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 deemphasis 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

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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 nofault compensation systems, with a view to determining their desirability in the Canadian environment.