates the problem and consequently, misdirects efforts to formulate changes needed to prevent a recurrence. It is also shaped by a practical consideration – while most adverse events do not reflect negligence, there is an often repeated concern that open disclosure and expressions of regret are or may be inhibited by (1) fears of legal exposure, both actual and perceived, and/or (2) concerns about affecting insurance coverage. While some of those fears are overstated, as the Legal Review commissioned by the Council’s Open Disclosure project noted (hereafter, the “Legal Review”), nonetheless, if open disclosure is to succeed, it must take into account stakeholders’ legal rights and substantive concerns.⁹⁸ Consequently, the Standard emphasizes limiting disclosures to patients to facts and expressions of regret, but not venturing opinion or criticism, and cautions health care providers against admitting that they or anybody else are liable for harm caused to the patient.⁹⁹

⁹⁷ *Supra*, n. 93.

⁹⁸ *Supra*, n.92 at 4.

⁹⁹ Standard, *supra*, n.93 at #7.3.

Will avoiding blame also mean not attributing responsibility, other than at a systems-level? While expressing support for root cause analysis, Commissioner Walker commented in his Final Report on the Special Inquiry into Camden and Campbelltown Hospitals: "...I fail to see why the cause of an adverse event must be only a systems failure".¹⁰⁰ That unease is understandable; many questions remain unanswered. What if there were individual shortcomings, with or without accompanying deficiencies in the system? Ought those issues be left entirely to other processes such as professional discipline? What assurance is there that they will be taken up in another forum? If they are, there will be concerns that information gathered as part of the open disclosure process will be disclosed to authorities and lead to professional or employment repercussions, and conversely, concerns that it will not, leaving individuals' problematic practices unaddressed.

Using Law to Encourage Disclosure

As for the ways in which law could be used to encourage disclosure, the Legal Review concluded that there are situations where providers and institutions may be legally obliged to disclose as part of the duties of care owed to patients or to comply with professional standards of practice.¹⁰¹ Additionally, if open disclosure were to be mandated by statute or regulation, health care providers' and institutions' incentives to comply would certainly be enhanced.

More generally, regulatory scholars have considered how best to foster compliance with programs meant to abate or control risk. Rejecting the traditional exclusive focus on deterrence, they have shifted to the study of the external and internal levers that may be used to foster compliance in organizations. John Braithwaite has been a prominent proponent of this approach, advocating reliance on concepts of the regulatory pyramid and responsive regulation.¹⁰² Briefly, the base of the regulatory pyramid begins with education and persuasive strategies that encourage trust and discourage defensiveness. Sanctions become progressively more onerous as one moves up the pyramid, with punitive sanctions reserved for situations where other strategies have clearly failed. Responsive regulation begins from the premise that regulators should be

¹⁰⁰ New South Wales. "Final Report of the Special Commission of Inquiry into Campbelltown and Camden Hospitals" (Bret Walker, Special Commissioner) (July 30, 2004) at 130, online at: http://www.lawlink.nsw.gov.au/lawlink/Corporate/ll_corporate.nsf/pages/sci_final_report (last accessed Dec. 2004).

¹⁰¹ Legal Review, *supra*, n.92 at 39.

¹⁰² Ayres, I., Braithwaite, J., *Responsive regulation: transcending the deregulation debate* (NY: Oxford U. Press, 1992).

responsive to the conduct of those they seek to regulate when deciding whether a more or less interventionist approach is needed; one regulatory strategy will not be appropriate in all situations, and a corrective strategy cannot necessarily be determined in advance.

The Council commissioned Braithwaite and colleagues to prepare a discussion paper to explore whether this approach could assist in improving patient safety and quality of care.¹⁰³ Braithwaite *et al.* suggest that (i) health care near-misses be addressed by means of “a no-blame approach that flows from a culture of learning”, (ii) where patients are hurt and ongoing underperformance attributable to an individual or systems failure can be identified, remedial action be taken, premised on a restorative justice approach to transcend blame, and (iii) where both of these have failed, response escalate to a legal accountability approach.¹⁰⁴ They also recognize the importance of a continuing, although more limited role for traditional command and control regulation. It is not clear that such a shift would be feasible in the health sector, or that it would achieve either compliance or reduced risk and safer outcomes. Recognizing this, Braithwaite *et al.* call for testing these hypotheses with empirical research in order to formulate the evidence base necessary to justify choices and combinations of regulatory strategies. In-depth assessment of the applicability of such an approach in the context of healthcare systems is beyond the scope of this paper. It is interesting to note, however, that the authors suggest tort law and systems approaches to improving performance may be inherently incompatible. However, since their one reference is to a regime of economic incentives in a different context, querying whether it could co-exist with tort, their point that further research is needed on this question is an important caveat.¹⁰⁵

Root Cause Analysis

Root cause analysis (RCA) is an incident investigation technique used to identify the causes of incidents and guide the development of preventive strategies.¹⁰⁶ The Council defined it as a systematic process whereby the factors that contributed to an adverse event are

¹⁰³ Braithwaite, J., Healy, J., Dwan, K., “The Governance of Health Safety and Quality: A Discussion Paper”, Commonwealth of Australia, 2005, at 33, online at: <http://www.safetyandquality.org/governance0705.pdf> (last accessed Nov. 2005). They propose that “no blame” be limited to the first level of near misses, since “it makes victims angry when they learn the institutional philosophy is that no one is to blame”, analogizing to the treatment of near misses as opposed to crashes in the aviation industry.

¹⁰⁴ *Ibid.*, at 35.

¹⁰⁵ *Ibid.*, at 45.

¹⁰⁶ Barraclough, *supra*, n.77 at 22. In Canada, see Davies, J., “Cause, Root Cause Analysis”, *The Canadian Patient Safety Dictionary* (Ottawa: Royal College of Physicians and Surgeons of Canada, 2003) at 38.

identified.¹⁰⁷ The Australians adapted their version of RCA from the Americans.¹⁰⁸ Its foundations are in systemic analysis focused on the fragility and fallibility of the system, rather than individuals. Critics caution that it is problematic because of fallible memories, poor records, and investigators' theoretical predilections, as well as the limitations inherent in strategizing change on the basis of single incidents.¹⁰⁹ Regardless, it has become ubiquitous in patient safety practice.

Council supported national workshops in 2003 to train a core of individuals who could lead root cause analysis training initiatives in their own jurisdictions. Each state is teaching health care staff root cause analysis methodology.¹¹⁰ Efforts to incorporate it into adverse event responses are underway. For instance, in New South Wales, health services have been required to subject the most severe incidents to root cause analysis since 2003, and the state recently extended qualified privilege to RCA.¹¹¹

Implementation, however, is uneven. Mandating root cause analysis of sentinel or serious events or similar processes does not mean that it always occurs. A 2005 review of health care systems in Queensland noted that although root cause analysis of sentinel events was required, "...the effectiveness of the incident management policy has been variable...due to a range of business processes being used, no comprehensive information system for incident reporting, lack of tools for incident analysis, limited training for staff in analysis techniques, and limited resources and capacity to set up and maintain systems".¹¹² It added that some medical and nursing staff advised that they do not report incidents because they receive no feedback on

¹⁰⁷ Council, *supra*, n.90.

¹⁰⁸ Barraclough, *supra*, n.77 at 18: the New South Wales Institute for Clinical Excellence adapted the methods employed by the U.S. Veterans Affairs National Center for Patient Safety for use in Australia (the V.A. in turn had adapted root cause analysis methodology for use in the American health care sector).

¹⁰⁹ See sources compiled in Maillard, N. *et al.*, "Patient Safety: an unsystematic review and bibliography (Sept., 2005), at 15-16; online at: [http://www.pcpoh/bham.ac.uk/publichealth/prsp/Pdf/patienta\safetybibliography_02_Sept.pdf\(02.09.05\)](http://www.pcpoh/bham.ac.uk/publichealth/prsp/Pdf/patienta\safetybibliography_02_Sept.pdf(02.09.05)) (last accessed March 2006).

¹¹⁰ Barraclough, B., "Dramatic changes for the better are already occurring", MJA 2005; 183(10): 544.

¹¹¹ New South Wales Department of Health, "Patient Safety and Clinical Quality Program. First report on incident management in the NSW public health system 2003-2004" (Sydney: NSW Dept. of Health, 2005), at 11; New South Wales. *Health Administration Act, 1982*, ss. 20L-U; *Health Administration Regulation 2005*.

¹¹² Forster, Peter, "Queensland Health Systems Review – Final Report" (September, 2005), online at: http://www.health.qld.au/health_sys_review/final/qhsr_final_report.pdf (last accessed Dec. 2005), at 183-184 (hereafter, the Forster Review).

how the information is used.¹¹³ When reporting does not seem to make any discernable difference, it will be limited. Drawing on experience in other sectors, Braithwaite *et al.* stress the importance of a non-defensive environment for accurate analysis, to avoid both over-servicing (“everything possible was done”), and scapegoating (senior personnel can be “very resourceful” in ensuring more junior personnel will be found at fault).¹¹⁴

Restrictions on what can be taken into account in determining root causes have the potential to undermine confidence in the resulting analysis. Some RCA frameworks specifically exclude consideration of financial resources. The impetus to do so is understandable, because limited resources are a reality in health care, and it is often simply too easy to blame whatever has gone wrong on a lack of money, without in-depth examination of what can be done to make care better and safer within existing parameters.¹¹⁵ However, sometimes inadequate financial resources truly have been a factor contributing to unsafe systems. As a case in point, the 2005 Report of the Queensland Public Hospitals Commission of Inquiry concluded that one of the root causes of unsafe conditions in the public hospitals examined was inadequate funding to provide the services promised.¹¹⁶ If RCA investigators cannot consider the role played by finances even though this affected patient outcomes, the risk is that the accuracy and comprehensiveness of their findings, utility of their recommendations, and respect for the integrity of the RCA process itself will be threatened. Deciding when and how financial factors can be taken into account

¹¹³ *Ibid.*, at 185. See also Royal Melbourne Inquiry, *infra*, n.165 at 3, noting a similar situation: some staff had decided there was little point in making complaints because they did not lead to action.

¹¹⁴ *Supra*, n.103 at 34.

¹¹⁵ As Bruce Barraclough testified before the Legislative Council General Purpose Standing Committee No. 2 Inquiry into Complaints Handling in New South Wales, (June, 2004), at 72, para. 5.18: “...it is how you spend the money, not the total amount of money”.

¹¹⁶ Queensland. “Queensland Public Hospitals Commission of Inquiry Report” (Davies, G., Commissioner) (Nov. 2005), online at <http://www.qphc.qld.gov.au> (last accessed Dec. 2005), at paras. 8.2, 8.8. See also McLean and Walsh, “Lessons from the inquiry into Obstetrics and Gynaecology services at King Edward Memorial Hospital 1999-2000”, (2003) 26(1) Aust.Health Rev. 12 at 21, who concluded that one of the limitations of the Inquiry into King Edward Memorial Hospital was that it “understated the consequences of poor policy and regulation...[and included] little or no consideration of government responsibility for ensuring the adequacy of recurrent funding and allocation...”; see also Eagar. K., “Learning the Hard Way: Quality, Safety and Scandal: The Weakest Link?” Aust. Health Rev. 2004; 28(1): 7-12, online at http://www.aushealthreviewcom.au/publications/articles/issues/ahr_28_1_300904/ahr_2 on resource allocation: “All of us – clinical leaders, managers, academics, commentators and politicians – are guilty of simply accepting, and remaining silent about, the size of the pie and how fairly it is sliced”. Although see Inquiry into Campbelltown and Camden Hospitals Final Report *supra*, n.100, at 80, in which Commissioner Walker commented approvingly that the HCCC’s statutory mandate precludes recommendations that affect appropriation of resources, because in his view, these “...truly political issues should never become the preserve of so-called experts or independent regulators”.

calls for careful consideration of the forum, its mandate, and the expertise needed, rather than outright preclusion.

Qualified Privilege

Health care professionals and institutions have used a variety of formal and informal means to review the safety and quality of care for a considerable period of time. In Australia, some of those processes are protected from disclosure by qualified privilege legislation. Qualified privilege has the potential to encourage disclosure, and yet may also constitute another barrier to communication.

Statutorily shielding some quality assurance activities and information from disclosure to third parties is meant to allow unconstrained analysis of adverse events and outcomes and encourage health care provider participation without fear of legal repercussions. “Quality assurance” (QA) describes a range of activities aimed at identifying and influencing factors contributing to health care outcomes, from monitoring rates of occurrence of selected events to identifying and investigating specific incidents. The availability, scope and extent of qualified privilege varies among states. Since qualified privilege allows relevant information to be withheld from the courts, the patients concerned, and the public, the result can be that none have access to material that would assist in learning about and evaluating what occurred. As the Council noted in its 2003 report, “Improving the Consistency of Approaches to Qualified Privilege Schemes”, the public interest in access to health care quality information is of primary concern, making it imperative that the case for the countervailing public interest in confidentiality be clearly demonstrated.¹¹⁷

Judging how to balance the public interests at stake is not always clear. In the Council’s view, protection from disclosure ought only be available “...to the extent necessary to ensure quality assurance activities are not hindered by health care professionals’ reasonable fear of unreasonable adverse professional consequences of disclosure of information”.¹¹⁸ On its face, this will be a difficult standard to apply with certainty or to monitor. Health care providers want to be sure that information they share as part of QA processes will not be disclosed further, and challenges to qualified privilege shake that confidence. However, as the Legal Review noted,

¹¹⁷ ACSQHC, (July, 2003), online at http://www.safetyandquality.org/QualifiedPrivilege_web.pdf (last accessed Dec. 2005) at p.10.; see also ACSQHC, “National Report on Qualified Privilege (July, 2002), online at: <http://www.safetyandquality.org/qual-priv1.pdf>. (last accessed Dec. 2005).

¹¹⁸ *Ibid.* (2003), at 2.

qualified privilege may be too easily or improperly invoked: "...It is also possible that the availability of qualified privilege protection will be identified by some health care providers as a legitimate strategy by which to avoid implementation of a fully open process of communication with patients and their carers when an adverse event has occurred".¹¹⁹ That concern is more than hypothetical. The 2005 Commission of Inquiry into Queensland Hospitals found that privilege had been improperly claimed, and at the highest levels. Commissioner Davies concluded that successive state governments had followed a practice of concealment and suppression of elective surgery waiting lists and measured quality reports, and had used Cabinet to improperly shield information from disclosure following requests under the *Freedom of Information Act*, and that others had improperly refused disclosure as well.¹²⁰

Implementing Open Disclosure

The number of units and health care staff participating in some form of open disclosure and root cause analysis, and consequently, reporting adverse events, is increasing. Given the ambivalence and concerns about legal repercussions noted previously, why is this occurring? Bruce Barraclough, former Chair of the Council, attributes it to two factors: first, people will participate if they believe there is a commitment to act on the results of investigations, i.e. that their participation will lead to change for the better, and second, people are coming to believe that systems issues will be fixed without inappropriate blame.¹²¹ With that understanding, the higher numbers of adverse events being reported are considered a positive development: they alert organizations and providers to what problems exist so that action can be taken to correct them and prevent harm.¹²² While variations of open disclosure have been implemented on a local or area basis, Council began a more systematic pilot program in 2004 at a number of sites nationally. It was placed on hold later that year to resolve legal and liability issues and resource implications.¹²³ In January 2005, the AHMC endorsed a revised plan to progressively

¹¹⁹ Legal Review, *supra*, n.92 at 62.

¹²⁰ *Supra*, n. 116 at 476-7, paras. 6.530, 6.534, 6.553-4.

¹²¹ Barraclough, B., personal communication, Nov. 9, 2004; Barraclough, B., *supra*, n.110, citing a thirtyfold increase in reporting in NSW alone.

¹²² NSW Complaints Handling Inquiry, *supra*, n.115 at 37, paras. 3.63-3.64; NSW Health, "Patient Safety and Clinical Quality Program. First report on incident management in the NSW public health system 2003-2004 (Sydney, NSW Dep't. of Health, 2005), at 21.

¹²³ NSW Health "Quality and Safety; Incident Management; open disclosure"; online <http://www.health.nsw.gov.au/quality/disclosure.html> (last accessed Nov. 2005).

implement the open disclosure standard across all health facilities. Pilot implementation guided by a national steering committee was to follow, with a report to AHMC in December 2006.¹²⁴

The importance of open disclosure has been widely accepted across a broad spectrum of stakeholders.¹²⁵ Acceptance in principle, however, has not always translated into action. The 2004 Report of the Inquiry, “Complaints Handling within NSW Health”, concluded: “Given the significant cultural barriers to openness about adverse events, the evidence to this inquiry indicates it is highly unlikely open disclosure is being practiced routinely in hospitals across the State”.¹²⁶ Vis a vis error reporting, as the Queensland Health System Review observed in its 2005 Report, medical and nursing staff in many areas advised that “...they do not report incidents (let alone near misses) because they receive no feedback on how the information is used”.¹²⁷ Implementation, then, remains partial, and still faces considerable resistance.

Are Patient Safety Initiatives Effective?

There have been questions about whether the many patient safety initiatives undertaken have resulted in safer care and reduced harm to patients. Ross Wilson, one of the original authors of the Quality in Australian Health Care study, and Martin Van Der Weyden argue that ten years after that study, there is insufficient information at the state or national level to determine whether the many efforts over the preceding decade have actually increased safety in hospitals.¹²⁸ In fairness, the absence of empirical studies does not mean that these programs are not having positive effects, but that they have not yet been assessed. Wilson and Van Der

¹²⁴ Australian Safety & Quality Council, “Consumer Update, Feb / Mar 2005”, at 1-2, online at: <http://www.safetyandquality.org> (last accessed Dec. 2005).

¹²⁵ New South Wales. Parliament. Legislative Council, General Purpose Standing Committee No. 2, “Complaints handling within NSW Health” (June, 2004), at 14, para 2.25 & 3.40, referencing support of medical indemnity insurer UMP; para.2.35, and the Victorian Health Services Commissioner, who calls Open Disclosure “the most important quality initiative that I have seen...” and at 30, para. 3.38, adding its own support. The Committee’s mandate was to assess (1) willingness to share information about errors and systems failure as an opportunity for learning, and (2) whether the system encouraged open discussion to improve care.

¹²⁶ *Ibid.* at 31, para. 3.41; see also Schoen, C., *et al.*, “Taking the Pulse of Health Care Systems: Experiences of Patients with Health Care Problems in Six Countries”, Health Affairs Web Exclusive (Nov. 3, 2005), W5-509-W5-525, at 30; online at: http://www.cmwf.org/publications/publications_show.htm?doc_id=313012 (last accessed Nov., 2005): 19% of 702 Australian patients surveyed reported that an error had been made in their treatment or medication, causing serious health problems for almost half of them, but 70% were not told about the error by doctors involved in their treatment.

¹²⁷ Forster Review, *supra*, n.112 at 185.

¹²⁸ Wilson, R., Van Der Weyden, M., “The safety of Australian health care: 10 years after QAHCA” MJA 2005; 182(6): 260-61. The Final Report of the Special Inquiry into Campbelltown and Camden Hospitals noted that on the information made available, no determination could be made about how the quality of patient care at the two hospitals compared to care at other hospitals –*supra*, n.100 at 7.

Weyden also contend that, despite its extensive work program, the Council had “limited relevance to or influence on the daily lives of health professionals”, and that its emphasis on policy and monitoring rather than “bottom up” activities “...can result in a considerable gap between what patient safety strategies are supposed to have been implemented in the workplace and what strategies are actually in place”.¹²⁹ They raise additional issues about how systems – for both delivering and overseeing health care -- actually respond when patients have been harmed, and about how to change the underlying conditions that are repeatedly identified as contributing to environments that allow unsafe patterns and practices to develop and continue. The high-profile investigations into problematic care at a number of Australian hospitals over the last several years lend credence to their observations about the gaps between theory and practice. The reports of these inquiries highlight the need to consider the prospects for uptake of patient safety initiatives in light of broader social and institutional contexts. Recent inquiries and their results are summarized in Appendix B to this chapter. More general observations on the relation between inquiries and patient safety initiatives follow.

Inquiries and Patient Safety Initiatives

A review of the history underlying the public inquiries reveals a number of characteristics in common: compromised patient safety over considerable periods of time that was not detected or addressed by accreditation processes, sentinel event reporting, or other safety and quality processes; problematic clinical governance; and health care professionals, who, frustrated by inaction after internal reporting of adverse events, brought the matter to the attention of politicians.¹³⁰ Targeted patient safety initiatives have a relatively short history, and implementation is still a work in progress. However, it is apparent from these inquiries that existing programs either did not reveal the existence of the deficiencies and harm to patients, or if the problems were known, did not result in effective action to resolve them.¹³¹

¹²⁹ *Ibid* (Wilson and Van Der Weyden).

¹³⁰ Faunce, T., Boisin, S., “Three Australian whistleblowing sagas: lessons for internal and external regulation:”, *MJA* 2004; 181(1): 44-47, at 44; Van Der Weyden, M. “The Bundaberg Hospital scandal: the need for reform in Queensland and beyond”, *MJA* 2005; 183(6): 284-285, at 284.

¹³¹ Eagar, K., “Learning the Hard Way: Quality, Safety and Scandal. The Weakest Link?” *Aust. Health Rev.* 2004; 28(1): 7-12, online at http://www.aushealthreview.com.au/publications/articles/issues/ahr_28_1_300904/ahr_2 (last accessed Dec. 2005), notes that all but one of the most serious initial cases in the Campbelltown and Camden Hospitals Inquiry were known to the organization, and all but one had been reviewed before the public allegations. She also notes that during this time, the Macarthur Health Service was reviewed by the Australian Council for Health Care Standards, receiving 2 years’ accreditation, and a number of commendations.

After lengthy, grueling and costly public inquiries, the recommendations that result are strikingly similar too. Broadly, in order to achieve safer health care, clinical governance structures need to be reformulated; systems implemented for reporting, investigating and analyzing adverse events; compliance and performance monitored through clinical audits and other means; and external oversight strengthened. Sufficient financial resources are required to make care safer, and quality and safety programs more effective.¹³² Some of the inquiries urge greater protection for whistleblowers, because it was only through their persistence that the shortcomings in care came to light and were addressed. All recognize the damage caused by a culture of concealment and blame, and strongly endorse the importance of openness, and reliable assurances to health care providers that they work in a just culture, or as one author put it, "...a reformed institutional ethos that encourages open transparency and respect for those committed to such processes, so that they will disclose what has gone wrong".¹³³ With the exception of the Royal Melbourne Hospital Inquiry,¹³⁴ the events and responses in each were intensely politicized. Finally, the tension between the traditional focus on individual professional accountability and the more recent emphasis on systemic analysis affected all of them, and in some (Campbelltown and Camden Hospitals in particular¹³⁵), ended up driving the process.

As Trebilcock and Austin note, the task of both investigating past acts and wrongdoings and formulating recommendations to prevent similar occurrences in the future magnifies the conflicts between "...lawyers' values, shaped by concerns with civil liberties and due process", and "policymakers' values".¹³⁶ These tensions are inherent in an endeavour that looks backward to assess what has gone wrong in order to look forward to determine how to improve. They are heightened because of the highly politicized and personal nature of health care. Media, public and political demands for accountability are intense, and accountability is understood to mean individual accountability for past delinquencies, not just formulating plans for a better and safer

¹³² Rubin, G., Leeder, S., "Health care safety: what needs to be done?" MJA 2005; 183 (10): 529-531, available online at http://www.mja.com.au/public/issues/183_10_211105/rub10814_fm.html.

¹³³ Faunce, T., Mure, K., Cox, C., Maher, B., « When silence threatens safety: lessons from the first Canberra Hospital neurosurgical inquiry", JLM 2004 Aug; 12(1):112-8.

¹³⁴ Victorian Health Services Commission, "Royal Melbourne Hospital Inquiry Report" (Wilson, B., Comm'r) (Aug. 2002), online at http://www.health.vic.gov.au/hsc/rmh_report0802.pdf (last accessed Dec. 2005).

¹³⁵ *Supra*, n.100. See Appendix B to this chapter.

¹³⁶ Trebilcock, M., Austin, L., "The Limits of the Full Court Press: Of Blood and Mergers" (1998) 48 U.T.L.J. 1, citing Innis and Pross, "Introduction", in Pross, A.P., I. Christie and J.A. Yogis, *Commissions of Inquiry* (Toronto: Carswell, 1996).

future. Starting from the position that “no one is to blame” even before investigating what occurred has the potential to exacerbate distrust of the patient safety agenda, and reinforce suspicions that it is simply a way to insulate health care providers and organizations from accountability. While patient safety advocates’ message calling for an end to individual blame has garnered some acceptance, where and how to draw the line between blameless and blameworthy behaviour is far from settled, and major disagreements remain about what the repercussions of each should be.¹³⁷ Failure to resolve that conflict will affect uptake of the patient safety movement’s insights into how error and injury occur and can be reduced, not only by health care professionals, but more importantly, by the public.

One of the more blunt discussions of the tension between a systemic focus and individual accountability (such as professional discipline proceedings, peer assessment or employment repercussions) is to be found in the Campbelltown and Camden Hospitals Special Inquiry Final Report. Commissioner Walker explained his support for an approach that combined the two:¹³⁸

“...I well understand a fear of witchhunts, and empathize with the unpleasantness of officially finding fault in others. But in my opinion, the willingness and capacity of the medical and nursing professions to insist on standards being attained and improved are essential to those professions acting in the public interest.... I was pressed with a deal of material urging a view that learning and encouragement to improve are more important than finding fault and punishing professionals. At a suitably abstract level, that sounds like a truism, but is of little practical value. In particular, it exhibits the same false dichotomy noted above – systemic learning and improvement and individual professional accountability are simply not mutually exclusive. Furthermore, it should be borne in mind that a patient care complaints system, in order to be respectful of the dignity and interests of the patients and families who make complaints or are involved in complaints, must respond to the complaint in a clear fashion. In my opinion, it is not good enough for them to be told, as it were, that their comfort should be that the experience they found so awful has been an interesting or useful learning experience for the profession. In many cases, the profession learning from error so as to avoid the repetition of tragedies or mishaps will be an outcome sought by complainants. But vindication of legitimate personal grievance is also an outcome sought by complainants – and in my view is the primary one sought by them. None of these comments...should be taken as derogatory of systemic approaches to the maintenance and improvement of standards of care in our hospitals. To the contrary, the material...strongly endorses the great benefits reasonably to be hoped for from energetic development of such approaches...

...it is high time the two camps [individual and systemic accountability] struck their separate tents and travelled together.”

¹³⁷ Health Care Complaints Commission, “Investigation Report: Campbelltown and Camden Hospitals Macarther Health Service” (December 2003), at ii.

¹³⁸ *Supra*, n.100 at 79-80, 89.

He went on to observe:¹³⁹

“The chimera of no-fault in health care should be banished. But the equal absurdity of expecting that all adverse outcomes – or even many of them at all – are due to some hapless doctor’s or nurse’s fault for which they should be blamed or condemned should also be exploded”.

Walker’s prescription of peaceful co-existence, however, ignores the stubborn reality that systems to investigate adverse events need the support of health care providers to be effective, and experience has shown that current structures and incentive systems often work against that end. No amount of exhortation or admonition will alter this, without other concrete changes. The nature of events giving rise to inquiries and the politicized environments in which they take place test providers’ faith that they will not be scapegoated for systemic shortcomings, and the public’s belief that any real accountability will result at all.

Patient Safety and Health System Restructuring

Safety and quality initiatives do not exist in a vacuum. They are affected by wider public and political environments, by legal frameworks such as the tort system, and most immediately, by the complex and diverse health care systems in which they are situated. Recent health system restructuring and reviews in Australia, although instituted in response to many different challenges, evidence a number of common themes. A trend towards centralization of governance is prominent. Patient safety has been no exception, particularly in the aftermath of public inquiries. Dwyer attributes the trend towards more direct control of health care provision by governments not only to financial pressures associated with greater demand for services, but also to the increasing disclosure of safety and quality problems, and the renewed emphasis on accountability that has resulted.¹⁴⁰ She notes that, although research indicates that “micro-management from above” tends to stifle innovative solutions, this approach will likely increasingly characterize future developments, especially given the intense politicization of

¹³⁹ *Ibid.*, 90.

¹⁴⁰ Dwyer, J., “Australian health system restructuring – what problem is being solved?”, (2004) 1 Aus & NZ Health Policy, online at: <http://www.anzhealthpolicy.com/content/1/1/6> (last accessed Dec., 2005).

health care.¹⁴¹ Consequently, structural reforms may be significantly shaped by efforts to manage reputational risk to healthcare providers, administrators and government.¹⁴²

III. Interactions between Patient Safety Initiatives and Tort Reform

Negligence law is seldom high on any political agenda. What crystallized the political will to undertake substantial tort reform in Australia? It was not patient safety advocacy. Rather, what galvanized the state, territorial and Commonwealth governments to work together and implement sweeping changes to the common law framework governing negligence claims was a financial crisis reducing the availability of insurance that threatened to significantly affect the life of the community, coupled with longstanding pressure for law reform by insurers and health professionals, and an environment in which public discourse increasingly held negligence law to blame for a wide variety of faults. The aim of the reforms was to resolve the insurance crisis, not to improve patient safety.¹⁴³

Nonetheless, have the reforms to the civil justice system and negligence law affected patient safety initiatives, even indirectly? On the whole, the far-reaching reforms to tort law have been largely incidental to work on patient safety and quality.¹⁴⁴ Much can be accomplished to improve the safety and quality of health care with no need for law reform at all.¹⁴⁵ Implementation of patient safety initiatives, such as open disclosure, is still a work in progress in Australia as elsewhere; it may be that additional statutory reforms will be needed so that these programs can operate effectively. The legal incentives that may be of the most use, however, will not necessarily involve negligence law. While there are some instances where legal reforms have been adopted in order to advance a patient safety agenda, they have been relatively minor.

Apologies

¹⁴¹ *Ibid.*

¹⁴² See generally Power, M., "The risk management of everything: Rethinking the politics of uncertainty" (London: Demos, 2004), online at: <http://www.demos.co.uk> (last accessed August, 2005).

¹⁴³ Commonwealth 2004 Report, *supra*, n.2 at 3.

¹⁴⁴ Personal communication with B. Barraclough, ACSQHC Chair, Nov. 9, 2004.

¹⁴⁵ Personal communication, Beth Wilson, Health and Disability Commissioner, Victoria, Nov. 17, 2004.

Some jurisdictions now expressly provide that an apology is not evidence of fault in a civil lawsuit.¹⁴⁶ While the exception was likely not strictly necessary, apologies are important for patients, and provider and insurer concerns had previously inhibited them.

Statutory Protection of Root Cause Analysis

Extensions of statutory privilege are meant to encourage disclosure, and root cause analysis is now being included within its purview. New South Wales, for instance, requires root cause analysis of the most severe adverse events to determine how and why they occurred. Recent legislative amendments regularize the status of and procedures for root cause analysis and make it the subject of qualified privilege. The legislation sets out the circumstances in which RCA must be undertaken, what RCA team reports must and must not contain, restricts disclosure of information acquired, outlines reporting responsibilities to health services organizations when there may have been unsatisfactory professional conduct, establishes a statutory privilege for RCA proceedings and results, and imposes conditions for eligibility.¹⁴⁷ Although espousing the goals of open disclosure, fair responses to human error, and a systems approach to understanding problems, NSW does not aim for an entirely blameless culture: personal responsibility is assigned “...where it is due, for example in cases of negligence or criminality”.¹⁴⁸ This is a broader set of circumstances than the National Open Disclosure Standard identified as appropriate for referral to disciplinary processes. The disparity highlights once again the unresolved tensions between systems and individual accountability, and between preserving confidentiality and ensuring access to information.

Qualified Privilege, Open Disclosure and Root Cause Analysis

Grafting open disclosure onto processes that follow an adverse event can introduce additional complications. Communication with the patient about the adverse event and the results of the investigation are essential parts of open disclosure. However, if information needed for the open disclosure process has been generated as part of a quality assurance investigation that is subject to qualified privilege, it can effectively become “trapped”, such that it cannot be revealed to the patient.¹⁴⁹ This is not likely to occur frequently; many adverse

¹⁴⁶ See eg. NSW *Civil Liability Amendment (Personal Responsibility) Act 2002*; Commonwealth 2004 and 2005 Reports, *supra*, n’s 2, 44.

¹⁴⁷ *Health Administration Act, 1982, ss.20L-U; Health Administration Regulation 2005.*

¹⁴⁸ New South Wales Department of Health, “Patient Safety and Clinical Quality Program, 2005”, at p.11.

¹⁴⁹ Standard, *supra*, n.93 at 14.

events that would be the subject of open disclosure will not trigger a QA activity that is protected by privilege, and most QA activities do not involve the detailed investigation of known individual adverse events that typifies open disclosure. Nonetheless, the potential for conflict calls for careful management. The Council suggested that a process to triage events to decide how best to investigate may be needed.¹⁵⁰ As noted above, there is also potential for conflict with other legislation, such as that governing freedom of information, and more generally, with the public interest in access. Different possibilities exist to control for such tendencies. The Final Report of the Special Inquiry into Campbelltown and Camden Hospitals recommended statutory protection for root cause analysis and other QA activities, but also that it be reviewed after a few years' operation to evaluate effectiveness, because empirical evidence to justify the privilege was lacking.¹⁵¹ The Legal Review suggested that either open disclosure must be reconciled with existing (protected) processes, or that the original model of qualified privilege should be re-thought in light of increasing expectations of openness.¹⁵²

The Impact of Reducing the Incidence of Malpractice Litigation:

a) More Monitoring and Oversight?

As noted previously, the reforms to negligence law will mean fewer lawsuits and lower recoveries. To the extent tort does function as a deterrent (one of its classic justifications, although often challenged), reduced litigation activity post-reform will attenuate its effectiveness in that role. Other accountability mechanisms may need to be strengthened and expanded as a result.

b) More Disclosure?

On the other hand, it is frequently argued that the reason physicians and other health care workers do not disclose adverse events and injury either to patients or in the workplace (hindering the development of effective responses) is because of fear of litigation. This is cited as the major obstacle to disclosure to patients, colleagues and administrators. If so, that fear should diminish post-reform, because the likelihood of being sued and the amount of damages

¹⁵⁰ *Ibid.*, at 15.

¹⁵¹ *Supra*, n.100 at 132 (this suggestion was not incorporated into the NSW legislation); but see Forster Review, *supra*, n.112 at xxxviii, Recommendation 9.13, and at 185-186 (recommending review of recent Queensland statutory confidentiality provisions allowing departmental access to determine impact on effective sharing of information by clinicians for QA purposes).

¹⁵² Legal Review, *supra*, n.92 at 62.

awarded will both be less. The Final Report of the Special Commission of Inquiry into Campbelltown and Camden Hospitals made a similar point: since the recent tort reforms “...are likely to reduce the circumstances in which clinicians are likely to be exposed to litigation”, and in any event, “...the level of apprehension and fear [by clinicians] is not matched by the empirical evidence”, they should be more willing to be open about medical errors, near- misses and adverse events.¹⁵³ The Special Commissioner suggested clinicians and their insurers and medical associations just needed to be educated about this new reality for change to occur. However, providers’ and insurers’ reluctance to disclose errors and near misses is longstanding and not easily assuaged; the prospect of any lawsuit is seen as too many. Doctors, nurses and health care workers typically overestimate the likelihood of being sued. Their evaluations of risk are unlikely to become more realistic as a result of these reforms. In any event, many factors in addition to the prospect of litigation inhibit health care providers’ willingness to be open when things have gone wrong and a patient has been hurt.

Patient Safety Insights and the Analysis of Causation in the Law of Negligence

The insights of patient safety advocates about the role that systemic causes play in error and patient injury, if incorporated into analysis of causation in negligence claims, could support a more sophisticated understanding of how injuries occur and where responsibility should lie, rather than simply concentrating on the individuals actually treating the patient. If adopted, this approach would often suggest a finding of enterprise liability, with attendant incentives for the organization to remedy unsafe systems in order to avoid future liability.

Missed Opportunities

Finally, part of the story of tort reform in Australia is what could have been. Accepting the need for negligence law reform, the government missed opportunities to tie the substantial financial assistance it was providing to physicians and their insurers to requirements to provide more extensive reporting on patient safety incidents, more detailed information about claims experiences, more changes in providers’ practices and participation in clinical governance structures in order to advance patient safety. Instead, it concentrated on requiring reporting to improve prudential regulation. The two did not have to be mutually exclusive.

¹⁵³ New South Wales. Special Commission of Inquiry into Campbelltown and Camden Hospitals. Final Report (Bret Walker, Special Commissioner) (July 30, 2004), online at: http://www.lawlink.nsw.gov.au/special_commission (last accessed Dec. 2004), at 132.

APPENDIX A

THE PROCESS OF OPEN DISCLOSURE IN AUSTRALIA

Once an incident has been identified as an adverse event and its severity assessed to determine the appropriate level of investigation (root cause analysis or similar in-depth examinations being reserved for more serious cases), the Standard calls for preliminary discussions among those involved and a senior health care professional within the institution, preliminary disclosure to the patient and support person, investigation, determining changes needed, communication with those affected (from patients to management), and action to avoid repetition. While those involved in the adverse event are consulted about what occurred, the investigation itself is conducted by a multi-disciplinary team led by an individual with “knowledge and status to make authoritative recommendations” (generally, a senior health care professional or manager who determines the scope of the investigation and issues raised). The investigation identifies the reasons for the adverse outcome and the underlying systems failures, and recommends improvement strategies. It is to find the facts and root causes, and make recommendations to support systems changes to prevent recurrence. There is follow-up with both the patient and the staff involved about what happened, and what changes will be made. Management is apprised of the results of the investigation and recommendations, must decide which to implement and allocate adequate resources to do so, and establish mechanisms to ensure changes are made and their outcomes. Final communication to the patient is to set out the facts, summarize factors that contributed to the incident, express regret for what happened, and provide information on steps taken or proposed to avoid a repetition, and on how those changes will be monitored. Lessons learned are to be communicated to staff and throughout the health system.¹⁵⁴

¹⁵⁴ Standard, *supra*, n.93.

APPENDIX B

PUBLIC INQUIRIES INTO PATIENT SAFETY IN HOSPITALS

King Edward Memorial Hospital

At King Edward Memorial Hospital in Western Australia, medical and nursing staff raised concerns with management throughout the 1990's about high error rates and a culture among consultants that minimized accountability and supervision of junior staff, but without satisfactory response. When efforts to implement change were repeatedly frustrated, the state Minister for Health established a formal inquiry.¹⁵⁵ It took eighteen months, cost more than \$7 million (Aus.), and resulted in a 5 volume, 2500 page report.¹⁵⁶ The state government undertook to implement all of its 237 recommendations for reform, and committed \$25 million in additional funding for the hospital over 4 years: \$10 million to implement and sustain the Inquiry recommendations and \$15 million redevelop key infrastructure.¹⁵⁷ The report's quality and safety recommendations included improved systems for reporting, reviewing and addressing adverse events,¹⁵⁸ the need for leadership in clinical governance to develop and support a culture of open disclosure and effective response, better staff performance management, ensuring hospital accreditation processes took real account of safety and quality, and improved staff credentialing systems.¹⁵⁹ Council published key findings from the Inquiry in 2002, so that these would be more widely available.¹⁶⁰

Canberra Hospital

In the Australian Capital Territory (ACT), a rehabilitation physician at Canberra Hospital, who had repeatedly been unable to have concerns about patient safety addressed satisfactorily internally, convinced the Health Minister to order the ACT Health Complaints Commissioner to conduct an inquiry into neurological services at the hospital in 2000.¹⁶¹ The report that resulted two years later, while critical of the standard of care, "acknowledged that the inquiry was so hampered by clinicians' reluctance to provide evidence as to render impractical a finding on the issue".¹⁶² Although not initially made public, the report was eventually tabled in the legislative assembly in late 2003, and raised sufficient concern to lead to a further external

¹⁵⁵ The factual background is summarized in Faunce, T., Boisin, S., "Three Australian whistleblowing sagas: lessons for internal and external regulation", MJA 2004; 181(1): 44-47.

¹⁵⁶ Minter Ellison, "King Edward Hospital Inquiry", available online at: <http://www.minterellison.com/public/connect/Internet/Home/Expertise/Track+Records/TR+> (last accessed Dec., 2005).

¹⁵⁷ Western Australia, Department of Health. KEMH Inquiry, Frequently Asked Questions, available online at <http://www.health.wa.gov.au/kemhinquiry/faq/index.cfm>.

¹⁵⁸ Maclean and Walsh, *supra*, n.116, note that the Inquiry heard that often, the first the hospital learned of problems was on receipt of a lawyer's letter.

¹⁵⁹ Western Australia. Dept. of Health, KEMH Inquiry Recommendations, online <http://www.health.wa.gov.au/kemhinquiry/recommendations/> (last accessed Dec. 2005); McLean, J., Walsh, M. "Lessons from the inquiry into Obstetrics and Gynaecology services at King Edward Memorial Hospital 1990-2000", Aust. Health Rev. 2003; 26(1): 12-23.

¹⁶⁰ ACSQHC, (2002), "Lessons from the inquiry into obstetrics and gynaecological services at King Edward Memorial Hospital 1990-2000", online at http://www.safetyandquality.org.articles/publications/king_edward.pdf (last accessed Dec., 2005).

¹⁶¹ Factual background and results are drawn from Faunce and Boisbin, *supra*, n.155.

¹⁶² Faunce and Boisbin., *supra*, n.155; Faunce, T., Mure, K., Cox, C., Maher, B., "When silence threatens safety: lessons from the first Canberra Hospital neurosurgical inquiry", J Law Med 2004 Aug; 12(1):112-8.

investigation.¹⁶³ Faunce *et al.* suggest one lesson from that inquiry is that recommendations of the type that are typically made -- reformulating clinical governance structures, early reporting of sentinel events, compulsory audits and so on -- will not succeed without a reformed institutional culture that supports not only transparency, but also respect for those who participate and do report.¹⁶⁴

Royal Melbourne Hospital

Victoria's Minister of Health requested the state Health Services Commissioner to conduct an inquiry into systems and procedures at the Royal Melbourne Hospital after serious allegations involving the administration of non-prescribed medications by two nurses became the subject of examinations by the Coroner and the Nurses Board of Victoria.¹⁶⁵ The Inquiry met with staff and management, reviewed medical records, conducted individual and group structured interviews, and consulted with experts, but did not interview patients, families or carers.¹⁶⁶ It focused on systems issues affecting the quality of patient care at the hospital, was completed at a cost of \$55,000 within the 3 month time frame set by the Minister, and reported in 2002.¹⁶⁷ Examinations by the Coroner/Police and the Nurses' Board were ongoing during and after its investigations.¹⁶⁸ Recommendations included structural changes, improving clinical governance, quality programs, systems for reporting adverse events and corporate and nursing leadership, clarifying standards and policies, and developing systems for staff support.¹⁶⁹ While in broad terms, its recommendations were similar to those made by other inquiries, their tone and the atmosphere in which it was conducted appear markedly different. The hospital cooperated with the Commissioner, and the Commissioner, for her part, undertook to create an atmosphere that reduced fears of recrimination and blame, and attributed much of the success of the Inquiry to having done so.¹⁷⁰ Indeed, in 2004, the Commissioner released a second report reflecting on how the Inquiry had been managed, since it had been a "successful, speedy and cost efficient investigation", and analysis of its strengths and limitations could assist others.¹⁷¹

Campbelltown and Camden Hospitals

Several nurses triggered a series of inquiries with complaints to the New South Wales (NSW) Minister of Health in 2002, after their attempts to have concerns about patient care and safety at Campbelltown and Camden Hospitals in the Macarthur Health Service addressed internally were unsuccessful. The Minister first referred the matter to the state Health Care Complaints Commissioner (HCCC) in 2002. In August 2003, NSW also appointed an Expert

¹⁶³ Faunce and Boisbin, *supra*, n.155.

¹⁶⁴ Faunce *et al.* *supra*, n.162.

¹⁶⁵ Victoria Health Services Commission, "Royal Melbourne Hospital Inquiry Report" (Wilson, B, Commissioner) (Aug. 2002), online at http://www.health.vic.gov.au/hsc/rmh_report0802.pdf (last accessed Dec. 2005) (hereafter, Melbourne Inquiry).

¹⁶⁶ *Ibid.*, at 13-15.

¹⁶⁷ Victoria Health Services Commission, "Analysis of the Inquiry held by the Health Services Commissioner 2002, into an Incident at the Royal Melbourne Hospital, Victoria" (Wilson, B., Commissioner), (Oct. 2004), available online at: <http://www.health.vic.gov.au/hsc/analysis.mih.pdf> (last accessed Dec. 2005), at 1 (hereafter, Melbourne Analysis).

¹⁶⁸ *Ibid.*, at 11.

¹⁶⁹ Melbourne Inquiry, *supra*, n.165 at 1-4; Melbourne Analysis, *supra*, n.167 at 1.

¹⁷⁰ Melbourne Analysis, *ibid.*, at 1.

¹⁷¹ *Ibid.*

Clinical Review Team to review systems of patient care in the Macarthur Health Service and identify opportunities for improvement.¹⁷² It reported in October, 2003, identifying shortcomings in staffing, a supported safe reporting culture, area-wide planning, clinical and management leadership and other areas, and recommending changes.¹⁷³ Additionally, a committee of the NSW Legislative Assembly launched an examination of complaints handling across the state health system.¹⁷⁴ Other reviews were undertaken as well. In December, 2003, the HCCC submitted its report analyzing 47 clinical incidents at the two hospitals during the period 1999-2003.¹⁷⁵ It found multiple systemic problems and made recommendations to address these.

Public and media reaction was intense and outraged. The response from the Minister of Health was sweeping. He dismissed the Health Care Complaints Commissioner, telling the media that, although the HCCC report had detailed clinical failures and deficiencies in management and supervision, it "...doesn't go far enough in terms of finding anyone accountable for these failures".¹⁷⁶ Physicians were suspended, some were referred to the state Medical Board, a number of deaths were referred to the state coroner for investigation, disciplinary proceedings were commenced against administrators, the local health board was dissolved, legislation was amended, and \$55 million in additional funds were committed over four years for improvements in patient safety and quality, as well as many millions more to improve health care in the region affected.¹⁷⁷ The Minister appointed a Special Commission of Inquiry to re-investigate and make recommendations, not only about further actions against individuals concerned, but also about how the HCCC had proceeded.¹⁷⁸ The Special Commissioner delivered his final report in July, 2004.¹⁷⁹ With respect to the HCCC, he concluded that, given its statutory mandate, it had inappropriately focused only on systemic issues, and incorrectly characterized the complaints as solely against the health service organization and not against individual health professionals.¹⁸⁰ The result was a lack of procedural fairness and inadequate

¹⁷² Sydney Morning Herald, "Health System in the Sick Bay", June 8, 2004, available online at: <http://www.smh.com.au/articles/2004/06/07/108640233501.html?oneclick=true> (last accessed Dec. 2004).

¹⁷³ *Supra*, n.100 at 154.

¹⁷⁴ Christian Democratic Party. "Inquiry into complaints handling procedures within NSW Health". Media Release (Nov. 15, 2003), available online at: <http://www.cdp.org.au/fed/mr/031215g.asp>. Its report was released in 2004.

¹⁷⁵ Health Care Complaints Commission. Investigation report: Campbelltown and Camden Hospitals Macarthur Health Service. December 2003. Available online at: http://www.health.nsw.gov.au/pubs/i/pdf/invstign_hccc_2.pdf (last accessed Dec.2005).

¹⁷⁶ Van Der Weyden, "The 'Cam affair': an isolated incident or destined to be repeated?", MJA 2004; 180(3):100-101, quoting Newsroom. Minister for Health. Government responds to HCCC Report in Camden and Campbelltown Hospitals. 11 Dec. 2003. Available online at: <http://www.health.nsw.gov.au/news/2003/dec/11-12-03.htm>.

¹⁷⁷ Van Der Weyden, *ibid.*; New South Wales, NSW Government Response to the General Purpose Standing Committee, *supra*, n.46 at 3.

¹⁷⁸ *Ibid* (Van der Weyden).

¹⁷⁹ New South Wales. "Final Report of the Special Commission of Inquiry into Campbelltown and Camden Hospitals" (Bret Walker, Special Commissioner) (July 30, 2004), online at http://www.lawlink.nsw.gov.au/lawlink/Corporate/ll_corporate.nsf/pages/sci_final_report (last accessed Dec. 2004) (hereafter, Campbelltown Special Inquiry Report).

¹⁸⁰ *Ibid*; Eagar, K., "Learning the Hard Way: Quality, Safety and Scandal. The Weakest Link?", Aust. Health Rev. 2004; 28(1): 7-12, online at http://www.aushealthreview.com.au/publications/articles/issues/ahr_28_1_300904/ahr_2 (last accessed Dec. 2004).

process for individual health care providers, because they had not been notified or given an opportunity to respond when the HCCC was investigating and evaluating their actions.¹⁸¹ At the same time, the failure to focus on individuals meant that individual clinicians were not named or referred for possible disciplinary action when in his view, they should have been. On the vexed subject of systemic versus individual accountability, Walker concluded the dichotomy posed was false, that both were essential and could co-exist, but that the HCCC's statutory mandate precluded it from pursuing systemic analysis to the exclusion of investigating individuals when the circumstances called for it.

The HCCC Inquiry and the events that followed highlight the difficulties and unresolved tensions in adopting systemic analysis and de-emphasizing individual fault-finding. The firing of the Health Care Complaints Commissioner led the Health Complaints Commissioners of Australia and New Zealand to issue a joint statement calling for an independent inquiry into the implications for the independence of the office, and decrying the return to "blaming and shaming'", extending now beyond health care providers and institutions to the office that had adopted a systemic approach to the investigation as a better way to improve patient safety.¹⁸²

Bundaberg Hospital

In 2005, a hospital scandal in Queensland triggered two more major inquiries. A nurse at Bundaberg Hospital whose complaints about a surgeon's care had been met with inaction and resistance internally and from health authorities, took her concerns to her Member of Parliament. In the result, a Commission of Inquiry was appointed to inquire into procedures for the oversight of foreign-trained physicians as well as to review how complaints about care by this physician and others at public hospitals were addressed (hereafter, the "Bundaberg Inquiry").¹⁸³ It reported in November, 2005. Queensland also commissioned an independent review of the state health department's administrative, workforce and performance management systems (the "Forster Review"), which reported in September, 2005.¹⁸⁴

On investigation, the Bundaberg Inquiry found that, unknown to the state medical board that approved the surgeon's registration in 2003, he had previously been disciplined by two American state medical boards; it concluded that his credentials had not been checked with

¹⁸¹ It is somewhat ironic that when an argument of the same nature was put to the Special Commissioner about his conduct of the inquiry, i.e. that he had inappropriately predetermined the issue of the legality of how the HCCC proceeded, he responded that the proceedings before the Inquiry were not adversarial, and that he was "entitled to form and express opinions about interpretations of the law without waiting for interested persons to give me the benefit of their own views, let alone their own arguments", although adding that he had ultimately taken all arguments into account – *ibid.*, at 56, 57.

¹⁸² Health Complaints Commissioners, Media Release (Dec. 12, 2003).

¹⁸³ Davies, G., "Queensland Public Hospitals Commission of Inquiry Report" (Nov. 2005), available online at: <http://www.qphci.qld.gov.au> (last accessed Dec. 2005). The original Commission of Inquiry, headed by Anthony Morris, was halted by court order on the basis of reasonable apprehension of bias against 2 hospital administrators. The Davies inquiry, which began in Sept. 2005, incorporated all the non-impugned evidence from the initial inquiry and proceeded to complete the investigation. The result of the 6 month inquiry was over 7000 pages of transcript, together with 500 exhibits adding thousands of additional pages, culminating in a 538 page report – Bundaberg Inquiry Report, Introduction. It is reported to have cost \$11.8 million (Aus.) – Foley, Meriah, "Panel: Police Should Investigate Surgeon", Associated Press News (Nov. 30, 2005), available online at: <http://www.comcast.net/news/international/australia/index.jsp?cat=AUSTRALIA&fn=/200> (last accessed Dec. 2005).

¹⁸⁴ Forster, P., "Queensland Health Systems Review Final Report" (Sept. 2005), available online at http://www.health.qld.au/health_sys_review/final/qhsr_final_report.pdf (last accessed Dec. 2005). 430 pages.

sufficient care. The Inquiry Report linked him to a number of patient deaths and injuries at Bundaberg Hospital and recommended criminal charges against him. It also recommended administrative proceedings against two hospital administrators whom it concluded had failed to respond adequately to complaints about him. More broadly, it found that a failure to assess doctors and inadequate complaints handling procedures were major factors that allowed the surgeon to continue working at the hospital. It identified deficiencies in five general areas at Bundaberg and other hospitals that had contributed to poor care: an inadequate budget defectively administered; defective administration of areas of need registration; absence of credentialling and privileging or any like method of assessment of doctors; failure to implement any adequate monitoring of performance or of complaints investigation; and a culture of concealment by government, Queensland Health administrators, and hospital administrators.¹⁸⁵ In the Inquiry's view, conflicts between budgetary constraints and patient safety were too often resolved "...in favour of an economic rationalist view of budget management, sometimes with harmful effects on patient health and safety".¹⁸⁶ Commissioner Davies found that the culture of concealment had started from the top. In his words: "The conduct of Cabinet, in successive governments...was inexcusable and an abuse of the *Freedom of Information Act*. It involved a blatant exercise of secreting information from public gaze for no reason other than that the disclosure of the information might be embarrassing to Government."¹⁸⁷ Government's readiness to conceal information had set the tone for Queensland Health staff, with similar results.¹⁸⁸

The Forster Review of the Queensland Health System concluded that, although the workforce generally was dedicated and professional, there were negative features of organizational culture that severely impeded its ability to deliver the best care. It proposed an expansive set of changes to improve the system, including shifting to clinician-led rather than centralized decision making, additional funding, implementing the National Open Disclosure Standard, re-organizing external governance mechanisms, expanding protection for whistleblowers, revamping clinical governance structures, analyzing serious and sentinel events and clarifying responsibility for follow-up (noting that despite mandated root cause analysis of sentinel events, implementation was lacking), enacting legislative protection for quality and safety assurance analysis (subject to a review to ensure effective sharing of information by clinicians for quality assurance programs results), and other measures to achieve the "just culture or workplace environment" considered an essential precondition to clinician support for open reporting.¹⁸⁹

¹⁸⁵ Bundaberg Inquiry, *supra*, n.183 at 538, para. 8.8.

¹⁸⁶ *Ibid.*, at para. 8.5.

¹⁸⁷ Forster Review, *supra*, n.184 at 483, paras. 6.559, 6.564(b).

¹⁸⁸ *Ibid.*, para 6.580.

¹⁸⁹ *Ibid.*, at 187, commenting that doctors did not trust confidentiality would be maintained, and were of the view that their employer, Queensland Health, was allowing them to be blamed in order to minimize adverse publicity directed against it.

CHAPTER 6. NEW ZEALAND

New Zealand is a common law country, but more than thirty years ago, it ended recovery through the tort system for people who had suffered personal injuries, and put in place an administrative system to compensate them instead. Its long experience with a no-tort system can provide valuable information on a number of issues: whether the tort system does function as a deterrent to behaviour that falls below the standard of care, whether being relieved of the prospect of civil liability for negligence makes health care providers less reluctant to disclose errors and adverse events, and how compensation and deterrence fare in the absence of tort.

I. COMPENSATION FOR ACCIDENTS

New Zealand did not eschew tort because of any concerns about a medical malpractice crisis or its effects on efforts to improve patient safety. At the time the Accident Compensation Corporation was put in place in 1974 to operate the new compensation system, there had been very few medical malpractice lawsuits.¹ Rather, its decision followed on the recommendation of a Royal Commission of Inquiry into Compensation for Personal Injury, which set out five principles for rehabilitation and compensation (community responsibility, comprehensive entitlement, complete rehabilitation, real compensation, and administrative efficiency), and vis a vis the fault-based liability system, concluded that it was too erratic and capricious in its operation for accident victims, who needed a secure source of support.² No-tort compensation determined and administered by the Accident Compensation Corporation (ACC), and an end to individuals' right to sue for damages for personal injury covered by the scheme were the result.

The accident compensation system as a whole is funded by premiums paid by employers and employees, government, and other sources.³ Costs of claims for injuries caused by health

¹ Burke, P., "A Brief Introduction to Medical Misadventure", (2004) 35 VUWLR 811 at 815, n.25, notes that between 1881 and 1972 (when the *Accident Compensation Act* was passed), there were only 7 reported medical malpractice judgments in the country; Corkill, B., "Medical Misadventure – Development of the Statutory Concept, and its Place in the Current Medico-Legal Environment" (Feb., 2002), online at <http://www.acc.co.nz>, (last accessed Nov., 2004), at 27, n.36, cites Palmer's figures: in 1970 in New Zealand, "there were no more than 60 arguably serious medical malpractice claims, and the total payout from insurance companies was \$150,000".

² New Zealand Commission of Inquiry into Compensation for Personal Injury, *Compensating for Personal Injury in New Zealand: Report of the Royal Commission of Inquiry* (Government Printer, Wellington, 1967) ("Woodhouse Report"); Easton, Brian, "Ending Fault in Accident Compensation: Issues and Lessons From Medical Misadventure", (2004) 35 VUWLR 821, at 821-2.

³ Von Tigerstrom, B., "Current Developments in New Zealand Health Law", (2004) 12 Health L. Rev. 18, at 19.

care are shared, with 45% of the cost borne by persons who are earning, and 55 % by government.⁴ Doctors and other health care providers do not pay levies to support compensation for harm suffered in the course of treatment. Administrative expenses account for approximately 10% of the ACC's expenditures.⁵

I refer to the New Zealand system as “no-tort” rather than “no-fault”, because until very recently, although claims were determined by an administrative system rather than in court, claimants injured in the course of medical treatment had to establish either fault (medical error) or that they had suffered a rare and serious complication of treatment (medical mishap) in order to be eligible for compensation. That was not the case at the inception of the scheme, but it was a requirement from 1992 until 2005, and it affected both the operation of the compensation system, and health care providers' willingness to participate in the claims determination process. No such requirement was imposed when injuries were incurred in the course of other types of activity, such as playing a sport. A brief outline of the legislative history of coverage for medical claims in the accident compensation system follows.

Eligibility for Accident Compensation Cover

As originally enacted, the accident compensation system provided compensation for victims of “personal injury by accident”, without further definition. The scheme was revised several times, but the 1992 reforms were particularly significant. Stephen Todd explains that, after a series of expansive judicial decisions, government reacted by reining in judicial discretion: “There was cover, as before, for personal injury caused by accident, by employment-related disease or infection, by medical misadventure and by treatment for personal injury, and also for mental or nervous shock suffered by the victims of certain specified sexual offences...[but] they were now treated as separate categories and made subject to a series of detailed definitions”.⁶ The main types of personal injury not covered by the accident compensation system are mental harm that is not consequent on physical injury or commission of a sexual offence, and disease that is not related to employment.⁷

⁴ New Zealand. “Foreword by the Minister for ACC”, in “Review of ACC Medical Misadventure Consultation Document”, (2003)

⁵ Bismark, M., and Paterson, R., “No-Fault Compensation in New Zealand: Harmonizing Injury Compensation, Provider Accountability, and Patient Safety”, (2006) 25 Health Affairs 278 at 281.

⁶ Todd, S., “Negligence liability for personal injury: a perspective from New Zealand” (2002) 25 UNSWLJ 895-903.

⁷ *Ibid.*

The 1992 Reforms: Introducing Fault to Claims for Medical Misadventure

Beginning in 1992, “medical misadventure”, which had been covered under the scheme from the outset but had not previously been defined, now had to fit within one of two categories: “medical error” or “medical mishap”. Medical error was defined as the failure to observe a reasonable standard of care and skill – essentially, negligence. Medical mishap was defined as a rare (occurring in less than 1% of cases) and severe (disability or prolonged hospitalization) adverse consequence of properly administered treatment.⁸ Causation also had to be established – i.e. that the personal injury was the result of medical misadventure. The fact that desired results were not achieved, or that in retrospect, a different decision might have produced better results, did not constitute medical error. Further, delay or failure attributable solely to resource allocation did not amount to medical error. Medical error could be committed by an organization, potentially allowing for systemic analysis of patient injury, but only if the ACC was not able to identify the individual(s) responsible.⁹

Residual Scope for the Common Law

The 1992 amendments not only made it more difficult to establish eligibility for compensation, but reduced the compensation payable as well. One change felt particularly keenly was the elimination of lump sum compensation and its replacement with a \$40 per week “independence allowance”.¹⁰ These changes were especially harsh on certain classes of claimant, such as non-earners (largely women) and people who had only a short time to live (sometimes as a result of the medical misadventure).¹¹ Duffy has pointed out the gendered effects of ending lump sum compensation for pain and suffering: not only were the victims of some of the most egregious health crises in New Zealand at the time women, but because women are often not in paid employment, when compensation for pain and suffering was excluded, they were entitled to very little in the way of ACC benefits at all, even though they had suffered

⁸ *Injury Prevention, Rehabilitation, and Compensation Act 2001*, 2001, No. 49. Doctors strenuously resisted findings of fault; perhaps bowing to the inevitable, of accepted “medical misadventure” claims, 86% were accepted as “medical mishap”, and only 14% as “medical error” – Accident Compensation Corporation, Annual Report ; personal communication, Ron Paterson.

⁹ Rogers, S., *Healthcare and the Law* (3rd N.Z. ed.) (Thomson Brookers, 2004), at 48, n.1.

¹⁰ Previous maximums (already seriously eroded by inflation) were a \$17,000 lump sum payment for physical impairment (paid on an objective percentage basis), and \$10,000 for pain and suffering and loss of amenities – Miller, J., “Trends in Personal Injury Litigation: The 1990’s”, (2003) 34 VUWLR 407 at 408.

¹¹ *Ibid.*

substantial harm.¹² Although lump sum compensation was reinstated in 2001, compensation for pain and suffering remained excluded; in Duffy's view, amounts awarded are still largely targeted at compensating injuries that interfere with the ability to earn.¹³

The result of the diminution in the statutory compensation scheme was a substantial increase in efforts to sue and obtain damages at common law.¹⁴ A cause of action still exists at common law for injuries that are not covered by the accident compensation system, and Duffy recounts "enormous effort" by lawyers acting for victims who would not benefit from the ACC to avoid cover under the legislation.¹⁵ However, the definition of "personal injury caused by accident" was broad, and most such attempts were unsuccessful.¹⁶ Limited ability remains to sue for mental harm that is not associated with physical injury, and for exemplary damages.¹⁷ While sympathizing with the reasons for trying to revive the common law in these circumstances, commentators have been hesitant to support one-off efforts to circumvent what is meant to be a comprehensive public system.¹⁸

Accident Compensation Benefits

Although an individual cannot sue if there is coverage under the ACC scheme, he or she does have a right to compensation in accordance with the terms of the statute once cover is established. Statutory entitlements fall into four categories: (1) treatment and rehabilitation (including aids and appliances, home help, child care, pharmaceuticals, home modifications and vocational training); (2) compensation for loss of earnings (80% of earnings at the time injured, to a set maximum, payable to claimants who cannot work because of the injury); (3) lump sum compensation for permanent impairment (maximum NZ \$100,000; minimum threshold 10%); and (4) death benefits (funeral grant and grant for spouse and dependents).¹⁹

The 2005 Reforms: An End to Fault

¹² Duffy, A., "The Common Law Response to the Accident Compensation Scheme", (2003) 34 VUWLR 367, 370.

¹³ *Ibid.* Lump sum compensation is available for permanent impairment. "Personal injury" includes mental injury (a defined term) suffered as a consequence of physical injury or by victims of certain criminal offences. Thus, if a claimant experienced "pain and suffering" that fell within the definition of "mental injury" under the Act, lump sum compensation could be awarded. I am grateful to Ron Paterson and Joanna Manning for clarifying this point.

¹⁴ Miller, *supra*, n.10 at 407.

¹⁵ *Supra*, n.12 at 368.

¹⁶ Miller, *supra*, n.10 .

¹⁷ Tobin, R., "Case Notes: Exemplary Damages in New Zealand: The end of the story?", (2003) 11 TLJ; Manning, J., "Health Care Law Part I: Common Law Developments", [2004] NZLR 181 (hereafter, Manning I).

¹⁸ See, eg. Ferguson, J., "Medical Misadventure under Accident Compensation: Diagnosis and Treatment of a Problem?", [2003] NZLR 485.

¹⁹ Bismark, M., Paterson, R., *supra*, n.5 at 279.

Ongoing dissatisfaction culminated in a government review, which concluded that both claimants and health professionals found the ACC's criteria used to determine cover in medical claims unfair, confusing and arbitrary. Coupled with the legislative requirement to find fault (and report findings of medical error to other authorities), the ACC's medical misadventure decisions were considered slow and unfair.²⁰ The governing legislation was amended as a result.

The *Injury Prevention, Rehabilitation and Compensation Amendment Act (No. 2) 2005*, which came into force in July, 2005, repealed the sections of the Act dealing with medical misadventure, medical error and medical mishap. Instead, claimants are entitled to compensation if they have suffered "personal injury caused by treatment", i.e. a "treatment injury".²¹ "Treatment" is defined broadly.²² There is no requirement that the injury meet any threshold of severity. However, a causal link must still be established: cover is available for personal injury suffered by a person seeking treatment from a registered health professional that is caused by treatment. There are some specific exclusions: injury caused by treatment does not include (a) personal injury caused by or attributable to the person's underlying health condition (maintaining the distinction between accident and illness), (b) personal injury that is a necessary, anticipated part or ordinary consequence of treatment,²³ (c) personal injury solely attributable to resource allocation; or (d) personal injury that results when the person unreasonably withholds or delays consenting to treatment. The fact that a treatment did not achieve a desired result does not in itself constitute a treatment injury.

With these amendments, New Zealand has harmonized the components of its accident compensation system, so that all forms of covered injury are compensable on a no fault basis. While it is too early to evaluate how the changes are operating in practice, the intent was certainly to simplify the law and streamline the claims process, so that claimants could establish

²⁰ New Zealand. "Executive Summary", "Review of ACC Medical Misadventure Consultation Document" (2003).

²¹ *Injury Prevention, Rehabilitation and Compensation Amendment Act (No. 2) 2005*, Part I, cl. 13 substitutes a new definition of "treatment injury" in IPRCA sections 32-33.

²² "Treatment" includes giving treatment; diagnosis; decision on the treatment to be provided, including deciding not to treat; failure or delay in treating; obtaining or failing to obtain consent to treatment; providing prophylaxis; failure of equipment used as part of treatment process; application of support systems (including policies, processes, practices and administrative systems used by the organization or persons providing treatment; and directly support the treatment) -- *ibid.*, s.33. The last of these is particularly congruent with a "systems approach" to adverse events. I am grateful to Joanna Manning for pointing this out.

²³ Judgments must take into account the person's underlying health condition, the treatment environment, circumstances in which treatment was provided, treatment required, treatment provided, consequences of treatment, and clinical knowledge at time treatment was provided. – *ibid.*, s. 32(2)

eligibility and receive compensation more quickly, and to entrench a “systems approach” to medical accidents. Secondly, the new approach was also meant to improve patient safety, because health care providers were expected to be less defensive about helping to identify what went wrong when they no longer faced the prospect of fault-finding as a necessary part of that process. Changes in the ACC’s reporting requirements were also meant to assuage health care providers’ concerns about potential professional repercussions from participating in the claims process; these had increased both the cost and time required for decisions about coverage.

II. ADVERSE EVENTS AND CLAIMS FOR COMPENSATION

A study of the occurrence and impact of adverse events in New Zealand public hospitals determined that the proportion of hospital admissions associated with an adverse event was 12.9%, of which nearly one fifth had occurred outside a public hospital (i.e. in doctors’ offices, patient’s home, rest home or private hospital).²⁴ Most adverse events had minor impact on the patient; less than 15% were associated with permanent disability or death.²⁵ More than one third of the adverse events identified, and half of those that occurred in hospitals, were preventable.²⁶ Overall, just over 5% of admissions to public hospitals in New Zealand were associated with a preventable adverse event of in-hospital origin.²⁷

Turning to patients’ perspective on medical error, a 2005 six country review of patients with health problems found that in New Zealand, 14% of the 704 patients surveyed reported a medical mistake was made in their treatment or care, and 25% reported having experienced medical error, medication error, or lab error in the past two years.²⁸ Medical errors and medication errors caused serious health problems for 54% of patients. For 63%, the medical or

²⁴ Davis, P., Lay-Yee, R., Briant, R., Ali, W., Scott, A., Schug, S., “Adverse events in New Zealand hospitals I: occurrence and impact”, (2002) 115(1167) NZJM, online at: <http://www.nzma.org.nz/journal/115-1167/271/> (last accessed July, 2004).

²⁵ *Ibid.*

²⁶ Davis, P., Lay-Yee, R., Briant, R., Ali, W., Scott, A., Schug., S., “Adverse events in New Zealand public hospitals II: preventability and clinical context”, (2003) 116(1183) NAJM, online at: <http://www.nzma.org.nz/journal/116-1183/624/> (last accessed July 2004).

²⁷ *Ibid.*

²⁸ Schoen, C., Osborn, R., Huynh, P.T., Doty, M., Zapert, K., Peugh, J., Davis, K., “Taking the Pulse of Health Care Systems: Experiences of Patients with Health Problems in Six Countries”, Health Affairs Web Exclusive, Nov. 3, 2005, W5-509-W5-525; online at: <http://www.cmwf.org/publications> (last accessed Nov., 2005).

medication errors occurred outside a hospital. 61% of patients were not told about the medical mistake or medication error by their doctor.²⁹

Claims related to health care have historically made up .05% of all claims made to the ACC, with approximately 2000 such claims per year, from a population of four million.³⁰ Prior to the 2005 reforms, the ACC paid about \$47 million (NZ) per year for medical misadventure claims; the new treatment injury provisions are expected to add \$8.6 million (NZ) to that figure.³¹ Only a small portion of preventable adverse events result in claims. Davis *et al.* estimated the ratio of potentially compensable events to successful claims to be approximately thirty to one.³² It appears that even if entitled to compensation, most patients do not submit a claim and may not be aware they had suffered an adverse event.³³ The extent of under-claiming for compensation even when entitled is surprising, given the existence of a simple, inexpensive, non-adversarial claims process. Removing the need to sue in order to recover compensation has not been sufficient on its own to overcome barriers to claiming.

III. PATIENT SAFETY AND THE LAW

Health and Disability Commissioner

While there are many patient safety initiatives in New Zealand,³⁴ the main interface between law and patient safety initiatives is through the office of the Health and Disability Commissioner (HDC). For that reason, although an evaluation of complaints systems is beyond the scope of this paper, I will briefly outline how the HDC functions.

In the late 1980's, a public scandal erupted when it became known that numerous women diagnosed with cervical carcinoma *in situ* had, without their knowledge and consent, been made

²⁹ *Ibid.*, at W5-514.

³⁰ Bismark & Paterson, *supra*, n.5 at 279. As noted previously, most accepted claims were for medical mishap, not medical error.

³¹ Fairfax New Zealand Limited, "Doctors welcome ACC changes", March 16, 2004, online at <http://www.stuff.co.nz/stuff/print/0,1478,2846904a7144,00.html> (last accessed November, 2004).

³² Bismark & Paterson, *supra*, n.5, citing Davis *et al.*, "Compensation for Medical Injury in New Zealand: Does 'No-Fault' Increase the Level of Claims Making and Reduce Social and Clinical Selectivity?", (2002) 27 J.H.P.P.L. 833-854.

³³ *Ibid.* at 281.

³⁴ See eg, New Zealand. Ministry of Health, "Reportable Events Guidelines", online at http://www.moh.govt.nz/moh.nsf/wpg_Index/Publications-Reportable+Events+Guidelin (last accessed Dec. 2005). The National Health Committee's "Final Report on Health Care Quality Improvement in New Zealand" (May, 2002), advocated a systems approach to quality improvement, and identified safety as one of five components of quality, but with little detailed direction on achieving either.

part of a research trial at a leading teaching hospital that withheld conventional treatment in order to study the course of the disease. The public inquiry appointed to investigate recommended, *inter alia*, that a Patients' Code of Rights be developed, and that a health ombudsman be appointed to investigate patients' complaints.³⁵ Pursuant to those recommendations, the office of Health and Disability Commissioner was created in 1994, and in 1996, the Code of Health and Disability Services Consumers' Rights became law.³⁶ The intent was to enable the HDC to take a broader focus in addition to resolving individual complaints, in order to promote quality improvement. Ron Paterson, the current Health and Disability Commissioner, explains that the heart of the Code is the right to services of an appropriate standard, understood as including both the traditional duty of care and modern concepts of patient safety and care coordination.³⁷ The main enforcement mechanism is through patient complaints, although the Commissioner does have the power to commence an investigation on his own initiative if a health care provider appears to be in breach of the Code.³⁸

The Health and Disability Commissioner is the single point of entry for complaints.³⁹ After an initial assessment, the Commissioner can decide to take no action, or refer the matter to an advocate for low-level resolution, to the provider for resolution, for mediation, or make other referrals as appropriate. In more complex or serious cases, the Commissioner can conduct an investigation and will then report to the parties and issue recommendations.⁴⁰ If a breach of the Code is found, remedies can include an apology, censure, specified quality improvement steps, and other measures.⁴¹ In more serious cases still, the Commissioner can refer the matter to the Director of Proceedings, who decides whether disciplinary or human rights tribunal proceedings

³⁵ Paterson, R., "The Patients' Complaints System in New Zealand", (2002) 21 Health Affairs 70-79 at 71; Cartwright, S., *The Report of the Cervical Cancer Inquiry* (Auckland: Government Printing Office, 1988).

³⁶ *The Health and Disability Commissioner Act 1994*; The Code of Health and Disability Services Consumers' Rights was promulgated as a Regulation under the *Health and Disability Commissioners Act* in 1996. Health care providers are required to "take reasonable actions in the circumstances to give effect to the rights and comply with the duties" in the Code.

³⁷ *Supra*, n.35 at 71.

³⁸ *Ibid.* at 73.

³⁹ Paterson, R., "Complaints and quality – handle with care!" (2004) 117 NZMJ, online at <http://www.nzma.org.nz/journal/117>.

⁴⁰ Manning reports that practitioner compliance with Commissioner recommendations in a breach opinion is high – Manning, J., "Health Care Law Part 2 – Legislative Developments", [2004] NZLR 385 at 392 (hereafter, Manning II).

⁴¹ Paterson 2002, *supra*, n.35 at 74.

are warranted.⁴² This is generally reserved for cases of major shortcomings in care or communication, sexual misconduct or unethical practice.⁴³

The current Health and Disability Commissioner is firmly of the view that a culture of blame is counter-productive, that rehabilitation should be a hallmark of the complaints process, and that adverse events ought to be used as opportunities to learn, in order to improve health services – as Paterson notes, the Commissioner’s motto is “Resolution, not retribution; learning, not lynching”.⁴⁴ In keeping with that philosophy, few practitioners are referred for consideration for discipline proceedings. The focus is on resolving complaints at the lowest level that is appropriate.⁴⁵ The HDC received 1124 new complaints in 2004-05; only 15% of complaints (172) proceeded to formal investigation of alleged individual or systemic failures.⁴⁶ A breach of the Code was found in 41% of the cases investigated. Fourteen (20%) of these were referred to the Director of Proceedings for potential disciplinary or human rights tribunal proceedings; of these, charges were upheld in 9 of 11 substantive hearings in 2004-05.⁴⁷

The HDC’s ability to widen the focus of investigation beyond an individual health care provider allows for identification of systemic shortcomings. For instance, the HDC’s Gisborne Hospital Report found breaches not only by health care providers (in the re-use of syringes and failed quality control in PSA testing), but also breaches in care and co-ordination by the hospital, resulting in a series of recommendations related to incident reporting and complaints handling.⁴⁸ Corkill notes that, while lawsuits focus on the experiences of one individual, generally at the hands of one practitioner, inquiries allow for a more wide-ranging consideration of systemic issues and consequently, more accurate identification of improvements needed.⁴⁹

As the HDC acknowledges, there is no direct evidence that the method New Zealand has adopted of combining a complaints mechanism with a broader quality focus has been effective;

⁴² Health and Disability Commissioner Annual Report, 2004 (Auckland: HDC, 2004); Health and Disability Commissioner Annual Report 2005, online at <http://www.hdc.org.nz/publications.php?publication=278> (last accessed Dec. 2005); Rogers, S. *supra*, n. 9 at 61. While the Human Rights Review Tribunal can award damages, it cannot do so for personal injury that is covered by the accident compensation scheme -- Manning II, *supra*, n.40 at 393.

⁴³ HDC Annual Report 2005, *supra*, n.42.

⁴⁴ Paterson 2004, *supra*, n. 39.

⁴⁵ Paterson 2002, *supra*, n. 35 at 74.

⁴⁶ Health and Disabilities Commissioner 2005 Annual Report, *supra*, n.42.

⁴⁷ *Ibid.*

⁴⁸ Paterson 2002, *supra*, n.35 at 76.

⁴⁹ *Supra*, n.1 at 34.

no outcomes-based data are available.⁵⁰ However, he considers the decline in discipline referrals (consistent with his office's rehabilitative focus), and the overall greater focus on patient safety to be positive signs. A recent study by Bismark *et al.* found that only .4% of adverse events, and 4% of serious preventable adverse events resulted in complaints to the HDC.⁵¹ The authors note that people who were more seriously injured were more likely to complain, but that patients who were elderly, socioeconomically deprived, or of Pacific ethnicity were least likely to complain. These findings raise concerns that very few of the preventable adverse events or harm to patients that occur will ever be reviewed.

Disclosure

Even in a no-tort system, disclosure remains an issue. This is evident in a number of areas. For instance, patients have a legal right under the Code of Health and Disability Consumers' Rights to open disclosure when they have been harmed by medical care.⁵² The Medical Council of New Zealand's standard of practice is to the same effect.⁵³ Yet many patients are not told by their physicians that a mistake was made in their care and they were injured as a result.⁵⁴

Privilege for quality assurance (QA) activities is also an issue. On application to the Minister of Health, quality assurance activities can be declared protected if it is in the public interest to do so.⁵⁵ The rationale for the protection is familiar – that confidentiality will encourage open and constructive examination of practices, to improve quality of care. However, the privilege also limits access to information and sharing of concerns about practitioners' competence. Once granted, with very limited exceptions, no one can be required to disclose the protected information or produce QA documents in any judicial proceeding or other investigation, including commissions of inquiry, police investigations, Health and Disability Commissioner investigations, and certain other inquiries.

⁵⁰ Paterson, 2002, *supra*, n. 35 at 76-7.

⁵¹ Bismark, M., Brennan, T., Paterson, R., Davis, P., Studdert, D., "Relationship between complaints and quality of care in New Zealand: a descriptive analysis of complainants and non-complainants following adverse events" (2006) 15 *Qual Saf Health Care* 17-22.

⁵² Paterson, "Candour and the Code", (HDC, May, 2002), online at: <http://www.hdc.org.nz/publications.php?publication=74> (last accessed Jan. 2006).

⁵³ Medical Council, of New Zealand, "Disclosure of harm 'Good medical practice'" (Oct. 2004).

⁵⁴ Schoen *et al.*, *supra*, n.28; Paterson, *supra*, n..51.

⁵⁵ Manning II, *supra*, n.40 at 387-388.

Third, the HDC has a policy of not identifying practitioners involved in the complaints process, other than disciplinary cases.⁵⁶ The rationale appears somewhat different – it is meant to avoid contributing to what is seen as a harmful trend towards “trial by media” before any determination in a case. The HDC adheres to this policy even in the case of a breach report, although recognizing a public interest argument for disclosure exists at that point.

A final example of the tension over disclosure is the change in ACC reporting requirements. This was one of the most controversial issues when the legislation was amended, particularly given recent inquiry findings that failures in inter-agency reporting of competence concerns about a practitioner had allowed him to continue practice, and continue harming patients.⁵⁷ Nonetheless, it was decided that in order to encourage greater cooperation by health professionals, the ACC’s reporting obligations would be limited. The legislation now provides that, where the ACC believes from information collected during the claims process that there is a risk of harm to the public, it must report the risk to the person or authority responsible for patient safety (such as the registration authority) or the Director-General of Health. It no longer has to report to the Health and Disability Commissioner. However, since authorities are required to notify the Health and Disability Commissioner of practitioners believed to pose a risk to the public, that information should still reach the HDC, albeit after passing through an additional stage.⁵⁸

Howell points out that the New Zealand system is heavily reliant on effective monitoring and enforcement; she is doubtful that proper and sufficient incentives have been built in to ensure that it takes place.⁵⁹ When separate silos of information are constructed to try to insulate information that one agency has from disclosure to another, the likelihood that cases of real concern will fall between the cracks and escape the attention of an agency with authority to take effective action increases.

Health Professionals’ Perceptions and Participation

Despite the HDC’s low-key approach to complaints resolution, health care professionals in New Zealand appear to feel almost as beleaguered as their counterparts in jurisdictions that

⁵⁶ HDC, Annual Report 2004, *supra*, n.42 at 4.

⁵⁷ Manning II, *supra*, n.40 at 408.

⁵⁸ *Ibid.* at 409; *Health Practitioners Competence Assurance Act 2003*, s.35.

⁵⁹ Howell, B., “Medical Misadventure and Accident Compensation in New Zealand: An Incentives-Based Analysis”, (2004) 35 VUWLR 857.

maintain tort regimes and liability for clinical negligence. A number of factors seem to have contributed to this state of affairs. The potential for multiple investigations into one incident, in each of which the practitioner could be called to account, has been a source of concern.⁶⁰ While that should have been alleviated somewhat by passage of the *Health Practitioners Competence Assurance Act 2003*, which established a single, multi-disciplinary tribunal to replace various professional bodies that used to hear discipline proceedings, and separated responsibility for discipline and governance functions,⁶¹ that too aroused professional opposition as an interference with professional freedom.⁶² Practitioners were also concerned about the possibility of criminal prosecution, in part because there had been an increase in criminal charges in the mid-1990's, at a time when the threshold required for proof was low. That trend ended with a change to the governing legislation.⁶³ Coroner's investigations that identified the practitioners involved were considered to lead to "...an early naming, blaming and shaming through media coverage".⁶⁴ The ACC's reporting requirements under the former medical misadventure regime were another source of tension, as Rogers explains: "...as a rule of thumb, if there is a question of professional incompetence or negligence [effectively, medical error], reporting is mandatory. Those reports at a minimum are made to the relevant professional body and to the Health and Disability Commissioner, with a view to disciplinary proceedings or prosecution."⁶⁵ Practitioners were reluctant to participate in ACC claims determinations as a result. In a 2000 study, 46% of specialists reported they were discouraged or not encouraged to report medical errors (a figure comparable to 44% of U.S. specialists, where litigation is a real threat).⁶⁶ The Health and Disability Commissioner, commenting on the initial increase in complaints after his office was founded, noted the negative impact on health professionals, who "report a sense of 'being under siege' and claim that the risk of complaint to an independent ombudsman is leading

⁶⁰ Rogers, *supra*, n. 9 at 47-48.

⁶¹ *Ibid.* at 59.

⁶² Rogers, S., "Culling bad apples, blowing whistles and the Health Practitioners Competence Assurance Act 2003 (NZ)", (2004) 12 JLM 119.

⁶³ Corkill, *supra*, n. 1 at 34. The first prosecution under the amended manslaughter law (requiring significant departure from the standard of reasonable care and skill) against a midwife was unsuccessful. The decision to lay charges was widely criticized – Otago Daily Times, March 23, 2006, online at: <http://www.odt.co.nz> (I am grateful to Ron Paterson for bringing this case to my attention).

⁶⁴ Rogers, *supra*, n.9 at 63.

⁶⁵ *Ibid.* at 49.

⁶⁶ Paterson, *supra*, n.52.

to the practice of defensive medicine”.⁶⁷ In 2002, the New Zealand Medical Association adopted a policy titled “Medico-Legal Peril”. It began by stating: “The New Zealand Medical Association is of the view that the medico-legal environment in New Zealand is a hostile one and constitutes a deterrent to good medical practice. The ‘blame and shame’ culture acts as a disincentive to quality initiatives, early detection and reporting of medical error”.⁶⁸

The environment may have improved somewhat since the NZMA’s statement. The Health and Disability Commissioner wrote in 2004 that only 43% of surgeons involved a lawyer in the complaints process, adding that he did not consider lawyers necessary because of the low risks to practitioners in the process.⁶⁹ Still, problems persist. Prior to the recent legislative amendments, the ACC’s claims determination processes in medical error cases continued to be slower and more costly because health professionals were uneasy about participating, and sought legal advice first.⁷⁰ And in the 2005 Commonwealth Fund study referenced earlier, 61% of patients reported that their physicians had not told them that a medical mistake or medication error had been made in their care.⁷¹ The new “treatment injury” regime implemented in 2005 (ending the requirement to find fault in order to establish a patient’s injury was the result of medical error) may ease tensions further, but law reform alone is unlikely to be sufficient to achieve that end.

IV. CONCLUSIONS

New Zealand recently returned to a “no fault”, rather than a “no tort” system for compensating personal injury caused by health care. As the preceding review has indicated, “no-tort” and “no-fault” can mean many different things. Criteria for eligibility can be made more or less strict, and benefit levels more or less adequate, affecting the overall fairness of the scheme. As with other no-fault administrative systems, such as workers’ compensation, entitlements are subject to political, economic and social pressure, the vagaries of the political process, and neglect.

⁶⁷ Paterson, 2002, *supra*, n. 35 at 77.

⁶⁸ New Zealand Medical Association, NZMA Policies, “Medico-Legal Peril”, adopted by NZMA Board Feb. 8, 2002; online at: <http://www.nzma.org.nz/news/medico.html> (last accessed Nov. 2004).

⁶⁹ Paterson, 2004, *supra*, n.39; see also Cunningham, W., “The impact of complaints on medical professionals”, (2005) 118 NZJM, online at: <http://www.nzma.org.nz/journal/118>.

⁷⁰ Easton, *supra*, n.2 at 822.

⁷¹ *Supra*, n.28 .

However, it is certainly true that under the accident compensation system, claims can be made more easily, and are less costly, more certain, and more quickly resolved than a lawsuit alleging clinical negligence. However, as noted earlier, under-claiming for compensation is as much a feature of the New Zealand system as in countries with tort systems. Those differences should be even more pronounced with the recent legislative changes ending the requirement to find fault in order to award compensation for medical error. While there are ongoing concerns about the low levels of benefits and lack of coverage for some types of harm that the system just does not recognize, the accident compensation system as a whole has broad support.⁷² There is no movement to return to a tort system for personal injury claims.

Data about adverse events in New Zealand hospitals indicate an incidence in the same range as that found in other countries that do have a tort system. It does not appear, then, that removing the threat of liability for clinical negligence has had a negative effect on the quality of care. One of the classic justifications of tort law is that judgments in tort cases serve as a deterrent to future unsafe behaviour, but it seems that New Zealand hospitals do not have higher rates of unsafe care causing harm to patients than elsewhere.

Conversely, it also does not appear that New Zealand hospitals are safer than those in countries with tort systems.⁷³ In the United States, Canada, the United Kingdom and Australia, health care providers' reluctance to disclose errors to patients, or to colleagues so their experience can be used to develop safer systems is often blamed on fear that the information will be used to fuel lawsuits. In New Zealand, there is no such threat. One would have hoped that practitioners would be more willing to share this type of information, and that quality assurance and quality improvement would be much advanced. That does not seem to be the case. Recent inquiries into substandard care reveal many of the same kinds of deficiencies in incident reporting, complaints handling, clinical governance and management as in other countries.⁷⁴ Many patients are not told that a mistake was made in their care, or even that they suffered an adverse event.

⁷² Manning II, *supra*, n.40.

⁷³ Bismark and Paterson, *supra*, n.5 at 282.

⁷⁴ See eg. Duffy, A., Barrett, D., Duggan, M., *Report of the Ministerial Inquiry into the Underreporting of Cervical Smear Abnormalities in the Gisborne Region* (Auckland: 2001); Health and Disabilities Commissioner, *Gisborne Hospital 1999-2000. A Report by the Health and Disabilities Commissioner* (Auckland: 2000), online at: <http://www.hdc.org.nz> (last accessed Dec. 2004); Cull, H., *Review of the process concerning adverse medical events* (Wellington: 2001), online at: <http://www.moh.govt.nz> (last accessed Dec. 2005).

The threat of legal liability for negligence is only one factor affecting practitioners' willingness to disclose error. They are also concerned about professional and employment repercussions, damage to reputation, their own self-image, and effects on their practice. Further, as Rogers points out, "shame and blame" is as much a part of the medical profession as it is of the legal system.⁷⁵ To an outsider, practitioners' estimation of the risks of negative repercussions seems somewhat overblown, particularly since (i) they face no prospect of tort liability, (ii) they pay no levies to support the accident compensation system and so are not financially affected by an increase in successful claims, and (iii) the Health and Disability Commissioner is a staunch believer in a rehabilitative approach to complaints whenever possible. Their level of apprehension significantly exceeds what a realistic assessment of the empirical evidence would support.

The principal tie-in between the law and patient safety initiatives in New Zealand is through the office of the Health and Disability Commissioner, the single entry point for complaints, and the gatekeeper for access to disciplinary and human rights review processes. With little other outlet for patients wishing to assert a claim against a practitioner, such as that provided (at least notionally) by the ability to sue, it is especially important to have an effective system for complaints. The HDC relies on patient complaints as the main enforcement mechanism, and while investigations are expanded to examine systemic issues where warranted, such a system is essentially reactive, with efforts after the fact to give HDC recommendations wider effect through education and advocacy. This makes the gap between preventable adverse events and the much smaller number of complaints particularly troubling.

The HDC has also expressed reservations about the complaints process and its effects. While still of the view that health complaints provide a "window of opportunity" to improve health services, he notes that "...emerging evidence shows that complaints are not necessarily the treasure trove of opportunity that quality improvement gurus would have us believe. Instead of providing reconciliation and closure, complaints can have toxic effects on patients and doctors, and may perhaps more accurately be described as a 'toxic treasure'".⁷⁶ Resolution of concerns about the complaints process remains elusive.

⁷⁵ *Supra*, n.62 at 131.

⁷⁶ Patterson, 2004, *supra*, n.39. He adds that although doctors are most often vindicated in the complaints process, they report being negatively affected by their involvement; as for patients, a 2004 survey of complainants using

The hope for the 2005 amendments to the accident compensation system is that patient safety will be enhanced as well. The government proclaimed that, not only would accident compensation be fairer and simpler, but "...a learning environment would be fostered for health providers and organizations now that punitive fault-finding was gone from ACC's processes".⁷⁷ The impact on patient safety from the anticipated (but not assured) indirect effects on provider attitudes from this change to the law is likely overstated. Commentators have pointed out that much will turn on how the ACC interprets its reporting obligations. Some argue it should adopt a high threshold before determining there may be a "risk to the public" requiring reporting, to avoid re-creating the "blame culture" that characterized the prior regime.⁷⁸ Others would urge more robust monitoring by the ACC.⁷⁹ While the legal environment is an important factor, major improvements in patient safety will require more than legal changes.

HDC services showed that only 46% were satisfied overall with the fairness of the process (in contrast to 80% of providers); this may be a product of the relatively low number of breach reports.

⁷⁷ New Zealand. "New ACC Treatment Injury law fairer and simpler", Press Release, May 9, 2005, online at: <http://www.scoop.co.nz/stories/print..html?path=PA0505/S00198.htm> (last accessed July, 2005).

⁷⁸ Coates, J., Smith, K., "Reform of ACC Medical Misadventure", (2004) 117 NZJM, online at: <http://www.nzma.org.nz/journal/117-1201-1050> (last accessed Dec. 2005).

⁷⁹ Howell, *supra*, n. 59.

CHAPTER 7. DISSEMINATION AND FUTURE DIRECTIONS

Dissemination:

Dissemination of preliminary results of the project began with a presentation to an international audience of health care professionals and administrators at the International Society for Quality in Healthcare conference in October, 2005. Presentations to Canadian and American legal academic audiences are scheduled for conferences in June, 2006. It is anticipated that additional presentations of the results of the research will be made at conferences and to professional, administrative, government and academic audiences, as well as to health care organizations. The report will be made available on the Osgoode Hall Law School website. Individuals with whom I met in Canada and the other countries for assistance with this project will be advised of the availability of the Final Report through the internet. In addition, papers will be prepared for publication based on the research, and the author plans to develop the study into a book-length manuscript for publication.

Future Directions for Research

1. Policy makers, stakeholders, academic analysts and the public are hampered by the lack of good quality data about the incidence, causes, costs and effects of medical liability litigation, and about the incidence of patient injury caused by negligence. Research is required to address this gap.
2. Similarly, domestic and international research is needed on what would be entailed in and what the effects would be of possible replacements for the tort system, such as a no-fault compensation system and/or administrative compensation mechanisms.
2. Research to gather empirical evidence on the effectiveness of patient safety initiatives and any unintended consequences (in the context of this report, particularly those that affect the operation of the civil justice system, such as qualified privilege for error reporting) is needed in order to assess whether the benefits of these provisions justify the cost of restricting access to information.
3. International and domestic research on models for and experience with more low-key, less adversarial alternatives for in-house and external complaints resolution mechanisms, including mediation.

4. Theoretical and empirical research on ensuring and strengthening provider and institutional accountability that would address, among other matters, the tension between individual, organizational and systemic accountability, and the implications, enforcement, interaction and appropriate scope of each.
5. Research on the appropriate role of professional regulation and how best to advance patient safety goals in ways that are consistent with regulators' obligations to protect the public, and ensure practitioners provide safe, quality care. This should include exploration of umbrella oversight of health professionals and institutions. Systems operative in New Zealand, the United Kingdom and Australia could provide useful initial information, but wider international research would be helpful as well.
6. Research examining the potential in linking governmental subventions for liability coverage to targeted patient safety goals and otherwise strengthening ties between policy on liability coverage and health policy generally.
7. Research assessing current legal developments on medical liability on an ongoing basis, to assess implications for patient safety initiatives.