

Patient Safety Law: From Silos to Systems

Appendix 1: KEY CONCEPTS

**Jocelyn Downie
William Lahey
Don Ford
Elaine Gibson
Mary Thomson
Tom Ward
Fiona McDonald
Alison Shea**

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Patient Safety and Governance

What is the most appropriate way to undertake the governance of patient safety in health systems is one of the policy questions of our times. In this appendix we define and discuss the concepts of patient safety and governance and the linkages between them and establish an analytical framework to assess the governance structures around patient safety that use law as a framework.

Delineating Patient Safety and Healthcare Quality

The quality of healthcare is a longstanding policy issue but it was not until the end of last century that the policy discussions around healthcare quality were overtaken by discussions of patient safety or the lack of it. At that point patient safety began to be addressed as a separate issue from healthcare quality – though some critics remain concerned about whether the separation of these issues accords any greater priority to one over the other and therefore greater improvements in safety or quality.¹ The health system was not alone in addressing these issues. Other sectors too are also addressing issues relating to safety and quality and there is also some debate whether making safety a distinct issue from quality is successful in respect of ensuring safety or quality.

Debates about the utility of separating the concept of healthcare quality and patient safety aside, this project does separate safety from quality as does current practice, policy and some new legislative initiatives. The focus of this project is therefore patient safety, so as a starting point it is as well to delineate the concept of patient safety from the concept of healthcare quality as each concept, either in meaning or application, overlaps with the other.

There are differing definitions or interpretations of ‘patient safety’. Broadly, ‘safety’ is defined in dictionaries to mean that a person is not in danger or likely to be harmed.² Safety, in the context of section 264(2)(b) of the *Canadian Criminal Code*, has been defined by the courts as “freedom from physical harm and apprehension of mental, emotional and psychological trauma.”³ These definitions recognize that harm is not purely a physical experience and is experienced at a number of levels including emotional, psychological and, perhaps also, spiritual. An obvious example of harm as expressed more broadly would be where blood transfusions are administered to a person of the Jehovah’s Witness faith – no physical harm may be experienced, indeed the

¹ See for example, Janet Storch, “Patient Safety: Is it Just Another Bandwagon?” (2005) 18:2 Can J. Nurs. Leadersh. 39.

² *Cambridge Advanced Learners Dictionary* online: Cambridge Dictionary <<http://dictionary.cambridge.org/>> The Oxford English Dictionary states safety is “the state of being safe; exemption from hurt or injury; freedom from danger” and “the quality of being unlikely to cause or occasion hurt or injury; freedom from dangerousness; safeness. *with safety*, without occasioning danger or risk.” Oxford English Dictionary, online: OED <<http://dictionary.oed.com/>>.

³ *R v. Theysen* (1997) 44 Alta. L.R. 3d 364 (Prov. Ct.).

opposite, but the emotional and spiritual trauma may be devastating.⁴ As much as avoidance of harmful outcomes is part of any definition of ‘patient safety’ and, more broadly, must be part of any discussion of what to do about patient safety, we believe that ‘harm’ should be more broadly defined to include mental, emotional, psychological and spiritual trauma – as distinguished from being unhappy or upset which is more in the realm of quality.

We note that much of the empirical studies of the incidence of unsafe care focus on assessing physical harms experienced by patients. There are a number of reasons why empirical research into patient safety focuses to a large extent on physical harms. First, physical harm is significantly easier to identify and is considered more objective, whereas emotional or spiritual harm is a more subjective experience. Non-physical harms are likely to be more difficult to identify in retrospective chart analyses. In short, physical harms are easier to study. Second, organized medicine also has a bio-medical orientation that focuses on physical harms and which has historically marginalized concerns about psychological, emotional, spiritual or even social harms.⁵ However, emotional, psychological, and spiritual harms can be just as, if not more so in some circumstances, destructive to the patient, his or her family, and the community, as physical harms.

In-as-much as legal considerations shape the discussion of safety, the law focuses primarily on physical harm, as a prerequisite for criminal offences and for civil actions seeking compensation. Some concerns about patient safety are placed into sharper relief in the public consciousness, and certainly in the consciousness of health care providers, as a consequence of legal mechanisms such as coroner’s inquests, public inquiries, criminal proceedings and civil proceedings. This in turn may shape policy-making so that it focuses on physical harm. Some suggest that the legal system, focusing as it does on harm, dwells too much on the outcome of error for the individual and does not sufficiently focus on the processes through which errors occur and, consequently, on learning from error (see further discussion below). A definitional requirement that an action must result in harm also has two other consequences. First, it turns considerations of patient safety into retrospective analyses of unsafe acts, rather than a prospective examination of systems and people. Retrospective analyses of events that resulted in harm may also foster a need to place of blame on individuals through legal processes and discourage learning from error. Second, focusing on harmful outcomes may mean that those events where no discernable harm results or where near misses occur are overlooked. However, it is also important to note that a focus on harms experienced by patients may limit or focus on blame. So, although harm is not an unimportant concept, it does not find a prominent place in our definition of “patient safety”.

The second approach, and the approach we prefer, is to focus primarily on the types of actions or omissions that may, if unchecked, result in harm. The Canadian Patient Safety Dictionary defines patient safety as “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

⁴ *Malette v Shulman* (1987), 72 O.R. (2d) 417 (C.A.). It also may be an issue for persons from other cultures.

⁵ See for example, Norman Daniels, *Just Health Care* (Cambridge: Cambridge University Press, 1985).

optimal patient outcomes.”⁶ The latter part of this definition is intended to be more expansive and positive, but moves towards the domain of quality illustrating the overlaps that can arise between quality and safety. Therefore, to distinguish as clearly as possible between safety and quality we focus on the first part of the definition. The Dictionary defines ‘unsafe acts’ as “error, violation and sabotage”. It explains:

Error should be defined as the failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim. Violation should be defined as representing a deliberate deviation from standards, rules or safe operating procedures. Sabotage should be defined as an activity in which both the acts and the harm or damage are intended.⁷

The Institute of Medicine (IOM) defines ‘patient safety’ as “freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximizes the likelihood of intercepting them when they occur.”⁸ The IOM’s focus on the mechanism through which harms occur, i.e. ‘accidental’ injury, excludes harm that arises from deliberate malicious acts by actors in the health care system. Malicious acts increase danger and likelihood of harm to patients and are a real safety issue in the health care system. A typology of this type is vulnerable to criticism that it creates room for a blame culture which is anathema to a systems approach to safety (discussed below). Given our focus on governance choices that involve the use of legal instruments to improve patient safety, a focus on types of unsafe care, as opposed to results, allows one mechanism of analyzing the intentions and effects of legal instruments.

Quality is a broader concept. To achieve quality one achieves a degree of excellence that encompasses measures to ensure patient safety, practice that is consistent with socially defined values and norms, practice that is consistent with current medical knowledge, and customization (the ability to meet customer specific values and expectations).

In respect of ‘quality’ the Institute of Medicine suggests that there are three domains of quality: safe care; practice that is consistent with current medical knowledge; and customization.⁹ We suggest that this formulation does not fully capture ‘quality’. The elusive domain missing from the IOM’s formulation is touched upon by Donabedian who suggests that quality also includes conformity to “socially defined values and norms that govern the interaction of individuals in general and in particular situations.”¹⁰ Socially defined values and norms may differ from customer specific values and experiences. Customer specific values imply a notion of an understanding of medicine and health care that has its roots in the market. Relationships with others who are in that market are

⁶ J. Davies, P. Hebert, C. Hoffman & the Royal College of Physicians and Surgeons of Canada, *Canadian Patient Safety Dictionary* (Ottawa: College of Physicians and Surgeons of Canada, 2003) at 12. [Canadian Patient Safety Dictionary.]

⁷ *Ibid* at 57.

⁸ Institute of Medicine, *To Err is Human: Building a Safer Health System*, (Washington, D.C.: National Academy Press, 2000).

⁹ *Ibid* at 18.

¹⁰ *Ibid*.

almost purely instrumental, relating to the purchase or use of products and focus on contractual obligations.¹¹ Socially defined values and norms include more expansive social, moral, ethical, and legal concerns, for example, such legal and ethical requirements as informed consent.

So, in practice, what are the distinctions between healthcare quality and patient safety? An ‘unsafe’ act may result from an isolated error and be a patient safety issue but it may not indicate an overall lack of healthcare ‘quality’. The best technical treatment may be ‘safe’ in the sense that it does not cause physical harm or emotional, psychological, or spiritual trauma but it may not be ‘quality’ care if it is delivered in a manner that overrides autonomy or is exploitative or humiliating. So called ‘defensive medicine’ may not physically or emotionally ‘harm’ the patient and therefore is ‘safe’, but it is not ‘quality’ care as it wastes societal resources to say nothing of putting the patient through unnecessary diagnosis or treatment.

As these distinctions illustrate, healthcare quality and patient safety overlap in places but are fundamentally different concepts with a substantially different focus: one takes a holistic view of what good care is; the other focuses on the avoidance of serious harm. However, the differences go further than this when one considers public perceptions. It may be fairly said that, to the general public, quality is important, but safety is paramount. A number of commentators have explored what they consider to be contemporary preoccupation with risk.¹² All note that the concerns of risk societies are defensive, focusing on risk avoidance and protection from harm.¹³ Patient safety focuses on the risk that a particular course of action may cause harm and how to manage the risk by developing strategies to prevent harm. Healthcare quality is seen to focus on how good services are and while safe care is certainly a component of this it is not the focus. Quality assurance processes and safety assurance processes are also very different in process and desired outcome.

The Patient Safety Problem

Now that we have defined some key concepts, we need to set out the problem and the problem is that the provision of health care, in Canada and in other countries around the world, is not as safe as it could be. A number of preventable episodes of unsafe care occur in every health care setting every day.

¹¹ Ruth Malone, “Policy as Product” (1999) 29:3 *Hastings Centre Report* 16.

¹² The most prominent are U. Beck, *Risk Society – Towards a New Modernity* (London: Sage, 1992) and A. Giddens *Modernity and Self-Identity* (Cambridge: Polity Press in Association with Blackwell Publishers Oxford, 1991).

¹³ H. Kemshall, “Conflicting Knowledge on Risk: The Case of Risk Knowledge in the Probation Service” (2000) 2:2 *Health, Risk & Society* 143 at 144.

The Problem

The problem is that the care and treatment that Canadians receive within all sectors of the health care system in Canada is not always safe. Canadians have a number of reasons to suspect that this is so – the publicity that some unsafe acts have garnered and anecdotal and empirical evidence that care and treatment received in hospitals and when receiving health care more generally can be unsafe. It has also become apparent that the costs of unsafe health services – personal and fiscal – to individuals, their families and their communities and to the state as a whole are high. Recent surveys indicate that indeed many Canadians have concerns about the quality of the health services that they are receiving. For example, the Commonwealth Fund 2002 International Health Policy Survey finds that one in four Canadians with health problems believes that the quality of health care in their country has deteriorated in the past two years.¹⁴

The Publicity

Over the past fifteen years there has been greater publicity about allegations of unsafe treatment and care within Canada and in other countries. In Canada, unsafe care has been highlighted in a number of fora in relation to a number of different aspects of the health care system. Some of these are listed below:

- In relation to public health, a Royal Commission of Inquiry investigated the management and operation of the blood system in Canada (1998),¹⁵ and an Independent Commission was established by the Government of Ontario under public health legislation to investigate how the SARS virus came to Ontario, how the virus spread and was dealt with (2004).¹⁶
- In relation to hospital care, a 1998 Coroner's Inquest investigated the deaths of 12 children who underwent pediatric cardiac surgery in Manitoba.¹⁷
- In relation to long-term care facilities, in 2004 there was extensive media coverage of allegations of abuse at long-term care facilities in Québec and Ontario. In Québec the Minister placed the institution at the centre of the allegations under trusteeship and conducted audits of all other facilities in the

¹⁴ The Commonwealth Fund, *The Canadian Health Care System: Views and Experiences of Adults with Health Problems. Findings from the Commonwealth Fund 2002 International Health Policy Survey* Pub no 641 (May 2003).

¹⁵ Commission of Inquiry on the Blood System in Canada, *Final Report: Commission of Inquiry on the Blood System in Canada*, by Horace Krever (Ottawa: Public Works and Government Services Canada, 1997).

¹⁶ Canada, Government of Ontario, *The Sars Commission*, online: Sars Commission <<http://www.sarscommission.ca/>>.

¹⁷ Winnipeg Provincial Court, *The Report of the Manitoba Pediatric Cardiac Surgery Inquest: An Inquiry Into Twelve Deaths at the Winnipeg Health Sciences Centre in 1994*, by Associate Chief Judge Murray Sinclair (Winnipeg: Provincial Court of Manitoba, 1998) online at: Pediatric Cardiac Inquest <<http://www.paediatriccardiacinquest.mb.ca/>>.

province. The Ordre des infirmières et infirmiers du Québec also instituted an investigation under the Nursing Act and a class action suit was brought by some residents and their families.¹⁸ In Ontario, the police investigated allegations of abuse in two facilities, and an internal investigator from the Ministry also investigated.¹⁹

- In relation to medications, in 2003/2004 the news media reported concerns about increases in the numbers of adverse drug reactions experienced, particularly by children, and allegations that Health Canada is not appropriately monitoring and acting upon concerns.²⁰
- In relation to medical research, James Dent died while participating in gene therapy research in Toronto.²¹ Commentators have expressed concerns about whether current systems that monitor the conduct of research are sufficient to ensure the safety of research participants.²²

At an international level, safety concerns relating to the delivery of health services have also been highlighted. While it is not possible, because of space constraints, to list all of the events that led to public concern about the safety of care internationally, the following list provides a sense of the concerns.

In the United Kingdom:

- A Public Inquiry was conducted into the quality of care and treatment provided to thousands of children who underwent pediatric cardiac surgery at the Bristol Royal Infirmary from 1984-1995.²³
- A Public Inquiry was held (2000-2005) into the conduct of Dr Harold Shipman, a family practitioner, who was convicted of murdering 15 patients and is suspected to have murdered 215 patients in total.²⁴

¹⁸ Gyslaine Desrosiers, "Recognising the Importance of Long-term Care" (2004) March/April Perspective Infirmière 10, online: OIIQ <<http://www.oiiq.org/uploads/periodiques/Perspective/vol1no4/editoA.pdf>>

¹⁹ James McCarten, "Union Calls for Public Inquiry into Abuse at Brantford, Ont., Nursing Home", *Canadian Press* (12 February, 2004) online: <http://www.medbroadcast.com/channel_health_news_details.asp?news_channel_id=1000&news_id=3337&channel_id=1001&relation_id=0>.

²⁰ "Faint Warning: Three Case Studies" *CBC Radio* (2004) online: CBC <<http://www.cbc.ca/news/adr/personal/>>, Paddy Moore, "From Coloured Tabs to Computerized Signals: How Canada Tracks Dangerous Drugs" *CBC News* (17 February 2004), online: CBC <<http://www.cbc.ca/news/adr/>>, "Sharp Increase in Children Hurt by Prescription Drugs" *CBC News* (17 February 2004), online: CBC <http://www.cbc.ca/stories/2004/02/17/drug_reaction040217>. For a compilation of stories reporting concerns about the monitoring of adverse reactions to approved drugs refer to online at health coalition <<http://www.healthcoalition.ca/drugs-media.pdf>>.

²¹ Jocelyn Downie & Fiona McDonald, "Revisioning the Oversight of Research Involving Humans in Canada" (2004) 12 *Health Law Journal* 159; Josephine Johnston & Françoise Baylis, "What Happened to Gene Therapy? A Review of Recent Events" (2004) 4 *Clinical Researcher* 11 and Jocelyn Downie, "Contemporary Health Research: A Cautionary Tale" (2003) *Health Law Journal*, Special Edition 1.

²² *Ibid.*

²³ U.K., The Bristol Royal Infirmary Inquiry, *The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol*, (Norwich: The Stationary Office Limited, 2001), online: The Bristol Royal Infirmary Inquiry <<http://www.bristol-inquiry.org.uk/>>.

In New Zealand:

- A Royal Commission of Inquiry was convened in 1988 to investigate allegations that doctors at the National Women's Hospital had, for research purposes, not treated women who presented with carcinoma *in situ*, many of whom subsequently developed invasive carcinoma unnecessarily and some of whom died.²⁵
- A Ministerial Inquiry was convened in 2000 to investigate allegations of under-reporting of cervical smears in the Gisborne region as a result of allegations made about the competence of the pathologist in that region.²⁶
- In 2001 the Health and Disability Commissioner investigated the treatment provided to a psychiatric patient who, within 24 hours of his discharge from Invercargill Hospital, murdered his mother.²⁷

In Australia:

- The Health Care Complaints Commission (New South Wales) issued a report in 2003 on the Campbelltown and Camden Hospitals suggesting that the hospitals and the administration systems in those hospitals needed significant reform. Four nurses had alleged questionable patient care, disregard for quality and safety, and an indifferent administration. The Minister of Health from New South Wales suspended two doctors and another nine were referred to the NSW Medical Board. Disciplinary proceedings were commenced against four administrators. Nineteen deaths examined in the H.C.C.C. report were referred to the State Coroner. The South West Area Health Board, that was ultimately responsible for the two hospitals, was dissolved.²⁸ There has since been a special parliamentary inquiry which reached the conclusion that there was a cover-up that extended to the Minister of Health.²⁹

²⁴ U.K., The Shipman Inquiry, *The Shipman Inquiry: Independent Public Inquiry into the Issues Arising from the Case of Harold Fredrick Shipman*, online: The Shipman Inquiry <<http://www.the-shipman-inquiry.org.uk/>>.

²⁵ N.Z., The Cervical Cancer Inquiry, *The Report of the Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and into Other Related Matters* (Auckland, N.Z.: Government Printing Office, 1988).

²⁶ Gisborne Cervical Screening Inquiry, online: Gisborne Cervical Screening Inquiry <<http://www.csi.org.nz/>>.

²⁷ Health and Disability Commissioner, N.Z., *Southland District Health Board Mental Health Services February - March 2001* (Wellington, N.Z.: Health and Disability Commissioner, 2002) online: HDC <http://www.hdc.org.nz/files/pagepublications/other_southlandreport.pdf>.

²⁸ Martin B Van Der Weyden, "The 'Cam Affair': An Isolated Incident or Destined to be Repeated?" (2004) 180:3 M.J.A. 100 online: Medical Journal of Australia <http://www.mja.com.au/public/issues/180_03_020204/van10893_fm-1.html> (date accessed 20 May 2004.)

²⁹ "Damning Findings in NSW Health Inquiry" *Australian Associated Press* (24 June 2004) online: Fairfax <<http://www.smh.com.au/articles/2004/06/24/1088046209784.html>>.

- There have also been high profile inquiries into the Canberra Hospital (2003) in Australian Capital Territory and the King Edward Memorial Hospital (1999) in New South Wales.³⁰

In the United States:

- The plight of 17-year-old Jessica Santillan who, whilst undergoing heart and lung transplant surgery, received organs of the wrong blood type and subsequently died received international attention in 2003.³¹
- Betsy Lehman, a health reporter for the Boston Globe, died in 1995 of cardiotoxicity after she received an overdose of chemotherapy medications. Her death and the others that preceded and followed it provoked significant investments by a number of players in the health care system into implementing systems to reduce medication errors.³²

Beyond the publicity garnered by these events empirical evidence also suggests that members of the public have a legitimate reason for concern about their concern about safety and quality in the Canadian health system.

The Evidence

Incidence

It is difficult to quantify with any certainty just how many adverse events occur in the health system. A number of countries (including Canada) have undertaken studies to assess the levels of unsafe acts within acute hospitals in each country (see Table 1). However, comparisons of these findings must be approached with caution due to differences in study methodology and in the health system in each country.

³⁰ T. Faunce & S. Bolsin, “Three Australian Whistleblowing Sagas: Lessons for Internal and External Regulation” (2004) 181:1 Medical Journal of Australia 44.

³¹ “Girl Tops Transplant list after error” *CNN* (19 February 2003) online: CNN <<http://www.cnn.com/2003/HEALTH/02/18/transplant.error/>> and Karen Frush, “Organizational Change in the Face of Highly Public Errors II. The Duke Experience” AHRQ Morbidity & Mortality Rounds on the Web (May 2005), online: AHRQ <<http://www.webmm.ahrq.gov/perspective.aspx?perspectiveID=4>>.

³² James B Conway & Saul Weingart, “Organizational Change in the Face of Highly Public Errors I The Dana Faber Cancer Institute Experience” AHRQ Morbidity & Mortality Rounds on the Web (May 2005), online: AHRQ <<http://www.webmm.ahrq.gov/perspective.aspx?perspectiveID=3>> www.medicalerrors.com,.

Table 1 – Unsafe Acts in Hospitals – Studies from Selected Countries

Study#	Date	Adverse Event Rate	Death or Permanent Disability Rate*
United States of America (Harvard Medical Practice Study) ³³	1991	3.7%	0.7%
Australia (Quality in Australian Health Care Study) ³⁴	1995	16.6% (50% preventable)	3%
United Kingdom (Vincent <i>et al.</i>) ³⁵	1999-2000	11.7% (50% preventable)	1.6%
Denmark (Schioler <i>et al.</i>) ³⁶	1998	9% (40.4% preventable)	
New Zealand (Davis <i>et al.</i>) ³⁷	2002	12.9%	2%
Canada (Baker <i>et al.</i>) ³⁸	2004	7.5% (37% preventable)	0.66% (deaths)

These studies use different methodologies so comparisons must be approached with caution.

* Adverse events may not always be a causal or contributory factor in these cases. Patients may die or be permanently disabled from disease progress, rather than as a result of an adverse effect.

The information set out in Table 1 provides an estimation of the extent of the problem in the acute care setting in the countries studied in this report but there has been little or no examination of the extent of unsafe acts in other care settings. For example, the levels of unsafe acts in primary care, public health, mental health services and non-acute institutions have only been studied in a limited fashion. The relative commonalities in the results in table 1 suggest that patient safety is a significant issue in all health systems, certainly in regards to the delivery of inpatient services, and that the levels of unsafe acts are unacceptably high. In real terms, 9,250 to 23,750 Canadians are estimated to die each year as a result of unsafe care and treatment and many thousands more are physically injured.³⁹

In addition, the Commonwealth Fund International Health Policy Survey found that one in four Canadians with health problems reported a medical or medication error in the past two years, with the majority stating that the error had caused serious health problems.⁴⁰

³³ T.A. Brennan *et al.* "Incidence of Adverse Events and Negligence in Hospitalized Patients. Results of the Harvard Medical Practice Study I" (1991) 324:6 N. Engl. J. Med. 370.

³⁴ R. Wilson *et al.*, "Quality in Australian Health Care Study (1996) 164:12 Med. J. Aust. 754.

³⁵ C. Vincent, G. Neale, & M. Woloshynowych, "Adverse Events in British Hospitals: Preliminary Retrospective Record Review" (2001) 322:7285 BMJ 517, erratum in: (2001) 322:7299 BMJ1395.

³⁶ T. Schioler *et al.*, Danish Adverse Event Study "[Incidence of Adverse Events in Hospitals. A Retrospective Study of Medical Records]" (2001) 163:39 Ugeskr Laeger 5370.

³⁷ P. Davis, *et al.*, "Adverse Events in New Zealand Public Hospitals I: Occurrence and Impact" (2002) 115:1167 N.Z. Med. J. U271.

³⁸ G. Baker, *et al.* "The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada" (2004) 170:11 C.M.A.J. 1678.

³⁹ *Ibid.*

⁴⁰ The Commonwealth Fund, *The Canadian Health Care System supra* note 14.

Costs

The provision of health services is a costly exercise – the percentage of the GDP allocated to the funding of health services was approximately 9.6 percent in 2002 – well before the recent increases in the federal contribution.⁴¹ Some of these costs are incurred in addressing problems that are preventable, such as unsafe care and illness caused by ‘lifestyle’. The analysis of the incidence of unsafe care, described above, suggests that some episodes of unsafe care are preventable and consequently that the costs associated with unsafe care can also be minimized. This is perhaps in contrast to ‘lifestyle’ related illnesses where the correlation is less directly true.

At a fiscal level unsafe care is expensive. Table 2 sets out some estimates of the monetary burden of unsafe acts in the health system.

Table 2 – Estimated Costs of Unsafe Care in Health Systems

Country	Direct Costs# per year	Total Costs* per year
United States (Thomas) ⁴²	U.S. \$8.5- 14.5 billion	U.S. \$17-29 billion
United Kingdom (D.H.) ⁴³	£2 billion (hospital days)	
Australia (Task Force) ⁴⁴	A\$867 million (hospital days)	
Australia (APSF) ⁴⁵		A \$2 billion

* Total national costs for preventable unsafe acts (including lost income, lost household production, and disability and health care costs).

Health care costs for preventable unsafe acts.

To place these figures in context, total spending on the health sector in England in 2004 was £69,369 billion⁴⁶ so if the direct cost of unsafe care is £2 billion this is approximately three percent of the total health budget. This figure does not account for the total costs of unsafe care including lost income and productivity which may double the costs to six percent of the total health budget in England.

Costs are not experienced solely at the level of government budgets – there are also very real costs, fiscal and otherwise, experienced by individuals, patients, friends and families, health providers and communities.

⁴¹ 2002 figures from the World Health Organization, *Canada* online: WHO <<http://www.who.int/countries/can/en/>>.

⁴² E. Thomas, D. Studdert *et al* “Costs of Medical Injuries in Utah and Colorado” (1999) 36 *Inquiry* 255.

⁴³ U.K. Department of Health, *An Organisation with a Memory*, (London: Department of Health, 2000).

⁴⁴ Task Force on Quality in Australian Health Care, *Final Report of the Task Force in Australian Health Care* (Canberra: Department of Health and Aging, 1996).

⁴⁵ Australian Patient Safety Foundation, *Iatrogenic Injury in Australia* (Canberra: Department of Health and Aged Care, 2000).

⁴⁶ HM Treasury (U.K.) *2004 Spending Review* (London: HM Treasury, 2004) online: HM Treasury <http://www.hm-treasury.gov.uk/media/801/75/sr2004_ch8.pdf>.

An individual patient may die or suffer increased pain, disability and psychological, emotional and spiritual harm as a result of unsafe care. The outcomes of unsafe care may impact on that individual's ability to care for his or her family, his or her contribution to the community, and his or her ability to work. It may result in increased costs for the individual, such as childcare, rehabilitation, time off work, transportation costs, legal fees and other associated costs. Families may have to go through a grieving process if a family member dies as a result of unsafe care. Families may need to provide supportive home-based care for injured family members or to support an individual to resolve, if possible, any psychological, emotional or spiritual harm. Families may incur extra costs such as time off work, accommodation, transportation costs and other associated costs. Family members may also feel guilt that they did not do enough to prevent the unsafe care from occurring, and may feel reluctant to access health care services in future. While the reality is that many of the factors listed above are consequences of illness and death, in the situation where an individual has received unsafe care these consequences were unnecessary and could have been prevented.

Health care providers may experience shame, guilt, and depression when care is provided in an unsafe manner, whether or not their actions contributed to the unsafe care. Health care providers' ability to work may be impaired, their personal life affected, and they may face additional expenses such as legal fees.

The community also bears the costs of unsafe care. The community is affected by the strains placed on individuals and their families. Workers may have to work longer hours to cover absent colleagues, teachers may have to deal with the various expressions of children's stress if a parent, sibling or other family member has died or is ill and the community feels the loss of volunteers. On another level, the community must bear the productivity losses felt by the economy and the direct fiscal costs of harms resulting from the provision of unsafe care must be borne ultimately by the community through the health or social systems.

Unsafe care therefore results in significant *preventable* costs to the health care system and also in significant *preventable* direct costs - fiscal, emotional and psychological to name but a few - to individuals, their communities and to the state. Minimizing the occurrence of unsafe care could result in significant savings that could be directed at the provision of additional health care services or other social supports, such as housing or income replacement that could improve health.

The Concept

The approach to patient safety is evolving in literature and also, although perhaps more slowly, in practice, policy and in law. Traditionally, patient safety has been addressed through a person-centered approach which focuses on apportioning responsibility to individuals that are seen to have caused the unsafe act. This is reflective of the structures of health systems in the past where individual health professionals provided services largely independently of one another or in simple teams or organizations. The increasing

complexity of the provision of services is reflected in the complex organization structures that surround the provision of care and the increasing technological innovations that also make care and treatment more complex. Environment therefore is an increasing influence, at times positive but sometimes negative, upon the manner in which health services are delivered. Accordingly, modern approaches to patient safety are increasingly system-centered, however, most agree that at times it is appropriate for individuals to be held accountable and so the person-centered approach will always have a role in the governance of patient safety.

Person-centered approach

A person-centered approach to patient safety is intuitively attractive as it assigns clear responsibilities and therefore accountabilities to an individual(s). It satisfies societal needs to identify a *person(s)* to blame for the harms caused. In contrast, there is a sense when systems are blamed that ‘they are going to get away with it’ because a faceless entity is identified with possibly amorphous accountabilities.

A person-centered approach is said to capture the three faces of individuals who may cause harm in the delivery of health services.

1. Human error (error)

This approach suggests that individual(s) cause errors. Reason, the leader in this field, primarily focuses on the psychological precursors of human error, such as inattention, forgetfulness, and carelessness.⁴⁷ However, competence can also be a cause of error – sometimes planned actions fail due to a lack of skill or competence, and, likewise, sometimes incorrect plans are made.

2. Violation

Violation is where there has been a deviation from standards, rules, or safe operating procedures.⁴⁸

3. Sabotage

Sabotage is where an individual intends the act *and* the harm that results; in short the individual’s actions are malicious.⁴⁹ Individual health providers may, very rarely, abuse their position to harm patients. The ultimate example of this is Dr. Harold Shipman, a general practitioner from Britain, who was convicted of murdering 15 patients through the use of lethal injections of an opiate or sedative while providing a health service. A public inquiry concluded that Dr. Shipman murdered a minimum of 215 of his patients.⁵⁰ The Honourable Mr. Justice Forbes said when sentencing Dr. Shipman, “None of your victims realized that yours was not a healing touch. None of them knew that in truth you had brought her death, death which was disguised as the caring attention of a good doctor.”⁵¹ Another example of sabotage is Dr. Morgan Fahey, a general practitioner from

⁴⁷ J. Reason, *Human Error* (Cambridge: Cambridge University Press, 1990).

⁴⁸ Canadian Patient Safety Dictionary *supra* note 6 at 27.

⁴⁹ *Ibid* at 27.

⁵⁰ Shipman Inquiry, *supra* note 24.

⁵¹ The Honourable Mr. Justice Forbes when sentencing Shipman on 31st January 2000.

New Zealand, who, during the course of examinations and treatments, abused female patients. He was convicted of 13 charges of sexual assault, including one charge of rape.⁵²

The person-centered approach is the dominant tradition within the academic literature on patient safety and has heavily influenced the use and design of legal instruments in the health sector. Legal instruments used to address person-centered safety issues are aimed at individuals rather than situations or systems and fall within the ‘compliance’ or control mode of regulation.⁵³ Examples include: the criminal law; tort law; professional regulation; and regulatory standards that purport to guide individual behaviour. Person-centered legal instruments create clear frameworks for individual accountability, which is important as individuals should most often be held accountable for their actions or omissions.

However, critics argue that a person-centered approach isolates unsafe acts from their context. The healthcare system is a complex environment where individual actors, organizations and technologies intersect to provide a continuum of care. Even in a case which seems self-evidently person-centered, such as Dr. Shipman’s, his actions were framed by the system in which he worked. Dr. Shipman was able to murder patients in the course of his medical practice because he could access high quantities of so-called ‘controlled drugs’ without being monitored. Whilst the legal process focused on holding Dr. Shipman accountable for his actions, broader safety related systems issues could not be ignored. A person-centered approach does not always recognize the complexities of systems and failures. In addition, a focus on ‘naming, shaming and blaming’ an individual is said by practitioners, and more latterly researchers, to inhibit open discussions about episodes of unsafe care and therefore an ability to learn from these episodes to facilitate the future provision of safe care.⁵⁴

Systems Approach

The so called systems-centered approach to patient safety is an emerging one in the patient safety literature and is influential in more recent policymaking in the health care sector. This approach places patient safety issues in a more complex framework. Individual failures are viewed in their broader context, so they are regarded as just one part of a picture. The premise is that all humans are fallible and that personal failures or abuses are inevitable but blame should be avoided to facilitate learning. This systems approach recognizes that actions or omissions of an individual are framed by upstream systemic factors. At an organizational level, these systemic factors can include an organization’s strategy, culture, and its attitude towards risk and uncertainty. There are

⁵² A. Horwood & J. Corbett, “Fahey- Sexual Predator in a White Coat” *New Zealand Herald* (2 June 2000) online: The New Zealand Herald <<http://www.nzherald.co.nz/storydisplay.cfm?thesection=news&thesubsection=&storyID=138943>> [date accessed 5 May 2004].

⁵³ Christopher Newdick, “N.H.S. Governance after *Bristol*: Holding on, or Letting Go?” (2002) 10:2 *Med. L. Rev.* 111 at 117.

⁵⁴ See for example, The Bristol Royal Infirmary Inquiry, *supra* note 23, J Bryan Sexton, Eric J Thomas, & Robert L Helmreich, “Error, Stress, and Teamwork in Medicine and Aviation: Cross Sectional Surveys” (2000) 320:7237 *B.M.J.* 745, Institute of Medicine. *To Err supra* note 8.

also external systemic drivers that shape safety and, more broadly, quality, such as regulation and legislative action and economic and other incentives/barriers including the norms and values of health professionals.

A systems approach recognizes that the human condition of fallibility cannot be changed, although it may be limited by changing the environments and conditions under which people work. It recognizes that most individuals or organizations that operate in circumstances where harm can result from their acts tend to develop barriers, defenses and safeguards to prevent harm. However, human elements can weaken these defenses by active failures and latent conditions.⁵⁵ Active failures are unsafe acts committed by individuals who directly provide care. Latent conditions arise from strategic decisions made by designers, builders, policy-writers and managers, who may create conditions that can translate into an environment that creates conditions that might provoke unsafe care, for example, a requirement that physicians work 24 hour shifts. Under the systems approach, when an unsafe act occurs, the important issues are not who made the error but how and why the defenses failed and what factors helped create the conditions in which the unsafe acts occurred. A systems approach to patient safety appears to us to put safety into a quality context.

Critics suggest that the systems approach potentially may limit or obscure legitimate individual or organizational accountabilities. At times it is appropriate that an individual(s) or organization(s) should be held accountable for unsafe acts and it is important that this aspect not be lost when focusing on systems factors. Proponents argue that accountability is important, particularly for egregious cases, but that there should not always be an assumption that an individual's failure is the principal or only cause of harms resulting from unsafe care, indeed they suggest that focus on individuals should be placed in the context of a system that may have failed at many points.

Both approaches to the governance of patient safety are currently being used. Patient safety related legislative frameworks are seeking to find a balance between demands for accountability, learning, and also restoration for the patient and the health provider.

One of the significant issues relating to the use of legal instruments in regard to patient safety is there is often little or no evidence that the mechanisms put in place by law are actually effective in improving patient safety. First, it is rare that the impacts of law on outcomes are studied. Second, even if they are studied many of the newer patient safety initiatives are too recent to provide reliable empirical data, although anecdotal evidence is often supportive. Third, the law of adverse events dictates that although a mechanism may appear to work in that one particular outcome or indicator improves, the consequences of the change may throw out of balance another aspect of the complex environment in which healthcare is provided thus negatively impacting patient safety outcomes in other areas. Fourth, what may work well in one context or culture may not work well in another. It is however clear that the use of legal instruments as part of the process of the governance of patient safety can be an effective tool in that it can improve accountability and transparency. The challenge of policy-making in this area appears to

⁵⁵ Reason, *supra* note 47.

be to identify and encourage the development of initiatives that will have a real and sustained impact upon patient safety but at the same time balance this with mechanisms that allow individuals and organizations to be held accountable when this is appropriate.

Governance, Legal Instruments, and Patient Safety

‘Governance’ can be defined as “the sum of the many ways individuals and institutions, public and private, manage their common affairs”.⁵⁶ Central to the concept of governance is the recognition that government is no longer, if it ever was, the sole actor in the policy sphere – there is a complex array of public and private actors, at the individual, local, regional, national and international level. These actors pursue a variety of policy objectives through the use of a dense mosaic of policy tools. Each actor plays an important role in the management of common issues of importance. There is a range of policy tools available for use, including legal instruments, many of which place public agencies in complex, interdependent relationships with a host of third party actors.⁵⁷

Government has somewhat asymmetrical relationships with the other actors that shape policy and practice due to the government monopoly over the process of establishing law.⁵⁸ Law grants the government power to impose top-down initiatives in respect of particular problems. However, many problems are too complex for a top-down solution, even if one were possible. Although the state may take a leadership position in relation to a certain issue, it can often most successfully work in collaboration with other individuals, agencies and groups to achieve a desired outcome. After all, the effectiveness of laws and legal frameworks can be undermined or defeated without the support of the governed.⁵⁹ Within this interconnected network of policy actors, government plays a role which at its most basic is to establish an “interlocking network of public powers that regulate and guide action in a relatively consistent way, providing minimum standards of conduct and relief from harm.”⁶⁰ A focus of this research is therefore to examine the limits of the state to recognize, define, respond to, to have

⁵⁶ Kernaghan Webb, “Sustainable Governance in the 21st Century: Moving Beyond Instrument Choice” in Pearl Eliadas, Margaret Hill & Michael Howlett, *Designing Government: From Instruments to Governance*, (Montreal & Kingston: McGill-Queens University Press, 2005).

⁵⁷ L. Salamon, “The New Governance and the Tools of Public Action: An Introduction” in L. Salamon ed. *The Tools of Government: A Guide to the New Governance* (Oxford: Oxford University Press, 2002) at 3.

⁵⁸ R. Rhodes, *Understanding Governance: Policy Networks, Governance, Reflexivity and Accountability*, (Buckingham: Open University Press, 1997).

⁵⁹ Studies have also indicated that health providers (and other non-health related actors), on occasion, have acted to subvert laws because they either do not agree with them, there is a perception that they create too much work or that they are impractical. This suggests that a greater degree of consultation and agreement is required before legal instruments are used, or alternatively that stronger enforcement mechanisms are required. See for example, Jill Peay, & N. Eastman, eds. *Law without Enforcement: Integrating Mental Health and Justice* (Oxford: Hart Publishing, 1999).

⁶⁰ P. Hirst, & G. Thompson, “Globalization and the Future of the Nation State” (1995) 24:3 *Economy & Society* 408.

available, and to use legal instruments that are necessary and most appropriate to take action in response to a defined problem.⁶¹

Patient safety is an issue upon which there seems to be general consensus amongst all policy actors in the various international health systems that some action is necessary. Indeed, in the last five to fifteen years there has been a significant engagement with the issue by policy actors, with what success we are only just beginning to find out. Policy actors at all levels of international health systems have used a variety of policy tools to address patient safety issues. This project focuses on governmental decision-making in relation to choices around whether or not to use legal instruments and what specific ones to use and why. It bears repeating that governments' use of legal instruments is only a part of a broader governmental governance strategy and, similarly, is only a part of a broader patient safety governance structure driven by a variety of non-government actors using a variety of policy tools.

Choice of Policy Tools

Policy objectives are pursued through the use of a dense mosaic of policy tools, such as the use of law, other forms of social regulation (e.g. guidelines and standards), contract, provision of inducements and so on.⁶² The process of choosing a particular policy tool to address a specific issue once identified is a complex and not well understood process. The process is influenced by the views, actions, and responsiveness of the other actors within the polity. It is clear from some of the countries studied that government intervention is often considered only after other policy actors have failed to either recognize the problem or effectively address it, or when there is a perception to this effect, so government steps in to compensate for failure. Choice of instrument type may also be affected by the nature of government's role in respect of a particular enterprise. For example, government may be more likely to intervene more directly and aggressively, when, in addition to having a responsibility to provide Hirst and Thompson's "minimum standards of conduct and relief from harm",⁶³ it also plans, funds, owns and operates a service. A service that is successful and safe in operation is moreover central to the public interest as defined in each country.

The Actors

The choice of instrument type also determines how directive the government chooses to be in its intervention and how it characterizes its relationship with other policy actors or networks. The development and maintenance of a public health system in Canada involves a complex array of public and private actors, at individual, local, regional, national and international levels. Governments play a leadership position in relation to the establishment of the public health system, but work in collaboration with other individuals, agencies and groups to achieve the desired outcome. The Canadian health

⁶¹ C. Tuohy, "Agency, Contract and Governance: Shifting Shapes of Accountability in the Health Care Arena" (2003) 28:2-3 J. Health Pol & Law 195 at 202.

⁶² Salamon, *supra* note 57 at 3.

⁶³ Hirst & Thompson, *supra* note 60.

system, and the health systems in other international jurisdictions, continues to depend upon the interdependent relationships between governments, government agencies, health care institutions, health professionals, professional and institutional associations, interest groups, insurers, consumers, and the public, to provide but an incomplete list. Governance choices are therefore often constrained or influenced by the nature of inter-relationships between policy actors. To use Tuohy's typology, a health system may be:⁶⁴

- a hierarchically, geographically organized system under the aegis of the state (for example the U.K. and New Zealand) with a high level of government involvement in governance but some deference accorded to physicians. Due to its hierarchical nature, this model enables a model of governance that favours top down control by government;
- a system weighted towards private finance and the market (for example, the U.S.). Reliance on the market enables a model of governance where government focuses on the use of contracts, inducements and declarations, with some concern about remedying asymmetry of information;
- a system that gives predominant weight to medical professional and collegial mechanisms (for example, Canada). This model may favour governance choices that are collaborative in nature and the use of contracts, agreements and partnerships.

As Rhodes notes, there are clearly limits and constraints on central intervention, whether through the use of legal instruments or not, because of the many interdependencies with which policy domains are riddled⁶⁵ and the degree of deference accorded some policy actors, such as physicians, may influence instrument choice.⁶⁶

The Constitutional Framework

The nature of the relationships between interdependent networks of policy actors will not be the only factor to effect instrument choice. Constitutional structures may also impose barriers upon the government's choice or ability to use policy instruments. In three of the countries studied, Canada, the United States and Australia, governmental decisions in relation to the use of legal instruments occur at federal and provincial levels. As Hogg states in respect of Canada:⁶⁷

Health is not a single matter assigned by the Canadian constitution exclusively to one level of government. Like inflation and the environment, health is an 'amorphous topic' which is distributed to the federal parliament or provincial legislatures depending on the purpose and effect of the particular health matter at issue.

⁶⁴ Carolyn Hughes Tuohy, *Accidental Logics: The Dynamics of Change in the Health Care Arena in the United States, Britain and Canada*, (New York: Oxford University Press, 1999).

⁶⁵ Rhodes, *supra* note 58.

⁶⁶ See for example, Tuohy, *Accidental Logics supra* note 64.

⁶⁷ P. Hogg, *Constitutional Law of Canada* [4th ed.] (Scarborough, Ont.: Carswell Publishing, 1997) at 445.

Federal and provincial laws often interact with each other in complex ways.⁶⁸ So in addition to negotiating with non-governmental actors, governments in these nations must also negotiate intra-governmentally with a number of governments and government agencies. This has been noted as a significant challenge in respect of ensuring consistency and continuity of outcomes across countries.

In the three other countries studied, Denmark, Britain and New Zealand, governance decisions in relation to legal instruments occur at the national level requiring less intra-government negotiations, although some are still required.

The Regulatory Context

In some countries the nature of the state's role in governance has been changing. The phrase 'the regulatory state' was first developed by Majone⁶⁹ and has been adopted by others.⁷⁰ From the introduction of the welfare state until the later part of the 20th century, in many states the role of government was relatively all-encompassing with government acting not merely as a regulator, but also as a service provider, job creator, property owner and employer. In the later part of the 20th century, new models of economic thought became dominant, particularly the so called New Public Management (NPM), and became influential. The NPM emphasizes the centrality of the citizen consumer; standards and measures of performance; results based accountability; private sector styles of management; purchaser/provider splits and the use of alternate service delivery mechanisms; de-bureaucratization; devolution; the supremacy of the market and the virtues of competition; hands-on professional management; and discipline and parsimony in resource use.⁷¹ Due to the de-regulatory rhetoric associated with the NPM, one of the key planks of the NPM platform was regulatory reform. Market competition was encouraged through a movement away from command and control models of regulation towards the use of alternate regulatory frameworks that were felt to be more flexible and market friendly. The state's retreat from the use of command and control regulation also opened a more expansive role for government focused on oversight of private and public operations. The transfer of public functions to private actors also transferred the management of public risks to private actors. Risks were also managed by government agencies, independent or otherwise, which were often in interdependent relationships with the private sector and operated under private sector principles. Governments recognized that the market does not always respond appropriately to managing and limiting public risks so some regulatory intervention by government to protect the public interest is therefore required. Thus regulation in its broadest sense increased, hence the regulatory state. Internationally there is a large degree of variability in the degree to which countries imported these principles into the governance of the public sector. An

⁶⁸ T. Jost, "Health Care Rationing in the Courts: A Comparative Study" (1997-1998) 21 *Hastings International & Comparative Law Review* 639 at 640-644. [Jost, Rationing].

⁶⁹ G. Majone, "The Rise of the Regulatory State in Europe" (1994) 17 *West Eur. Pol.* 77.

⁷⁰ See for example: Michael Moran, "Understanding the Regulatory State" (2002) 32 *Brit. J. Pol. Sci.* 391; J. Braithwaite, "Accountability and Governance under the New Regulatory State" (1999) 58:1 *Aus. J. Pub. Admin.* 90; Symposium, "Getting Beyond Cynicism: New Theories of the Regulatory State" (2002) 87 *Cornell L. Rev.* 267; C. Scott, "Accountability in the Regulatory State" (2000) 27:1 *J.L. & Soc'y.* 38.

⁷¹ See for example, N. Lewis, "Responsibility in Government: The Strange Case of the United Kingdom" (1995) 1:3 *Eur. Pub. L.*

examination of the differences in the degree of the uptake of these principles within the health systems of each country may point to differences in the regulatory state that may shape and condition responses to the choice of policy instruments used.

The regulatory state is a state that is conditioned to respond through regulatory means, often through the use of law, although not exclusively, to problems relating to the management of risk. Many states are changing the manner in which they use law, particularly in regard to the governance of certain sectors. Some of these states are moving from traditional self-regulatory models that devolve responsibility for management of the common affairs of a sector or professional group, and the responsibility for providing standards for conduct and relief from harm to that group or sector. These states are turning to so-called meta-regulation or in other words are moving to regulate the regulators. Others are moving or have moved from self-regulatory models to what could be called professional regulation – where the state reclaims in whole or in part some or all of the functions of previously self-regulating bodies. The state now exercises these functions through the use of a variety of quasi-independent government bodies. Changes in the governance framework around patient safety, particularly changes involving the use of policy instruments, must be viewed not in isolation but as part of a broader development in the way government thinks about its governance role and responsibilities.

The Problem Context

How a particular issue is conceived may also affect policy instrument choice. Significant legal reforms to establish a more rigorous governance framework for patient safety have occurred in countries with histories of widely publicized and publicly investigated scandals involving unsafe care. Absent such issue-related public pressure to enact top-down reform, governments may choose less intrusive policy instruments to work collaboratively with other policy actors to affect change.

Use of Legal Instruments

Legal instruments are a relatively common tool used by government in the governance of the health system. In every country there are complex webs of legal instruments which establish a framework within which services are provided. Legal instruments govern the financing, expenditures, functioning and structure of social insurance or national health services, the licensing and monitoring of professionals and institutions, the protection of public health, and the funding of health care research and education, to name but a few.⁷² More specifically in regard to patient safety legal instruments can empower individual health professionals, organizations (such as the Colleges of Physicians and Surgeons) and institutions to take action to improve patient safety.⁷³ Second, they can provide a call for action from an external agency which requires a response or else sanctions are imposed.⁷⁴ Third, they can require all institutions, organizations and professions to make minimum

⁷² Jost, Rationing *supra* note 68 at 640.

⁷³ Institute of Medicine. *To Err supra* note 8 at 19.

⁷⁴ Jost, Rationing *supra* note 68 at 640-644.

investments in safety and quality⁷⁵ creating a system where all persons, wherever they might live in a country or province, have health services provided safely. Fourth, they can create oversight systems to police individuals, professions, organizations and institutions. Fifth, they can empower members of the public to demand safe care. Sixth, they can provide a check to ensure that a patient's fundamental human and constitutional rights, such as autonomy, are not undermined or ignored during the process of establishing and maintaining safe systems. Seven, law can balance the need to create environments that facilitate the open discussion of and learning from episodes of unsafe care with a patient's right to know information about his or her treatment and with the demands of individuals and the public for accountability for egregious acts. However, it is also important to note that regulation or legislation can create disincentives for individuals, professions, organizations or institutions to practice safely, such as laxly enforced or conflicting standards.

Administrative agencies created by law also play a role in health care systems. Administrative agencies may, amongst other functions, regulate professionals and institutions, manage public purchasing decisions and provision and make determinations in respect of individual patients. Agencies issue rules and adjudicate disputes in respect of health care relationships.⁷⁶ The courts in most countries oversee health care relationships by reviewing and enforcing administrative decisions, protecting those who suffer criminal or tortious harms and by interpreting and enforcing health-related legislation, regulation and contracts.⁷⁷

Coerciveness

Legal instruments can also be considered not just in terms of what effect they are meant to achieve but also within a continuum of coerciveness. The Bemelmans-Vidac typology is an example of a typology that considers the degree of coerciveness attached to each instrument.⁷⁸ The typology considers instruments as being:

- sticks (in other words “you must comply or face penalties”). Sticks are usually expressed as commands involving mandatory participation combined with monitoring and enforcement mechanisms;
- carrots (in other words “we’d like you to do this and if you do we’ll do something nice for you”). Carrots are usually expressed as some form of scheme, typically involving the use of such tools as contracts and tax incentives involving inducements;
- sermons (in other words “it’s the right thing to do”). Often this is expressed through the creation of government agencies with educative or research functions, but also may just be a declaration of the level of importance of the issue, for example, government awards for patient safety initiatives or a declared patient safety week.

⁷⁵ *Ibid.*

⁷⁶ *Ibid.*

⁷⁷ *Ibid.*

⁷⁸ Marie-Louise Bemelmans-Vidac, Ray Rist & Evert Vedung, eds., *Carrots, Sticks and Sermons: Policy Instruments and Their Evaluation*, (New Brunswick, N.J.: Transaction Publishers, 1998).

Often government uses a mix of legal instruments throughout the coercive spectrum to address identified patient safety needs. The degree to which governments choose to use a coercive tool depends on the factors discussed earlier – namely the degree of interdependency with other actors in the health system which may in turn be influenced by the traditional structures of the health systems and the design of constitutional systems.

Evaluation

We evaluated the legal instruments used in each country and sector against the following criteria.

1) Effectiveness.

This has to be the most basic criteria for evaluating the success of legal instruments. If an instrument does not achieve its intended outcomes, then it may be of little value.

2) Efficiency

Efficiency measures results against costs. The paradox is of course that the most effective instrument may not be the most efficient one.

In relation to both effectiveness and efficiency, there are some barriers to gauging the respective effectiveness and efficiency of legal instruments used in respect of patient safety. First, legal instruments often have multiple, at times conflicting or uncertain, outcomes which makes evaluation more complex. Second, many patient safety initiatives that are expressed through the use of legal instruments are relatively new; those that are not so new, such as professional regulation, may have been recently substantially reformed. Given the relatively recent emergence of some of these initiatives there is often very little empirical data as to effectiveness or efficiency, although there may be much anecdote. Even in the other non-health related sectors that were reviewed, there has often been little examination of the effectiveness or efficiency of the initiatives and of the legal instruments used. Third, legal instruments must also be reviewed as part of an integrated governance framework in respect of a particular issue. Effectiveness may depend, at least in part, upon the interactions with other instruments in that framework. Fourth, it is important to note that the effectiveness and/or efficiency of a particular initiative expressed through a particular form of legal instrument may not be replicable in another country or sector, due to differences in culture. Cultural differences can be crucial to the success or failure of legal instruments and legal frameworks.

3) Equity

Equity is a third crucial criterion against which legal instruments can be measured. One of government's most important roles is to ensure individuals and groups are treated fairly and equally. This criteria is not always applicable to some of the instruments that have been examined but is an important underlying value that must inform any analysis.

4) Transparency

Transparency is of key import as it enhances democracy by correcting asymmetry of information between the public and its agent, government. It has a valuable educative function and so enables effective public involvement in decision-making. It also enables public accountability for actions and omissions at all levels of activity, from individuals to government. Transparency can be established through an assessment within each instrument of the accessibility of information about issues of concern and of information about processes that address these issues and how these processes function.

5) Accountability

Broadly, there are five forms of accountability for public action: (1) legal, (2) financial, (3) administrative, (4) professional, and (5) political. This concept imports conceptions of taking responsibility for actions but this can be through a process of being answerable to the public at large or to individuals, rather than necessarily being associated with blame and fault. Blame or fault is almost inevitably part of legal accountability in respect of patient safety due to the current systemic structure of malpractice suits in most countries. Again, this can largely be assessed through a scrutiny of each legal instrument.