

Regulating Compensation for Injuries Associated with Medical Error

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Abstract

There is now agreement that around 10 per cent of all hospital admissions to acute care hospitals give rise to preventable adverse events. These high levels of injury throw into sharp relief the unfairness of the tort based system of compensation for medically related injury where a relatively small number of plaintiffs recover compensation. These high levels of injury also highlight the relative ineffectiveness of tort law in improving levels of safety by deterring unsafe conduct. This article argues that in the field of medically related injury tort law is not a good model for providing compensation to patients who sustain injuries associated with medical error. In this field tort law does not and cannot accommodate regulatory initiatives that are designed to improve levels of patient safety. While tort law focuses on particular instances of fault these regulatory initiatives adopt a systemic approach to improving safety. Against this background this article then argues for an experimental and localised approach to developing systems of compensation for injuries associated with medical error. This approach is based on the principle that compensation should be integrated into particular regulatory initiatives that are designed to improve patient safety by reducing the levels of particular classes of preventable adverse events.

1. Introduction

This article is about the problem of establishing a system of compensation for 'iatrogenic injuries' associated with 'adverse events' and 'medical errors'.¹ There is an emerging awareness of the magnitude of the problem of iatrogenic injury.² There is now some agreement that around 10 per cent of all admissions to acute care hospitals are associated with a preventable adverse event.³ In Australia the

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1 'Iatrogenic injury' is an injury 'arising from or associated with health care rather than the underlying disease of injury'. An 'adverse event' is 'an incident in which unintended harm resulted to a person receiving health care'. A 'preventable adverse event' is an adverse event that is 'potentially avoidable in the relevant circumstances'. A 'medical error' 'will be taken as a generic term to encompass all those occasions in which a planned sequence of events fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some chance agency'. See generally Australian Council for Safety and Quality in Health Care, *List of terms and Definitions for Safety and Quality* (2004) <<http://www.safetyandquality.org>> (4 March 2006).

health care costs associated with adverse events are greater than those caused by road accidents.⁴ The most immediate result of the identification of the magnitude of the problem of iatrogenic injury has been a concerted effort to improve levels of patient safety.⁵

The central issue concerning compensation for medical injuries is what kind of compensation scheme will provide fair and effective compensation for those who sustain injuries associated with medical error. The current system of compensation for medical injuries is a fault based system that relies predominantly on the tort of negligence. This body of law gives a right to claim compensation to any person who has sustained harm that was caused by the negligence of a health care professional or institution.

This system of compensation is one that is beset by a number of problems. This system is not fair in the sense that the tort of negligence delivers compensation to a very small number of patients who sustain injury as the result of a medical error.⁶ Some law reform bodies have argued for the introduction of a fairer system of compensation. These proposals are aimed to broaden the rights to claim compensation and make the process of claiming compensation simpler.⁷

The tort based system of compensation also has other functions, notably that of deterring unsafe practices and exacting corrective justice.⁸ The function of allowing for corrective justice is a complex one that this article will not address directly. The effectiveness of tort in achieving this goal is however closely related to concerns over the limited number of people who are able to claim compensation and the complex and difficult process for obtaining compensation. By contrast the position is much clearer when considering whether tort law improves levels of safety by deterring unsafe practices. In the field of safety tort based compensation has a limited capacity to deter unsafe practices associated with the high level of medical error.⁹

2 Australian Council for Safety and Quality in Health Care, *Achieving Safety and Quality in Health Care Sixth report to the Australian Health Ministers Conference*(2005) (hereinafter *Achieving Safety and Quality in Health Care*): <<http://www.safetyandquality.org.au/annualrep0705.pdf>> at 8 (2 Mar 2006) (The Australian Council on Safety and Quality has now been succeeded by the Australian Commission on Safety and Quality in Health Care). Ross Wilson et al, 'The Quality in Australian Healthcare Study' (1995) 163 *The Medical Journal of Australia* 458. Institute of Medicine, *To Err is Human, Building a Safer Health Care System* (2000) at 1–5 (hereafter *To Err is Human*) (For an analysis of the level of public interest in *To Err is Human*, see Robert Wachter and Kaveh Shojania, *Internal Bleeding* (2004) at 55–64). Department of Health, *An Organisation With a Memory, Report of an Expert Group Learning from Adverse Events in the NHS Chaired by the Chief Medical Officer* (2000, United Kingdom) at 9–18. P Davis et al, 'Preventable in-hospital medical injury under the "no fault" system in New Zealand' (2003) 12 *Quality and Safety in Health Care* 251 at 252.

3 William Runciman & J Moller, *Iatrogenic Injury in Australia, A Report prepared by the Australian Patient Safety Foundation for the National Health Priorities and Quality Branch of the Department of Health and Aged Care of the Commonwealth of Australia* (2001) at 4, 19 <http://www.apsf.net.au/dbfiles/Iatrogenic_Injury.pdf> (hereafter *Iatrogenic Injury in Australia*). See also Australian Council for Safety and Quality in Health Care and National Institute of Clinical Studies, *Charting the Safety and Quality of Health Care in Australia* (2004) at 69 (hereafter, *Charting the Safety and Quality of Health Care in Australia*).

4 *Iatrogenic Injury in Australia*, above n3 at 21.

There are roughly two approaches to ameliorating or overcoming these difficulties with the tort-based system of compensation for medical error. One approach is to make changes to tort law that deal with each of these problems. The aim of this approach is that by dealing with the particular problems it will be possible to integrate this system of compensation with the existing regulatory approaches to improving levels of patient safety.¹⁰ A second approach is to argue that this approach is insufficient because there is a more fundamental problem with tort based liability as it applies to injuries associated with medical error. Those following this model of reform often put forward proposals for no-fault compensation schemes.¹¹ One argument for the introduction of no-fault schemes of compensation is that such schemes would increase the effectiveness of regulatory initiatives to improve patient safety by 'taking clinical error out of the courts and the tort system'.¹²

This article makes a contribution to the debate about developing a system of compensation for injuries associated with medical error in two ways. The first part of the argument is that the tort-based system of compensation does not and cannot accommodate or facilitate the broad system of regulation that is designed to improve levels of patient safety and to improve the quality of the delivery of health care. It is not just that the tort based system of compensation provides compensation for a relatively small number of injured patients or that this system of compensation is an inadequate and counter-productive regulatory mechanism. More importantly, the argument here is that the tort based scheme of compensation

5 See for example, *Achieving Safety and Quality in Health Care*, above n2 at 9-19 (reviewing the effectiveness of the Council in promoting improved levels of safety); *Clinical Excellence Commission 2004/2005 Annual Report* (NSW) at 20-21 (CEC Implementation Plan 2005-2008); Australian Council for Safety and Quality in Health Care, *State and Territory Highlights: Improving Patient Safety* (2005) <http://www.safetyandquality.org.au/state_territory0705.pdf> (2 Mar 2005). See also Ross McL Wilson and Martin Van Der Weyden, 'The safety of Australian healthcare: 10 years after QAHCS' (2005) 182 *Medical Journal of Australia* 260, 260-261; Drew Altman et al, 'Improving Patient Safety – Five Years after the IOM Report' (2004) 351 *New England Journal of Medicine* 2041; Donald Irvine, 'Health service reforms in the United Kingdom after Bristol' (2004) 181 *Medical Journal of Australia* 27.

6 *Iatrogenic Injury in Australia*, above n3 at 25 (On one estimate only one person in 250 who sustains injury following a potentially preventable adverse event receive any compensation). See also David Studdert, Michelle Mello & Troyen Brennan, 'Medical Malpractice' (2004) 350 *New England Journal of Medicine* 283 at 285 ('Only 2 per cent of negligent injuries resulted in claims').

7 See for example, Australian Health Ministers Advisory Council Legal Process Reform Group, *Responding to the Medical Indemnity Crisis: An Integrated Reform Package* (2002) at Chapter 5 ('Reducing the need to litigate and encouraging early finalisation'), Chapter 6 ('What is fair compensation?') (hereafter AHMAC, *An Integrated Reform Package*). See also Chief Medical Officer, *Making Amends* (A consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS) (2003) at 117-127 (hereafter *Making Amends*). The NHS Redress Bill 2006 (UK) is currently before the UK Parliament. The aim of this Bill is 'to reform the way lower value clinical negligence cases are handled in the NHS to provide appropriate redress, including investigations, explanations, apologies and financial redress where appropriate, without the need to go to court, thereby improving the experience of patients using the NHS' (2006) <<http://www.dh.gov.uk/PublicationsAndStatistics/Legislation/ActsAndBills/fs/en>> (6 March 2006).

is not effectively integrated into the regulatory arrangements that are designed to improve patient safety. This system of compensation does not accommodate, support or facilitate the regulatory system which is aimed at increasing patient safety by reducing the rate of preventable adverse events.

The second part argues for that in order to create a fair and effective system of compensation for injuries associated with medical error it will be necessary to develop innovative approaches to no-fault compensation. Many proposed no-fault schemes of compensation do not provide a good model for developing fair and effective schemes of compensation for these injuries. The approach in this article is to argue for the transfer of responsibility for developing rights to compensation to those who have responsibility for improving patient safety. Those responsible for improving patient safety should be required to build systems of compensation into particular regulatory initiatives that are designed to identify and respond to injuries that are caused by particular classes of preventable adverse events. In practical terms the system of compensation should be a part of the system of regulation that is aimed at reducing the level of occurrence and severity of particular classes of preventable adverse events. In this sense the problem of defining a fair and effective system of compensation is a central part of the project of regulating the delivery of health care services to improve levels of patient safety.

The health care system is complex and it is neither, possible or desirable to require regulators and those responsible for delivering health to create such a system of compensation in one single set of changes. It is however both possible and desirable to incrementally develop such schemes where regulatory initiatives to improve patient safety are in place or are being developed. The main purpose of this article is not to deny the importance of many proposed reforms to the operation of tort law as it applies to injuries associated with medical error.¹³ Under this proposal the law of tort would continue to have a role in providing compensation for medically related injury. Rather, the aim of the article is to argue that the integration of compensation into regulatory frameworks aimed at improving patient safety is an approach that should receive consideration and support. It should receive this support because it has the potential to produce a fairer and more effective system of compensation for these injuries.

8 Studdert, Mello & Brennan, above n6 at 286.

9 See below text accompanying nn14-21.

10 See for example, AHMAC, *An Integrated Reform Package*, above n7 at Chapter 5. This Report discusses improved complaints procedures, strategies to avoid litigation, 'early no-liability payment schemes, early settlement options, the use of alternative dispute resolution procedures, speeding up court processes, and procedures to protect health professionals from adverse publicity.

11 See for example, David Studdert, Eric Thomas, Brett Zbar, Joseph Newhouse, Paul Weiler, Jonathon Bayuk & Troyen Brennan, 'Can the United States Afford a "No-Fault" System of Compensation for Medical Injury' (1997) 60 *Law and Contemporary Problems* 1.

12 *Making Amends*, above n7 at 97; Office of the Minister for ACC, 'Medical Misadventure Review – Conclusions and Recommendations (Paper prepared for the Cabinet Social Development Committee), <http://www.acc.co.nz/wcm001/groups/external_providers/documents/internet/wcmz002405.doc> at para 29, 41 (6 March 2006) (hereafter *Medical Misadventure Review*).

13 See above n19.

The article is made up of four sections. The first section reviews the impact of regulation on our understanding of the role of compensation. The second and third sections develop the proposition that the current tort based system of compensation does not facilitate or support regulatory frameworks that are designed to improve patient safety. The final part of the article proposes a different approach for developing a system of compensation for injuries associated with medical error.

2. *Regulating Torts*

The central argument in this article is that a regulatory analysis of tort law provides some important insights into the way in which systems of compensation and systems of regulation interact. The importance of a regulatory analysis is not that it reveals the direct impact of tort law, or compensation law, on the conduct of activities and institutions and individuals. The limits of a tort based system of compensation as a form of command and control regulation are well understood by tort lawyers.¹⁴

The obligation to pay compensation to an injured person operates as a 'command' to those providing health care services.¹⁵ Compliance with the command requires the introduction of safer practices, the avoidance of injury and hence avoidance of the obligation to pay compensation. There is a lack of evidence to support the claim that tort law does actually deter unsafe practices. In the field of medical negligence a leading scholar has argued:

Considered as a whole, the evidence that the [malpractice] system deters medical negligence can be characterised as limited at best.¹⁶

The lack of success in achieving this goal is not surprising.¹⁷ The failure of tort law as a direct form of command and control regulation aimed at achieving safer delivery of health care services roughly parallels the experience with this form of regulation in other contexts.¹⁸

While the tort based system of compensation does not achieve its goal of accident deterrence there are claims that it does have adverse regulatory impacts. It is claimed that the current system of tort liability may encourage some health care professionals to cease offering particular health care services. The particular focus for this concern is the rate of increase in insurance premiums paid by some

14 See for example, Harold Luntz and David Hambly, *Torts Cases and Commentary* (5th ed, 2002) at 1–62 (A review of the impact of tort law on the occurrence of accidents).

15 Christine Parker, *The Open Corporation, Effective Self-regulation and Democracy* (2002) at 7.

16 Studdert, Mello & Brennan, above n6 at 286. See also Alan Merry and Alexander McCall Smith, *Errors, Medicine and the Law* (2001) at 48–51 (limited effectiveness of tort law and compensation in deterring accidents).

17 See for example, Merry and McCall Smith, above n16 at 96–97 (limited usefulness of focusing on individual blame as method for improving safety). See also John Braithwaite, Judith Healy and Kathryn Dwan, *The Governance of Health Safety and Quality* (Commonwealth of Australia, 2005) at 33–34 (Importance of developing a learning culture based around root cause analysis of adverse incidents. This is preferable to a blame culture aiming to identify instances of negligence).

18 Parker, above n15 at 8–12; Braithwaite, Healey & Dwan, *The Governance of Health Safety and Quality*, above n17 at 6.

health care professionals.¹⁹ It is also claimed that tort liability may produce high levels of defensive medicine though this is difficult to verify.²⁰ Finally, and importantly for the purposes of this article, it seems that the current system of tort liability may increase the difficulty of introducing measures that are aimed reducing the level of medical errors. In particular that the fault based standard of legal responsibility in negligence makes it more difficult to encourage health care providers to participate in processes of regulation which are focused around notions of ‘systemic responsibility’ for harm associated with medical error.²¹

The central insight provided by a regulatory analysis is that it reveals a way of understanding the indirect connections between tort law, that is concerned with compensation, and broader systems of regulation that are concerned with achieving public policy outcomes. It is the range of indirect relationships between systems of compensation and regulation that help to provide an insight into the design of fair and effective systems of compensation that enable or facilitate the achievement of public policy goals by regulation.

There are claims that we live in an era of the ‘new regulatory state’.²² This claim is sometimes challenged on the grounds that the regulation by and through law has been a feature of our legal system at least since the industrial revolution.²³ There is, however, a significant change in how we have come to understand the role of regulation in society. It is not only that ‘there has been an empirical proliferation of law across time and space motivated by regulatory objectives and sharp growth in the number of regulatory agencies’.²⁴ It is the notion that effective regulation involves not only the use of rules but the harnessing of all available resources, legal and non-legal, formal and informal, to achieve public policy outcomes.

19 AHMAC, *An Integrated Reform Package*, above n7 at 3-6, 13-25. See generally, Department of Health, *Premium Support Scheme*, <<http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-medicalindemnity-faq-pss.htm>> (2 March 2006)(The PSS is an Australian Government scheme that helps eligible doctors with the costs of their medical indemnity insurance. Eligible doctors see the benefit of the PSS through reductions in the level of premiums charged to them ...). See also Studdert, Mello & Brennan, above n6 at 286.

20 Eg, Merry and McCall Smith, above n16 at 215-216 (‘caution should be exercised in attributing changes in practice solely to medico-legal factors’); Studdert, Mello & Brennan, above n6 at 286.

21 See for example, Troyen Brennan & Michelle Mello, ‘Patient Safety and Medical Malpractice: A Case Study’ (2003) *Annals of Internal Medicine* 267 at 272 ([The current tort system] ‘pollutes what otherwise might be a useful exercise in root-cause analysis leading to quality improvements’). See also *Iatrogenic Injury in Australia*, above n3, 94-98; *Making Amends*, above n7 at 110; Merry & McCall Smith, above n16 at 96-97; Wachter and Shojania, above n2 at 293-314.

22 Christine Parker & John Braithwaite, ‘Regulation’ in Peter Cane & Mark Tushnet (eds), *The Oxford Handbook of Legal Studies* (2003) at 119, 122–126.

23 Christine Parker, Colin Scott, Nicola Lacey & John Braithwaite, ‘Introduction’ in Christine Parker, Colin Scott, Nicola Lacey & John Braithwaite (eds), *Regulating Law* (2004) at 1–13 (hereafter *Regulating Law*).

24 John Braithwaite & Christine Parker, ‘Conclusion’ in *Regulating Law*, above n23 at 270. See also Braithwaite, Healey & Dwan, above n17 at 5–6.

Regulation can mean more than just the enforcement of legal rules. It is normally taken to include the enforcement of informal rules...promulgated by supranational bodies such as the World Trade Organisation or the European Union, and subnational bodies such as professional associations. On its broadest reading, regulation means even more than that. Much regulation is accomplished without recourse to rules of any kind. It is secured by organising economic incentives to steer business behaviour, by moral suasion, by shaming, and even by architecture. On this broadest view, regulation means influencing the flow of events.²⁵

One consequence of this broader understanding of regulation is the recognition of its limits. The notion of regulation as one concerned with 'influencing the flow of events' is very different from the traditional one of the state commanding compliance with directives of those being regulated. It is thus rare to find systems of regulation which rely predominantly on command styles of regulation.²⁶ In the context of tort law this means that it is neither useful nor productive to conceive of a right to compensation based on the tort of negligence as a form of command aimed at achieving public policy goals. This is because tort law is not effective as a form of command and control regulation,²⁷ and because tort law is not designed as a command and control system of regulation.²⁸

Regulation in this broad sense is therefore complex both in its institutional structure and in the range of mechanisms that are integrated into a 'system' designed to achieve public policy goals. Regulation is in this sense multi-dimensional.²⁹ It is concerned with creating a system that makes use of a large number of mechanisms that are integrated so that each of the mechanisms interact to increase the capacity of the system to achieve regulatory outcomes.³⁰ The most well-known version of this systemic approach to regulatory design is the 'regulatory pyramid'.³¹ In context of this 'systemic' approach to regulation, a right to claim compensation will need to be integrated with other regulatory mechanisms.

One metaphor to better understand this complex, multi-dimensional regulatory perspective is that of regulation occurring within 'regulatory space'. This concept involves an analysis of the interaction between bodies of law, practices and conduct, cultures and institutions:

The chief idea of the regulatory space metaphor is that resources relevant to holding of regulatory power and exercising capabilities are dispersed and

25 Parker & Braithwaite, above n23 at 119.

26 Braithwaite, Healey & Dwan, above n17 at 44–45 argue that there is still a role for command and control regulation in specific institutional contexts where regulatees do not have the capacity to support self-regulatory strategies.

27 Studdert, Mello & Brennan, above n6 at 286.

28 See, for example, Jane Stapleton, 'Regulating Torts' in *Regulating Law*, above n23 at 122.

29 Ian Ayres & John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (1992) at 17.

30 Braithwaite, Healey & Dwan, above n17 at 25–35.

31 *Id* at 37–42.

fragmented. These resources are not restricted to formal, state authority derived from legislation or contracts, but also include information, wealth and organisational capacities. The possession of these resources is fragmented among state bodies, and between state and non-state bodies. The combination of information and organisational capacities may give to a regulated firm considerable informal authority, which is important in the outcome even of formal rule formation or rule enforcement processes. Put another way, capacities derived from possession of key resources are not necessarily exercised hierarchically within the regulatory space, regulator over regulatee.³²

This metaphor provides a useful way of thinking about the complexity of regulatory schemes that are designed to achieve important public policy goals:

It can be fruitful to think of regulation occurring in a 'regulatory space' in which the operation and competition of various regulatory regimes influences regulatory impact. At this level of analysis, regulatory research also examines how the intended effects of regulation are modified and mediated by social customs and structural realities (non-legal ordering).³³

There is currently much debate and interest in the design of regulatory frameworks to improve patient safety. Regulatory initiatives to improve patient safety have to operate in an environment where there is competition with other regulatory regimes, and where the impact of those initiatives are modified and mediated by non-legal ordering. There is a broad review of the regulatory strategies designed to improve patient safety in the second part of this article.

The regulatory space metaphor helps bring into focus the way in which particular institutions, laws, practices and cultures interact with each other when regulatory space is disturbed, for example, by the introduction of a set of regulatory initiatives. This interaction will involve these institutions, laws, practices and cultures changing as they respond to regulatory change. Each of these responses will, in a general sense, either accommodate, enable and facilitate regulatory change or, alternatively, will limit the effectiveness of such change. In this sense, it is useful from a regulatory perspective to inquire as to whether these institutions, laws, practices and cultures have the self-regulatory capacity to accommodate, enable and facilitate regulatory change. If any of these elements lack a capacity to re-orient themselves in relation to regulatory change, this is an indicator that this particular part of regulatory space needs to be changed in order to increase the likelihood that regulatory change will reach its stated goals.

In this sense, one of the primary questions for regulators is to define the boundaries of systems of regulation. Those concerned with regulatory design have to decide which institutions, laws, practices and conduct need to be explicitly included in a set of regulatory initiatives and which have the inherent self-regulatory capacity to accommodate and facilitate the achievement of public

32 Colin Scott, 'Analysing Regulatory Space: Fragmented Resources and Institutional Design' [2001] *Public Law* 329 at 330.

33 Parker, Scott, Lacey & Braithwaite, 'Introduction' in *Regulating Law*, above n23 at 7.

policy goals. An example of the complexity of this problem of defining the boundaries of systems of regulation is the role of purchasing departments in hospitals. A purchasing department of a hospital can reduce the level of some kinds of adverse events by integrating protocols so that the hospital does not acquire certain kinds of unsafe products.³⁴ The problem for those designing a system of regulation that is designed to improve patient safety is whether or not the purchasing department has the capacity to integrate safety protocols into its decision-making process without reducing its capacity to fulfil its primary function of acquiring at reasonable cost the products and services required for use in the hospital. If the purchasing department does not have this capacity the system of regulation will have to be directed towards the implementation of steps that are designed to develop this capacity.

This is a particularly useful way to analyse the relationship between law and regulation. The legal system is made up of institutions and semi-independent categories of law. Each of these institutions and categories of law that make up the legal system will have to respond to regulatory change. This regulatory perspective will consider whether these institutions and categories of law have the capacity to accommodate, enable and facilitate regulatory change. In this article, the focus is on the relationship between regulatory initiatives to improve patient safety and the law concerning compensation. The question is therefore whether the tort-based system of compensation for injuries associated with medical error does accommodate, enable and facilitate regulatory change that is designed to improve patient safety.

A self-regulatory capacity to accommodate, enable or facilitate regulation is a multi-dimensional capacity. It is not merely a question of whether the legal obligation to pay compensation for harm produces a higher level of patient safety. It involves analysis of whether the process for obtaining compensation, the test of legal responsibility, and the liability to pay compensation, accommodate and support the system of regulation designed to improve patient safety. In this sense the question is whether the system of law concerned with compensation for injuries associated with medical error has the capacity to accommodate regulatory initiatives designed to improve patient safety. Where tort law has this self-regulatory capacity, the process for obtaining compensation, the test of legal responsibility and the outcome in the form of the obligation to pay compensation will mould around a regulatory framework without any direct changes to this area of law.

In some areas tort law arguably does have the self-regulatory capacity to integrate regulatory change in a way that accommodates and facilitates regulation. This is particularly clear in the field of recovery for pure economic loss.³⁵ A second area in which this capacity is present is in law the concerning directors' duties in corporate regulation. The obligations have their source in the common

34 See below n68 and accompanying text.

35 Angus Corbett, 'The "Self" Regulation of Law: A Synergistic Model of Tort Law and Regulation' (2002) 25 *UNSWLJ* at 616.

law, equity and statute. These areas of law have the capacity to integrate regulatory change, particularly change in the disclosure of information in a way that facilitates the underlying purposes of this area of regulation.³⁶ It is arguable that these areas of law concerned with compensation have a capacity to integrate the main features of the system of corporate regulation into the decision-making processes that determine whether particular individuals receive compensation.

This article is not concerned with analysis of whether tort law as a whole accommodates or facilitates regulatory change. Insofar as it is arguable that tort law does accommodate regulatory change it will be dependent upon the interaction between tort law and particular bodies of regulation. The argument in this article is that tort law has not been able to accommodate or facilitate the particular system of regulation that is concerned with the goal of improving patient safety. This is because the process for obtaining compensation and the model of legal responsibility used in tort law are inconsistent with some of the central features of this system of regulation. The inability of tort law to accommodate regulatory change is the main reason the regulatory system needs to be expanded to accommodate a system of compensation for injuries associated with medical error.

3. *Regulating Patient Safety*

A. *The Empirical Evidence*

The raw numbers used to indicate the size of the problem of injury associated with medical error are an indicator of the importance given to the issue of patient safety. As a result of comparing studies done in Australia and the US, the generally-agreed figure is that 10 per cent of all admissions to hospitals are associated with a 'preventable adverse event'.³⁷ There is also general agreement that 0.3 per cent of hospital admissions were associated with iatrogenic death and 1.7 per cent of admissions were associated with major iatrogenic disability.³⁸ When these findings were applied to all hospital admissions in Australia in 1992, the figure for iatrogenic deaths associated with all admissions to acute-care hospitals was 14,000 each year.³⁹

In addition to these measures of the number of adverse events, there is another measure of the level of patient safety which focuses on the quality of health care services delivered to patients. These measures include the percentage of patients that receive treatments that have proven effective, and the percentage that receive harmful or unnecessary treatment. A recent review of the use of evidence-based medicine stated that:

Patient care and outcomes could be significantly improved if the knowledge gained from health research was better translated into practice. This is the

36 Angus Corbett & Stephen Bottomley, 'Regulating Corporate Governance' in *Regulating Law* above n23 at 60.

37 See above n2.

38 *Charting the Safety and Quality of Health Care in Australia*, above n3.

39 *Iatrogenic Injury in Australia*, above n3 at 23.

message from studies suggesting that 30 per cent – 40 per cent of patients do not receive treatments of proven effectiveness and that 20 per cent – 25 per cent have treatments that are unnecessary or potentially harmful.⁴⁰

These measures of the quality of health care delivered to patients include the delivery of sub-optimal care as well as care that may cause injury by exacerbating an existing condition or by more directly causing harm. The measure of quality of care is thus broader than the measure of rate of occurrence of adverse events. Both measures of quality of health care and measures of the occurrence of adverse events indicate the extent of the problem of iatrogenic injury.

There are several ways that commentators and those concerned with patient safety have tried to give a more immediate sense of what these measures of the rate of adverse events mean. In the United States, the figure for the annual number of preventable deaths caused by iatrogenic injury following admission to hospital was between 44,000 to 98,000.⁴¹ This amounted to the same level of death that would result from the crash of a jumbo jet every day. Although the meaningfulness and veracity of this comparison has been challenged, it does give a sense of the comparable levels of safety in health care and civil aviation.⁴² Another way of highlighting the issue of patient safety is to say that being an inpatient in a hospital is only ten times safer than jumping out of an aeroplane with a parachute and is forty times more dangerous than being in traffic.⁴³

The studies from which these figures are taken are now more than a decade old, but there is no reason to indicate that the overall magnitude of the problem has diminished.⁴⁴ There are some recent projects that have the aim of identifying, assessing and reporting on the status of safety and quality of health care in Australia.⁴⁵ There are more recent figures that indicate that in 1997 and 1998, 2.2 per cent of deaths in hospitals were identified as 'having an adverse event as an underlying cause of death'.⁴⁶ In Western Australia, a recent study revealed that adverse events 'caused death in 3 per cent of surgical mortality cases' and contributed to death in 18 per cent of surgical mortality cases.⁴⁷ There is

40 Heather Buchan, Jillian Sewell & Melissa Sweet, 'Translating Evidence into Practice' (2004) 180 *Med J Aust* S43 at S43.

41 *To Err is Human*, above n2 at 26.

42 Troyen Brennan, Atul Gawande, Eric Thomas & David Studdert, 'Accidental Deaths, Saved Lives, and Improved Quality' (2005) 353 *New Eng J Med* 1405 at 1406 (reporting debate over measurement of rate of occurrence of adverse events but stating 'None of this means that we do not have a safety problem in United States health care').

43 *Iatrogenic Injury in Australia*, above n3 at 11.

44 See, for example Braithwaite, Healey & Dwan, above n17 at 2; Wilson & Van Der Weyden, above n5. For the United States, see Brennan, Gawande, Thomas & Studdert, above n42.

45 See, for example, *Charting the Safety and Quality of Health Care in Australia*, above n38 at 72. See also *Achieving Safety and Quality Improvements in Health Care* above n2 at 28–29 (process for developing of measures that 'encompass a broader context that describes and analyses both the positive and negative indicators of safety and quality').

46 *Charting the Safety and Quality of Health Care in Australia*, above n38 at 72.

47 *Id* at 78–79. In a study covering surgical mortality in Western Australia there were a total of 663 audited deaths. Adverse events 'caused' 20 deaths and caused or contributed to a further 122 deaths.

continuing evidence of high levels of adverse drug events, hospital acquired infections and hospital acquired pressure ulcers.⁴⁸

There have been some attempts to identify the costs associated with iatrogenic injury. At the time of the study on quality in health care in 1992 in Australia, it was estimated that 8 per cent of all bed days in Australian hospitals were associated with preventable adverse events.⁴⁹ Subsequent research indicates that the direct costs to the health care system could be of the order of \$2 billion annually.⁵⁰ This figure only includes direct health care costs and does not include full lifetime costs of iatrogenic injury.

Finally, and perhaps most importantly, the prevalence of preventable adverse events is not necessarily a diminishing phenomenon. There is no reason to assume that as technology proceeds there will be fewer adverse events. If anything, it is more likely that the contrary is true. Increasing complexity in the delivery of health care services creates the potential for increases in the prevalence of adverse events. In simple terms, 'medicine's history over the last fifty years is that of ever-increasing complexity – and with it, a parallel growth in the opportunity for errors'.⁵¹ In summary, the availability of more complex and sophisticated health care services increases the risk of exposure to adverse events.

B. The Regulatory Response

The recognition of the high incidence of medical error has given impetus to regulatory initiatives that are aimed at improving patient safety. The important element of these findings concerning the level of iatrogenic injury is not just the raw numbers of adverse events, but the large number of 'preventable adverse events'. It is the existence of the high number of 'preventable' injuries to patients admitted to hospital which is the trigger for regulatory concern.

At the heart of the regulatory response to the recognition of the high level of iatrogenic injury is a shift in regulatory focus. The focus has shifted from a concern with remedying instances of individual fault and error to a concern with remedying systemic failures that allow individual error to cause harm to patients. In basic terms, this is a shift from individualised notions of responsibility for harm, to ones that centre on a conception of systemic responsibility for harm. This shift is evident in the classic studies that first set out to measure the rate of occurrence of adverse events.

The forerunner for the Quality in Australian Health Care Study was the Harvard Medical Practice Study.⁵² This study found that 27.6 per cent of adverse events were due to negligence.⁵³ The definition of 'negligence' used in this study was 'care that fell below the standard expected of physicians in their community'. This reflected the tort standard of care.⁵⁴ By contrast the Quality in Australian

48 Id at 72.

49 *Iatrogenic injury in Australia*, above n3 at 22.

50 Ibid.

51 Wachter & Shojania, above n2 at 53. See also, *Charting the Safety and Quality of Health Care in Australia*, above n38 at 9; *To Err is Human*, above n2 at 35–37; Merry & McCall Smith, above n16 at 48–49.

Health Care Study used a quite different concept of 'preventability'. An adverse event was defined as 'preventable' where the adverse event was the result of an 'error in management due to the failure to follow accepted practice at an individual or system level'. 'Accepted practice' was defined as 'the current level of expected performance for the average practitioner or system that manages the condition in question'.⁵⁵ The Harvard Medical Practice Study focus on the 'negligent adverse events' is consistent with an individualised approach for determining responsibility for harm. By contrast, at the very heart of the concept of the 'preventable adverse event' is the notion that harm sustained by patients results from the failures in the system of health care.

The shift from the notion of individual failure producing medical error to the notion that error may be the result of system design failure is fundamental to current strategies for reducing the level of medical errors. This focus on the capacity of a system to produce error builds on the idea that the level of medical errors cannot be reduced by simply increasing levels of training or by calling on health care providers to work harder and more carefully.⁵⁶ Indeed it has been suggested that:

One of the most subtle mistakes made is a failure to realise that the best-motivated and most highly-trained professionals are also potentially lethal agents.⁵⁷

There are two senses in which there is a failure to recognise the lethal potential of the best motivated and most highly trained professionals. Firstly, that the delivery of health care is the result of interaction of teams of health care professionals and administrators. A focus on the capacities of individual professionals will miss the way in which the interaction and communication between professionals and administrators can cause adverse events. Secondly, there is the potential for highly trained professionals and administrators to commit errors which may cause harm. The notion of the professional as a lethal agent is centred on the view that the safety of the patient should be protected by more than reliance on individual professionals to deliver health care services. For example, the decision as to whether a particular patient, who is about to undergo surgery, is having the right surgery on the right part of the body should not be dependent solely on the skilled

52 Troyen Brennan, Lucian Leape, Nan Laird, Liesi Herbert, Russell Localio, Ann Lawthers, Joseph Newhouse, Paul Weiler & Howard Hiatt, 'Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study' (2004) 13 *Quality and Safety in Health Care* 145 at 146.

53 Id at 145.

54 Ibid.

55 Ross Wilson, Bernadette Harrison, Robert Gibberd & John Hamilton, 'An Analysis of the Causes of Adverse Events from the Quality in Australian Health Care Study' (1999) 170 *Med J Aust* 411 at Box 1 'Terms and Definitions'.

56 Australian Council for Safety and Quality in Health Care, *Setting the Human Factor Standards for Health Care: Do Lessons from Aviation Apply?* (2003): <www.safetyandquality.org/aviation.pdf> at 13 (1 Mar 2005) (hereafter *Setting the Human Factor Standards for Health Care*).

57 Id at 12.

surgeon about to make an incision with a scalpel. In this sense, improvements in safety will follow from recognition of the importance of these ‘human factors’, that is, the ‘universal nature of human fallibility’.⁵⁸ The central idea supporting attempts to improve levels of patient safety is the attempt to ‘optimise the relationship between technology and the human.’⁵⁹

One pathway for this transition that was adopted by those interested in safety and quality issues in health care was to look to organisations concerned with other industrial activities, for example, nuclear power, chemicals and aviation, in which a ‘systems focus’ had produced higher levels of safety.⁶⁰ One point of focus on this new pathway was the work of Professor James Reason, whose expertise was in the field of industrial safety.⁶¹ In a recent book dealing with medical error the authors, who were doctors, described one theme of Professor Reason’s work in the following way:

Most human endeavours, he believed, could be compared to a chisel, with a sharp end that splits the wood and a blunt end that receives the hammer blows to drive it. After major accidents, people generally blame those operating at the “sharp end” of the activity: the surgeon slicing his scalpel through a patient’s skin, the pilot adjusting the plane’s rudder, the pharmacist dispensing a medication, and the oil rig worker operating a massive drill. The “blunt end” of the process — managers setting priorities, supervisors preparing schedules, administrators processing forms, regulators enforcing rules — is seldom examined; usually only after a failure pattern has become so obvious that it can no longer be ignored.⁶²

The central idea behind the use of the chisel metaphor is the idea that there are at least two ways to view an adverse event. One way is to focus on the ‘sharp end’, that is, the person who actually administers the incorrect drug, or who fails to check a patient before finishing their shift. A second way is to think of the whole health care system as making up the chisel. The adverse event is then the result of the capacity of the chisel to deliver to an individual patient a service that may have lethal consequences. The ‘cause’ of the adverse event in this latter sense is not the particular health care professional who administers the wrong drug but rather the health care system which creates the structure that support the professional in delivering a lethal dose of a drug. There may be a range of relevant factors that ‘cause’ the adverse event. These include the lack of attention of the professional due to fatigue caused by long shifts, the failure of health administrators to ensure that there are sufficient nurses and doctors to deliver appropriate levels of care, the failure to ensure that a second person verified the administration of the correct dose of the correct drug, or the failure to label and name drugs in an appropriate fashion.

This shift has revealed an extraordinarily complex regulatory space. One report gives some sense of the elements in this regulatory space:

58 Id at 14.

59 Id at 7.

60 Id at 14, 17, 26–29.

61 James Reason, *Human Error* (1990). See also *Iatrogenic Injury in Australia*, above n3 at 12–13.

62 Wachter & Shojania, above n2 at 43.

Health care is now delivered in a dynamic environment with complex interactions between patients, their pathophysiological and disease processes, medical and other staff, infrastructure, equipment, policies and procedures. Although human error does play a role in 70 per cent to 80 per cent of incidents and accidents arising from complex systems, it should be seen against a background of organisational, technical and equipment-interface problems which may not only set the stage for incidents and accidents, but be the prime causes. Equipment or system failure and human error are rarely the sole causes of problems — up to 90 per cent have elements of both.⁶³

In this framework an accident resulting in harm will be the result of the alignment of a number of conditions which create the space for error to cause harm. The regulatory response to this potential source of harm is to build in multiple layers of support that are designed to neutralise the potential for error to cause harm.⁶⁴

The complexity of the regulatory space is further complicated because there are a large number of adverse events that occur at very low levels of frequency. When the results of the studies indicating high levels of medical error were released, many medical professionals expressed surprise and disbelief.⁶⁵ One reason for this surprise was that many of the adverse events reported in these studies occurred at very low levels of frequency. Indeed, ‘only one-quarter of all adverse events occur with sufficient frequency to be amenable to prospective tracking, even in large teaching hospitals’.⁶⁶

These low-frequency events increase the complexity of the regulatory problem of improving patient safety in two ways. Firstly, they require sophisticated data collection exercises to identify patterns of occurrence of adverse events. One of the strategic directions identified by the Clinical Excellence Commission that was established in NSW is to develop ‘a robust and integrated information base regarding key areas of risk that are of public interest’.⁶⁷ Secondly, these low-frequency adverse events may require complex changes to the way in which health care services are delivered. For example, prevention of administration of a lethal dose of a drug may involve more training, different approaches to staffing, re-packaging of drugs and the development of new protocols for administering the drug. These changes then need to be implemented across the entire system in order to reduce the potential for this event to occur.

A number of examples give some indication of the complexity of the regulatory space and of the multi-level, integrated regulatory interventions needed to reduce

63 *Iatrogenic injury in Australia*, above n3 at 12. See also *Achieving Safety and Quality Improvements in Health Care*, above n2 at 8.

64 *Setting the Human Factor Standards for Health Care: Do Lessons from Aviation Apply?*, above n56 at 14–17 (the ‘Swiss cheese model’, all the holes align to produce the accident).

65 See, for example, Martin B Van Der Weyden, ‘Politics and publishing: The Quality in Australian Health Care Study’ (1995) 163 *Med J Aust* 453.

66 *Iatrogenic Injury in Australia*, above n3 at 19.

67 Clinical Excellence Commission, *Annual Report* above, n5 at 18. See also NSW Health, *Incident Management Policy* (2005): <http://www.health.nsw.gov.au/policies/pdf/2005/pdf/PD2005_604.pdf> (28 Mar 2006).

the level of harm caused by medical error. One example is of the capacity for a ‘Seldinger wire’ to cause harm when inserted into a patient’s heart.⁶⁸ Harm may result from the incorrect insertion of a Seldinger wire with one sharp end performing the right atrium ventricle. Although the error is rare, it has the potential to cause death or serious harm that is preventable.

One solution is to purchase Seldinger wires with two ‘floppy ends’ so that there is no possibility for the heart to be perforated even where the wire is inserted incorrectly. This solution may be difficult to implement because, Seldinger wires are not manufactured in Australia as regulation of manufacture is not feasible. There are multiple *suppliers* of Seldinger wires some of which have one sharp end. Decisions to purchase products like Seldinger wires are made by individual hospital procurement departments who may have no insight into the significance of the difference between different forms of Seldinger wires. Without this awareness they may focus only on the price difference between the relevant products.

Medical professionals who use and insert the Seldinger wires are not able to use the safer product because the products they are given are purchased by another entity in the health system over which they have no authority and with which they may have no contact. This relatively simple example highlights the complexity of the problem of integrating the various elements of the health care system in order to reduce the risk of serious harm and death. Similar examples involving similar issues arise in relation to the packaging of drugs (colour coding in ready-to-use syringes),⁶⁹ and the design of syringes to prevent the inappropriate admission of drugs.⁷⁰

A second example of the multi-dimensional nature of the regulatory problem of a systemic approach involves the introduction of monitors to measure the level of oxygen in the blood and the effectiveness of ventilation during general anaesthesia. During the period of the 1980s and 1990s the level of mortality directly caused by anaesthesia fell from 1 in 20,000 to 1 in 150,000. This was attributable to the use of more effective monitors. The process for the introduction of these monitors was a multi-dimensional one that involved manufacturers, anaesthetists and their professional knowledge, the College of Anaesthetists, and hospital administrations.⁷¹

In the first instance many anaesthetists acted on the basis that more effective monitoring would increase the complexity of the process with the effect that the costs of the monitors would outweigh the benefits. This ‘professional knowledge’ had no empirical basis. In the late 1980s an incident monitoring system was introduced. This monitoring system identified a number of ‘anaesthesia-related’ incidents and an analysis of these revealed that oximetry⁷² and capnography⁷³ had

68 *Iatrogenic Injury in Australia*, above n3 at 70, 73.

69 *Id* at 75.

70 *Setting the Human Factor Standards for Health Care: Do Lessons from Aviation Apply?*, above n56 at 14–16.

71 *Iatrogenic Injury in Australia*, above n3 at 67–68, 81–82.

the potential to detect up to 90 per cent of the incidents and, more importantly, that 65 per cent of the incidents could be detected before the occurrence of any organ damage.

The first stage of the regulatory response involved the collection of information about adverse events associated with anaesthesia. This stage involved co-ordination between anaesthetists, medical professionals, including nurses, and hospital administrators. The second step involved the acquisition of monitors by hospitals and the support and training needed to make effective use of these monitors.⁷⁴ Each step in the process involved co-ordination and communication between diverse elements of the health care system. The task of encouraging this level of co-ordination and of establishing channels of communication is difficult and complex but also yields significantly higher levels of safety for patients undergoing general anaesthesia.

These examples give some sense of both the complexity of the regulatory space and of the *level* and *significance* of change in the health care system as these initiatives cascade through all layers of service delivery. It is not only that regulatory initiatives aimed at improving patient safety by reducing the level of occurrence of adverse events involve a large number of changes that have to be implemented by a large number of health care professionals and administrators. It is also that these changes have to be effectively integrated into the system delivering health care services because it is the impact of the combined changes which will improve patient safety.

One indicator of the magnitude of the regulatory task is the set of key action areas or objectives which the Australian Council on Safety and Quality included in its Strategic Plan. These key action areas 'emerged from analysis of risks and opportunities deemed critical to the success of the Council in improving patient safety'.⁷⁵ These key action areas are:

- Build capacity of the health workforce to deliver safer patient outcomes;
- Improve the use of data and performance information to promote care;
- Lead practice improvement in key areas of harm;
- Promote consumer and community involvement in improvements in care;
- Influence safer design of equipment, processes, environment and improved information technology for health;

72 Sarah-Jane Fearnley, 'Pulse Oximetry' (1995) 5 *Practical Procedures* 2: <http://www.nda.ox.ac.uk/wfsa/html/u05/u05_003.htm> (8 Mar 2006) (pulse oximetry is a simple non-invasive method of monitoring the percentage of haemoglobin (Hb) which is saturated with oxygen).

73 Bovani-Shankar Kodali, 'Capnography' *A Comprehensive Educational Website*: <<http://www.capnography.com/Homepage/HomepageM.htm>> (8 Mar 2006). Capnography 'the measurement and display of carbon dioxide (CO₂) on a digital or analogue monitor. Maximum inspiratory and expiratory CO₂ concentrations during a respiratory cycle are displayed.' 'The primary goal of anaesthesiologists is to prevent hypoxia, and capnography helps to identify situations that can lead to hypoxia if uncorrected. Moreover, it also helps in the swift differential diagnosis of hypoxia before hypoxia can lead to irreversible brain damage'.

74 *Ibid.*

75 *Achieving Safety and Quality Improvement in Health Care*, above n2 at 22.

- Build awareness and understanding of safety and quality issues;
- Increase effective safety and quality governance and investment; and
- Develop strategic partnerships and future direction.⁷⁶

Health care systems in Australia have been coming to grips with the problem of identifying and implementing the changes that are necessary to improve the level of patient safety.⁷⁷ In particular the role and interaction between regulatory strategies focusing on patient safety, and reduction of levels of occurrence of adverse events, and strategies focusing on improving the quality of health care services is still in a state of flux.⁷⁸ The key action areas identified by the Australian Council on Safety and Quality in Health Care include references to both strategies.

One of the challenges for those concerned with regulation in complex environments is the effective integration of the various elements of regulation into an effective system of regulation. The key action areas identified by the Australian Council on Safety and Quality in Health Care include regulatory strategies that affect the health workforce, the practices of health care professionals, consumers and the broader community, health care administration, and the design of health care products and information technology. The integration of these elements into a system of regulation is an important challenge because there can be no 'command' structure to co-ordinate the implementation of these strategies. Rather, institutions and individuals associated with the delivery of health care services have to develop the capacity to integrate changes initiated by reform in all of these areas into their own practices and activities.⁷⁹ This is a major area of interest for those concerned with developing effective systems of regulation in many different contexts.⁸⁰

The broad problem that this article addresses is how to integrate a system of compensation into the broader pattern of regulation concerned with improving patient safety. The problem is to identify what sort of system of compensation can support, enable and facilitate these regulatory changes. This problem is addressed directly in the fourth part of the article. The next section focuses on a more specific problem. It sets out to show why the tort-based system of compensation is unable to facilitate or accommodate these regulatory changes.

⁷⁶ Ibid.

⁷⁷ Id at 23–63. See also Australian Council for Safety and Quality in Health Care, *State and Territory Highlights: Improving Patient Safety* (2005): <http://www.safetyandquality.org/state_territory0705.pdf> (4 Mar 2006).

⁷⁸ See, for example, *Charting the Safety and Quality of Health Care in Australia*, above n38 at 7, 11–12. See also NSW Health, *Patient Safety and Clinical Quality Program: Final Report* (2005): <http://www.health.nsw.gov.au/policies/pd/2005/pdf/PD2005_608.pdf> (28 Mar 2006); Brennan, Gawande, Thomas & Studdert, above n42.

⁷⁹ See, for example, Australian Council for Safety and Quality in Health Care, *Open Disclosure Standard: A National Standard for Open Communication in Public and Private Hospitals Following an Adverse Event in Health Care* (2003) at 1–2 (hereafter *Open Disclosure Standard*). The Standard 'aims to foster commitment from health care organisations' to take the necessary steps to facilitate open communication between health care professionals, patients and support persons. This includes the commitment to identify, investigate, and respond to adverse events, and to support patients and health care providers.

⁸⁰ See generally, Braithwaite, Healey & Dwan, above n17 at 25–46.

4. *Regulating Patient Safety and Tort*

There is an important change in focus underlying regulatory initiatives that are designed to improve levels of patient safety. In broad terms this is the change from an 'individualistic' understanding of high levels of error to a multi-dimensional understanding of the capacity of the 'system' of health care to produce both medical error *and* good health outcomes for patients. This part of the article addresses the problem of what happens when this systemic approach to regulation interacts with an individualistic fault-based system of compensation for medically-related harm.

The specific question addressed in this section is whether this fault-based system of compensation can accommodate, enable or facilitate regulatory initiatives aimed at improving patient safety. The question is not whether the payment of damages following successful claims by plaintiffs in tort improves levels of safety by deterring accidents. There is little evidence to indicate that liability in tort law for medically-related injury does deter accidents.⁸¹ This is not surprising because as noted earlier in this article, there are many reasons why tort law could not achieve this goal. Rather, the question is whether the process of determining liability for medically-related harm directly or indirectly enhances and supports the broad range of regulatory initiatives that are designed to improve patient safety. The conclusion in this part is that the tort-based system of compensation neither supports nor facilitates regulation aimed at improving patient safety.

The claim that tort law adversely impacts on the capacity of health care professionals to deliver safe and effective health care services is not a new one. While the evidence indicates that tort law has limited capacity to deter accidents and improve safety, there is some evidence that tort law affects the delivery of health care in undesirable ways because of its capacity to encourage 'defensive' medical practices.⁸² In addition, there is a perception that tort law is a cause of the increasing cost of medical indemnity insurance.⁸³ Both of these concerns have provided an impetus to reform tort law that has been directed at reducing the frequency of actions to recover compensation and the amount of damages received by successful claimants.

There have been reforms aimed at reducing the number and amount of claims seeking compensation for harm caused by the negligence of another. These include changes to the standard of care expected of the defendant and to the defences that defendants could use to either reduce or remove the amount of liability owing to a plaintiff.⁸⁴ In addition, in NSW there have been disincentives introduced to

81 Studdert, Mello & Brennan, above n6 at 286.

82 Ibid. See also David Studdert, Michelle Mello, William Sage, Catherine DesRoches, Jordon Peugh, Kinga Zapert & Troyen Brennan, 'Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment' (2005) 293 *JAMA* 2609 at 2609.

83 Dominic Villa, *Annotated Civil Liability Act 2002 (NSW)* (2004) at xli-xliii. See also AHMAC, *An Integrated Reform Package*, above n7 at 15-22, noting that this perception about the role of tort law may not be well founded. See also, Studdert, Mello & Brennan, above n6 at 286-287.

impose penalties on legal professionals who advise their clients to initiate actions to recover compensation where there are no reasonable prospects of success.⁸⁵ Finally, there have been important changes to the rules that govern the calculation of personal injury damages.⁸⁶

The basis for these reforms is the belief that the problem with fault-based liability is that it is too easy to recover compensation and that the amounts of compensation obtained by patients are too large.⁸⁷ The argument in this article is that the immediate intuitive appeal of these assumptions hides a far more profound reason for the failure of tort law to accommodate or facilitate regulatory change aimed at improving patient safety. A central feature of this argument is that the current strategies for tort law reform will have little impact on improving the capacity of tort law to accommodate and respond to regulatory change.

Before proceeding it is important to note the overall importance of this regulatory analysis when considering the question of whether the tort-based system of compensation establishes a fair and effective system of compensation. This is because the empirical evidence, which is patchy, suggests that relatively few people who sustain injury following a negligent adverse event are able to gain access to the law of tort to claim compensation.

There is a significant body of empirical evidence to suggest that 10 per cent of hospital admissions will result in a preventable adverse event.⁸⁸ There is less certainty concerning the rate of 'negligent preventable events', that is, where the adverse event was directly or indirectly caused by a defendant's negligent act or omission. Two studies completed in America using data from the early 1990s have come up with figures that indicate that negligent adverse events range from 27.6 per cent⁸⁹ of adverse events to 32 per cent.⁹⁰ The more important figure is that in one study only 3 per cent of those who sustained negligent injury claimed compensation.⁹¹ In the Harvard Medical Practice Study only 1.5 per cent of patients who had adverse events caused by medical negligence brought a negligence claim.⁹² One estimate in Australia is that only 1 person in 25 who

84 *Civil Liability Act 2002* (NSW) (Assumption of responsibility for obvious risks (Pt 1A, Div 4), Liability for obvious risks, and waiver of contractual duty of care for recreational activities (Pt 1A, Div 5), Standard of care for professionals (Pt 1A, Div 6), Contributory negligence (Pt 1A, Div 8), Liability of good samaritans and volunteers (Pts 8 and 9), Apologies (Pt 10). Rules dealing with assessment of damages (Part 2).

85 *Legal Profession Act 2004* (NSW), Division 9 and 10 of Part 3.2.

86 *Civil Liability Act 2002* (NSW) (Part 2).

87 Villa, above n83 at xxxvii–xlili.

88 See above n2.

89 Brennan, Leape et al, above n52 at 145.

90 David Studdert, Eric Thomas, Helen Burstin, Brett Zbar, John Orav & Troyen Brennan, 'Negligent Care and Malpractice Claiming Behavior in Utah and Colorado' (2000) 38 *Medical Care* 250 at 254–255.

91 Id at 253 (97 per cent of those who sustained negligent injury did not sue).

92 Russell Localio, Ann Lawthers, Troyen Brennan, Nan Laird, Lyeisi Hebert, Lynn Peterson, Joseph Newhouse, Paul Weiler & Howard Hiatt, 'Relation Between Malpractice Claims and Adverse Events Due to Negligence. Results of the Harvard Medical Practice Study III' (1991) 325 *New Eng J Med* 245.

sustains injury as a result of a negligent adverse event will successfully make a negligence claim.⁹³

The broad conclusion is that a system of compensation that inhibits regulation aimed at improving patient safety *and* provides compensation to a very small percentage of those patients who sustain harm is one that should be changed. Potential models for reforming the system of compensation are discussed in the following part of this article.

A. Why Does Tort Inhibit Regulation?

A plaintiff who is seeking compensation for harm that is associated with the occurrence of an adverse event must establish that a particular person or institution's act or omission was negligent. The test for determining whether a person or institution is in breach of their duty of care is an objective one. This test is concerned with determining whether the particular person or institution acted in a way that a reasonable person or institution would act in light of the foreseeable risks of harm to the patient.⁹⁴ Where the defendant is a professional the standard of care refers to what is 'widely accepted in Australia by peer professional opinion as competent professional practice'.⁹⁵ Finally, the plaintiff must establish that the particular act or omission that is in breach of the defendant's breach of duty was a cause of the plaintiff's harm.

The most significant feature of this cause of action is the requirement that the plaintiff must single out the particular act that amounts to a breach of duty from a complex sequence of events. This act or omission that amounts to a breach of duty by the defendant must then be a cause of the plaintiff's harm. This process of singling out individual causes from a complex sequence of events is part of a process of 'individuation of events'.⁹⁶ This process of individuation of events involves identifying particular acts as the focus of attention for the person seeking compensation. This is in contrast to the multi-dimensional analysis of the cause of adverse events that lies at the heart of regulatory initiatives aimed at improving patient safety.

The process of individuation of events necessarily focuses on the individual causes of medical error. This focus on individual acts and omissions as the cause of medical error has two important consequences. Firstly, it focuses attention on the individual conduct of professionals and not on the systemic causes of iatrogenic injury.⁹⁷ One of the goals of regulation to improve levels of patient safety is to upset the 'medical culture' which is founded on the notion of 'error-

⁹³ *Iatrogenic Injury in Australia*, above n3 at 25.

⁹⁴ *Civil Liability Act 2002* (NSW) s5B. Compare with *Wyong Shire Council v Shirt* (1980) 146 CLR 40.

⁹⁵ *Civil Liability Act 2002* (NSW) s5O. The standard of care in relation to the giving of advice to patients set out in *Rogers v Whitaker* (1992) 175 CLR 479 is preserved by s5P which provides that s5O does not apply to the provision of advice concerning risk of injury or death.

⁹⁶ Merry & McCall Smith, above n16 at 144–145.

⁹⁷ See, for example, Braithwaite, Healey & Dwan, above n17 at 31–35 (importance of a learning culture in supporting systems of self-regulation). See also nn60–64 and accompanying text.

free practice'.⁹⁸ The basis of this argument is that one of the reasons that medical professionals fail to develop error prevention strategies is the difficulty of assimilating the idea that error is an inevitable part of practice.⁹⁹ Secondly, the focus on individual blameworthiness increases the difficulty in developing effective reporting systems for adverse events and for incidents and near-misses. This is for the obvious reason that potential defendants are less likely to identify and report errors which may subsequently be used against them in legal proceedings.¹⁰⁰

These concerns about the way in which the tort of negligence interacts with the delivery of health care services are well recognised by health care professionals.¹⁰¹ These concerns do indicate that the process of determining whether a person is entitled to claim compensation sets up a competing and different approach to an understanding of the causes of medical error and of the responsibility for those errors. The individualistic model of causation and responsibility fostered by tort law has the effect of inhibiting the effectiveness of regulation aimed at improving patient safety. It does this by inhibiting the emergence of a 'systemic' understanding of the process of delivery of health care services. In particular, it inhibits the emergence of a sense of individual responsibility amongst the individual health care providers who are of central importance in making systemic approaches to regulation work effectively. One consequence of this is that it is more difficult to implement specific regulatory initiatives, for example, the development of systems to report on the occurrence of adverse events. In this sense tort-based compensation inhibits rather than accommodates regulation.

There are two other features of the way tort law operates that further limit the capacity of tort law to accommodate regulation. These features of tort law have the effect of introducing a large measure of 'noise' or arbitrariness into the process for determining liability for harm. The tendency of tort law to produce arbitrary outcomes for defendants is an important reason why tort-based compensation for medically-related injury inhibits regulatory initiatives to improve patient safety.

B. Impact at the Sharp End

As a system of compensation, tort law does not affect all those responsible for delivering health care services in a uniform way. In order to understand the impact of tort law across the health care system, we need to return to Professor Reason's metaphor of the health care system as a chisel.¹⁰² The health care system has the capacity to bring a great deal of force to bear on the patient. This is because the blunt end of the chisel is able to absorb high levels of energy and deliver this energy to the sharp end of the chisel. The tendency in the law of tort is to focus on those health care providers who deliver treatment at the 'sharp end' of the health

⁹⁸ *Iatrogenic Injury in Australia*, above n3 at 6.

⁹⁹ *Id* at 6–7.

¹⁰⁰ See Brennan & Mello, above n21.

¹⁰¹ See, for example, William Runciman, Alan Merry & Fiona Tito, 'Error, Blame and the Law in Health Care – An Antipodean Perspective' (2003) 138 *Annals of Internal Medicine* 974.

¹⁰² See Reason, above n62.

care system. There are fairly obvious reasons for focusing on the health care professional with the scalpel or needle where their use causes harm to a patient. This is the point at which the capacity of the health care system to produce adverse events is most seemingly transparent. This focus on sharp-end health care providers as the primary targets for identifying fault and hence for liability to pay compensation has some important consequences for the operation of tort law.

In addition to the obvious reasons for focusing on those who directly administer health care services to the patient, there are important structural reasons in tort law why the responsibility of the administrators and managers at the 'blunt end' of the health care system for harm caused by medical error is not tested. It is not that those administrators and managers are not 'responsible' for harm caused by medical error in the sense that they, along with others, can take steps that would assist in preventing the occurrence of adverse events. Rather, it is that it is very difficult for the system of tort law to make determinations of fault against those administrators and managers.

The acts and omissions of those administrators, managers and other service providers at the 'blunt end' of the health care system play a role in creating the potential for the occurrence of medical error. These service providers create the space for the occurrence of medical error through the creation of 'latent errors'. Latent errors:

[T]end to be removed from the direct control of the operator and include things such as poor design, incorrect installation, faulty maintenance, bad management decisions, and poorly structured organisations.¹⁰³

The acts of these administrators, managers and other service providers will escape findings of responsibility in tort law for two reasons. Firstly, the actions of administrators will often involve the exercise of discretion in allocating resources within an organisation. There are very important limitations on the capacity of courts to impose liability for such 'policy' decisions. Chief Justice Gleeson succinctly expressed the reasons for this limitation:

Subject to any insurance arrangements that may apply, people who sue governments are seeking compensation from public funds. They are claiming against a body politic or other entity whose primary responsibilities are to the public. And, in case of an action in negligence against a government of the Commonwealth or a State or Territory, they are inviting the judicial arm of government to pass judgment upon the reasonableness of the conduct of the legislative or executive arms of government; conduct that may involve action or inaction on political grounds.¹⁰⁴

It is possible for governments and their related instrumentalities to be responsible for some 'operational', or sharp-end, decisions just in the same way as 'private' institutions and individuals. However, many decisions of those at the blunt end of the health care system will involve decisions by governments about the allocation of resources where courts will refuse to make any finding of negligence.

¹⁰³ *To Err is Human*, above n2 at 56.

¹⁰⁴ *Graham Barclay Oysters Pty Ltd v Ryan* (2002) 211 CLR 540 at 553 (Gleeson CJ).

There are many examples of this kind of decision-making within the health care system. One example relates to the system for organising and managing the delivery of drugs to patients. Problems with medicines account for between 2 and 3 per cent of all hospital admissions.¹⁰⁵ In 2001, around 70,000 hospital admissions were associated with an adverse drug event. A significant proportion of these adverse drug events occurred within hospitals and there is evidence that approximately 43 per cent of adverse drug events occurring within hospitals were preventable.¹⁰⁶

One particular source of adverse drug events is the problem encountered by hospitals in managing access to drugs. An example of this problem was encountered by the Royal Adelaide Hospital. The hospital recognised that the failure to manage access to drugs could be a cause of adverse drug events. The Chief Executive Officer of the Royal Adelaide Hospital was faced with a decision to purchase automatic monitoring devices used by anaesthetists or standardised trolleys that would allow for more effective management of access to drugs. Initially the CEO ranked the automatic monitoring devices above the proposal to purchase the trolleys for the management of drugs. After further representations made by anaesthetists and others the decision was reversed.¹⁰⁷ The decision to purchase or not to purchase the trolleys would be an example of a 'policy' decision. As a policy decision a court would not be able to make a finding that the decision to purchase, or not purchase the trolleys, was in breach of a duty of care. This would be the case whether or not the purchase of the trolleys would reduce the probability of occurrence of adverse drug events.

Also, as a matter of principle, the decisions of those at the blunt end of service delivery will generally bear too indeterminate a relationship with the plaintiff's harm to be captured as a potential cause of the harm. For example, a plaintiff injured as a result of an adverse drug event could make a claim against the sharp-end service provider who administered the drug incorrectly.¹⁰⁸ However it would be much more difficult to make a claim against the hospital if the hospital decided not to purchase the trolleys. Even if the plaintiff could show that the failure to purchase the standardised trolleys was a breach of the duty of care, the plaintiff would then have to establish that the failure to purchase the trolleys was a cause of their harm.¹⁰⁹ Often the connection between this kind of decision and the plaintiff's injury will simply be too tenuous to be regarded as a cause of the plaintiff's injury.

This tendency to focus on those health care providers at the sharp end of service delivery has two important consequences. Firstly, the health care professional who incorrectly administers a drug will be required to bear responsibility for others in the health care system whose own acts and omissions added to the risk of the occurrence of an adverse drug event. It may be that this tendency to impose

105 *Charting the Safety and Quality of Health Care in Australia*, above n38 at 84–85.

106 *Ibid.*

107 *Iatrogenic Injury in Australia*, above n3 at 72.

108 See, for example, Merry & McCall Smith, above n16 at 12–15.

109 *March v E & MH Stramare (E & MH) Pty Ltd* (1991) 171 CLR 506.

liability on individual health care providers for 'organisational' failings is one of the causes of the high cost of medical indemnity insurance for those individual health care providers.¹¹⁰ Nonetheless this level of responsibility for health care providers at the sharp end of the health care system does mean that those health care providers can experience the imposition of liability as unreasonable and unfair. This will clearly make regulatory initiatives designed to improve patient safety more difficult to implement and will in all likelihood reduce the effectiveness of those initiatives.

C. *Slips and Lapses*

The second consequence of the focus of the system of compensation on those at the sharp end of the health care system is the treatment of some kinds of medical error. The tort of negligence will arguably impose liability on professionals for some kinds of errors even though those errors are both predictable and inevitable. This is the result of the process for determining when an error will amount to a breach of duty. The standard of care in cases of medical negligence is 'that of the ordinary skilled person exercising and professing to have that special skill'.¹¹¹ A medical professional should be able to attain this standard of care over a period of time. It does not follow however that a medical professional will be able to reach this standard on *each and every* occasion on which they carry out the procedure.

This argument applies to some kinds of errors that are an inevitable part of the practice of health care professionals. Many human activities, including those of highly-trained professionals delivering health care services, are learned as 'cognitive chunks', that is, they are learned as a sequence of events. This capacity to complete a complex series of actions has been described as 'skill-based' performance.¹¹² The capacity to automatically engage in activities involving high levels of skill is distinguished from slower and more effortful types of reasoning that have been described as 'deliberative', 'reflective' or 'knowledge-based' forms of reasoning.¹¹³ When a skilled medical professional is performing an activity exercising skill-based performance forms of reasoning it is generally accepted that there will be a predictable level of error that results from slips and lapses in attention.¹¹⁴ Slips and lapses will produce errors where the learned sequence of events is disrupted by an event that distracts the attention of the person engaging in the activity. Such slips and lapses are an integral part of medical practice and are a source of medical error.¹¹⁵

110 See above n19.

111 *Rogers v Whitaker* (1992) 175 CLR 479 at 483 (Mason CJ, Brennan, Dawson, Toohey & McHugh JJ). Section 50 of the *Civil Liability Act 2002* (NSW) now specifies that a professional meets the standard of care if the 'professional acted in a manner that (at the time the service was provided) was widely accepted in Australia by peer professional opinion as competent professional practice'.

112 Merry & McCall Smith, above n16 at 65.

113 *Id* at 57–58.

114 *Id* at 75; see also nn59–63 and accompanying text.

115 *Id* at 72–97. See also *Iatrogenic Injury in Australia*, above n3, 12–14; *Making Amends*, above n7 at 21–25; Wachter & Shojania, above n2 at 16–249.

The tort of negligence does make allowance for some errors of judgment or mistakes. An error of judgment will not amount to a breach of duty where the error of judgment was compatible with the exercise of reasonable care.¹¹⁶ This will be the case where the error of judgment was the kind that a reasonably skilled professional could have made. This allowance for errors of judgment will not protect health care professionals from findings of breach of duty for errors in the form of slips and lapses.

In theory, then, some mistakes will be permissible. In practice, though, most errors will be viewed as incompatible with the exercise of due care because due care, at the time, would have prevented them. The point is that a reasonably competent person will, *over a period of time*, manifest a lack of care for short spells, simply because it is humanly impossible to satisfy a requirement of full care all the time. But the assessment of such a person will not be based on their record over time but will look at a particular moment.¹¹⁷

The result is that the process of the individuation of events increases the likelihood that errors in the form of slips and lapses will be treated as breaches of the duty of care in negligence.

Imposition of liability for errors in these circumstances has a number of important consequences. It increases the likelihood that health care providers will experience the legal system as arbitrary and capricious. This is because liability will be imposed on professionals for both errors that are an inevitable part of practice as well as for violations of professional standards of conduct.¹¹⁸ The latter category of violations will include circumstances where the defendant does not intend to harm a patient but where that person knowingly fails to comply with a professional standard of conduct, for example, washing hands. For the purposes of determining whether plaintiffs receive compensation the tort of negligence may not distinguish between errors and violations.¹¹⁹

By contrast with the operation of the tort-based system of compensation, regulation designed to improve levels of patient safety has a quite different focus. This form of regulation is multi-dimensional and is concerned with integration of a number of changes in the delivery of health care that together may reduce the level of adverse events. It deals with the occurrence of slips and lapses by building in systems to prevent these slips and lapses causing harm to patients. This means that rather than focusing on an individual health care professional's failure to read a label on a drug, regulation will be concerned with the way in which drugs are labelled, and when and how they are administered.

116 *Whitehouse v Jordan* [1981] 1 All ER 267 at 280–281 (Lord Fraser). See also Merry & McCall Smith above n16 at 172–173.

117 Merry & McCall Smith, above n16 at 173.

118 Merry & McCall Smith state, 'A violation is a deliberate – but not necessarily reprehensible – deviation from those practices appreciated by the individual as being required by regulation, or necessary or advisable to achieve an appropriate objective while maintaining the safety of people and equipment and the ongoing operation of a device or system' Id at 101.

119 Id at 172–175.

There is therefore an important contrast between regulatory initiatives designed to improve patient safety and the operation of the tort-based system of compensation. This contrast suggests that the tort-based system has the effect of inhibiting effective regulation aimed at improving patient safety. It is not only that there is a conflict between an individualistic approach to fault in tort and systemic approach to error in regulation. Rather, the problem is that the law of tort applies individualist notions of fault to the delivery of health care services in a way that makes regulation more difficult. It does so because the determination of fault introduces a level of indeterminacy and arbitrariness into determinations about liability to pay compensation. In this sense, the actual operation of tort law fails to accommodate, enable or facilitate regulation.

D. Outcome Bias

The lack of capacity of the tort-based system of compensation to accommodate regulation is further exacerbated by an important feature of tort law. This feature of tort law is concerned with the way in which courts make a determination about whether a particular act or omission of a defendant amounts to a breach of duty.

In order to determine whether a defendant's act or omission amounts to a breach of duty a court must consider the reasonable person's response to a foreseeable risk of harm. In determining what a defendant should do in response to a foreseeable risk of harm courts apply the 'calculus of negligence'. Section 5B of the *Civil Liability Act 2002* (NSW) states that:

- (1) A person is not negligent in failing to take precautions against a risk of harm unless:
 - (a) the risk was foreseeable (that is, it is a risk of which the person knew or ought to have known), and
 - (b) the risk was not insignificant, and
 - (c) in the circumstances, a reasonable person in the person's position would have taken those precautions.
- (2) In determining whether a reasonable person would have taken precautions against a risk of harm, the court is to consider the following (amongst other relevant things):
 - (a) the probability that the harm would occur if care were not taken,
 - (b) the likely seriousness of the harm,
 - (c) the burden of taking precautions to avoid the risk of harm,
 - (d) the social utility of the activity that creates the risk of harm.

The 'calculus of negligence' requires consideration of the probability of the harm and the seriousness of the harm. In general, the higher the probability of harm occurring and the more serious the harm that may result from a failure to exercise reasonable care, the greater the level of precautions the defendant is required to put in place to prevent the harm.¹²⁰

¹²⁰ *Wyong Shire Council v Shirt* (1980) 146 CLR 40 at 47–48 (Mason J) (statement of calculus of negligence prior to *Civil Liability Act 2002* (NSW)).

One of the most problematic areas for the application of the tort of negligence generally is where there is a low probability that harm will occur, but where the harm in question is very serious. Where the cost of avoidance of harm are very high courts will usually find that the defendant has not been negligent in deciding not to take the precautionary action. An example of such a case is *Romeo v Conservation Commission of the Northern Territory*.¹²¹ The plaintiff in this case fell over a cliff after consuming alcohol at a party held in a National Park near Darwin. The plaintiff suffered a very serious injury in circumstances where the probability of the occurrence of that injury was low. The majority of the court ultimately found that the defendant was not in breach of duty because the precautions to avoid this injury were very expensive, that is, fencing off large amounts of the cliff line.

The position may be different where the precautionary costs of avoiding the serious injury appear to be much smaller in amount. An example of this is the decision of the High Court in *Naxakis v West General Hospital*.¹²² In this case, the plaintiff sustained serious physical and intellectual impairments as the result of a head injury. The issue in this case was whether the defendant hospital, and the doctors for whom it was vicariously liable, should have considered an alternative diagnosis and treatment for an unusual injury sustained by the plaintiff. This case involved the combination of a very serious injury that was very unlikely to occur. The steps taken by those providing medical care seemed, with the benefit of hindsight, to be relatively limited in nature, that is, there was little consideration of an alternative diagnosis of and treatment for the head injury.¹²³

These cases are difficult because the court is required to make an assessment of the precautionary steps which a defendant should take to avoid serious injuries that do not occur very often. This presents a very real difficulty in the health care field because there are a large number of types of injury which are very unlikely to occur and which have serious impacts on patients. One finding of the QAHCS was that only 'one-quarter of all adverse events occur with sufficient frequency to be amenable to prospective tracking, even in large teaching hospitals'.¹²⁴

The large number of low probability adverse events creates real problems for the application of tort-based liability to the delivery of health care services. One possible response to these kinds of injuries is for courts to make findings of negligence in those cases where the injuries are very serious. This may be a source of explanation for the occurrence of 'outcome bias' in the application of tort law. An important follow up study of the Harvard Medical Practice Study found that the most important predictor of the success of the plaintiff's claim was the extent of the plaintiff's injury and not the presence of negligence.¹²⁵ There is a very significant debate about whether tort law does filter out the most meritorious

121 (1998) 192 CLR 431 at 446–447 (Brennan CJ), 454–455 (Toohey & Gummow JJ), 458–459 (Gaudron JJ), 479–482 (Kirby J), 490–491 (Hayne J).

122 (1999) 197 CLR 269. See also *Chappel v Hart* (1998) 195 CLR 232.

123 *Naxakis v West General Hospital* (1999) 197 CLR 269 at 276–277 (Gaudron J), 294–297 (Kirby J), 311 (Callinan J).

124 *Iatrogenic Injury in Australia*, above n3 at 19.

claims for compensation.¹²⁶ However, the presence of a large number of low probability, high impact adverse events in the health care system does suggest that there is an increased likelihood of outcome bias in the determination of compensation claims.

The presence of low probability, high impact adverse events in the health care system makes the application of fault as the criterion for compensation more difficult in the health care system. It makes it more likely that the tort-based system of compensation will produce arbitrary outcomes. This is particularly important because as already noted in this article, the tort-based system of compensation already has a tendency to focus attention on the fault of those delivering services at the sharp end of the health care system.

The difficulties experienced in applying a fault standard in the health care system are evidence of the lack of capacity of tort law to accommodate regulatory changes designed to improve patient safety. It is quite possible to ameliorate some of the adverse impacts of tort law as it applies to the health care system.¹²⁷ However, the amelioration of some of the impacts of the tort-based system of compensation will not significantly increase the capacity of tort law to accommodate regulatory arrangements designed to improve patient safety. The problem with the application of individualised fault from a regulatory perspective is that it inhibits the development of initiatives to improve patient safety. The process of individuation, as part of the process of determining fault, makes it more difficult to develop and implement multi-dimensional regulatory strategies that have the capacity to improve patient safety. The result is that the process of individuation inhibits the emergence of the systemic and organisational capacities that are needed to deliver safe and effective health care services.

One of the important characteristics of an emergent systemic understanding of the health care system is the development of a new understanding of 'personal responsibility'. One of the features of regulatory initiatives to improve patient safety is to shift attention away from the commission of errors in the delivery of health care services towards the creation of practices that prevent the occurrence of harm that may otherwise result from these errors. In this context one of the challenges facing those responsible for the delivery of health care services is the development of a sense of responsibility for making these practices effective in their operation. For example, it may be that health care professionals have to develop a sense of responsibility about their participation in regulatory strategies aimed at improving patient safety, for example, the reporting of adverse events and of near-misses.¹²⁸ The focus on individual fault as a criterion of liability for compensation inhibits the development of this form of personal responsibility for harm.

125 Troyen Brennan, Colin Sox & Helen Burstin, 'Relation Between Negligent Adverse Events and the Outcomes of Medical-Malpractice Litigation' (1996) 335 *New Eng J Med* 1963 at 1963.

126 Studdert, Mello & Brennan, above n6 at 285.

127 AHMAC, *An Integrated Reform Package*, above n7.

128 Braithwaite, Healey & Dwan, above n17 at 33–34.

5. *Regulating Compensation*

The broad argument in this article is that the development of a fair and effective system of compensation for injuries associated with medical error is a regulatory problem. This means that those concerned with introducing regulatory initiatives that are aimed at reducing the level of occurrences of preventable adverse events, or improving the quality of health care, should modify those regulatory frameworks to accommodate a fair and effective system of compensation.

This final part of the article defines the broad outlines of how a regulatory approach to compensation for injuries associated with medical error could possibly function. This part includes an analysis of how regulatory initiatives to reduce the occurrence of preventable adverse events could be modified to accommodate a right to claim compensation for an injury that is associated with the occurrence of such an event. This part is necessarily tentative in its conclusions. It is designed to highlight some of the steps that would be needed to encourage the development of these new systems of compensation. It also sets out to show why those concerned with the delivery of health care services should undertake the arduous and complex task of building rights to compensation into regulatory frameworks that are designed to reduce the level of occurrence of medical error.

Before proceeding to this argument it is necessary to consider an alternative approach. This is a form of no-fault system of compensation which uses the regulatory concept of the 'preventable adverse event' as a trigger for determining when injured patients should receive compensation. In such a system the right claim to compensation arises when the patient's injury is caused by a preventable adverse event. In this system of compensation the occurrence of a preventable adverse event is a form of systemic failure and it is systemic failure that supports the obligation to pay compensation.

The concept of the 'preventable adverse event' is a central feature of regulation that is designed to improve levels of patient safety. The concept of 'preventable adverse event' can be defined as an 'error in management due to the failure to follow accepted practice at an individual or system level'. 'Accepted practice' is then defined as the 'current level of expected performance for the average practitioner or system that manages the condition in question'.¹²⁹ It is the presence of large numbers of preventable adverse events associated with the delivery of health care services that supports the development of regulatory initiatives aimed at improving patient safety.

The centrality of the concept of a preventable adverse event in developing regulation to improve patient safety does not however make it an effective foundation for developing a system of compensation for injuries associated with preventable adverse events. The identification of high levels of preventable adverse events is an indicator of the *potential* impact which regulation can have in improving levels of patient safety. The finding that a class of adverse events is preventable is not based on the existing capacity of the health care system to

¹²⁹ Wilson, Harrison, Gibberd & Hamilton, above n55.

prevent that class of harms. This introduces an important element of indeterminacy into the definition of a 'preventable adverse event'.¹³⁰ This indeterminacy in the definition of a preventable adverse event makes it an unacceptable basis for a system of compensation.

A. No-Fault Schemes of Compensation

There are a number of kinds of no-fault compensation for injuries associated with medical error. One approach is that followed in New Zealand. The *Injury Prevention, Rehabilitation and Compensation Act 2001* (NZ) provides that a person may claim compensation for personal injury where that person has suffered a 'treatment injury'.¹³¹ 'Treatment injury' is defined to include injury caused by 'treatment'.¹³² The effect of the full definition is that a 'treatment injury' can be described as an 'adverse medical event'.¹³³

In considering the coverage of the accident compensation scheme for medically-related injuries, the New Zealand Government specifically rejected a criterion of 'preventability' of medical harm as the basis for recovery of compensation.¹³⁴ There were two reasons given to support the broad operation of this scheme of compensation. The first reason was that the removal of considerations of fault would assist with regulatory initiatives to improve patient safety. Secondly, the broad definition of 'treatment injury' was consistent with the broad right to recover for other kinds of personal injury.¹³⁵ This scheme of compensation is wider than that which operates in Sweden, and for the purposes of the following argument, the criticisms outlined concerning the Swedish system of compensation also apply to the New Zealand system of compensation.

There are a number of Scandinavian jurisdictions which have created an entitlement to claim compensation for those who sustain harm as a result of health care treatment where that harm could have been avoided.¹³⁶ Perhaps the best known of these is the system adopted in Sweden.¹³⁷ This scheme operates in conjunction with remedies available under the civil law.¹³⁸ This scheme is made

130 Brennan, Gawande, Thomas & Studdert, above n42 at 1406.

131 Section 20(2)(b).

132 Id at s32(1)(b).

133 Accident Compensation Corporation, *About the Injury Prevention, Rehabilitation and Compensation Act 2001*: <http://www.acc.co.nz/wcm001/idcplg?IdcService=SS_GET_PAGE&ssDocName=WCM000139&ssSourceNodeId=3860#P89_6378> (4 Mar 2006).

134 *Medical Misadventure Review*, above n12 at 11–12.

135 Id at 7, 12.

136 Accident Compensation Corporation, *ACC Background Paper: Comparison of International Schemes that Compensate for Medical Injury* (2003): <http://www.acc.co.nz/wcm001/groups/external_claims_care/documents/internet/wcmz002318.pdf> (6 Mar 2006) (hereafter *ACC Background Paper*).

137 This scheme is administered under the *Patient Injury Act 1997*. See generally Carl Espersson, *The Patient Injury Act: A Comment* (2000): <http://www.lof-forsakring.com/documents/otherlang/pat_inj_com.pdf> (6 Mar 2006). See also The Scottish Parliament, *The Macfarlane Trust and No-Fault Compensation* (2001) <http://www.scottish.parliament.uk/business/research/pdf_res_notes/m01-80.pdf> (6 March 2006) (hereafter *The Macfarlane Trust and No-Fault Compensation*).

up of two components. One component imposes an obligation on all health care providers to purchase patient insurance.¹³⁹ The second component gives those who have sustained a 'patient injury' the right to recover compensation.¹⁴⁰

Section 6 of the *Patient Injury Act* defines 'patient injury' with reference to six categories of injury. The first category is 'treatment injury'. A treatment injury includes an injury caused by treatment provided that the injury:

- Could have been avoided by a different manner of performing the procedure in question, or
- By the choice of some other available procedure that could have satisfied the medical requirements in a less risky manner.¹⁴¹

The standard of care in determining whether an injury is avoidable is based either on the experienced general practitioner or experienced specialist in the field concerned. The assessment of whether an injury was avoidable is made with reference to the information available at the end of the procedure and not on the information available to the practitioner at the time of giving the treatment.¹⁴²

The focus on whether the adverse event which produced the injury was avoidable or preventable transforms the entitlement to compensation from a fault-based inquiry to one that is based on a test of whether the injury could have been avoided either by the provision of the treatment in a different way or by the use of a different treatment. There is no longer any concern with the question of whether individual health care professionals acted with reasonable care in the provision of treatment or in the diagnosis of an injury. Rather, the question is whether there were steps which could hypothetically have been taken to prevent the occurrence of the adverse event, and the subsequent injury to the patient.¹⁴³

The process for deciding upon claims for compensation for injury associated with adverse preventable events is an administrative process. In Sweden, the first point of determination is made by the insurer who provides insurance for the health care provider. Patients who are dissatisfied with the decision of the insurer have a choice of having the decision reviewed by the Patient Claims Panel or proceeding to a court of general jurisdiction.¹⁴⁴ The administrative process of determination is a crucial element of the scheme because the basis for determination lies in an analysis of the appropriateness of the treatment or the avoidability of the adverse event. These are matters of expert opinion. They appear to involve the kinds of decisions made by those investigators attached to the Quality of Australian Health Care Study which decided whether an adverse event was a preventable adverse event.¹⁴⁵

138 Espersson, above n137 at 8.

139 Id at 4.

140 Id at 4-6.

141 Id at 5.

142 *ACC Background Paper*, above n136 at 16.

143 *The Macfarlane Trust and No-Fault Compensation*, above n137 at 9.

144 Espersson, above n137 at 8-9.

145 Wilson, Harrison, Gibberd & Hamilton, above n55.

There are two important qualifications that are relevant in considering the operation of the Swedish scheme of compensation for avoidable patient injuries. The first qualification is that although the definition of 'patient injury' appears to be vague, those responsible for assessing claims for compensation 'assert that it has been possible to demarcate the complications that should reasonably be indemnified and those that, because they are unavoidable consequences of a disease or its necessary treatment, should not be indemnified'.¹⁴⁶ The second qualification is that the Swedish scheme of compensation is structured around the broader set of entitlements to social security. Access to the scheme is only available when other remedies and entitlements have been exhausted.¹⁴⁷ It has been suggested that the relatively low cost of the scheme in Sweden is founded in part on the generous levels of social security available to all Swedish citizens.¹⁴⁸

A recent review of the proposals for reforming the approach to clinical negligence in the National Health System in the United Kingdom recommended against the adoption of a no-fault scheme based on the Swedish model.¹⁴⁹ The predominant reason that this report, entitled *Making Amends*, gave for the rejection of this option was the cost of such a scheme. The estimated cost of a no-fault scheme based on the preventability of injuries associated with adverse events was significantly larger than the negligence-based system of compensation. The cost of a scheme of compensation using 'preventability' as a criterion for determining a right to claim compensation was based on a number of assumptions about the number of claims made, the amount of the benefits available, and the costs of administration. The estimates for the cost of this scheme of compensation range from a figure of two and a half times the current costs of compensation up to a figure of four to five times the cost of the current system.¹⁵⁰ The main ground for rejecting this scheme of compensation was a simple one. It was that the money expended on compensation reduced the amount available to provide health care services.¹⁵¹

There are some who challenge the validity of the cost estimates used in the *Making Amends* report.¹⁵² However the extent of the costs associated with a Swedish-type scheme based on the preventability of adverse events causing injuries does highlight one major problem with this scheme. The Swedish compensation scheme appears to base entitlement on whether or not the adverse event was preventable.¹⁵³ This was the methodology used in the Quality in Australian Health Care Study for determining whether adverse events were

146 Studdert, et al, above n11 at 7.

147 Carl Espersson, *The Swedish Patient Injury Act* (2005): <http://cgood.org/assets/attachments/Carl_Espersson_USA.pdf> AT 9 (6 Mar 2006).

148 Paul Fenn, Alastair Gray & Neil Rickman, 'The Economics of Clinical Negligence Reform in England' (2004) 114 *Economic Journal* F272 at F286–F287.

149 *Making Amends*, above n7 at 112–113.

150 Fenn, Gray & Rickman, above n148 at F288–F289. See also *Making Amends*, above n7 at 110–112; Studdert, et al, above n17 at 29–30 (cost of compensating '[a]ll Swedish compensable events in Utah and Colorado in 1992' was approximately 50 per cent greater than for negligent events).

151 *Making Amends*, above n7 at 111.

preventable.¹⁵⁴ A finding that an adverse event is preventable is quite different to a finding that the health care system, or its constituent elements, had the existing capacity to prevent the particular adverse event.

The distinction between a preventable adverse event, that is, an adverse event that could be prevented with the introduction of appropriate prevention strategies, and one where there is a presently existing capacity to reduce the likelihood of occurrence of that adverse event is a fundamental one in the creation of a scheme of compensation. A system of compensation for injuries associated with preventable adverse events will compensate patients whether or not the health care system had the presently existing capacity to introduce the necessary prevention strategies. This is important because the decision to introduce such strategies will often involve the commitment of a significant level of resources which are scarce, both in terms of the direct costs and in the limited human resources to manage the introduction of such changes. The decision as to when and how to implement prevention strategies will involve decisions about the use of these scarce resources.

In this sense, a scheme of compensation based on injuries associated with preventable adverse events may compensate patients where policy makers within the health care system have decided not to introduce prevention strategies. This may be because of the cost, or because of the lack of human or organisational resources to immediately introduce those strategies. The effect is to decouple the linkage between the health care system's existing capacity to reduce the level of preventable adverse events and the payment of compensation. Decoupling this linkage may have the effect of limiting the capacity of the scheme of compensation to facilitate the introduction of effective strategies to reduce the level of preventable events. It may also mean that funds that would be otherwise available for the delivery of health care services are used to pay compensation.¹⁵⁵

In a tort-based system of compensation, there is no liability where decision-makers make 'policy' decisions that involve allocation of resources.¹⁵⁶ One rationale for this rule is that the concept of 'fault' is not amenable to decisions that involve political decisions about allocation of resources in the community. A no-fault scheme based on compensation for injuries associated with the preventable adverse events is not based on individual fault or any notion of organisational or systemic responsibility. It is founded only on a notional capacity to prevent the harm. The creation of a *right* to claim compensation for injuries associated with all

152 Harold Luntz, 'Medical Treatment No-Fault' (2004) <<http://www.ucc.ie/law/odg/home.htm>>, (6 March 2006). Professor Luntz noted that the changes proposed in broadening the right to cover in New Zealand were expected to be modest. See *Medical Misadventure Review*, above n12 at 18–19. It is not clear however that the costs relating to compensation for treatment injury in New Zealand should be used as a guide to the costs of such a scheme in United Kingdom or Australia. The New Zealand accident compensation scheme, like the Swedish compensation scheme, operates in institutional and financial environments that are very different to those that exist in the United Kingdom or in Australia.

153 This appears to be the approach taken by Fenn, Gray & Rickman, above n148 at F287–F290.

154 Wilson, Harrison, Gibberd & Hamilton, above n55.

155 *Making Amends*, above n7 at 111–113.

156 See above nn104–107 and accompanying text.

preventable adverse events creates an obligation to *pay* compensation even where there are policy decisions that particular prevention strategies cannot be introduced at the time of the injury.

The decoupling of the linkage between organisational capacity to reduce the level of preventable adverse events and the payment of compensation is an important limit on the capacity of these no-fault schemes to accommodate, enable and facilitate regulation aimed at improving patient safety. As others have argued, it is possible to reduce the impact of the cost of these no-fault compensation schemes by reducing or capping damages.¹⁵⁷ However, the primary effect of the use of avoidability or preventability of harm as a criterion of liability, is to broaden the entitlement to claim compensation. The following section argues that it is preferable to have a narrower set of entitlements as a way of ensuring that the cost of a compensation scheme does not significantly reduce the level of funding available to support the delivery of health care services.

B. Systemic Responsibility for Error

The argument in this article is that a right to compensation should be built into regulatory initiatives that are designed to reduce the occurrence of particular categories of preventable adverse events. One way of achieving this goal is to attach a right to claim compensation to any set of regulatory initiatives that are designed to reduce the level of occurrence of a particular class or kind of adverse event. When a health care institution makes a decision about the appropriate level of safety that it is prepared to accept, it is fair and reasonable that it bear the cost of the preventable adverse events which continue to occur.¹⁵⁸ In this way the institution accepts responsibility for the continuing occurrence of preventable adverse events by being required to bear the costs of harm that are associated with those injuries. The payment of compensation is in this sense an integral part of the decision about the level of investment required to improve levels of patient safety. This form of compensation is a form of enterprise liability rather than a no-fault scheme of compensation.

When a health care institution makes a decision about the appropriate level of investment needed to improve safety in relation to the occurrence of a particular class of preventable adverse events, it is unlikely that the result of these regulatory initiatives will be to reduce to zero the level of this class of adverse event. A finding that an adverse event is 'preventable' involves a finding that:

When describing [adverse events], *preventability* refers to the identification of an avoidable error that led to the adverse event. This is not to say that the error could be avoided on every occasion, and that the adverse event would not occur. Rather,

¹⁵⁷ Studdert, et al, above n11 at 31–32.

¹⁵⁸ See, for example, *E v Australian Red Cross Society* (1991) 27 FCR 310 at 380–381 (Wilcox J) (the community should recognise an obligation to provide recompense where the 'applicant bears the burden of the protecting the wider public interest' in the sense that the applicant was exposed to a risk of harm because the continued availability of the service that produced the risk of harm was in the public interest).

it implies that, with the current state of knowledge and technology, it is possible to identify and avoid that particular error, and hence reduce the probability of an [adverse event].¹⁵⁹

Initiatives that are designed to improve patient safety therefore have the goal of reducing the probability of the occurrence of adverse events. Thus, a decision by a health care authority to introduce particular strategies designed to improve patient safety, will mean that there will be a reduced probability that those particular adverse events will occur.

The institution responsible for the delivery of health care is required to make a decision about how much to invest in regulation designed to improve patient safety. This decision involves consideration of the cost of any investments in patient safety and the reduction in the probability of the adverse event after that investment. A health care institution could reasonably decide not to reduce the level of preventable adverse events to the lowest possible level because the size of the investment would be too great after taking into account the consequent improvements in safety. If an institution responsible spends too much on improvements in safety and quality, this may potentially have the effect of increasing the costs of the service, with the effect that the availability of those services would be reduced. This would mean that some patients would not get the benefit of those services.

A right to claim compensation would therefore arise where two overarching conditions had been met. Firstly, that the institution responsible for delivering the health service had already ascertained that the particular adverse event was 'preventable'. Secondly, that compensation would only be payable where the institution responsible for delivering the particular service had in place mechanisms that were designed to reduce the probability of that particular class of adverse events. This means that in determining whether a person had a right to claim compensation, it would not be necessary for an independent body, such as a court or tribunal, to determine whether a particular adverse event was preventable. The court or tribunal would simply have to determine whether the claimant's injury was causally related to the occurrence of the relevant adverse event. It would be the responsibility of the health care institution to decide upon the particular classes of preventable adverse events that would be amenable to regulatory strategies aimed at improving patient safety.

This proposal for developing a system of compensation from injuries associated with medical error would have the following components:

- It would be incremental in the sense that particular health care authorities would be given the capacity to experiment with enterprise liability or no-fault schemes that are integrated into regulatory frameworks that are designed to improve patient safety.¹⁶⁰
- It would operate by way of exclusion from the existing tort-based scheme of compensation, that is, tort law would continue to operate until a recognised

¹⁵⁹ Wilson, Harrison, Gibberd & Hamilton, above n55 at 411.

scheme of compensation excluded it. One of the advantages for developing this form of enterprise liability is that it would allow that institution to remove itself from the tort-based scheme of compensation in relation to those particular classes of preventable adverse events.

- It would build upon existing regulatory initiatives that are designed to improve patient safety, for example, the Australian Council for Safety and Quality in Health Care, *Open Disclosure Standard*.¹⁶¹ This Standard aims to facilitate open communication between health care professionals, patients and their support persons, managers and staff, generally following an adverse event.
- It would require the development of incentives to encourage institutions responsible for delivering health care to integrate compensation rights into regulatory frameworks designed to improve patient safety.
- This scheme of compensation would need enabling legislation to support its operation. This would include guidelines that would set out the basic elements of an acceptable system of compensation. Compliance with these guidelines would be the basis for excluding the operation of tort-based compensation. These guidelines would include matters concerning the amounts of compensation that would be paid to patients, the process for claiming compensation and review of decisions concerning the payment of compensation.
- There would need to be legislation to set up a funding structure to support the system of compensation. It is likely that payment for the scheme would be by way of the institutions responsible for controlling and regulating the delivery of health care services. This is consistent with the proposed system of compensation being a form of enterprise liability.

6. Conclusion

The broad aim of this article is to make a contribution to the debate about the appropriate form of compensation for injuries associated with medical error. The main point of this argument is that it is possible and desirable to integrate systems of compensation with systems of regulation. A failure to integrate the right to claim compensation into systems of regulation will inhibit the development of regulatory initiatives that are designed to improve patient safety. More importantly, the integration of compensation and regulation can produce a fair and effective system of compensation that facilitates, enables and supports regulation aimed at improving patient safety.

160 David Studdert & Troyen Brennan, 'No-Fault Compensation for Medical Injuries: The Prospect for Error Prevention' (2001) 286 *JAMA* 217 at 222 (the authors argue against a rapid shift to a no-fault model of compensation and instead suggest that governments enable selected organisations to experiment with no-fault schemes and enterprise liability).

161 *Open Disclosure Standard*, above n79.

This article aims to make this argument by setting out a different framework for considering proposals for reform of compensation for injuries associated with medical error. The first step in developing this argument was a negative one. It involved showing that tort law could not accommodate changes in the regulatory systems that are aimed at improving patient safety. The effect of this was to suggest that common law, fault-based systems of compensation continue to operate not because they are either fair or effective but because of the lack of any clear alternatives.

The second step is a more positive one. The final part of the article argues that it is possible to develop a system of compensation for injuries associated with medical error that is fair and just. The proposed approach to developing a new system of compensation eschews the use of broadly defined no-fault schemes of compensation. The main reason for this is that these broadly based no-fault schemes of compensation will have similar difficulties in accommodating regulatory frameworks designed to improve patient safety. The proposed model of compensation is therefore based upon the idea that institutions in the health care system should be encouraged to experiment with integrating rights-to-claim compensation with particular regulatory strategies aimed at improving patient safety.

The proposed model of compensation is a form of enterprise liability. It is the liability of institutions to regulate and control health care, for the occurrence of particular classes of preventable adverse events, where those institutions have in place regulatory frameworks that are designed to reduce the level of those particular classes of adverse events. The entitlement to compensation arises where a patient sustains an injury as a result of the occurrence of a preventable adverse event where there are strategies in place to reduce the probability of occurrence of that particular category of adverse event. The tentative proposal includes a broad analysis of the administrative and legislative arrangements needed to support it. These arrangements form part of the process by which arrangements for the payment of compensation can be integrated into regulatory frameworks that are designed to improve patient safety.