



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

**Patient Safety and the Law:
A Multi-Jurisdictional Comparative
Assessment of Strategies to Reduce Medical
Error and Improve Patient Safety**

**Michelle Katherine Marie Buddecke
B.C.L., LL.M., Barrister-at-Law**

**A thesis submitted to the
School of Law
University of Dublin, Trinity College
for the degree of Doctor of Philosophy**

July 2017

Supervisor: Dr. Desmond Ryan LL.B., B.C.L., M.A., Ph.D., Barrister-at-Law

Declaration

I declare that this thesis has not been submitted as an exercise for a degree at this or any other university and it is entirely my own work.

I agree to deposit this thesis in the University's open access institutional repository or allow the Library to do so on my behalf, subject to Irish Copyright Legislation and Trinity College Library conditions of use and acknowledgement.

A handwritten signature in black ink, appearing to read 'Michelle Buddecke', written in a cursive style.

Michelle Buddecke
July 2017

Summary

In 1999, the Institute of Medicine released their landmark report *To Err is Human: Building a Safer Health System*. The report drew wide-spread attention to the unacceptable number of adverse events occurring within the American healthcare system, the fundamental role of systemic error and healthcare culture in the causation of these events, and the necessity for prevention over deterrence. The philosophy ‘To Err is Human’ has become the foundation on which the ‘The Patient Safety Movement’ is based. To date, patient safety methodology has concentrated primarily on cultural change and accountability; incident reporting and analysis; reformed education standards; improved communication, teamwork, and consensus building; patient and family engagement, and patient and family-centred care; the use of evidence-based practices; and system redesign. All of these strategies, born of out the patient safety movement, will be examined in significant depth throughout this thesis in the context of medical error reduction. In contrast, legal strategies to prevent and respond to medical error (operating in tandem with the above) have traditionally been adversarial in nature, based primarily on the principles of deterrence and retribution, and enforced by way of civil and criminal legislation and jurisprudence. While the analysis within this thesis is strongly premised on the argument that the threat of legal, financial, or disciplinary penalties on their own are ineffective at furthering patient safety, this should not be taken as negating the role for both civil litigation and criminal prosecution when an individual or organisation has been negligent, reckless, or acted intentionally—these legal avenues undoubtably remain necessary for fostering safety and promoting accountability. For the purposes of scoping, this thesis is predominantly concerned with the interaction between patient safety methodology and the civil law, and accordingly, will focus on legislative and organisational reform intended to reduce the secrecy and fear associated with medical error common within healthcare culture. Contemporary legislative and organisational initiatives within the patient safety agenda to improve safety and reform culture have been directed primarily towards enabling the flow of communication between healthcare professionals, organisations, regulators, and patients. In particular, the use of alternative dispute resolution to reduce the length and cost of potential medical malpractice claims, as well as limiting

liability from the disclosure of an incident or offering of an apology. While attempts to reform healthcare culture and implement the aforementioned strategies has consequently given way to the larger discussion of the appropriate role and application of accountability in healthcare—a challenge that will be examined at great length throughout this thesis in reference to a ‘just culture’—patient safety theory continues to be fundamental in moving the conversation away from deterrence and towards prevention.

The question that guides this thesis is: *‘An assessment of strategies which, operating in tandem with medical malpractice actions, will improve patient safety (and based on comparative analysis of how these strategies have worked in different jurisdictions.)’* Using a literature review and analysis methodology, and concentrating primarily on the healthcare and legal systems of the United States, England, Canada, Ireland, and New Zealand—the theoretical framework of this thesis is based on two intrinsically connected themes: an assessment of strategies for reducing medical error based on patient safety methodology, and second, the role of medical malpractice law and litigation in the reduction and mitigation of medical error. In this respect, this thesis does not focus its attention on how patient safety methodology fits into the legal structure, but rather how the current and proposed legal mechanisms fit within and further patient safety. Additionally, this thesis advocates the view that above all other strategies for the reduction of medical error, those which improve healthcare communication are paramount. As a contribution to the growing body of patient safety literature, my analysis will assess the aforementioned multi-disciplinary strategies for improving patient safety, and will demonstrate that the adoption of strategies that address healthcare culture and communication by way of legislative and organisational reform are the most effective mechanism by which to reduce medical error because they are uniquely capable of bridging the dichotomy between the collaborative ideals of the patient safety movement and the inherently adversarial nature of the legal system.

Acknowledgments:

I am immensely grateful to my supervisor, Dr. Des Ryan, for his support, patience, encouragement, and advice.

I am also grateful to Prof. Neville Cox of the School of Law, Trinity College Dublin, and Prof. Deirdre Madden of the School of Law, University College Cork for their invaluable recommendations during the examination process.

My sincerest appreciation goes to the School of Law, Trinity College Dublin for accepting me amongst their prestigious list of PhD candidates, and for the opportunity to research a field I am truly passionate about.

Lastly, I would like to thank the College of Medicine and the College of Law at the University of Saskatchewan for allowing me to use their research facilities while I was visiting Canada.

This thesis is dedicated to my Mum,

Judith Buddecke RN

Table of Contents

Summary	iii
Chapter 1: Introduction	1

The Legal System and Medical Error

Chapter 2: The Role of Medical Malpractice Law and Litigation in the Reduction of Medical Error	24
--	----

Claims of the Patient Safety Movement

Chapter 3: The Origins of the Patient Safety Movement	52
Chapter 4: Healthcare Culture and Accountability	67
Chapter 5: Human Factors vs The System	128
Chapter 6: The Nature of Medical Error	148

Alternative Strategies for Improving Patient Safety (Working in Tandem with Medical Malpractice Litigation) by Removing Systemic Error in Order to Prevent Error

Chapter 7: Safety Interventions: Preventing Patient Safety Incidents and Medical Error	168
Chapter 8: Case Study: Resident Duty Hours	207

Alternative Strategies for Improving Patient Safety (Working in Tandem with Medical Malpractice Litigation) by Removing Systemic Error in Order to Respond Error

Chapter 9: Incident Reporting and Analysis	235
Chapter 10: Communication: Bridging the Patient-Physician Relationship	265
Chapter 11: Communication: Disclosure and Apology	288
Chapter 12: Alternative Dispute Resolution in Healthcare	340
Chapter 13: Conclusion	388
Bibliography	415

Detailed Table of Contents

Summary iii

Chapter 1: Introduction

1.1 Overview and Statement of the Problem 1
1.2 Methodology 6
1.3 Core Concepts and Terminology 8
1.4 Summary of the Chapters 10

Chapter 2: The Role of Medical Malpractice Law and Litigation in the Reduction of Medical Error

2.1 Introduction 24
2.2 Components and Objectives of Medical Negligence Law 27
2.3 The Effect of Medical Malpractice Litigation on Patients and
Healthcare Professionals 31
2.4 The Role of Medical Malpractice Law and Litigation in the
Reduction of Medical Error 35
2.5 The Role of the Criminal Law Following Medical Error 47
2.6 Conclusion 50

Chapter 3: The Origins of the Patient Safety Movement

3.1 Introduction 52
3.2 The United States 52
3.3 England 56
3.4 Canada 58
3.5 Ireland 60
3.6 The World Health Organization 62
3.7 Conclusion 65

Chapter 4: Healthcare Culture and Accountability

4.1 Introduction 67
4.2 Healthcare and the Culture of Blame 68

4.3 A Just Culture	77
4.4 Accountability in a Just Culture	95
4.4.1 Clinical Governance, Risk Management, and Audit	96
4.4.2 Organisational and Professional Regulation	106
4.4.3 Necessity of Civil Litigation in the Accountability Process	115
4.5 Conclusion	124

Chapter 5: Human Factors vs The System

5.1 Introduction	128
5.2 Human Factors vs The System	129
5.3 Reason’s “Swiss Cheese” Model	137
5.4 Conclusion	146

Chapter 6: The Nature of Medical Error

6.1 Introduction	148
6.2 Identifying Medical Error	149
6.2.1 Active Failure and the Sharp End	150
6.2.2 Latent Failure and the Blunt End	154
6.3 Causes of Medical Error	155
6.3.1 Work Environment Factors	155
6.3.2 Individual Factors	159
6.3.3 Social and Organisational Factors	163
6.4 Conclusion	166

Chapter 7: Safety Interventions: Preventing Patient Safety Incidents and Medical Error

7.1 Introduction	168
7.2 Safety Interventions	170
7.2.1 Interventions Around the Patient	171
7.2.2 Interventions Around the Caregiver	180
7.2.3 Interventions Around the Workplace and System	189
7.3 Intervening on Adverse Drug Events	197
7.4 Conclusion	205

Chapter 8: Case Study: Resident Duty Hours

8.1 Introduction	207
8.2 The United States	209
8.3 Canada	219
8.4 The European Working Time Directive	223
8.5 Impact of the Resident Duty Hour Restrictions	225
8.6 Conclusion	232

Chapter 9: Incident Reporting and Analysis

9.1 Introduction	235
9.2 Key Elements of Incident Reporting Systems	237
9.3 Incident Analysis	252
9.4 Barriers to Incident Reporting	256
9.5 Conclusion	262

Chapter 10: Communication: Bridging the Patient-Physician Relationship

10.1 Introduction	265
10.2 Communication in the Wake of Medical Error	266
10.3 The Psychological Consequences of Medical Error and Disclosure	271
10.4 Constructive Communication	274
10.5 Communication Programs	279
10.6 Internal Dispute Resolution	282
10.7 Conclusion	285

Chapter 11: Communication: Disclosure and Apology

11.1 Introduction	288
11.2 The Obligation to Disclose: An Ethical and Legal Duty	289
11.3 Barriers to Disclosure	298
11.4 Procedure	309
11.5 The Decision to Apologise	323
11.6 Communication and Disclosure Programs	330
11.7 Conclusion	335

Chapter 12: Alternative Dispute Resolution in Healthcare

12.1 Introduction 340

12.2 Analysis of Alternative Dispute Resolution in Healthcare 342

12.3 Healthcare Mediation 349

 12.3.1 Types of Mediation 351

 12.3.2 Evaluation of the Mediation Process 364

 12.3.3 Mandatory Mediation 371

12.4 Conclusion 385

Chapter 13: Conclusion

13.1 Summary of Chapters 388

13.2 Dissonance Between Patient Safety and Medical Malpractice Litigation ... 395

13.3 The Law in a Just Culture 404

13.4 Reducing the Barriers to Healthcare Communication 407

Bibliography 415

- Chapter 1 -

Introduction

1.1 Overview and Statement of the Problem

In 1999, the Institute of Medicine released their landmark report *To Err is Human: Building a Safer Health System*.¹ The report drew widespread attention to the unacceptable number of preventable adverse events occurring within the American healthcare system; estimating that as many as 98,000 patients die every year from medical error in an acute care setting. Although this aspect of the report garnered the most publicity, it was the IOM's emphasis on the role of complex system factors and healthcare culture in the causation of adverse events that has been most influential for quality and safety reform. As Dr. Lucian Leape, a pioneer of the patient safety movement and co-author of *To Err is Human*, wrote in his 1998 article 'Promoting Patient Safety by Preventing Medical Error':

“As a culture we continue to rely primarily on the threat of legal, financial, or disciplinary penalties to ensure patient safety, operating on the assumption that most patient injuries are the result of bad behavior, eg, incompetence, negligence, or corporate greed. This deterrent approach to safety, and the extensive legal and regulatory structures that support it, has had limited impact on reducing patient injuries. It is now clear that an additional approach is needed that continues to hold health care providers accountable, but moves beyond blame in investigating why health care accidents happen and how the risks of future accidents can

¹ Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999).

be best identified.”²

It is this philosophy that has guided the development of the patient safety movement and is the foundation on which this thesis is based. The World Health Organization have defined ‘Patient Safety’ as:

“... a fundamental principle of patient care and a critical component of quality management. Its improvement demands a complex system-wide effort, involving a wide range of actions in performance improvement, environmental safety and risk management.... It embraces nearly all health care disciplines and actors, and thus requires a comprehensive multifaceted approach to identifying and managing actual and potential risks to patient safety in individual services and finding broad long-term solutions for the system as a whole.”³

To date, research in the field of patient safety has concentrated primarily on cultural change and accountability; incident reporting and analysis; reformed educational requirements; improved communication, teamwork and consensus building; patient and family engagement, and patient and family-centred care; the use of evidence-based practices; and system redesign.⁴ All of these strategies, born of out the patient safety movement, will be examined in significant depth throughout this thesis in the context of medical error reduction.

² L Leape et al., ‘Promoting Patient Safety by Preventing Medical Error’ (1998) 280(16) JAMA 1444-1445.

³ World Health Organization (Report by the Secretariat), *Quality of Care: Patient Safety* (23 March 2002) A55/13. [10].

⁴ C Sammer et al., ‘What is Patient Safety Culture? A Review of the Literature’ (2010) 42(2) Journal of Nursing Scholarship 156, 157-163; V Roberts and M Perryman, ‘Creating a Culture for Health Care Quality and Safety’ (2007) 26(2) Health Care Manager 155; J Scott-Cawiezell et al., ‘Moving From a Culture of Blame to a Culture of Safety in a Nursing Home Setting’ (2006) 41(3) Nursing Forum 133. The development of the patient safety movement is examined in greater detail within Chapter 3 ‘The Origins of the Patient Safety Movement.’

In contrast, legal strategies to prevent and respond to medical error (operating in tandem with the above) have traditionally been adversarial in nature, based primarily on the principles of deterrence and retribution, and enforced by way of civil and criminal legislation and jurisprudence. However, as Leape argued above, the threat of censure, blame, and liability have had a limited impact on reducing the occurrence of healthcare harm. The adversarial nature of the civil law's deterrent approach has largely contributed to the so-called 'culture of blame' within healthcare, which has had two significant repercussions limiting quality and safety improvement: first, the fear of unjust censure inhibits effective communication between healthcare professionals and their patients. Second, it inhibits effective communication between healthcare professionals, the organisation, and regulators—thereby limiting the opportunity to learn, mitigate and prevent reoccurrence. As healthcare disputes are inevitable, from a patient safety perspective, incorporating the use of legal mechanisms that aid—rather than obstruct—safety and quality initiatives is fundamental.

This thesis advocates the view that above all other strategies for the reduction of medical error, those which improve healthcare communication are paramount. The consequences of poor communication have been well-documented. For example, the breakdown of communication was reported by the Joint Commission to be the second leading root cause of sentinel events (those involving serious disability or death) in the United States in 2013.⁵ Similarly, in Australia, communication issues were found to be a contributing factor in nearly twice as many preventable adverse events as compared to the inadequate skill level of the clinicians involved.⁶ The adoption of strategies that improve healthcare communication by way of legislative and organisational reform are

⁵ Joint Commission, 'Seminal Event Data: Root Causes by Event Type 2004-2Q 2014.' (The Joint Commission, 30 September 2014) <http://www.jointcommission.org/assets/1/18/Root_Causes_by_Event_Type_2004-2Q_2014.pdf> accessed: 18 December 2014. The Joint Commission define a seminal event as a Patient Safety Event resulting in death, permanent harm or severe temporary harm and intervention required to sustain life. See further: Joint Commission, '*Seminal Event Policy and Procedures*' (The Joint Commission, 19 November 2014) <http://www.jointcommission.org/Sentinel_Event_Policy_and_Procedures/> accessed: 18 December 2014.

⁶ C Zinn, '14,000 Preventable Deaths in Australia' (1995) 310 BMJ 1487.

the most effective mechanism by which to reduce medical error because they are uniquely capable of bridging the dichotomy between the collaborative ideals of the patient safety movement and the inherently adversarial nature of the legal system. Implementing these legislative and organisational reforms to improve communication cannot be done in isolation however. Cultural change is equally fundamental, and as such, significant consideration will be given throughout this thesis to the implementation of a 'just culture' and the role of accountability. When an incident occurs, a just culture requires that healthcare professionals and organisations are held accountable for mitigating, learning from, and preventing the system and human failures that caused its occurrence. This includes holding healthcare professionals and organisations accountable to the standards set out by their professional bodies, legislation, and jurisprudence (i.e. the standard of care). Deconstructing this point further, Bismark and al., have categorised healthcare accountability into four categories: communication (i.e. requiring an explanation, an apology or expression of responsibility); correction (i.e. competence review, system change); restoration (i.e. compensation, intervention); and sanction (i.e. professional discipline, other punitive measures).⁷ Each of these categories will be examined in greater depth throughout this thesis when assessing strategies which, operating in tandem with medical malpractice actions, will improve patient safety. Additionally, the role of accountability structures in the the proactive management and reduction of error will also be discussed. While attempts to implement cultural change have consequently given way to the larger discussion of the appropriate role and application of accountability in healthcare, early patient safety theory was fundamental in moving the conversation away from deterrence and towards prevention. The challenge for contemporary patient safety methodology going forward is to ensure that the accountability systems implemented have enforceable consequences, and that those consequences contribute to prevention and safety improvement, not punishment and fear.

⁷ M Bismark et al., 'Accountability Sought by Patients Following Adverse Events from Medical Care: The New Zealand Experience' (2006) 175(8) Canadian Medical Association Journal 889.

While the analysis within this thesis is strongly premised on the argument that the threat of legal, financial, or disciplinary penalties on their own are ineffective at furthering patient safety, this should not be taken as negating the role for both civil litigation and criminal prosecution when an individual or organisation has been negligent, reckless, or acted intentionally--these legal avenues undoubtedly remain necessary for fostering safety and accountability. For the purposes of scoping, this thesis is primarily concerned with the interaction between patient safety methodology and the civil law, accordingly, I have chosen to focus on legislative and organisational reform intended to reduce the secrecy and fear associated with healthcare culture. Contemporary legislative and organisational initiatives within the patient safety agenda to improve safety and reform culture have been directed primarily towards enabling the flow of communication between healthcare professionals, organisations, regulators, and patients. Specifically, the use of alternative dispute resolution to reduce the length and cost of potential medical malpractice claims, as well as limiting liability from the disclosure of an incident or offering of an apology will all be examined.⁸ To date, the literature has predominantly focused on their ability to reduce liability. While progressive in their acknowledgement that physicians and organisations have both a legal and ethical duty to disclose preventable incidents to their patients, disclosure and apology laws have thus far been inconsistent in their application, subject to jurisdictional limitations, and focused predominantly on liability reduction as opposed to quality and safety improvement or cultural change. Similarly, the voluntary nature of mediation process and the prioritization of compensation have equally limited its use and effectiveness.

Research Question

The question that guides this thesis is: *'An assessment of strategies which, operating in tandem with medical malpractice actions, will improve patient safety (and based on*

⁸ T Gallagher et al., 'Disclosing Harmful Medical Errors to Patients: Current Concepts' (2007) 356 NEJM 2713; K Sack, 'Doctors Say "I'm Sorry" Before "See You in Court"' *New York Times* (New York, 18 May 2008) <<http://www.nytimes.com/2008/05/18/us/18apology.html?fta=y>>.

comparative analysis of how these strategies have worked in different jurisdictions.) The theoretical framework of this thesis is based on two intrinsically connected themes: an assessment of strategies for reducing medical error based on patient safety methodology, and second, the role of medical malpractice law and litigation in the reduction and mitigation of medical error. In this respect, this thesis does not focus its attention on how patient safety methodology fits into the legal structure, but rather how the current and proposed legal mechanisms fit within and further patient safety. For this reason, chapter 2 will extensively examine the role and purpose of medical malpractice actions as they relate to medical error; chapters 3 - 6 will examine the claims of the patient safety movement and corresponding methodology; chapters 7 and 8 will consider alternative strategies for improving patient safety (which work in tandem with medical malpractice litigation) designed to remove systemic error in order to *prevent* error; and lastly, chapters 9 - 12 will similarly consider alternative strategies for improving patient safety (which work in tandem with medical malpractice litigation) designed to remove systemic error in order to *respond* to error.

1.2 Methodology

After writing my LLM thesis on defensive practice in the context of the compensation culture, I concluded that the most efficient way to reduce the so-called 'litigation crisis' was by preventing healthcare harm in the first place—by employing the practices of the patient safety movement.⁹ Quantitative research within the field of patient safety has increased significantly since the publication of *To Err is Human*;¹⁰ with the majority of research to date focusing on specific clinical quality and safety interventions, and their potential to improve patient outcomes. My research on the relationship between patient safety and legal reforms will provide a contribution to the literature by analysing legal strategies in the context of quality and safety improvement, as distinct

⁹ M Buddecke, 'Defensive Medicine and Obstetrics' (LLM Thesis, University College Cork, 2009).

¹⁰ Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999).

to malpractice reform and liability reduction. On this point, it is important to note at the onset that while this thesis is written with a focus towards medical error reduction, the broader objective of quality and safety improvement is often cited as well. This is because medical error reduction is intrinsic to this broader agenda and the recommendations made throughout are equally applicable.

My research has been conducted based on a literature review and analysis methodology; incorporating academic, conceptual, and empirical research. I have concentrated primarily on the acute care systems, legislation, and jurisprudence from the United States and England, and to a lesser extent: Canada, Ireland, and New Zealand. I chose these jurisdictions for various reasons. As set out in greater detail within my literature review, the United States and England largely pioneered the implementation of patient safety theory at the local and federal levels. Although Australia was also an early adopter of patient safety theory, for the purposes of scoping, it has not been analysed in any detail within this thesis. Additionally, England's NHS structure provides a unique and well documented example of Clinical Governance at the federal level. The analysis within this thesis is intended to represent current best practices within the field of patient safety and quality improvement, and it is for this reason that a wide variety of literature from multiple jurisdictions has been referenced. Furthermore, my research has been drawn from various disciplines, including patient safety, medical negligence law, and therapeutic jurisprudence. Literature review and analysis was the most appropriate form of research by which to examine both patient safety literature and conduct an analysis of legal mechanisms that have only recently gained prominence in a medico-legal context. A limitation of this thesis is that it does not contain quantitative research to support a direct connection between disclosure legislation and mediation, and the reduction of medical error or improved patient outcomes. This is due primarily to the contemporary nature of these processes in a clinical setting, and the challenges of measuring cultural change

in a short period following the implementation of specific interventions.¹¹ As these initiatives gain prominence, future empirical research will ideally study this connection. This thesis will (hopefully) contribute to that momentum.

1.3 Core Concepts and Terminology

It is worth noting that within patient safety literature, various terms have been used to describe fundamental concepts. Distinct from ‘patient rights’ which are shaped around policies, legislation, and jurisprudence strengthening the role of the patient in their care;¹² the doctrine of ‘patient safety’ focuses on a multidisciplinary and multifactorial approach to improving safety and quality. ‘Quality’ and ‘safety,’ can also be distinguished insofar as quality healthcare can be considered “the overarching umbrella under which patient safety resides.”¹³ Quality is defined as, “The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”¹⁴ In addition to safety improvement, quality also includes integrated governance, accountability structures, an emphasis on the organisation’s financial objectives,

¹¹ C Vincent, *Patient Safety* (2nd edn, UK: Wiley-Blackwell, 2010) 373-375; T Scott et al., ‘The Quantitative Measurement of Organizational Culture in Health Care: A Review of the Available Instruments’ 38(3) *Health Services Research* 941-942.

¹² WHO Regional Office for Europe, *Patient Safety and Rights: Developing Tools to Support Consumer Health Literacy* (Denmark: World Health Organization, 2010) 2. <http://www.euro.who.int/__data/assets/pdf_file/0018/133128/e94739.pdf> accessed: 20 May 2012.

¹³ P Mitchell, “Defining Patient Safety and Quality Care” in R Hughes (ed), *Patient Safety and Quality: An Evidence-Based Handbook for Nurses: Volume 1* (Rockville: Agency for Healthcare Research and Quality, 2008) 1.

¹⁴ World Health Organization, *Glossary of Patient Safety Concepts and References* (January 2009) 33 <http://www.who.int/patientsafety/taxonomy/icps_technical_annex2.pdf> accessed: 16 March 2015; Institute of Medicine (Committee on Quality of Health Care in America), *Crossing the Quality Chasm: A New Health System for the 21st Century*. (Washington: National Academy Press, 2001).

clinical audit, and benchmarking.¹⁵ The patient safety movement significantly contributed to the already existing quality improvement movement that began in the 1950's.¹⁶ As Vincent has noted, "Some of the core ideas and concepts of patient safety could certainly be identified in earlier writings from the quality pioneers, though often in rather embryonic form. Safety however, did enrich the quality movement by bringing new force, new ideas and new approaches to bear on the shared quest to improve healthcare. Most importantly, we began to realize that patients were suffering much more than had previously been thought and were being let down by the healthcare system."¹⁷

I have chosen to use terminology consistent with the World Health Organization's *International Classification for Patient Safety*.¹⁸ For example, the term 'patient safety incident' ("An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient") has been used, as opposed to 'adverse event' ("An event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient.") Although

¹⁵ J Wright and K Shojania, 'Measuring the Quality of Hospital Care' (2009) 338 *BMJ* 783-784; World Health Organization, *Glossary of Patient Safety Concepts and References* (January 2009) 8 <http://www.who.int/patientsafety/taxonomy/icps_technical_annex2.pdf> accessed: 16 March 2015; citing: Joint Commission on Accreditation of Healthcare Organizations (eds) *Lexicon: Dictionary of Health Care Terms, Organizations, and Acronyms*. (2nd edn, Oakbrook Terrace: Joint Commission on Accreditation of Healthcare Organizations, 1998) Noting, "Continuous measurement of a process, product, or service to those of the toughest competitor, to those considered industry leaders, or to similar activities in the organization in order to find and implement ways to improve it. This is one of the foundations of both total quality management and continuous quality improvement.'

¹⁶ V Harpwood, *Medicine, Malpractice and Misapprehensions* (Oxon: Routledge-Cavendish, 2007) 71; citing: A Ahmed, *Review and Practice in Medical Care-Steps for Quality Assurance* (London: George McLaughlan, Nuffield Press, 1981). In examining quality improvement within the NHS, Harpwood notes, "Although the concept of "Totally Quality Management" was first developed in the 1950's, and had been widely adopted in industry in developed countries over the following decades, the idea was applied only slowly to healthcare. The NHS may have escaped rigorous scrutiny because of the traditional deference accorded to doctors by society in general, and despite early attempts to monitor standards of medical practice through self-regulation and the voluntary system of confidential inquiries, patient satisfaction was not a significant factor in quality assurance until the early 1980's."

¹⁷ C Vincent, *Patient Safety* (2nd edn, UK: Wiley-Blackwell, 2010) 42.

¹⁸ World Health Organization, *Glossary of Patient Safety Concepts and References* (January 2009) <http://www.who.int/patientsafety/taxonomy/icps_technical_annex2.pdf> accessed: 16 March 2015.

arguably a rhetorical distinction in an academic context, I chose the term 'patient safety incident' because it also includes incidents that did not result in harm to the patient, often referred to 'near-misses.'¹⁹ The term 'adverse event' has been used where appropriate, due to its prominence within the literature. Additionally, I chose to use the term 'patient' as opposed to 'consumer/customer,' because I believe the word 'patient' better exemplifies the therapeutic nature of the physician-patient relationship. The terms 'patient-centred care' and 'patient engagement' have been used as opposed to 'patient and family-centred care' and 'patient and family engagement.' This, however, should not be interpreted as implying the family is not an essential component of the care process, it is merely for the purpose of brevity. In regards legal terminology, the American/Canadian term 'disclosure' has been used as opposed to the English 'duty of candour.' Similarly, the term 'Medical and Surgical Resident' has been used as opposed to the Irish term 'Non Consultant Hospital Doctor.' It is important to note, however, that these terms are interchangeable. Lastly, the terms 'professional negligence', 'medical malpractice', 'medical negligence', and 'clinical negligence' have all been used somewhat interchangeably owing to the different jurisdictions examined throughout this thesis. Although I have attempted to distinguish where appropriate, particularly when speaking of malpractice law as a branch of medical negligence.

1.4 Summary of Chapters

By way of introduction, it is now useful to set out in greater detail the contents of this thesis.

Chapter 2: 'The Role of Medical Malpractice Law and Litigation in the Reduction of Medical Error'

Chapter 2 provides the comparative basis for the legal component of this thesis, specifically the role of medical malpractice law and litigation in the reduction of medical error, which will be later contrasted throughout the chapters with quality

¹⁹ *ibid.*

improvement strategies originating from the patient safety movement. Furthermore, it examines and provides context when considering the dichotomy between the legal system's and medical system's approach to quality and safety improvement. The first section of this chapter will briefly outline the requirements for an action in negligence, and examine the policy objectives of medical negligence law. The second section will analyse the advantages and disadvantages of medical malpractice litigation as it relates to patients, healthcare professionals, and healthcare culture. In particular, it will examine the diverse reasons patients initiate a medical malpractice claim and the adverse consequences of such a decision for all of the parties involved. The third section of this chapter will consider in further detail the role of malpractice litigation and address the question of what role the law currently has, and ideally should have, in the reduction of medical error. The use of compensation caps, the doctrine of informed consent, vicarious liability, and role of privileged communications will all be examined. Lastly, it is important to note that where negligent, reckless, or intentionally harmful care has been provided, healthcare professionals may also be subject to criminal prosecution. For the purpose of this thesis, liability in the context of the tort of negligence will be examined in depth. However, as criminal charges may be brought where care has been particularly egregious, it will also be briefly examined in the fourth and final section of this chapter.

Chapter 3: 'The Origins of the Patient Safety Movement'

This chapter will examine the seminal publications that have influenced the development of the Patient Safety Movement within the United States, England, Canada, Ireland, and the World Health Organization. The patient safety movement challenged contemporary wisdom surrounding the causes and magnitude of healthcare harm by addressing the high rates of preventable adverse events, and emphasising the role of systemic factors, as distinct from human factors generally associated with liability and individual responsibility. In addition, the patient safety movement stressed the need for cultural change with healthcare institutions to reduce

the fear of blame and punishment as a means of facilitating organisational learning. This chapter will provide the foundation for the remainder of this thesis in which the key elements of the patient safety movement will be extensively analysed for their ability to reduce medical error, both in their own right and working in tandem with medical malpractice actions.

Chapter 4: 'Healthcare Culture and Accountability'

Chapter 4 will critically analyse the role of healthcare culture and accountability in the prevention of medical error. Traditionally, the fear of blame, liability, and professional regulatory censure have dominated healthcare culture and lead to the so-called 'culture of blame.' A culture of blame can be defined as, "... a set of norms and attitudes within an organization characterized by an unwillingness to take risks or accept responsibility for mistakes because of a fear of criticism or management admonishment."²⁰ In contrast, the patient safety movement has sought to dispel the role of blame, instead moving towards a culture that recognises human error as inevitable and concentrates on prevention, accountability, transparency, learning, and mitigation. This chapter will begin by examining the consequences of a culture dominated by blaming behaviour. Two specific examples will be used to illustrate this: first, the consequence of organisational silence, in which there is a "collective-level phenomenon of saying or doing very little in response to significant problems that face an organization."²¹ Second, the pervasive requirement of 'error-free practice' in which errors are viewed as a failure of one's own character and detached from latent system-based failures

²⁰ N Khatri et al., 'From a Blame Culture to a Just Culture in Health Care' (2009) 34(4) Health Care Management Review 312, 314.

²¹ K Henriksen and E Dayton, 'Organizational Silence and Hidden Threats to Patient Safety' (2006) 41(4) Health Services Research 1539. In the context of healthcare and error, silence can be defined as "noncommunication resulting from a conscious decision of employees to hold back seemingly important information, including suggestions, concerns, or questions." See further: N Khatri et al., 'From a Blame Culture to a Just Culture in Health Care' (2009) 34(4) Health Care Management Review 312, 315.

occurring within the organisation.²² Both organisational silence and perfectionism have the adverse effect of preventing communication and valuable lessons within the organisation from being learned that can aid in systemic improvements, prevention, and transparency.

In contrast, a 'just culture' can be defined as "... a values-supportive model of shared accountability. It's a culture that holds organizations accountable for the systems they design and for how they respond to staff behaviors fairly and justly. In turn, staff are accountable for the quality of their choices and for reporting both their errors and system vulnerabilities."²³ A just culture integrates the principles of a safety culture (i.e. a focus on learning, prevention, transparency) and balances it with organisational and professional accountability. The second section of this chapter will analyse the core components of a just culture, including the role of safety culture methodology, communication, and accountability.

The third section will examine in greater depth the role of, and requirements for, accountability in a just culture. Beginning first with an analysis of the contribution of clinical governance, risk management, and audit in the promotion and maintenance of safe accountable care. Second, the equally fundamental contribution of organisational and professional regulation will be examined. Both governance and regulatory structures are essential to quality and safety improvement by ensuring clear lines of accountability, transparency, and communication between the organisation, staff, and patients. As well, governance and regulatory structures contribute to the reduction of medical error by ensuring staff are practicing at a standard consistent with best professional practices, and that proactive and continuous systemic improvement is

²² L Leape, 'Error in Medicine' (1994) 272(23) JAMA 1851; D Cohen and M Rhydderch, 'Support for Tomorrow's Doctors: Getting it Right, Meeting Their Needs' (2013) 63(1) Occupational Medicine 2; M Peters, 'Perfectionism in Doctors' (2012) 344 BMJ 1674.

²³ K Griffith, 'The Growth of a Just Culture' (2009) 9(12) Joint Commission Perspectives on Patient Safety 8.

undertaken in light of emerging best practices.²⁴ In the final section, New Zealand's unique no-fault compensation system will be analysed as a means of examining whether monetary liability and blame are inescapable prerequisites for ensuring accountability.

Chapter 5: 'Human Factors vs The System'

This chapter will critically compare the role of human factors and system factors in the causation of patient safety incidents. Following in the path of High Risk Organisations, the patient safety movement has sought to bring attention to the critical role of system-design in the prevention of patient safety incidents and medical error. A systems-centred approach begins with the presumption that error is inevitable and as such, the goal is to engineer error-tolerant systems. In contrast, the person-centred approach focuses on the role of human factors which include the organisational, environmental and individual cognitive, social and personal factors that influence the way in which individuals interact within their working environment.²⁵ Understanding why human error occurs must include the recognition that human cognitive performance has limitations.²⁶ However, a focus on personally liability and human infallibility has continued to present a challenge to viewing error as systemic. This is primarily due to the traditional presumption of human factors as the sole cause of error, reinforced by the legal system's proclivity towards individual responsibility. This chapter will further examine the significant contribution of Reason's "Swiss Cheese" Model (SCM) as a means of demonstrating the causal relationship between human factors and system-design. Criticisms of the SCM model, as well as the adapted Healthcare Error Proliferation model will also be examined. The role of systems theory is significant to

²⁴ Department of Health and Children (Ireland), *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance* (Dublin: Stationary Office, 2008) 61-62.

²⁵ P Fortune et al. (eds), *Human Factors in the Healthcare Setting: A Pocket Guide for Clinical Instructors* (UK: Wiley-Blackwell, 2013) 6.

²⁶ A Merry and A McCall-Smith, *Errors, Medicine and the Law* (Cambridge: Cambridge University Press, 2001) 96.

the discussion of the patient safety movement because it provides the foundation on which current strategies for quality and safety improvement are based.

Chapter 6: 'The Nature of Medical Error'

Having examined in the previous chapter the role of human and system factors that operate at the blunt end and sharp ends of the healthcare spectrum, this chapter will extend that analysis by identifying and critically exploring the diverse causes of human and system failure that contribute to medical error. Patient safety theory categorises medical error by both the type of error, and by where it originates within the system. Referring back to Reason's "Swiss Cheese" model, the 'sharp end' is comprised of those who provide direct patient care and is most closely connected to 'active failure' involving human factors. This is distinct from the 'blunt end' which includes those primarily responsible for policy decisions and oversight. The blunt end is generally identified with 'system-produced error' characterised by latent failures. This chapter will begin by identifying the many diverse causes of active failure at the sharp end. For the purposes of categorisation, active errors will be described first using the generic error-modeling system (GEMS) which divides error into three broad categories: knowledge-based, rule-based, and skill-based.²⁷ In addition, errors will be examined according to their cognitive basis; namely error as a result of a slip, lapse, mistake or violation. In the second section, factors that contribute to the occurrence of both active and latent failure, and lead to medical error, will be critically examined. Beginning first with work environment factors that inhibit safe care, including: the normalisation of deviance, diffusion of responsibility, division of labour, and the 'work-around'. Second, individual factors that leave the system vulnerable will be examined. These include: bias, fundamental attribution error, the use of heuristics, and maintaining the status quo. Lastly, in contrast to social factors related to individuals within a clinical setting, organisational factors primarily related to philosophies and

²⁷ M Jenicek, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011) 33; citing: J Reason, *Human Error* (Cambridge: Cambridge University Press, 1990).

decisions originating at the blunt end will be identified, including: unchallenged beliefs, the 'good provided fallacy' and neglect of the interdependencies.²⁸

Understanding the diverse causes of active and latent failures that contribute to error is essential for the development of a just culture, the epidemiological analysis of patient safety incidents, ensuring accountability is appropriately directed, and intervention strategies effectively designed and implemented.

Chapter 7: 'Safety Interventions: Preventing Patient Safety Incidents and Medical Error'

Having examined the role of culture, system redesign, and the multifactorial nature of medical error, this chapter will build on that analysis and examine specific safety and quality intervention strategies that operate in tandem with medical malpractice actions. Safety interventions are designed with one purpose: to prevent patient safety incidents and patient harm. Intervention strategies can be ranked according to their effectiveness at preventing patient safety incidents, forming a 'safety spectrum.'²⁹ In the first section, intervention at the level of the patient and caregiver will be analysed. Specifically, this section will focus on the importance of patient and family engagement, patient and family-centred care, and patient education in the context of medical error reduction. This will be followed by an examination of interventions at the level of the caregiver. In contrast to intervention at the patient level which is idiosyncratic, intervention at the caregiver level is designed to standardise and simplify processes that commonly result in medical error. Specifically, the use of checklists, teamwork and accountable care units will be examined. Although behavioural norms and customs are the most difficult to intervene on and lowest on the safety spectrum with respects to intervention,³⁰ patient safety incidents are the

²⁸ K Henriksen and E Dayton, 'Organizational Silence and Hidden Threats to Patient Safety' (2006) 41(4) Health Services Research 1539, 1548-1550.

²⁹ H Woodward et al., 'What Have We Learned About Interventions to Reduce Medical Errors?' (2010) 31 Annual Review of Public Health 479, 480-481.

³⁰ *ibid* 481.

result of numerous failed barriers but only take one successful barrier to prevent. For this reason, it is necessary to examine intervention strategies at all levels—both at the blunt and sharp end. Subsequently, intervention strategies within the workplace and system will be analysed. Workplace interventions include those that alter behaviour created within that environment. Examples of workplace interventions include implementing cultural change,³¹ improving the rate of incident reporting,³² and reducing workplace fatigue.³³ Similarly, system level interventions are designed to reduce patient safety incidents by intervening on both human and system failure. This section will critically examine specific examples of workplace and system interventions strategies that can be implemented so as to improve quality and safety. Lastly, the second section will examine the prevention of a specific category of patient safety incidents: adverse drug events. An adverse drug event is defined as “an injury resulting from medical intervention related to a drug.”³⁴ Preventing adverse drug events is multifaceted, as such, this section will examine intervention strategies that can be applied at both the blunt and sharp end. This section is useful in understanding how a specific patient safety incident can be targeted within the organisation and prevented.

Chapter 8: ‘Case Study: Resident Duty Hours’

Despite the very clear consequences of workplace fatigue well borne out by the literature, regulation of medical and surgical resident duty hours—by the courts, legislation, professional regulators, or hospital policy—continues to be a significant challenge to implement. This chapter will critically explore the consequences of

³¹ See further: Chapter 4.3 ‘A Just Culture.’

³² See further: Chapter 9 ‘Incident Reporting and Analysis.’

³³ See further: Chapter 8 ‘Case Study: Resident Duty Hours.’

³⁴ D Bates et al., ‘Incidence of Adverse Drug Events and Potential Adverse Drug Events: Implications for Prevention. ADE Prevention Study Group.’ (1995) 274(1) JAMA 29; World Health Organization, *Glossary of Patient Safety Concepts and References* (January 2009) 4 <http://www.who.int/patientsafety/taxonomy/icps_technical_annex2.pdf> accessed: 16 March 2015.

workplace fatigue by way of a case study contrasting developments towards the regulation of resident duty hours in the United States, Canada, and the European Union. Beginning in the first section with an examination of how the tragic 1984 death of Libby Zion resulted in State legislation and brought to a national and international stage the consequences of resident fatigue. The implementation of the 2003 and 2011 Accreditation Council for Graduate Medical Education Common Duty Hour Standards, which limited the number of hours residents within the United States could be continuously scheduled for duty, will also be examined.³⁵ The second section will analyse the use of collective bargaining agreements in Canada to reduce resident duty hours. In particular, the arbitration case of *McGill University Health Centre v Association des Résidents de McGill*.³⁶ This case set precedent within the province of Québec by acknowledging the dangers of excessive duty hours for both residents and patients. The third section will consider legislative and judicial developments within Europe. Specifically, the European Working Time Directive and the 2015 Irish case of *European Commission v Ireland*³⁷ which excluded ‘training hours’ from the definition of working time set out within the Directive. The final section will critically analyse the impact of the resident duty hour restrictions, and explore the main arguments against their further reduction. In particular, that a further reduction will increase the number of handovers between residents, thereby disrupting continuity of care and creating a risk to patient safety. Ultimately, an argument will be put forth for their reduction in light of both worker and patient safety. This chapter is relevant in the context of safety and quality improvement because it clearly illustrates the extraordinary challenges of cultural change and safety intervention when legislative intervention is absent, and when governments and regulatory organisations are reluctant to reform the status quo.

³⁵ I Philibert et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME, 2011).

³⁶ *McGill University Health Centre v Association des Résidents de McGill* (Arbitration Board, Québec, Canada. 07 June 2011. Grievance No. 4-CUSM-0809-01) [1].

³⁷ Case C-87/14 *European Commission v Ireland* [2015] ECLI:EU:C:2015:449.

Chapter 9: 'Incident Reporting and Analysis'

This chapter will critically analyse the role of incident reporting and incident analysis in the response to, and prevention of, medical error; as well as illustrate the necessity and challenges of data collection, analysis and trending. From a patient safety perspective, the primary purpose of both mandatory and voluntary incident reporting is to discover underlying system defeats and—through analysis—prevent their reoccurrence.³⁸ In addition, mandatory reporting systems seek to hold healthcare organisations and professionals accountable for the care they provide. Balancing accountability with organisational learning is key to achieving a just culture, and ultimately, quality and safety improvement. This chapter will begin with a critical comparison of mandatory and voluntary incident reporting systems. Mandatory reporting systems are generally enacted in accordance with legislation or accreditation requirements, and seek to ensure accountability to the public for the care provided. In contrast, voluntary reporting systems focus primarily on learning through the dissemination of information gathered, and cultural change within the organisation. For voluntary reporting systems to be effective, confidentiality must be ensured and the risk of punitive sanctions removed. Examples illustrating the varying objectives of national reporting systems from the United States, England, and Canada will be analysed. Furthermore, the appropriateness of mandatory reporting and the extent of what should be mandatory to report will also be critically analysed.

In the second section, the necessity of incident analysis will be addressed in greater detail. In particular, the process of root-cause analysis which seeks to identify the causation of patient safety incidents and specifically, the latent and active failures that contribute to their occurrence. This section will argue that it is only through the analysis of incident reports and trending that systemic issues can be addressed, and mechanisms for prevention put in to place. Root cause analysis is a critical component

³⁸ WHO World Alliance for Patient Safety, *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems: From Information to Action* (Geneva: World Health Organization, 2005) WHO/EIP/SPO/QPS/05.3. p28.

of the mitigation process after an incident has occurred, particularly where there is the prospect of early disclosure and resolution. Lastly, this chapter will conclude in the third section with an analysis of the barriers to incident reporting. Barriers to incident reporting can be categorised under two main headings: cultural barriers and administrative barriers. The primary cultural barrier to incident reporting is an environment underlined by the threat of blame, disciplinary action, and liability. Administrative barriers can result from a lack of standardisation, discrepancies as to what information should be reported, and a lack of adequate response and feedback from the organisation. Countermeasures to reduce barriers to incident reporting will be suggested.

Chapter 10: 'Communication: Bridging the Patient-Physician Relationship'

This chapter will analyse the pivotal role patient-physician communication has within healthcare, and in particular following an adverse incident. This chapter is largely intended as a foundation for the following chapters in which early and full disclosure and alternative dispute resolution mechanisms will be strongly advocated as a means of reducing communication barriers, and improving quality and safety. Despite significant efforts, the threat and fear of litigation continues to limit communication within the clinical setting. For this reason, this chapter will begin by examining the challenges of communication in the wake of medical error. Following on, the second section will then consider the psychological consequences of medical error and the impact of such on patients and physicians, particularly as it relates to communication between the parties. This analysis is not limited to only patient communication, open and factual communication with the organisation by staff and physicians is also an essential component for safety improvement. The third section will consider the benefits and barriers to constructive communication. Lastly, the fourth and fifth sections will examine the use of in-hospital communication programs and internal dispute mechanisms designed to enable physician-patient communication. The objective of this chapter is to examine the role and benefits of healthcare

communication in the pursuit of reducing litigation and medical error. In this respect, this chapter will consider both the response to medical error, and strategies for improving patient safety.

Chapter 11: ‘Communication: Disclosure and Apology’

As set out in the previous chapter, communication in the course of patient care and following a medical error is fundamental to improving quality and safety. The disclosure of medical error has traditionally been a contentious process. Despite evidence that patients desire information following a patient safety incident, the disclosure of such incidents has been fraught with concern—both by the physician and healthcare organisation—over legal liability. As a result, dissonance between the immediate needs of patient and the potential consequences faced by the physician and healthcare organisation have prevented the effective communication of incidents and medical errors. As Rabinovich-Einy argues, “The shadow of legal doctrine provides distorted incentives which yield suboptimal results: high conflict rates, difficulties in communication, limited avenues for addressing disputes, and increased risk of litigation. Most important, this state of affairs has affected not only the manner in which members of medical staffs communicate, but also the quality of services they provide.”³⁹ In an effort to deconstruct the “shadow of legal doctrine,” the first section of this chapter will critically analyse the legal and ethical duty placed on physicians and healthcare organisations in the United States, Canada, and England to disclose an adverse incident, including medical error. Despite both legal and ethical obligations, barriers continue to restrict physicians and healthcare organisations from early and thorough disclosure. For this reason, the second section will examine the legal and psychological barriers preventing the effective disclosure of medical error. In the third section, best practices for disclosure as identified by the literature will be considered. This approach has been taken as jurisdictional requirements may vary; however, the

³⁹ O Rabinovich-Einy, ‘Escaping the Shadow of Malpractice Law’ (2011) 74 Law and Contemporary Problems 241, 243.

ultimate goal of incident disclosure is to enhance patient-physician communication, and ensure informed consent. The fourth section of this chapter will critically analyse apologies given in the course of disclosure. Apologies for preventable incidents continue to be legally contentious despite the desire by patients for their inclusion. This section will examine the law in the United States, Canada, and England as it applies to apologies given in the course of disclosing error. Finally, this chapter will conclude in the fifth section with specific examples of disclosure and communication programs that have had a demonstrable benefit in educating and enabling physicians to provide effective disclosure of patient safety incidents and medical error to patients. This chapter will address one of the main barriers to healthcare communication: elusiveness surrounding disclosure policies, procedures, and laws.

Chapter 12: 'Alternative Dispute Resolution in Healthcare'

This chapter will analyse the use of alternative dispute resolution (ADR) in the context of healthcare disputes. By way of introduction, the first section will identify and critically explore the primary forms of alternative dispute resolution engaged to resolve clinical disputes. This includes the traditional forms of dispute resolution, namely: mediation, arbitration, and negotiation. In addition, contemporary forms of ADR will be examined, including: 'mediation-arbitration,' early neutral evaluation, and healthcare screening panels. In the second section, the mediation process and its applicability to healthcare disputes will be examined in greater detail. The argument will be put forth that the mediation process is ideally suited to resolve healthcare disputes, as compared to alternative forms of ADR and litigation. From a patient safety perspective, this is primarily due to the facilitative nature of the process and its ability to promote communication between the parties, early disclosure, and apology. Moreover, mediation provides the means by which to effect cultural change through information sharing and the use of mutually agreed nonmonetary remedies, both of which strongly support the objectives of the patient safety movement. Key aspects of the mediation process will be considered within the second section, beginning first

with an analysis of the facilitative and evaluative methods of mediation. As distinct from evaluative mediation in which the mediator evaluates and gives an opinion on the parties claims; facilitative mediation is based on the premise that the mediator facilitates communication and enables the parties to reach a mutually acceptable agreement. Second, the strengths and weaknesses of the facilitative mediation process will be examined, as an alternative to litigation. This analysis is particularly relevant to deconstructing the barriers preventing the wide scale implementation and use of healthcare mediation. The last section will address the primary barrier to mediation's wide spread use: the voluntary nature of the process and the prioritization of compensation. Specifically, this section will argue for a legislative requirement for mediation at the first instance of a litigable healthcare dispute, and answer two questions: how can a plaintiff be incentivised to engage in a mediation conference and accept early compensation offers when litigation would result in a larger award of compensation? Second, how can the defendant be incentivised to engage in a mediation conference and offer early compensation when there is a genuine dispute regarding liability, or the consequence of an offer is increased regulatory scrutiny?

Chapter 13: 'Conclusion'

Beginning with the publication of *To Err is Human*,⁴⁰ the patient safety movement fundamentally changed the way in which human and system performance were understood and delivered. Despite this, dissonance continues to exist between patient safety methodology and the legal system's response to, and prevention of, medical error. The conclusion chapter will analyse and synthesise the arguments set out throughout this thesis as they relate to my thesis statement: *'An assessment of strategies which, operating in tandem with medical malpractice actions, will improve patient safety (and based on comparative analysis of how these strategies have worked in different jurisdictions).'*

⁴⁰ Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999).

- Chapter 2 -

The Role of Medical Malpractice Law and Litigation in the Reduction of Medical Error

2.1 Introduction

Traditionally, the regulation of quality and safety in healthcare was based on the notion of individual responsibility and facilitated by way of professional self-regulation, legislation, and legal jurisprudence. The belief that safe care could be ensured by threatening legal, financial or disciplinary penalties has since been challenged by contemporary theories derived from the introduction of the patient safety movement that focus on evidence-based safety interventions and system redesign, healthcare culture, alternative methods of dispute resolution, and nonlinear accountability structures.¹ Although civil litigation continues to be an essential mechanism for plaintiffs to receive, *inter alia*, monetary compensation and legal determinations of fault; a criticism of the process is that by its very nature it is retrospective, idiosyncratic, and time and cost consuming. By focusing on the actions of individuals and the consequences of the negligent act, the argument will be put forth that the legal system is ill-equipped to remedy the underlying systemic causes of medical error and prevent reoccurrence. Even attaching a defendant organisation by way of vicarious liability does not comprehensively ensure that the underlying systemic flaws are corrected as it remains the individual's actions that are most closely scrutinised. On that point, in a critique of the traditional approach to liability in tort law, Ennis and Vincent have critically argued, "The tort system tends, unfortunately, to mean that the actions of a particular individual are singled out for scrutiny while the actions of senior staff, hospital management, or government are seldom called into question at any hearing."² From the early 1990's, a growing recognition of the high levels of error occurring in acute care—as recognised by the patient safety movement—began to shift

¹ L Leape et al., 'Promoting Patient Safety by Preventing Medical Error' (1998) 280(16) JAMA 1444.

² M Ennis and C Vincent, 'The Effects of Medical Accident and Litigation on Doctors and Patients' (1994) 16(2) Law & Policy 97, 114.

the conversation from individual responsibility to the role of complex system factors that fall under the purview of those at the blunt end (i.e. senior staff, hospital management and government, as Ennis and Vincent identify above).

This chapter will provide the comparative basis for the legal component of this thesis, specifically the role of medical malpractice law and litigation in the reduction of medical error, which will be later contrasted throughout the chapters with quality improvement strategies originating from the patient safety movement. Furthermore, it examines and provides context when considering the dichotomy between the legal system's and medical system's approach to quality and safety improvement. As Lang summarises well, "Both groups have very different theories as to the cause of the current crisis: Doctors tend to blame the legal system, but attorneys tend to blame negligent doctors."³

The first section of this chapter will briefly outline the requirements for an action in negligence, and examine the policy objectives of medical negligence law. Specifically, its role in providing a framework for the regulation of quality, skill and care, as well as in the compensation, deterrence, education, and restitution following a malpractice action involving medical error.

The second section will analyse the advantages and disadvantages of medical malpractice litigation as it relates to patients, healthcare professionals, and healthcare culture. This section will argue that while filing a medical negligence claim may be a necessary—and indeed preferable—option for a patient harmed in the course of care; the process as a whole is ineffective in proactively promoting quality and safety in healthcare and reducing the rates of medical error. Both the fear of liability and a culture of blame have undermined quality improvement by preventing adequate

³ A Lang, 'A New Approach to Tort Reform: An Argument for the Establishment of Specialized Medical Courts' (2004) 39 Georgia Law Review 293, 301.

communication, incident reporting, and organisational learning.⁴ As Hoppe has insightfully argued, the fear of liability created by an overly litigious environment "... invariably leads to an environment incapable of producing the kinds of systemic learning curves required to prevent future harm resulting from a similar adverse incident."⁵ The recognition of the deficiencies of the litigation process in quality and safety improvement has paved the way for alternative methods to be introduced, a subject that will be analysed in extensive detail throughout this thesis.

The third section of this chapter will consider in further detail the role of malpractice litigation and address the question of what role the law currently has, and ideally should have, in the reduction of medical error. The use of compensation caps, the doctrine of informed consent, vicarious liability, and the role of privileged communications will all be examined.

Lastly, it is important to note that patient care is regulated by the legislation and jurisprudence of two distinct areas of law: civil law and criminal law. In accordance with civil law, healthcare professionals and healthcare organisations may be subject to liability under the tort of negligence, contract law or consumer legislation.⁶ Where negligent, reckless, or intentionally harmful care has been provided, healthcare professionals may also be subject to criminal prosecution. For the purpose of this thesis, liability in the context of the tort of negligence will be examined in depth. However, as criminal charges may be brought where care has been particularly egregious, it will also be briefly examined in the fourth and final section of this chapter.

⁴ H Morreim, 'Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank' (2012) 27(1) *Ohio State Journal on Dispute Resolution* 109, 117-118; citing: E Dauer and L Marcus, 'Adapting Mediation to Link Resolution of Medical Malpractice Disputes with Health Care Quality Improvement' (1997) 60 *Law and Contemporary Problems* 185, 198-99, 204. The authors note, "The adversarial tort system, focused as it is on pinpointing blame, systematically inhibits essential communication and thereby impairs system-level quality improvement."

⁵ N Hoppe, 'Medical Ethics and Patient Safety' in J Tingle and P Bark (eds) *Patient Safety, Law Policy and Practice* (Oxon: Routledge, 2011) 83.

⁶ E Jackson, *Medical Law: Text, Cases and Materials* (Oxford: Oxford University Press, 2006) 105-106.

2.2 Components and Objectives of Medical Negligence Law

Components of Medical Negligence Law

By way of introduction, it is useful to consider the definition of *negligence*. In *Blyth v Birmingham Waterworks Company* [1856], Baron Alderson defined the concept of negligence as:

“... the omission to do something which a reasonable man, guided upon those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do. The defendants might have been liable for negligence, if, unintentionally, they omitted to do that which a reasonable person would have done, or did that which a person taking reasonable precautions would not have done.”⁷

From this definition, four main principles emerge as necessary for an action in negligence to succeed. These include:

- (i) The existence of a ‘duty of care’;
- (ii) A breach of that duty;
- (iii) “Loss or damage occurring to the person affected by the failure to take care”; and
- (iv) “The loss or damage must have been caused by the failure to conform to the required standard.” This is generally referred to as causation.⁸

In the context of the doctor-patient relationship, establishing a duty of care rarely gives rise to a dispute where both the physician consents to provide care and the patient

⁷ *Blyth v Birmingham Waterworks Co* [1856] 11 Ex Ch 781, 784.

⁸ S Mills, *Clinical Practice and the Law* (Dublin: Butterworth (Ireland), 2002) 144; J McHale et al., *Health Care Law: Text and Materials* (2nd edn, London: Sweet & Maxwell, 2007) [6.01-6.50].

consents to accept it. Likewise, a healthcare organisation may vicariously owe a duty of care to the patient for the acts of a healthcare professional employed within their organisation.⁹ In the wake of a medical error, establishing a breach of the duty of care, loss or causation often proves more difficult. Where the patient has given their informed consent, it must be established—on the balance of probabilities—that the care provided by the defendant-physician deviated from the standard of care and ‘but for’ the actions of the defendant-physician, the harm or loss suffered by the plaintiff-patient would not have occurred. Establishing causation may prove a significant hurdle for the plaintiff, as well as burdensome to rebut for the defendant, particularly where it involves highly technical evidence that leads to lengthy, costly, and complex litigation.¹⁰ The standard of care to be applied in medical negligence cases is subject to the jurisdiction in which the dispute is being heard; however, for the purposes of this chapter, it can be defined as that, “... which is ‘medically indicated’ and that which is ‘legally required,’ the latter reflecting the standards of the community.”¹¹ This includes legal precedent specific to the jurisdiction and medical speciality. Where the plaintiff is pleading a breach of the standard of care, it must be established objectively that no responsible body of medical opinion would have approved of acting in such a way.¹² Medical custom is often influential in the court’s decision in this matter, so too may a defendant be immune from liability where they acted in good faith.¹³ Owing to the gravity and complexity involved, the organisation will often conduct an extensive root

⁹ J Herring, *Medical Law and Ethics* (2nd edn, Oxford: Oxford University Press, 2008) 95.

¹⁰ For a discussion of causation in medical negligence proceedings, see generally: J Herring, *Medical Law and Ethics* (2nd edn, Oxford: Oxford University Press, 2008) 102-104.

¹¹ R Anderson, ‘Billions for Defense: The Pervasive Nature of Defensive Medicine’ (1999) 159 *Archives of Internal Medicine* 2399, 2401. For a counter-argument to the application of the Standard of Care, see further: L Brenner et al., ‘Beyond the Standard of Care’ (2012) 470 *Clinical Orthopaedics and Related Research* 1357. The authors argue that the “standard of care is an inaccurate measure of medical negligence because it is premised on the faulty notion of conformity to norms.”

¹² For example, in the seminal case of *Bolan v Friern Hospital Management Committee* [1957] 2 ALL ER 635, McNair J stated, “A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a reasonable body of medical men skilled in that particular art.” See generally: J Herring, *Medical Law and Ethics* (2nd edn, Oxford: Oxford University Press, 2008) 96.

¹³ A Linden and B Feldthusen, *Canadian Tort Law* (Toronto: LexisNexis Canada, 2015) 220-221, 230.

cause investigation, which includes at the onset a medical quality review (both internally and externally) so as to establish the extent of disclosure required and whether to challenge the claim of breach of the standard of care. Within the aforementioned jurisdictions, medical quality reviews are protected by quality improvement privilege. The result is that it is often necessary in practice to conduct simultaneous investigations for the purposes of quality improvement, and then separately in anticipation of legal proceedings (which will attach solicitor-client and/or litigation privilege in their own right). Although, in regards to medico-legal proceedings, this thesis will strongly advocate for the use of early compensation offers and alternative methods of early dispute resolution, it may well be in the interests of the individual and organisation to challenge the claim in court where they deem the standard of care has been met or where causation is unclear. In an ideal world, or indeed a jurisdiction like New Zealand (examined in chapter 4), all patients harmed would be compensated to the extent of their treatment needs, but under our current fault-based system, that is neither practical nor desirable because it would be inherently unfair to hold liable a defendant who met the standard required of them. How such a fault-based system effects quality and safety, however, will be examined further below. First, it is useful to briefly outline the objectives of medical negligence law.

Objectives of Medical Negligence Law

The law of torts, under which healthcare law and negligence fall, has numerous objectives. Although a significant theoretical debate in its own right, there are at least four generally cited purposes for the law of tort. These include: the *compensation* for and *deterrence* of negligent, reckless or intentional harm; *restitution* of unjust enrichment resulting from the tortious act; and *education* to prevent future negligent, reckless or intentional behaviour.¹⁴ In addition, healthcare law provides the framework

¹⁴ See further generally: A Linden and B Feldthusen, *Canadian Tort Law* (Toronto: LexisNexis Canada, 2015) 4-26.

for the regulation of quality, skill and care—all fundamental for safe practice and intrinsic to the standard of care that is legally recognised. Traditionally, it was believed that by attaching personal liability to the practice of medicine, quality and safety of care could be improved. As James observes,

“... one of the policy reasons for which we apply the same principles of skill and care to health professionals as to others is that it is believed that the prospect of personal liability to compensate the injured will encourage error prevention. This, it is hoped, will raise quality.”¹⁵

However, the law of negligence’s primary focus on causation and personal liability has also proved disadvantageous. As Wears and Leape asserted in 1999, prior to the release of *To Err is Human*,¹⁶ traditional methods of addressing medical error had proven increasingly counterproductive.¹⁷ Growing rates of litigation have since led to the so-called ‘malpractice crisis,’ the consequence of which has been escalating healthcare defense expenditure and insurance premiums.¹⁸ In addition, an adversarial culture dominated by fears of liability and blame have arguably resulted in defensive communication and practice with regards to patient care, as well as hampered safety and quality improvement efforts by keeping error and underlying systemic defects

¹⁵ T James, ‘Fault and Blame in the NHS: Review and Replacement of the Clinical Negligence System in the UK’ in J Tingle et al. (eds), *Regulating Healthcare Quality: Legal and Professional Issues* (Edinburgh: New York: Butterworth-Heinemann, 2004) 55.

¹⁶ Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington National Academy Press, 1999).

¹⁷ R Wears and L Leape, ‘Human Error in Emergency Medicine’ (1999) 34 *Annals of Emergency Medicine* 370; M Greenberg et al., RAND Institute for Civil Justice, *Is Better Patient Safety Associated with Less Malpractice Activity? Evidence from California* (CA: RAND Corporation, 2010) 15. Similarly, Greenberg et al. have argued, “... the traditional legal doctrine of malpractice, which focuses on deterring negligence and related injuries, is at best incomplete in addressing the underlying problem of patient safety in U.S. health care facilities.”

¹⁸ F Hellinger and W Encinosa, ‘The Impact of State Laws Limiting Malpractice Damage Awards on Health Care Expenditures’ (2006) 96(8) *American Journal of Public Health* 1375, 1376.; D Kessler et al., ‘Impact of Malpractice Reforms on the Supply of Physician Services’ (2005) 293 (21) *JAMA* 2618.

hidden.¹⁹ For the purposes of assessing safety and quality improvement strategies and their ability to work in tandem with medical malpractice litigation, it is useful to examine the dichotomy between the collaborative ideals of the patient safety movement and the inherently adversarial nature of the legal system. This dichotomy is examined at numerous points throughout this thesis, but in greatest depth below.

Because this thesis takes a critical stance on the suitability of malpractice litigation to improve quality and safety, it is necessary to clearly outline some of the benefits and disadvantages of the litigation process. Arguably nowhere is this more evident than on the effect the process has on patients and healthcare professionals. The next section will address these factors before continuing on to the role of malpractice litigation in quality and safety improvement.

2.3 The Effect of Medical Malpractice Litigation on Patients and Healthcare Professionals

Referring back, to bring a claim in medical negligence, a plaintiff must establish on balance that the duty of care owed to them was breached, and that the defendant did not meet the requisite standard of care. Instances in which this may occur can include, for example: a medical mishap, a deviation from practice guidelines,²⁰ failure to obtain informed consent,²¹ or a failure to maintain patient confidentiality.²² On the face of it, a

¹⁹ For an interesting discussion of defensive practice prior to reform, see further: K DeVille, 'Act First and Look up the Law Afterward?: Medical Malpractice and the Ethics of Defensive Medicine' (1998) 19 *Theoretical Medicine and Bioethics* 569.

²⁰ A Block, 'Disclosure of Adverse Outcomes and Apologizing to the Injured Patient' in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 286.

²¹ *ibid*; O Rabinovich-Einy, 'Escaping the Shadow of Malpractice Law' (2011) 74 *Law and Contemporary Problems* 241, 247-248; citing: P Gulick, 'E-health and the Future of Medicine: The Economic, Legal, Regulatory, Cultural and Organizational Obstacles Facing Telemedicine and Cybermedicine Programs' (2001-2002) 12 *Albany Law Journal of Science and Technology* 351, 373.

²² A Block, 'Disclosure of Adverse Outcomes and Apologizing to the Injured Patient' in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 286.

medical negligence claim may be brought by the plaintiff in an effort to, *inter alia*, receive compensation or recover medical expenses resulting from the incident, for a legal determination of fault and wrong-doing, or in an attempt to have corrective measures put in place so that the incident “never happens again.”²³ In instances where communication has been poor or defensive, a patient may also initiate a claim as a means of achieving closure and emotional healing, or to potentially gain information and public vindication.²⁴ From a patient safety perspective and central to my analysis, a focus on compensation as the primary remedy to a medical malpractice claim ultimately neglects the diverse motivations that lead a patient to file a claim in the first place. On this point, a study concerning the motivations of patients to bring a negligence claim found that only one-quarter of medical malpractice plaintiffs sued to obtain compensation.²⁵ This study suggests that the motivations of patients are more complex than simply greed (a contention often asserted in relation to the imposition of tort reforms and the notion of a ‘compensation culture’, discussed further below). This argument is further consistent with the objectives of tort law as set out previously, i.e. that the role of the law, in addition to compensation, is also deterrence, restitution, and education.

When one questions the role of medical negligence litigation, all of these potential outcomes are relevant, necessary, and align closely with the objectives of tort law cited

²³ A Howe and P Walsh, ‘The Impact on Patients and Healthcare Professionals’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 41; E Zonana, ‘Getting Healthier: A Proposal for Improving Medical Malpractice Mediation’ (2001) 5 *American Journal of Mediation* 9, 20; citing: E Dauer et al., ‘Prometheus and the Litigators: A Mediation Odyssey’ (2000) 21 *Journal of Legal Medicine* 159, 161; A Halligan, ‘Clinical Governance’ in M Powers, N Harris and A Barton (eds), *Clinical Negligence* (4th edn, Haywards Heath: Tottel, 2008) 40. In this regard, Halligan states, “... the primary motivation is not money or revenge, it is to ensure that the same mistake does not happen to other patients. Doctors and health professionals share this motivation, although the threat of litigation and disciplinary procedures cripples a culture of openness and learning.”

²⁴ N Meruelo, ‘Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.’ (2008) 29 *Journal of Legal Medicine* 285, 293.

²⁵ E Dauer and L Marcus, ‘Adapting Mediation to Link Resolution of Medical Malpractice Disputes with Health Care Quality Improvement’ (1997) 60 *Law and Contemporary Problems* 185, 203-204.

in the previous section. It is worth reemphasising that the while litigation may not be the most appropriate avenue for preventing and responding to medical error, it nonetheless is fundamental to the proper functioning a healthcare system. It is absolutely essential that parties have the ability to adjudicate conflict and access remedies. My analysis is based on the argument that litigation is most appropriately used as a *last resort* because it inherently encompasses many disadvantages for all parties involved within the process. For example, by default, litigation is cost and time prohibitive, as well, the contentious nature of the adversarial system makes it a poor vehicle for healing and continuity of care.²⁶ Where a claim falls outside of the clearly defined test for negligence, the possibility of a successful counterclaim can have a “chilling effect” on the plaintiff who may experience difficulty finding representation.²⁷ Ultimately, beyond an award of compensation, a judgment by the court may fail to meet the ancillary needs of a plaintiff-patient such as vindication, retribution, or as a means of prevention.

Healthcare Culture and a Fear of Liability

The legal system’s primary focus on individual responsibility and fault has had a profound impact on the culture of healthcare, and illustrates the dichotomy between legal and medical cultures.²⁸ From a clinical perspective, a highly litigious environment

²⁶ A London, ‘Med-Mal Mediation Offers Promise, but Systemic Obstacles Remain’ (2006) 61 (3) *Dispute Resolution Journal* 26, 26-27. London makes the observation that, “Plaintiffs appear for depositions, during which their answers are narrowly circumscribed by a question and answer format; if they attempt to offer an open-ended narrative expressing their feelings, defense counsel cuts off the monologue as ‘non-responsive.’”

²⁷ B Lee, ‘Countersuits by Health Care Providers’ in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 521; N Meruelo, ‘Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.’ (2008) 29 *Journal of Legal Medicine* 285, 287-288; citing: H Farber and M White, ‘Medical Malpractice: An Empirical Examination of the Litigation Process’ (1991) 22 *Rand Journal of Economics* 199, 200.

²⁸ The role of healthcare culture is set out in significant detail in Chapter 4 ‘Healthcare Culture and Accountability.’

restricts effective communication and error reporting.²⁹ Likewise, the fear of litigation and blame can have physical and psychological repercussions for healthcare professionals leading to the modification of clinical behaviour.³⁰ An example of this can be seen in the inclination to practice defensively. Defensive medicine involves the avoidance of particular patients or procedures, as well as the excessive use of diagnostic testing, procedures, or hospitalisation in an effort to avoid liability.³¹ Although the argument can be made that the physician is practicing prudently rather than defensively, the ancillary consequences of such behaviour may submit the patient to unnecessary intervention or harm. This, in turn, could arguably be a deviation of the standard of care, and in effect become a paradox: exposing the physician to liability they were otherwise attempting to avoid.³² Although attempts have been made via tort reform to reduce the practice of defensive medicine, commentators such as Kavanagh have argued their implementation has been ineffective because they do not adequately

²⁹ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 45; M Greenwood and B Garren, 'Patient Safety and Health Care Quality' in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 265; V Lachman, 'Patient Safety: The Ethical Imperative' (2008) 20(2) *Journal of the Dermatology Nursing Association* 134, 136; citing: V Sharpe, 'Promoting Patient Safety: An Ethical Basis for Policy Deliberation.' (2003) 33(5) *Hastings Center Report* S3-18. See further: Chapter 11 'Communication: Disclosure and Apology' and Chapter 9 'Incident Reporting and Analysis.'

³⁰ H Morreim, 'Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank' (2012) 27(1) *Ohio State Journal on Dispute Resolution* 109, 115-116; citing: E Dauer, 'A Therapeutic Jurisprudence Perspective on Legal Responses to Medical Error' (2003) 24 *Journal of Legal Medicine* 37, 45; T Shanafelt et al., 'Suicidal Ideation Among American Surgeons' (2011) 146 *JAMA Surgery* 54, 57. Morreim notes that after being a party to litigation following a medical error, physicians suffer a marked increase in depression, fatigue, and suicidal ideation, as well as an increased chance of being named in another claim within two years. See further: Chapter 11.3 'Barriers to Disclosure.'

³¹ J Thomas et al., 'Low Costs Of Defensive Medicine, Small Savings From Tort Reform' (2010) 29 *Health Affairs* 1578; United States Congress, Office of Technology Assessment, *Defensive Medicine and Medical Malpractice*, OTA-H-602 (Washington: US Government Printing Office, July 1994) 10.

³² K De Ville 'Act First and Look up the Law Afterward?: Medical Malpractice and the Ethics of Defensive Medicine' (1998) 19 *Theoretical Medicine and Bioethics* 569, 577-579; R Anderson, 'Billions for Defense: The Pervasive Nature of Defensive Medicine' (1999) 159 *Archives of Internal Medicine* 2399, 2401.

address the cultural aspects of the behaviour.³³ As defensive practices are particularly evident where organisational support mechanisms are lacking or unavailable, a more effective solution would be to place a stronger emphasis on promoting a just culture, enforcing non-linear accountability structures (i.e. By appropriate directing accountability based on causation and who is in the best position to correct the root cause), and mitigating the consequences of medical error by actively engaging staff and patients following the incident.³⁴ Defensive practice remains, however, an unfortunate by-product of a litigious environment, and one that cannot be ignored when considering the role and value of medical malpractice litigation.

As the primary suggestion to the above concerns is legislative reform, it is now useful to examine the potential role of legislative reform on safety improvement.

2.4 The Role of Medical Malpractice Law and Litigation in the Reduction of Medical Error

The Compensation Culture and Legislative Reform

Compensation for negligence is a necessary and defining feature of the law of torts. However, the increasing use of the courts as a means to gain compensation—particularly following the abundance of publicity given to high jury awards³⁵—has led to the perception that a so-called ‘compensation culture’ exists. In this regard, Harpwood pragmatically defines a ‘compensation culture’ as,

³³ K Kavanagh et al., ‘The Relationship Between Tort Reform and Medical Utilization’ (2014) 10(4) *Journal of Patient Safety* 222.

³⁴ E Zonana, ‘Getting Healthier: A Proposal for Improving Medical Malpractice Mediation’ (2001) 5 *American Journal of Mediation* 9, 24.

³⁵ V Harpwood, *Medicine, Malpractice and Misapprehensions* (Oxon: Routledge-Cavendish, 2007) 48-48; citing: D Giesen, ‘Medical Malpractice and the Judicial Function in Comparative Perspective’ (1993) 1(3) *Medical Law International* 3, 4. See also: A Howe and P Walsh, ‘The Impact on Patients and Healthcare Professionals’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 41.

“... a state in a society in which it is acceptable for anyone who has suffered an injury to seek compensation by means of litigation from some person or organization connected with the injury, even if the injury is trivial or has a tenuous connection with the alleged wrong.”³⁶

In practice, there are numerous reasons suggested in the literature for the increase in litigation. Over the past several decades, the role of the patient has changed dramatically.³⁷ Patients are increasingly informed about their care and have higher expectations due to greater volumes of information being available, particularly via the internet³⁸ and in the media.³⁹ Perhaps somewhat paradoxically, the legal obligation to obtain informed consent and the deference given to the patient’s choice of treatment may further contribute to the patient’s expectations and decision to bring a claim.⁴⁰ The increasing complexity of care in conjunction with new technology⁴¹ and financial pressures facing physicians has also been credited with increasing litigation.⁴² On the latter point, commentators have argued that such financial pressures lead to ‘work-

³⁶ V Harpwood, *Medicine, Malpractice and Misapprehensions* (Oxon: Routledge-Cavendish, 2007) 83.

³⁷ Postgraduate Medical Education and Training Board, *Patients’ Role in Healthcare - The Future Relationship Between Patient and Doctor* (London: PMETB, 2008).

³⁸ V Harpwood, *Medicine, Malpractice and Misapprehensions* (Oxon: Routledge-Cavendish, 2007) 74. The author notes that, ‘Even outside the internet, better general knowledge and social awareness of illnesses, injuries and their causes may well have led people to understand their injuries and attribute blame for them more accurately than in the past.’

³⁹ For a discussion of the media’s impact on the culture of healthcare, see further: V Harpwood, *Medicine, Malpractice and Misapprehensions* (Oxon: Routledge-Cavendish, 2007) 106-129; G Watts, ‘Health Care Errors, Patient Safety and the Media’ in B Huritz and A Sheikh (eds), *Health Care Errors and Patient Safety* (Oxford: Wiley-Blackwell, 2009) 262-296.

⁴⁰ A Block, ‘Disclosure of Adverse Outcomes and Apologizing to the Injured Patient’ in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 286.

⁴¹ V Harpwood, *Medicine, Malpractice and Misapprehensions* (Oxon: Routledge-Cavendish, 2007) 48-48; citing: D Giesen, ‘Medical Malpractice and the Judicial Function in Comparative Perspective’ (1993) 1(1) *Medical Law International* 3, 4.

⁴² O Rabinovich-Einy, ‘Escaping the Shadow of Malpractice Law’ (2011) 74 *Law and Contemporary Problems* 241, 247-248; citing: J Blum, ‘Beyond the Bylaws: Hospital-Physician Relationships, Economics and Conflicting Agendas’ (2005) 53 *Buffalo Law Review* 459, 463.

arounds' which increase the risk of medical error. This further leads to clinicians failing to maintain adequate resources or performing invasive procedures away from the hospital in an effort to reduce expenses, a practice that can also lead to the increased occurrence of adverse incidents and medical error.⁴³

In response to the 'malpractice crisis', many solutions for reform have been proposed and implemented to varying degrees of success. As Mello notes,

"The primary objective of traditional tort reforms is to reduce the volume and cost of malpractice litigation. This is done through measures that focus on 3 different strategies. One group of reforms imposes barriers to bringing suits or reaching trial, a second group limits the amount of compensation that plaintiffs may recover, and a third group changes how damages awards are paid."⁴⁴

While the extent of the 'compensation culture' and 'malpractice crisis' have been disputed,⁴⁵ conventional legislative reform has concentrated on retrospective intervention, specifically: tort compensation caps, reducing the statute of limitations on medical negligence claims, pre-suit notification laws, certificates of merit, judge

⁴³ J Filkins, 'Criminalization of Medical Negligence' in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 510; see further: Chapter 6.3.1 'Work Environment Factors.'

⁴⁴ M Mello et al., 'The Medical Liability Climate and Prospects for Reform' (2014) 312(20) *JAMA* 2146, 2148; see also: A Alexander, 'Complaints, Grievances, and Claims Against Physicians: Does Tort Reform Make a Difference?' (2010) 30(1) *Journal of Healthcare Risk Management* 32-42.

⁴⁵ M Lunney and K Elephant, *Tort Law: Text and Materials* (Oxford: Oxford University Press, 2010) 34; citing: Better Regulation Task Force, *Better Routes to Redress* (London: Cabinet Office Publications, 2004).

directed negotiation, limiting counsel fees, and medical courts.⁴⁶ Commentators have argued that legislative reforms have the ability to reduce the frequency and severity of malpractice claims, lower healthcare expenditure rates,⁴⁷ increase growth of physician supply, and lower insurance premiums.⁴⁸ These methods, however, are not without criticism. As Mello has observed, "... traditional reforms do not address problems with the malpractice system's 2 core functions—compensating negligently injured patients and deterring substandard care."⁴⁹ Furthermore, by focusing legislative reform exclusively on the reduction of litigation and compensation, complex system factors are ignored, and opportunities to learn and prevent are missed.⁵⁰ Therefore, the ability of statutory intervention to deter negligence or address the true rates or causes of

⁴⁶ D Kessler et al., 'Impact of Malpractice Reforms on the Supply of Physician Services' (2005) 293 (21) JAMA 2618, 2619-2624; A Lang, 'A New Approach to Tort Reform: An Argument for the Establishment of Specialized Medical Courts' (2004) 39 Georgia Law Review 293; J Lenzer, 'Medical Courts Could Ease US Malpractice Crisis, Group Says' 2005 BMJ 330; L Miller, 'Health Courts: An Alternative to Traditional Tort Law (2011) 25(2) Journal of Perinatal & Neonatal Nursing 99; M Mello et al., 'The Medical Liability Climate and Prospects for Reform' (2014) 312(20) JAMA 2146; T Driver et al., 'Responding to Clinicians Who Fail to Follow Patient Safety Practices: Perceptions of Physicians, Nurses, Trainees, and Patients' (2014) 9 Journal of Hospital Medicine 99; H Tan, 'Minimizing Medical Litigation: A Review of Key Tort and Legal Reforms' (2009) 5(2) International Journal of Law in Context 179; F Hellinger and W Encinosa, 'The Impact of State Laws Limiting Malpractice Damage Awards on Health Care Expenditures' (2006) 96(8) American Journal of Public Health 1375, 1376.

⁴⁷ For example, in a 1996 study evaluating the twenty-five year period following the enactment of California's Medical Injury Compensation Reform Act 1975, Kessler and McClellan found that the effect of statutory compensation caps on non-economic damages reduced overall healthcare costs by between 5-9%. See: D Kessler and M McClellan, 'Do Doctors Practice Defensive Medicine?' (1996) 111(2) The Quarterly Journal of Economics 353.

⁴⁸ In reference to data collected throughout the United States, the General Accounting Office concluded that "rates of growth in malpractice premiums and claims payments have been slower on average in states that enacted certain caps on damages for pain and suffering... than in states with more limited reforms." See: United States General Accounting Office, *Medical Malpractice Insurance: Multiple Factors Have Contributed to Increased Premium Rates* (Washington: US General Accounting Office, June 2003) 6; as taken from: F Hellinger and W Encinosa, 'The Impact of State Laws Limiting Malpractice Damage Awards on Health Care Expenditures' (2006) 96(8) American Journal of Public Health 1375, 1377. See further: D Kessler et al., 'Impact of Malpractice Reforms on the Supply of Physician Services' (2005) 293 (21) JAMA 2618.

⁴⁹ M Mello et al., 'The Medical Liability Climate and Prospects for Reform' (2014) 312(20) JAMA 2146, 2148. See also: A Alexander, 'Complaints, Grievances, and Claims Against Physicians: Does Tort Reform Make a Difference?' (2010) 30(1) Journal of Healthcare Risk Management 32-42.

⁵⁰ H Morreim, 'Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank' (2012) 27(1) Ohio State Journal on Dispute Resolution 109, 111.

negligently inflicted harm is arguable as the majority of negligent care does not lead to a filed claim,⁵¹ and of those claims filed, not all are brought on the basis of medical negligence or breach of professional duty.⁵² By its very nature, statutory tort reform is generally not designed to affect the root causes of error, but rather to effect the outcome of a claim. Where the plaintiff-patient is awarded compensation, the amount awarded may nevertheless inadequately compensate the patient; particularly where an award has been ‘capped’ or a large majority goes to cover the costs of litigating.⁵³ Similarly, limiting the statute of limitations or requiring early pre-suit notification on a claim may be advantageous from a risk management perspective (i.e. for its ability to reduce insurance premiums) but ultimately its objective to deprive the claimant of access to the court and legal remedies, again, does not mitigate or remedy the original wrong. Owing to the advantages and disadvantages set out above, it is useful to re-examine and consider what the proper role of medical malpractice litigation should be and how, if at all, it fosters patient safety.

The Role of Medical Malpractice Law and Litigation in the Reduction of Medical Error

In regards to the above strategies for the reduction of litigation, a reasonable question would be to ask what is the proper role of medical malpractice law and litigation, and how, if at all, does it foster patient safety? It is important to note that my analysis throughout this thesis is primarily directed towards a critique of the litigation process,

⁵¹ N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005) 61.

⁵² H Tan, ‘Minimizing Medical Litigation: A Review of Key Tort and Legal Reforms’ (2009) 5(2) *International Journal of Law in Context* 179; D Hetzler et al., ‘Conflict Management in Hospital Systems: Not Just For Leadership’ (2011) 5 *American Journal of Mediation* 65, 73-74; citing: D Studdert et al., ‘Claims, Errors, and Compensation Payments in Medical Malpractice Litigation’ (2006) 354 *NEJM* 2024, 2024-2033.

⁵³ H Morreim, ‘Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank’ (2012) 27(1) *Ohio State Journal on Dispute Resolution* 109, 113-114; citing: D Studdert et al., ‘Claims, Errors, and Compensation Payments in Medical Malpractice Litigation’ (2006) 354 *NEJM* 2024, 2028-29.

not the law generally. This is an important distinction when I speak of negligence/ malpractice law versus negligence/ malpractice litigation. My argument throughout is that malpractice litigation (i.e. the experience of a publicly prolonged claim that is ultimately adjudicated by a judge/ jury) is detrimental for the numerous reasons cited above. Alternatively, legislation/ jurisprudence that dictates how a negligence claim can proceed (i.e. rules of court, statutes setting out caps on damages or time limitations) is, although obviously theoretical, separate for the purposes of this analysis. Without a doubt, both are necessary, however, it is this distinction that forms the basis for later chapters which argue strongly in favour of the use of alternative dispute resolution—specifically mediation. Put another way, I am not suggesting “the law” in general is detrimental. Indeed, it would be impossible to envision a process for managing healthcare (or any area of activity) and dispute resolution that does not have some form of legislative basis. Rather, I am arguing in favour of reducing litigation because the adversarial process is contrary to the collaborative, patient-centred principles that are at the heart of the patient safety movement, the same principles I believe are necessary for effective, permanent, safety and quality improvement. The “law” sets standards, how we adjudicate them in the wake of a dispute is the issue. For example, does the early disclosure of information in the wake of medical error, or the mediation process when the situation has escalated, improve safety? While drawing a specific correlation between the two is difficult, namely because disclosure and communication laws are still in their relative infancy and cultural change takes a significant amount of time to document and trend, chapter 10 to 12 of this thesis does outline in significant detail the benefits of legislation that support increased patient-physician communication, as well as patient-centred care. By collaboratively working with families in the wake of an adverse event, as opposed to taking a “deny and defend” mentality, healthcare professionals and organisations first have the opportunity to prevent litigation by giving the patient information or an apology which they may otherwise sue to obtain. Second, it has the potential to contribute to quality and safety improvement by reducing the adversarial culture within their

environment, as well as facilitating patient engagement and patient-centred care. As Meruelo observes, “It may turn out that, simply by paying attention to the enormous importance of meeting the patient’s emotional needs in addition to providing medical care, the physician may avoid a lawsuit even if he or she makes a mistake.”⁵⁴ Third, healthcare professionals and organisations have a unique opportunity to expand their base of potentially contributing factors by considering alternative experiences and points of view—namely the patient’s and family’s. Again, this may provide invaluable information regarding systemic issues that can be fed back into the system and corrected.

As I noted above, the distinction between negligence law and litigation is largely theoretical because one is based on the other. But it is useful now to explore where they overlap and how, pragmatically, in a litigious culture, each can be used to foster safety. This analysis is in no way intended to be comprehensive of all of the legal avenues available to foster safety, I am merely choosing a select few so as to illustrate the ways in which the patient safety movement and malpractice law can work in tandem. While I continue to hold the view that the same safety improvements could be accomplished without resorting to a courtroom, where the parties are not (or no longer) open to alternative dispute resolution, it may be the last and only resort. Owing to the critical stance I have taken to litigation, an appropriate question would be: what is the role of litigation and should legislation attempt to limit its use and applicability? In this particular instance, the legislating of compensation caps is a useful example.⁵⁵

Speaking to the role of litigation, as I stated above, litigation is an essential *last resort* to promote accountability, achieve legal determinations of fault and awards of

⁵⁴ N Meruelo, ‘Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal For a Specific Model of Mediation.’ (2008) 29 *Journal of Legal Medicine* 285, 296.

⁵⁵ It should be noted that although not discussed in any detail within this chapter, the same arguments can also be made regarding a reduction in the statute of limitations applicable to negligence claims.

compensation, and arguably provide a public avenue for vindication.⁵⁶ As Herring has identified, "... cases which go to court and make the headlines tend to be those where the negligence is more borderline."⁵⁷ Although not applicable to all cases, the disadvantages of litigation (in my opinion) at best rival the advantages. Alternative mechanisms of resolution and accountability can be equally (if not more so) as effective as pursuing the path of litigation.⁵⁸ Owing to this, I have advocated, perhaps somewhat paradoxically, for the use of compensations caps—an argument I will set out briefly below and then in greater detail in chapter 12 in relation to mandatory mediation.⁵⁹ As also noted above, the most common form of compensation cap limits the amount of general (non-economic) damages a successful plaintiff may recover in a tort action. Compensation caps have gained legislative popularity as a means of reducing the increasing insurance premiums which have resulted from increased claiming, this additionally is believed to reduce behaviours associated with the fear of liability. The ability of compensation caps to reduce premiums is debatable however and, as Nelson points out, is statistically reliant on caps being set below \$500,000.⁶⁰ Essentially, the goal is to reduce the amount of compensation an unsuccessful defendant (albeit by way of insurance) will be liable to pay. The caps do not take into account ancillary costs such as legal fees or special (economic) damages.

The problem with compensation caps in the context of this thesis, which concerns itself primarily with patient safety intervention strategies, is two-fold. First, from the patient's perspective, they are arguably contrary to the broader goal of a just culture.

⁵⁶ A Linden and B Feldthusen, *Canadian Tort Law* (Toronto: LexisNexis Canada, 2015) 19. In regards to public vindication, the authors note: "... the thought that a trial is available, if needed, should give some comfort and hope to the alienated."

⁵⁷ J Herring, *Medical Law and Ethics* (2nd edn, Oxford: Oxford University Press, 2008) 120.

⁵⁸ See further: Chapter 12 'Alternative Dispute Resolution in Healthcare.'

⁵⁹ See further: Chapter 12.3.3 'Mandatory Mediation.'

⁶⁰ For a review of the implementation of compensation caps in the United States and their effect on malpractice premiums, see further: L Nelson et al., 'Damages Caps in Medical Malpractice Cases' (2007) 85(2) *Milbank Quarterly* 259-286.

With the exception of a utilitarian argument which supports the socialisation of medical funds, it is difficult to argue that limiting a harmed patient's compensation is *just* to the individual plaintiff-patient. Second, and again in line with the objective of this thesis and the methodology of the patient safety movement, compensation caps do not prevent the event from happening, nor do they deter future safety incidents from happening. In fact, one might argue that they actually reduce accountability because the fear of financial sanctions is reduced, although this may only be relevant in regards to insurance premiums since few (if any) healthcare professionals or organisations are themselves personally financially liable. The one counter-argument to this is that compensation caps may be influential in reducing the adversarial and litigious culture within healthcare because they are intended to reduce the fear of litigation. In practice, however, it is difficult to see them being hugely influential in this regard, primarily because the fear of litigation is based on the fear of professional admonishment and blame, not solely monetary liability (again, this is especially true when awards are covered by a physician's mandatory indemnity insurance.) Their ability to reduce the adversarial culture may be more relevant to the issue of vicarious liability, since an organisation would likely be less concerned with lower value awards. Given that a healthcare professional's liability and healthcare organisation's vicarious liability are reliant on one another, however, again potentially negates the value of compensation caps to influence culture.

Despite these arguments against compensation caps, I have argued in chapter 12.3, in favour of their imposition because of their value in incentivising the use of alternative dispute resolution, and specifically medical mediation. While there are very real and substantial arguments to be made against them, as above, there is also an argument to be made that compensation caps reflect the true cost of the harm and prevent emotion

based awards by juries.⁶¹ Similarly, where potential awards are subject to compensation caps, a plaintiff may be more likely to engage in open dialogue with the defendant physician and healthcare organisation. Ideally increased plaintiff-defendant communication would contribute to organisational learning, and at a minimum, it may reduce some of the costs and time associated with traditional litigation—both of which could be more usefully directed back into the healthcare system and patient care.

This leads to another interesting question with regards to liability and safety improvement, namely what is the role of vicarious liability in the correction of systemic errors and does the imposition of vicarious liability reduce elements of a blame culture? On the first point, it is useful to reemphasise that malpractice law and litigation are essential for the enforcement of standards; this includes: the duty to maintain objective professional standards, meet regulatory standards, practice and provide services with reasonable care and skill, as well as the duty to meet the standard of clinical care.⁶² While a healthcare organisation can be held directly liable for systemic error that can be *directly* traced to their own negligence or recklessness, vicarious liability holds the employer responsible for the acts or omissions of their employees and (potentially) contractors.⁶³ How does this relate to the reduction of medical error? The threat of vicarious liability, much like the presumed threat of personal liability, is intended to act as a means of deterrence from negligence and reckless behaviour and conditions. While negligence and recklessness, by its very nature, is not intentional, allowing systemic errors to continue can contribute to negligent and reckless practices. Both an employer's direct liability and vicarious liability are intended to deter

⁶¹ See generally: L Nelson et al., 'Damages Caps in Medical Malpractice Cases' (2007) 85(2) *Milbank Quarterly* 259; C Sharkey, 'Unintended Consequences of Medical Malpractice Damages Caps' (2005) 80(2) *New York University Law Review* 391; A Edwards, 'Recent Development: Medical Malpractice Non-Economics Damages Caps' (2006) 43 *Harvard Journal on Legislation* 213.

⁶² A Linden and B Feldthusen, *Canadian Tort Law* (Toronto: LexisNexis Canada, 2015) 18-26, 185, 193.

⁶³ The challenges of attaching a claim of vicarious liability in the context of independent contractor physicians continues to be notoriously difficult in practice. For historical examination of the challenges, see further: *Roe v Minister for Health* [1954] 2 QB 66 and *Cassidy v Minister for Health* [1951] 2 KB 343.

corporate malfeasance and incentivise safer practices through the imposition of liability, this it is hoped, will raise standards. An excellent example of vicarious liability being used to produce change can be seen in chapter 8 which discusses in significant detail the consequences of excessive resident duty hours. Indeed by over scheduling medical residents, and placing extraordinary expectations on them, the hospital was ultimately held vicariously (although not directly) liable when the residents' negligent errors caused harm.⁶⁴ For the purposes of this analysis, this is relevant because it produces at least two important cultural effects. First, it reinforces the responsibility of employers to ensure that standards are being met, even when those standards are directly within the scope of the individual. Second, in regards healthcare culture, it again reinforces the roles and responsibilities of the organisation to ensure that policies and procedures do not contribute (even indirectly) to negligent or reckless behaviour. This can be a particularly useful avenue in regards to systemic error because it can be difficult to directly link causation. If we return to Mello's comments regarding traditional tort reform in which she notes, "... traditional reforms do not address problems with the malpractice system's 2 core functions—compensating negligently injured patients and deterring substandard care."⁶⁵ Vicarious liability can be seen as one potential avenue for addressing these issues and supporting the goal of improved patient safety.⁶⁶ To be clear however, I am advocating the use of vicarious liability in the same way that I will, throughout this thesis, advocate personal liability—by way of alternative methods of dispute resolution, and only as a last resort through litigation.

A third way in which it has been suggested to use medical negligence law to improve safety is to link the standard of care for informed consent to the reporting of incidents.

⁶⁴ *Zion v New York Hospital* [1992] N.Y. App. Div. 590 N.Y.S.2d 188. See further: Chapter 8 "Case Study: Resident Duty Hours."

⁶⁵ M Mello et al., 'The Medical Liability Climate and Prospects for Reform' (2014) 312(20) JAMA 2146, 2148. See also: A Alexander, 'Complaints, Grievances, and Claims Against Physicians: Does Tort Reform Make a Difference?' (2010) 30(1) Journal of Healthcare Risk Management 32-42.

⁶⁶ See further: A Linden and B Feldthusen, *Canadian Tort Law* (Toronto: LexisNexis Canada, 2015) 591.

Put another way, that to be considered “informed” patients would need to be told that a report has been submitted regarding the incident. While in theory this may increase the rates of reporting because it would add an ethical and legal requirement, in practice there are a number of concerns related to this objective. First, one must ask what minimum standard of harm would be necessary to trigger having to inform the patient. Since none of the jurisdictions examined within this thesis require that near-misses or even minimally harmful incidents be disclosed to the patient, a minimum standard would need to be considered.⁶⁷ This would, just as the notion of informed consent is, be highly subjective and difficult to enforce. Second, while there is certainly some merit in having patient participation in the reporting process regardless of the level of harm, this too calls into question the nature of mandatory and voluntary reporting, as well as the significant time commitment that patient involvement would have.⁶⁸ For example, if because of a lack of communication a patient is required to wait an additional hour for a CT scan, this may or may not result in a delayed diagnosis but should be voluntarily reported to ensure there is not a systemic flaw in process. Is there therapeutic value in having the patient participate? Perhaps. Could that be linked to informed consent because it may affect their decisions going forward, again perhaps. But it is difficult to see this being a realistic option considering the scale and varying gravity of incidents that occur routinely within healthcare. Another issue that may arise is that an incident report may not be completed until a later point in time. Procedurally, this too could be impractical for staff to have to track down a patient and include them. There is also the issue of confidentiality. While an incident report generally is not privileged nor confidential to the patient, since they can apply under the relevant jurisdiction’s Freedom of Information Act to access the information, that does not necessary entitled them to know the names of all who may be involved in the incident since it may be that workplace health and safety legislation, regulations or

⁶⁷ For an examination of the ethical and legal requirement of disclosure, see further: Chapter 11 ‘Communication: Disclosure and Apology.’

⁶⁸ See further: Chapter 9 ‘Incident Reporting and Analysis’, regarding the reporting and analysis of adverse incidents.

organisational policies prevent such information from being disclosed without a subpoena. To link reporting to informed consent would be, in my opinion, highly problematic for anything but moderate to serious events—in particular those events that are legally and ethically required to be disclosed in the first place.

Lastly, it is important to note that one of the most significant ways that the law supports quality improvement in a litigious culture is through the use of quality improvement privilege. Because the nature of privileged work-product is examined at numerous points throughout this thesis, it will not be discussed in this chapter in any depth. However, it is important to acknowledge the significant role of quality improvement privilege in allowing human and systemic error to be examined without the fear of liability.⁶⁹

2.5 The Role of the Criminal Law Following Medical Error

Although rare, the last two decades have seen a rise in the occurrence of criminal prosecutions for clinical negligence. Proponents have argued that the criminal prosecution of healthcare professionals supports utilitarian and retributive theories of justice on the basis of accountability, deterrence and punishment—particularly where there has been a gross deviation from the standard of care or there was an intention to harm.⁷⁰ Alternatively, the argument has been put forth that the central role of the criminal law in a healthcare context is not deterrence, but rather lies in its “symbolic

⁶⁹ For further analysis of the role and basis of quality improvement privilege, see further: Chapter 9 ‘Incident Reporting and Analysis.’

⁷⁰ See generally: E Monico et al., ‘The Criminal Prosecution of Medical Negligence’ (2006) 5(1) *Internet Journal of Law, Healthcare and Ethics*. <<https://ispub.com/IJLHE/5/1/5237>> accessed: 21 November 2014; C Kollas, ‘Criminal Prosecutions of Physicians Providing Palliative or End-of-Life Care.’ (2008) 11(2) *Journal of Palliative Medicine* 233; F McDonald, ‘The Criminalisation of Medical Mistakes in Canada: a Review.’ (2008) 16 *Health Law Journal* 1; J Filkins, ‘“With No Evil Intent”: The Criminal Prosecution of Physicians for Medical Negligence’ (2001) 22 *Journal of Legal Medicine* 467; J Filkins, ‘Criminalization of Medical Negligence’ in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007); J West, ‘Criminalization of Medical Errors: When is a Mistake More Than Just a Mistake?’ (2007) 27(1) *Journal of Healthcare Risk Management* 25.

and expressive significance, publicly proclaiming that the highly culpable mistreatment of others is wrongful and worthy of public censure and sanction.”⁷¹ Although one only need to look to examples such as the horrific case of Dr. Harold Shipman to understand the necessity (both legally and publicly) of criminally prosecuting healthcare professionals who internationally harm patients; a question arises where the harm caused has been unintentional.⁷²

In the wake of the Mid-Staffordshire Inquiry,⁷³ the National Advisory Group on the Safety of Patients in England (lead by Prof. Donald Berwick) were highly critical of holding individuals criminally liable when the care provided does not meet the standard of ill-treatment or willful negligent. With respects to the imposition of sanctions, the National Advisory Group were very clear: “Applying criminal sanctions, or indeed any sanctions, can be appropriate only in the very rare cases of neglect or wilful misconduct.” Consideration must be given to whether the act or omission would be undertaken by a reasonable person or organisation in similar circumstances, the degree of control the person/organisation had over the situation, and whether the incident was part of a pattern of ongoing and persistent failures to engage with, improve or address safety.⁷⁴ As a result, the National Advisory Group recommended that a new criminal offence of ill-treatment or wilful neglect of patients and service users be created, punishable as both a summary and indictable offence, based largely

⁷¹ K Yeung and J Horder, ‘How Can The Criminal Law Support the Provision of Quality in Healthcare?’ (2014) 23 *BMJ Quality & Safety* 519.

⁷² In relation to the crimes of Dr. Harold Shipman, see further: J Smith, *The Shipman Inquiry. Volume 1: Death Disguised* (Manchester: The Shipman Inquiry, 2002); J Smith, *The Shipman Inquiry. Volume 2: The Police Investigation of March 1998* (Manchester: The Shipman Inquiry, 2002); J Smith, *The Shipman Inquiry. Volume 3: Death Certification and Investigation of Deaths by Coroners* (Manchester: The Shipman Inquiry, 2002); R Bhopal, ‘Fallout From the Shipman Case. Death Registers in General Practice Would be a Means of Preventing Malpractice and Murder’ (2000) 320(7244) *BMJ* 1272.

⁷³ R Francis, *Report of the Mid-Staffordshire NHS Foundation Trust Public Inquiry* (London: The Stationery Office, 2013).

⁷⁴ Department of Health (UK), *Strategy and External Relation Directorate/ Quality Regulation, New Criminal Offence of Ill-Treatment or Wilful Disregard* (London: Stationary Office, 2014) 35. “Wilful” in this regard would include those acting deliberately or recklessly.

on that contained within Section 44 of the UK Mental Capacity Act 2005. The recommended offence, as described, was officially enacted in section 20-25 of the Criminal Justice and Courts Act 2015.⁷⁵ The offence does not consider the harm caused, rather it is intended to focus entirely on the conduct of the care worker and care provider.⁷⁶ Berwick usefully explains the basis for this:

“Even apparently simple human errors almost always have multiple causes, many beyond the control of the individual who makes the mistake. Therefore, it makes no sense at all to punish a person who makes an error, still less to criminalise it. The same is true of system failures that derive from the same kind of multiple unintentional mistakes. Because human error is normal and, by definition, is unintended, well-intentioned people who make errors or are involved in systems that have failed around them need to be supported, not punished, so they will report their mistakes and the system defects they observe, such that all can learn from them. On the other hand, harm caused by neglect or wilful misconduct does warrant sanctions in health care, just as it does in other settings.”⁷⁷

In this respect, both Berwick and the aforementioned legislation acknowledge quite rightly that not all harm meets the threshold for prosecution, nor it is appropriate to hold individuals accountable for factors outside their control.

As will be examined in the following chapter, the patient safety movement is premised on the belief that ‘To Err is Human’ and therefore, efforts must be directed towards prevention, as opposed to solely deterrence and retrospective censure. This is because

⁷⁵ Criminal Justice and Courts Act 2015, sections 20-25.

⁷⁶ Department of Health (UK), *Strategy and External Relation Directorate/ Quality Regulation, New Criminal Offence of Ill-Treatment or Wilful Disregard* (London: Stationary Office, 2014) 15.

⁷⁷ D Berwick, *A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England* (London: Department of Health, 2013) 12.

error causation is multifaceted, and deterrence measures may be ineffective when the error is caused by factors outside the control of the individual, e.g. factors relating to the system.⁷⁸ Although the thesis is solely concerned with civil liability, similar arguments can be made against the use of criminal liability as a deterrent.

2.6 Conclusion

This chapter has sought to provide the comparative basis for the legal component of this thesis, specifically the role of medical malpractice law and litigation in the reduction of medical error, which will be later contrasted throughout the chapters with quality improvement strategies originating from the patient safety movement. Furthermore, it has sought to examine the dichotomy between the legal system's and medical system's approach to quality and safety improvement. In this pursuit, the first section of this chapter briefly outlined the requirements for an action in negligence, and examined the policy objectives of medical negligence law. The second section analysed the advantages and disadvantages of medical malpractice litigation as it relates to patients, healthcare professionals, and healthcare culture. In particular, it examined the diverse reasons patients initiate a medical malpractice claim and the adverse consequences of such a decision. The third section considered in further detail the role of malpractice litigation and addressed the question of what role the law currently has, and ideally should have, in the reduction of medical error. The use of compensation caps, the doctrine of informed consent, vicarious liability, and the role of privileged communications were all examined. Lastly, fourth section examined the role of the criminal law in the case of medical error.

The primary argument in support of medical malpractice litigation—that it provides a deterrent effect against negligent behaviour and medical error—is debatable. While this is in no way to suggest that litigation does not have a fundamental role in the reduction of medical error, it is clear from its continued occurrence that the threat of

⁷⁸ See further: Chapter 6 'The Nature of Medical Error.'

litigation is not enough. As will be analysed in the next chapter, from the early 1990's, the patient safety movement has highlighted the high rates of medical error, notwithstanding the increasing rates of litigation. Where malpractice litigation by its very nature focuses on human factors, the patient safety movement has concentrated its efforts on the role of systemic error in the cause and prevention of patient safety incidents and medical error, as well as the role of intervention. Governmental bodies, professional regulators, and healthcare organisations, alternatively, have focused on the development of clinical governance structures, which incorporate, *inter alia*, risk management and clinical audit, the use of practice guidelines,⁷⁹ and revised standards for medico-legal clinician education.⁸⁰ Contemporary legal initiatives, in addition to those examined throughout this chapter, have been directed primarily towards the appropriate assignment of non-linear accountability, and the mitigation and early resolution of incidents involving medical error and harm. The following chapters will examine in greater detail the fundamental role of accountability in the promotion of safety and quality, as well as the role of harm mitigation. Balancing a learning culture with accountability has been an evolving challenge for both the legal system and the patient safety movement. The result has been the implementation of just culture methodology which attempts to dispel the destructive role of blame while using the law, professional regulation, and organisational regulation to appropriately assign accountability and liability. The next chapter will provide the foundation for the remainder of this thesis by examining the origins of the patient safety movement.

⁷⁹ L Leape et al. 'Adherence to Practice Guidelines: The Role of Specialty Society Guidelines' (2000) 145 *American Heart Journal* 19. See further: Chapter 7.2 'Safety Interventions.'

⁸⁰ K De Ville, 'Act First and Look up the Law Afterward?: Medical Malpractice and the Ethics of Defensive Medicine' (1998) 19 *Theoretical Medicine and Bioethics* 569, 573; O Quick, 'Patient Safety and the Problem and Potential of Law' (2012) 28(2) *Journal of Professional Negligence* 78, 85-89.

- Chapter 3 -

The Origins of the Patient Safety Movement

3.1 Introduction

In contrast to the traditional legal approach that focuses on personal liability for medical error; the patient safety movement is premised on the pragmatic philosophy that 'To Err is Human.'¹ From 1991, seminal research in various jurisdictions throughout the world began to acknowledge that errors in healthcare were occurring at a significantly higher rate than was previously known or considered acceptable. The response has since been profound. The resulting patient safety movement sought to advance strategies for safety and quality improvement that moved away from the need for deterrence by preventing the circumstances that make error possible in the first place. While the acceptance of human error as inevitable has equally given way to the larger discussion of the appropriate role and application of accountability in healthcare,² early patient safety theory was fundamental in moving the conversation away from deterrence and towards prevention. This chapter will outline the development of the patient safety movement in the United States, England, Canada, Ireland, and on a global front through the World Health Organization. These jurisdictions, through policy developments and legislation, have begun to change the way medical error is understood and responded to.

3.2 The United States

The United States was the first jurisdiction in which the high levels of preventable adverse events in acute care were recognised. In the first study of its kind, Brennan and Leape reviewed the hospital records of 30,195 patients within 51 acute care hospitals in

¹ Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999).

² Accountability in the context of a just culture will be examined in greater depth in Chapter 4 'Healthcare Culture and Accountability.'

New York State to determine the rate of adverse events that occurred as a result of inpatient care. The *Harvard Medical Practice Study* (as it is known) concluded that adverse events occurred in 3.7% of hospitalisations. Of those, 58% were found to be preventable and 27.6% were found to be due to negligence.³ Using the same methodology as the *Harvard Medicine Practice Study*, Thomas et al., found that the rate of adverse events for hospitalisations in Utah and Colorado during 1992 was 2.9%, with approximately 30% resulting from negligence.⁴

In 1999, the seminar report *To Err is Human: Building a Safer Health System* was published by the Institute of Medicine.⁵ The report highlighted the high number of medical errors occurring with US acute care hospitals. Through a review of published literature to date, the authors concluded that between 44,000 and 98,000 patients die every year as a result of medical errors. Furthermore, the report stressed the importance of, *inter alia*, the development of a 'culture of safety;' the impact of system factors on the healthcare environment (as had been previously recognised in other high-risk environments); involving patients in the care process; as well as mandatory and voluntary reporting systems.⁶ Interestingly, the original intention of the Institute of Medicine's report was to bring awareness to the role of system factors in the causation of adverse events.⁷ However, the staggering number of deaths and preventable adverse

³ T Brennan et al., 'Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I' (1991) 324 NEJM 370; L Leape et al., 'The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II' (1991) 324 NEJM 377.

⁴ E Thomas et al., 'Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado' (1999) 38(3) Medical Care 261.

⁵ Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999). See also: L Leape and D Berwick, 'Five Years After To Err is Human. What Have We Learned?' (2005) 293 JAMA 2384-2390.

⁶ *ibid.*

⁷ M Donaldson, 'An Overview of *To Err is Human is Human: Reemphasizing the Message of Patient Safety*' in R Hughes (ed), *Patient Safety and Quality: An Evidence-Based Handbook for Nurses: Volume 1* (Rockville: Agency for Healthcare Research and Quality, 2008) 1-37.

events cited—in addition to a highly successful marketing strategy that directly approached the public and media organisations—drew widespread attention to the issue of patient safety.⁸

Following *To Err is Human*, the Institute of Medicine published a further report in 2001 entitled *Crossing the Quality Chasm: A New Health System for the 21st Century*. The report provided for a more detailed account of the dichotomy between current practice and ideals in healthcare. Notably, the report identified six key ‘Aims for Improvement’ that are fundamental to quality healthcare; specifically, that healthcare must be: safe, effective, patient-centred, timely, efficient and equitable.⁹ Notable, the IOM included safety as only one aspect of quality care. However, this is not to suggest that the other five ‘aims’ are mutually exclusive from patient safety theory. Indeed, quality issues can quickly become safety issues and vice-versa.

On the 29 July 2005, then President George W. Bush signed into law the Patient Safety and Quality Improvement Act 2005.¹⁰ The Act received bi-partisan support and was a major milestone in the patient safety movement. The Act designated patient safety work product as privileged and not admissible in civil, criminal, or administrative proceedings, or disclosure under the Freedom of Information Act.¹¹ While the Act was clearly influential in reducing liability connected to the reporting of safety incidents for

⁸ R Philip, ‘The Healthcare Policy Context’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 37.

⁹ Institute of Medicine (Committee on Quality of Health Care in America), *Crossing the Quality Chasm : A New Health System for the 21st Century*. (Washington: National Academy Press, 2001).

¹⁰ Patient Safety and Quality Improvement Act 2005, S 544, HR 3205, Public Law 109-41.

¹¹ Patient Safety and Quality Improvement Act 2005, S 544, HR 3205, Public Law 109-41, section 7. Section 7 of the Act defines ‘Patient Safety Work Product’ as: “... any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—“(i) which—“(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or“(II) are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or“(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.”

quality purposes, it did not alleviate liability concerns connected to patient communication, nor encourage patient communication. For this reason, in 2006, then Senators Hillary Clinton and Barack Obama published an article in the New England Journal of Medicine entitled 'Making Patient Safety the Centerpiece of Medical Liability Reform' in which they argued that,

"To improve both patient safety and the medical liability climate, the tort system must achieve four goals: reduce the rates of preventable patient injuries, promote open communication between physicians and patients, ensure patients access to fair compensation for legitimate medical injuries, and reduce liability insurance premiums for health care providers."¹²

Although ultimately unsuccessful having died in the committee process, Clinton and Obama introduced the National Medical Error Disclosure and Compensation Act 2005, intended to achieve the four aforementioned goals.¹³ Five years later, the Patient Protection and Affordable Care Act 2010 was successfully passed¹⁴ and signed into law on 23 March 2010 by former President Barack Obama.¹⁵ The legislation includes a number of provisions designed to improve patient safety efforts; including a national

¹² H Clinton and B Obama, 'Making Patient Safety the Centerpiece of Medical Liability Reform' (2006) 354(21) NEJM 2205–2208

¹³ National Medical Error Disclosure and Compensation (MEDiC) Act 2005, S 1784, 109th Cong, 1st Sess.

¹⁴ This was despite significant political and corporate objection, ongoing repeal efforts, and constitutional challenges. For example, see further: Heritage Foundation, 'The Case Against Obama Care' (2010) <<http://www.heritage.org/research/projects/the-case-against-obamacare>> accessed: 29 November 2014; D Blanton, 'Fox News Poll: Majorities Understand, Oppose ObamaCare' (Fox News, 27 March 2014) <<http://www.foxnews.com/politics/2014/03/27/fox-news-poll-majorities-understand-oppose-obamacare-1122817668/>> accessed: 29 November 2014; *National Federation of Independent Business v Sebelius* [2012] 132 S. Ct. 2566, in which the US Supreme Court, *inter alia*, upheld the constitutionality of the individual mandate provision within the Act.; *King v Burwell* [2015] 135 S. Ct. 475, in which the US Supreme Court, *inter alia*, upheld the constitutionality of subsidies distributed in States using the federal exchange.

¹⁵ Patient Protection and Affordable Care Act 2010, HR 3590 (111th), 42 US Code § 18001.

strategy for quality improvement in health care¹⁶ and the creation of ‘The Center for Quality Improvement and Patient Safety.’¹⁷ Furrow notes that in the area of patient safety, the primary goal of the Patient Protection and Affordable Care Act 2010 is to, “... fund billions of dollars in research in comparative effectiveness, best practice, and system integration. Linage of such research findings with payment reform in other sections of PPACA means that the fragmented American system is likely to develop integration through electronic medical records, accountable care organisations, and other system reforms in response to both data and dollars.”¹⁸

3.3 England

Following in the footsteps of *To Err is Human*,¹⁹ the report *An Organisation with a Memory* was published in England by the Chief Medical Officer, Liam Donaldson. The report found that an estimated 850,000 adverse events occur in the NHS hospitals each year with roughly half being potentially preventable.²⁰ Interestingly, the report concluded that, “The NHS paid out around £400 million in clinical litigation settlements in the financial year 1998/99 and has a potential liability of around £2.4 billion from existing and expected claims; when analysed many cases of litigation show potentially avoidable causes.” Adding further that the direct cost of hospital stays that resulted from such incidents within the NHS was £2 billion per year.²¹

¹⁶ Patient Protection and Affordable Care Act 2010, HR 3590 (111th), 42 US Code § 18001, section 3011.

¹⁷ Patient Protection and Affordable Care Act 2010, HR 3590 (111th), 42 US Code § 18001, section 3013.

¹⁸ B Furrow, ‘Patient Safety in American Health Care’ in J Tingle and P Bark (eds) *Patient Safety, Law Policy and Practice* (Oxon: Routledge, 2011) 303-304.

¹⁹ Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999).

²⁰ Department of Health (UK), *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS* (London: Department of Health, 2000).

²¹ *ibid* 5; citing: National Audit Office, *NHS Summary Accounts 1998/99*. (London: The Stationary Office, 2000).

In 2001, the *Bristol Inquiry* was established to investigate the inadequate care and deaths of children undergoing surgery at the Bristol Royal Infirmary from 1984-1995. The events had a dramatic effect on the public's perception of safety and the medical profession, with some commentators noting, "Bristol is different because it marks the moment when many people's trust in doctors first wavered significantly."²² The Inquiry Report called for, *inter alia*, increased transparency of healthcare services and greater scrutiny of the medical profession.²³ The *Bristol Inquiry* led to the creation of patient safety oriented health legislation and organisations such as the National Institute for Clinical Excellence²⁴ and the National Patient Safety Agency.²⁵

That same year, the UK Department of Health published *Building a Safer NHS for Patients: Implementing an Organisation with a Memory* as a means of operationalising the recommendations set out in *An Organisation with a Memory*.²⁶ A fundamental feature of *Building a Safer NHS* was the establishment of the National Reporting and Learning System (NRLS). The NRLS was established under the National Patient Safety Agency and was the first national reporting system of its kind. It was designed to confidentially collect information on patient safety incidents throughout England and

²² D Sanford, 'Why Bristol is So Important' *BBC News* (London) <<http://news.bbc.co.uk/1/hi/health/1443081.stm>>.

²³ I Kennedy, *Learning from Bristol: The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984–1995*. (London: The Stationery Office, 2001)

²⁴ In April 2013, in accordance with the Health and Social Care Act 2012, the National Institute for Clinical Excellence became a Non Departmental Public Body; the name was formally changed to the 'National Institute for Health and Care Excellence' to reflect a wider emphasis on developing guidance and quality standards in social care. See further: <www.nice.org.uk> accessed: 25 November 2014.

²⁵ The UK National Patient Safety Agency was created in 2001 following the recommendations of *An Organisation with a Memory*; however, in 2012, the National Patient Safety Agency was abolished in accordance with section 281 of the Health and Social Care Act 2012. The key functions and expertise of the NPSA were transferred to the NHS Commissioning Board Special Health Authority, including responsibility for the National Reporting and Learning System discussed further in IV: 5. See further: J Scarpello, 'After the Abolition of the National Patient Safety Agency' (2010) 341 *BMJ* 6076.

²⁶ Department of Health (UK), *Building a Safer NHS for Patients: Implementing an Organisation with a Memory* (London: Department of Health, 2001).

Wales.²⁷ Building on the aforementioned reports, the National Patient Safety Agency published the *Seven Steps to Patient Safety*. By way of guidance for NHS organisations, the seven steps included: 1. Building a safety culture; 2. Leading and supporting staff; 3. Integrating risk management activities; 4. Promoting reporting; 5. Involving and communicating with patients and the public; 6. Learning and sharing safety lessons; 7. Implementing solutions to prevent harm.²⁸

Despite the undertaken safety initiatives, nearly a decade later, an investigation was launched following numerous complaints of poor conditions and high mortality rates within the Stafford Hospital. The *Mid-Staffordshire Report*, published in February of 2013, reemphasised the need for, *inter alia*, greater openness, transparency and candour throughout the healthcare system by way of a culture of patient and family-centred care, the use of evidence-based standards, and greater accountability of those in the health service.²⁹ The report provided clear evidence that further reform within the NHS is necessary.

3.4 Canada

In 2004, the Canadian Institute for Health Information published *The Canadian Adverse Events Study*.³⁰ The study was the first in Canada to estimate the incidence of adverse events in Canadian acute care hospitals. Using similar methodology to the *Harvard*

²⁷ *ibid* 31-44; National Patient Safety Agency, *Building a Memory: Preventing Harm, Reducing Risks and Improving Patient Safety* (UK) (London: National Patient Safety Agency, 2005) 17.

²⁸ National Patient Safety Agency (UK), *Seven Steps to Patient Safety* (London: National Patient Safety Agency, 2004).

²⁹ R Francis, *Report of the Mid-Staffordshire NHS Foundation Trust Public Inquiry* (London: The Stationery Office, 2013); S Dekker and T Hugh, 'A Just Culture After Mid-Staffordshire' (2014) 23 *BMJ Quality & Safety* 356. The authors discuss prevention strategies for avoiding recurrence while also addressing the need for justice following the events at Mid-Staffordshire.

³⁰ G Baker et al., 'The Canadian Adverse Events Study: the Incidence of Adverse Events Among Hospital Patients in Canada' (2004) 170 *Canadian Medical Association Journal* 1678.

Practice Study,³¹ Baker reviewed patient medical records from four randomly selected hospitals in five Canadian provinces during the year 2000.³² Overall, the rate of adverse events was found to be 7.5%. Of those, 36.9% were considered preventable.³³ Based on this, the Canadian Institute for Health Information found that preventable adverse events to be one of the leading causes of death within Canada.³⁴

As in England, in the wake of *To Err is Human*, the National Steering Committee on Patient Safety in Canada released its report in 2002 entitled *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care*. The authors advocated a ‘culture of safety’ be adopted throughout the Canadian Healthcare System which could be achieved through, *inter alia*, improvement of legal and regulatory processes, measurement and evaluation processes, information and communication processes; as well as the establishment of educational and professional development programs.³⁵ The report further advocated for the development of a National Patient Safety Institute to facilitate a national integrated strategy for the improvement of patient safety through the healthcare system. In response to the report, the Canadian government established the Canadian Patient Safety Institute (CPSI) in 2003. The CPSI continues to be the primary body in Canada responsible for fostering

³¹ T Brennan et al., ‘Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I’ (1991) 324 NEJM 370; L Leape et al., ‘The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II’ (1991) 324 NEJM 377.

³² This included one teaching, one large community and two small community hospitals in British Columbia, Alberta, Ontario, Quebec, and Nova Scotia.

³³ G Baker et al., ‘The Canadian Adverse Events Study: the Incidence of Adverse Events Among Hospital Patients in Canada’ (2004) 170 Canadian Medical Association Journal 1678.

³⁴ Canadian Institute for Health Information, *Health Care in Canada in 2004* (Ottawa: Canadian Institute for Health Information, 2005) 42-43; as taken from: J Gilmour, “Patient Safety and the Law in Canada” in J Tingle and P Bark (eds) *Patient Safety, Law Policy and Practice* (Oxon: Routledge, 2011) 245.

³⁵ National Steering Committee on Patient Safety (CA), *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care* (Ottawa: 2002) 11-12. <http://www.royalcollege.ca/portal/page/portal/rc/common/documents/advocacy/building_a_safer_system_e.pdf> accessed: 29 November 2014.

collaboration between federal and provincial governments and stakeholders; focusing on education, research, interventions, programs and resources in the area of patient safety.³⁶

3.5 Ireland

In 2007, the Commission on Patient Safety and Quality Assurance was established by the Irish Minister for Health and Children. The commission sought to bring together the body of international and Irish research and governmental reports previously published, and identify a system-wide response to improving healthcare quality and healthcare outcomes in Ireland.³⁷ The result was the report *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance*, chaired by Dr. Deirdre Madden. The report emphasised the importance and necessity of clinical governance; patient and carer participation; leadership and accountability; clinical effectiveness, audit and reporting/learning systems. The report also led, based on its recommendations, to the establishment of the Patient Safety First Initiative which is responsible for ensuring quality services are designed and delivered to patients

³⁶ See further: Health Canada, 'Patient Safety' <http://www.hc-sc.gc.ca/hcs-sss/qual/patient_securit/index-eng.php> accessed: 01 December 2014; Canadian Patient Safety Institute, 'Canadian Patient Safety Institute' <<http://www.patientsafetyinstitute.ca>> accessed: 01 December 2014; J Gilmour, 'Patient Safety and the Law in Canada' in J Tingle and P Bark (eds) *Patient Safety, Law Policy and Practice* (Oxon: Routledge, 2011) 250.

³⁷ Department of Health and Children (Ireland), *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance* (Dublin: Stationery Office, 2008) 39. See further: Department of Health and Children (Ireland), *Primary Care: A New Direction*. (Dublin: Stationery Office, 2001); Department of Health and Children (Ireland), *Quality and Fairness: A Health System for You* (Dublin: Stationery Office, 2001); Department of Health and Children (Ireland), *Health Service Reform Programme*. (Dublin: Stationery Office, 2003); Department of Health and Children (Ireland), *National Health Information Strategy* (Dublin: Stationery Office, 2004).

through multi-agency participation, including the Quality and Patient Safety Division of the Health Services Directorate.³⁸

Although created prior to the report, success of the recommendations has relied heavily on two key governmental branches: the Health Service Executive (HSE) and the Health Information and Quality Authority (HIQA).³⁹ The Health Information and Quality Authority was established in 2007, pursuant to the Health Act 2007. The work of the HIQA is fundamental to safety and quality improvement in Ireland. The HIQA primary role is to “develop standards, inspect and review health and social care and support services, and support informed decisions on how services are delivered.”⁴⁰

The HSE was created pursuant to the Health Act of 2004, with the objective of streamlining Ireland’s health and social services. Fundamental to the HSE governance and accountability structure was the Office of Quality and Risk, responsible for ensuring an appropriate framework for quality and safety improvement, as well as risk management throughout the Health Service. In 2015, the Quality Improvement Division, and the Quality Assurance and Verification Division took over the duties of the Office of Quality and Risk. The Quality Improvement Division is responsible for, *inter alia*, supporting a quality and safety agenda at all levels of the Health Service; staff

³⁸ Department of Health and Children (Ireland), *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance* (Dublin: Stationary Office, 2008). See further: Health Service Executive, Quality and Patient Safety Division, *Report of the Quality and Safety Clinical Governance Development Initiative – Sharing our Learning* (Dublin: Stationary Office, 2014); Health Information and Quality Authority, *‘As Is’ Analysis of Patient Safety Intelligence Systems and Structures in Ireland* (Dublin: Stationary Office, 2016); Health Service Executive, Quality and Patient Safety Directorate, *A Practical Guide to Clinical Audit* (Dublin: Stationary Office, 2013).

³⁹ Both the HSE and HIQA were established following the recommendations of the *Audit of Structures and Functions of the Health System* Report, and the work of the Commission on Financial Management and Controls in the Health Service. See further: Department of Health and Children (Ireland), *Audit of Structures and Functions of the Health System* (carried out by Prospectus Consultants), (Dublin: Stationary Office, 2003); Department of Health and Children (Ireland), *Report of the Commission on Financial Management and Controls in the Health Service* (Dublin: Stationary Office, 2003).

⁴⁰ Health Information and Quality Authority, *‘As Is’ Analysis of Patient Safety Intelligence Systems and Structures in Ireland* (Dublin: Stationary Office, 2016) 3.

and patient engagement; elements of clinical audit in collaboration with, and support of, the National Office of Clinical Audit. The Quality Assurance and Verification Division is responsible for, *inter alia*, clinical risk management and the implementation of recommendations made across the health and social care sectors, Healthcare Audit, and includes the work of the National Performance Oversight Group.⁴¹ Under the Department of Health, a National Patient Safety Office is also in the process of being established as a means of strengthening the DOH's current patient safety role.⁴²

3.6 The World Health Organization

In 2002, in response to growing research and initiatives within the USA,⁴³ UK⁴⁴ and Australia;⁴⁵ the World Health Organization (WHO) published a report and subsequent resolution urging member states to recognise the need to promote patient safety as a

⁴¹ Health Service Executive, 'Quality Improvement Division' < <http://www.hse.ie/eng/about/Who/qualityandpatientsafety/> > accessed: 17 March 2016; Health Service Executive, 'Healthcare Audit' < <http://www.hse.ie/eng/about/Who/qualityandpatientsafety/auditservices/> > accessed: 17 March 2016.

⁴² Department of Health and Children (Ireland), 'National Patient Safety Office' < <http://health.gov.ie/patient-safety/national-patient-safety-office/> > accessed: 17 March 2016.

⁴³ T Brennan et al., 'Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I' (1991) 324 NEJM 370; L Leape et al., 'The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II' (1991) 324 NEJM 377; Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999).

⁴⁴ Department of Health (UK), *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS* (London: Department of Health, 2000).

⁴⁵ R Wilson et al., 'The Quality in Australian Health Care Study' (1995) 163 Medical Journal of Australia 458: Following the same methodology as the *Harvard Practice Study* by using medical records and hospital admissions, the Taskforce on Quality in Australian Health Care in 1995 used a retrospective analysis of medical records and hospital admission rates, finding that the rate of adverse events in Australian hospitals was 16.6% or likely 230,000 preventable adverse events occurring in Australian hospitals each year. See further: E Thomas et al., 'A Comparison of Iatrogenic Injury Studies in Australia and the USA. I: Context, Methods, Casemix, Population, Patient and Hospital Characteristics.' (2000) 12(5) International Journal for Quality in Health Care 371; W Runciman et al., 'A Comparison of Iatrogenic Injury Studies in Australia and the USA II: Reviewer Behaviour and Quality of Care' (2000) 12(5) International Journal for Quality in Health Care 379.

fundamental principal of all health systems.⁴⁶ In particular, the resolution called on Member States to “(1) ... pay the closest possible attention to the problem of patient safety; (2) to establish and strengthen science-based systems, necessary for improving patients' safety and the quality of health care, including the monitoring of drugs, medical equipment and technology.”⁴⁷ The 2002 resolution led to the development of a global programme for policy development in the area of patient safety. The WHO's 2004 *World Alliance for Patient Safety* sought to be a framework for understanding and collaborating global patient safety initiatives.⁴⁸ The World Alliance for Patient Safety Programme focused on six key areas:

1. The formation of a Global Patient Safety Challenge
2. Improving patient and consumer involvement
3. Developing a patient safety taxonomy
4. Research in the field of patient safety
5. Solutions to reduce the risk of healthcare and improve its safety
6. Reporting and learning to improve patient safety.⁴⁹

Using this framework, the WHO have advocated the enhancement of patient safety through three complementary actions: by preventing adverse events, making them visible through reporting and investigation, as well as mitigating these effects when they do occur.⁵⁰ More recently, the WHO have continued to be influential in the area of patient safety through a number of global campaigns that focus on, for example: hand

⁴⁶ World Health Organization (Report by the Secretariat), *Quality of Care: Patient Safety* (23 March 2002) A55/13; World Health Organization (Resolution of the Fifty-fifth World Health Assembly), *Quality of Care: Patient Safety* (18 May 2002) WHA55.18.

⁴⁷ World Health Organization (Resolution of the Fifty-fifth World Health Assembly), *Quality of Care: Patient Safety* (18 May 2002) WHA55.18.

⁴⁸ WHO World Alliance for Patient Safety, *World Alliance for Patient Safety Forward Programme* (Geneva: World Health Organization, 2004).

⁴⁹ *ibid* 7-24.

⁵⁰ *ibid* 4.

hygiene in healthcare,⁵¹ surgical checklists⁵² as well as education and training for both healthcare practitioners and patients.⁵³

The World Health Organization have also been progressive in their work through the Patients for Patient Safety program, established in 2005 in accordance with the London Declaration.⁵⁴ The program aims to, "... incorporate the patient, family and community voice into all levels of health care through engagement and empowerment."⁵⁵ One of their many prominent initiatives thus far includes the Patients for Patient Safety Global Network that brings together patient advocates (many of whom are patients or family members affected by unsafe care) to represent the 'patient voice' at medical school councils, on hospital boards, at policy tables and at professional conferences. Other initiatives include the 5th of May 'Save Lives: Clean Your Hands' campaign to increase hand hygiene; the 'WHO Mother-Baby 7 day mCheck tool' to increase awareness of dangers signs in the first seven days post-birth; and the Patient Engagement Guide for Hospitals, designed to inform and encourage collaboration between healthcare organisations and patients.⁵⁶

Additionally, the WHO have actively partnered with other international organisations such as International Society for Quality in Health Care (ISQUA). The ISQUA was

⁵¹ World Health Organization, 'Clean Care is Safer Care' <<http://www.who.int/gpsc/en/>> accessed: 01 December 2014.

⁵² World Health Organization, 'Safe Surgery' <<http://www.who.int/patientsafety/safesurgery/en/>> accessed: 01 December 2014.

⁵³ World Health Organization, 'Education and Training' <<http://www.who.int/patientsafety/safesurgery/en/>> accessed: 01 December 2014. For the most recent progress report on WHO Patient Safety Initiatives, see further: World Health Organization (Report by the Secretariat), *Progress Report* (23 November 2012) EB132/42.

⁵⁴ *London Declaration by Patients for Patient Safety* (17 Jan 2006) <http://www.who.int/patientsafety/patients_for_patient/London_Declaration_EN.pdf>.

⁵⁵ World Health Organization, 'Patients for Patient Safety' <http://www.who.int/patientsafety/patients_for_patient/en/> accessed: 20 March 2016.

⁵⁶ World Health Organization, *Patients for Patient Safety: Partnerships for Safer Health Care* (2013) WHO/HIS/PSP/2013.2. p5-7.

created in 1984 with the mission to “inspire and drive improvement in the quality and safety of healthcare worldwide through education and information sharing, external evaluation, supporting health system and connecting people through global networks.” To achieve these aims, the ISQua work in collaboration with representatives from over 100 countries, assisting with technical and policy advice, developing educational programmes, and offering international voluntary accreditation to healthcare organisations.⁵⁷

3.7 Conclusion

This chapter has sought to outline the early developments of the patient safety movement within the United States, England, Canada, Ireland, and the World Health Organization. Additionally, this chapter is intended to provide the foundation for the remainder of this thesis in which the key elements of the patient safety movement will be extensively analysed for their ability to improve patient safety, both in their own right and working in tandem with medical malpractice actions. The patient safety movement brought public recognition to the high levels of preventable adverse events, and also alternative methods by which to prevent and manage their occurrence. Patient Safety, as opposed to a focus on legal risk, has become the benchmark for which healthcare systems strive towards. Perhaps most importantly, the patient safety movement addressed the role of system factors in the occurrence of preventable adverse events, a position that conflicts with traditional legal principles of individual responsibility. As a result, early patient safety efforts focused heavily on the need to move from a litigious culture of blame to a safety culture that acknowledges various origins of error, prioritises learning, and facilitates reporting. Certainly incidents such as those detailed in the Mid-Staffordshire Report⁵⁸ make clear that there is still work to be done in practice. This has led to an increased emphasis on both patient safety

⁵⁷ International Society for Quality in Health Care, ‘Who we are?’ <<http://www.isqua.org/who-we-are/who-we-are>> accessed: 05 April 2016.

⁵⁸ R Francis, *Report of the Mid-Staffordshire NHS Foundation Trust Public Inquiry* (London: The Stationery Office, 2013).

efforts, and the need for greater accountability within healthcare services. The following chapter will examine in greater depth the appropriate role and application of accountability in healthcare.

The Institute of Medicine's publication, *To Err is Human* contributed to a watershed moment in healthcare.⁵⁹ The report critically distinguished errors as a sign of humanity and not incompetence. Their conclusion—that the vast majority of adverse events were the result of failed systems and procedures as opposed to negligent clinicians—challenged conventional beliefs about error causation.⁶⁰ Subsequent patient safety publications in England, Canada and Ireland have been equally influential. For example, the report *An Organisation with a Memory*⁶¹ paved the way for the current Clinical Governance structures with England's National Health Service. The significance of this was predicted by Donaldson and Scally in their seminal 1998 article in which they argued, "Clinical governance is to be the main vehicle for continuously improving the quality of patient care"⁶² For this reason, it is examined in greater depth within the following chapters of this thesis.

⁵⁹ Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999).

⁶⁰ *ibid.*

⁶¹ Department of Health (UK), *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS* (London: Department of Health, 2000) 5; citing: National Audit Office, *NHS Summary Accounts 1998/99*. (London: The Stationary Office, 2000).

⁶² L Donaldson and G Scally, 'Clinical Governance and the Drive for Quality Improvement in the New NHS in England' (1998) 317 *BMJ* 61.

- Chapter 4 -

Healthcare Culture and Accountability

4.1 Introduction

The culture of an organisation can be defined as “the values shared among organization members about what is important, their beliefs about how things operate in the organization, and the interaction of these with work unit and organizational structures and systems, which together produce behavioral norms in the organization that promote safety.”¹ Transforming the culture of a healthcare organisation from one that utilises blaming behaviour as a deterrent, to a just culture that balances learning with accountability, is one of the main objectives of the patient safety movement. As Nieva and Sorra have observed in regards to early patient safety theory:

“In recent years there has been increasing understanding within the healthcare industry that various factors... combine to create a culture contradictory to the requirements of patient safety. Increasingly, the culture of the healthcare industry is regarded as a potential risk factor threatening the patients for whom it provides care.”²

Appreciating the role of healthcare culture in the delivery of safe care is fundamental to implementing quality and safety reform. Although early patient safety theory argued in favour of removing blame entirely from the equation, contemporary patient safety theory has questioned both the possibility and appropriateness of this. As a result,

¹ S Singer et al., ‘Relationship of Safety Climate and Safety Performance in Hospitals’ (2009) 44 Health Services Research 399, 400.

² V Nieva and J Sorra, ‘Safety Culture Assessment: a Tool for Improving Patient Safety in Healthcare Organizations’ (2003) 12(Suppl II) BMJ Quality & Safety ii17; citing: D Gaba et al., ‘Production Pressure in the Work Environment. California Anesthesiologists’ Attitudes and Experiences’ (1994) 81 Anesthesiology 488–500; L Leape, ‘Error in Medicine’ (1994) 272 JAMA 1851–1857; T Krizek ‘Surgical Error: Ethical Issues of Adverse Events’ (2000) 135 JAMA Surgery 1359–1366.

the 'just culture' movement has sought to combine safety methodology with progressive mechanisms for ensuring accountability.

This chapter will critically analyse the role of healthcare culture and accountability in the prevention of unsafe care. In the first and second sections, the fear of blame, liability and professional regulatory censure that combine to create a 'culture of blame' will be examined. Organisational silence and perfectionism, both consequences of a blame culture, will be considered in the context of illustrating the adverse effect of blaming behaviour. In contrast, the patient safety movement has sought to dispel the role of blame, by moving towards a 'just culture' that recognises human error as inevitable, and concentrates on prevention, accountability, transparency, learning, and mitigation when an incident does occur. The third section will examine in greater depth the role of, and requirements for, accountability in a just culture. Beginning first with an analysis of the contribution of clinical governance, risk management, and audit in the promotion and maintenance of safe accountable care. Second, the equally fundamental contribution of organisational and professional regulation will be examined. In the final section, New Zealand's unique no-fault compensation system will be analysed as a means of examining whether monetary liability and blame are inescapable prerequisites for ensuring accountability.

4.2 Healthcare and the Culture of Blame

The beliefs and customs of those working within a healthcare organisation are fundamental to the success or failure of quality and safety improvement. Traditionally, healthcare has been dominated by beliefs largely founded on the legal notion of individual responsibility. This has come to be known as the 'culture of blame.'

According to Khatri et al., a culture of blame can be defined as:

“... a set of norms and attitudes within an organization characterized by an unwillingness to take risks or accept responsibility for mistakes because of a

fear of criticism or management admonishment. This culture cultivates distrust and fear, and people blame each other to avoid being reprimanded or put down, resulting in no new ideas or personal initiative because people do not want to risk being wrong.”³

A blame culture, as distinct from a culture that prioritises safety and learning, is not intentionally chosen but rather is the result of a bureaucratic management style that utilises blame as a tool for prevention, and disproportionately holds individuals accountable for factors outside of their control.⁴ Blaming behaviour and a ‘fear of blame’ are synonymous with a culture of blame. However, for the purposes of this analysis, it is useful to distinguish between them. A culture of blame is descriptive of the organisation’s conduct and beliefs; a ‘fear of blame’ and blaming behaviour are descriptive of the beliefs and actions of the individuals working within the organisation. Blaming behaviour has two significant repercussions. First, important lessons for the improvement of quality and safety may fail to be learned, and accountability may be disproportionately directed towards individual behaviour and not systemic causes. As Merry and McCall-Smith note, “... current processes may fail to identify the important lessons to be learned from a tragedy simply because they focus on blame. Thus the doctor’s behaviour may not constitute a legally actionable wrong or sustain a criminal or disciplinary charge, but may nevertheless warrant constructive intervention.”⁵ This passage is significant because it recognises that by focusing distinctly on the principle of individual fault, systemic conditions surrounding the event may not be corrected. Furthermore, it clarifies that it is not only those preventable patient safety incidents that merit legal or regulatory censure that

³ N Khatri et al., ‘From a Blame Culture to a Just Culture in Health Care’ (2009) 34(4) Health Care Management Review 312, 314.

⁴ *ibid* 314-315.

⁵ A Merry and A McCall-Smith, *Errors, Medicine and the Law* (Cambridge: Cambridge University Press, 2001) 11.

should be corrected. Thus, simply meeting the requisite standard of care does not ensure safe accountable care is being delivered.

The second repercussion of blaming behaviour is that it inhibits information sharing and learning. As Jenicek explains:

“Accomplished health professionals are often hesitant to share information because it may lead to third-party analysis for psychological, legal, or monetary and otherwise punitive reasons. In addition, their lack of willingness to share is encouraged by hospital, insurer, and attorney suggestions to avoid words like *error*, *harm*, *negligence*, *fault*, or *mistake*, whose meanings may vary and which may trigger litigation.”⁶

Jenicek’s argument is a legitimate one. The culture of blame is sustained in part by the very real possibility of professional or legal sanctions by the hospital, professional regulatory bodies or the patient and family. The fear of litigation and professional censure (i.e. as a result of a concurrent complaint to the clinician’s regulatory body) can consequently inhibit incident reporting, the disclosure of preventable incidents to the patient and healthcare organisation, as well as encourage defensive practice and communication.⁷ As will be examined in the following section, these practices are antithetical to safety and quality improvement. By way of example, it is now instructive to consider two of the primary consequences of a culture of blame and blaming behaviour. These include: organisational silence and perfectionism within medicine.

⁶ M Jenicek, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011) 171; citing: T Delbanco and S Bell, ‘Guilty, Afraid and Alone—Struggling with Medical Error’ (2007) 357(17) *NEJM* 1682-1683.

⁷ See further: Chapter 9 ‘Incident Reporting and Analysis.’ Additionally, a culture of blame can contribute to low levels of error disclosure. See also: Chapter 11 ‘Communication: Disclosure and Apology.’

Organisational Silence

Where the culture of a healthcare organisation is dominated by a fear of blame, regulatory scrutiny and liability, healthcare professionals are likely to refrain from offering suggestions, asking questions, or reporting patient safety incidents and near-misses.⁸ On a larger scale within an organisation, organisational silence can be both a symptom and contributor to the culture of blame. In the context of healthcare and error, 'silence' can be defined as "noncommunication resulting from a conscious decision of employees to hold back seemingly important information, including suggestions, concerns, or questions."⁹ Extending this further to the organisation, Henriksen and Dayton, have defined 'organisational silence' as, "a collective-level phenomenon of saying or doing very little in response to significant problems that face an organization."¹⁰

Although not exhaustive, three of the main causes of 'organisational silence' include an unwillingness to raise concerns when one becomes aware of unsafe practices or situations, organisational disregard, and 'cultural censorship.' In regards the former, healthcare professionals may be inclined to remain silence where there is a lack of confidence, concerns over the effect of involvement, or a fear of retaliation.¹¹ Similarly, organisational silence can include organisational disregard, in which there is a failure by the organisation to act on the concerns raised or undervalue employee contributions.¹² The style of leadership at the local level strongly contributes to the

⁸ For a detailed analysis of organisational and employee silence, see further: N Deniz et al., 'The Relationship between Employee Silence and Organizational Commitment in a Private Healthcare Company' (2013) 99 *Procedia Social and Behavioral Sciences* 691, 692-695.

⁹ K Henriksen and E Dayton, 'Organizational Silence and Hidden Threats to Patient Safety' (2006) 41(4) *Health Services Research* 1539. See further: N Khatri et al., 'From a Blame Culture to a Just Culture in Health Care' (2009) 34(4) *Health Care Management Review* 312, 315.

¹⁰ *ibid.*

¹¹ *ibid* 1541; citing: D Maxfield et al., *Silence Kills—The Seven Crucial Conversations for Healthcare* (Provo, UT: VitalSmarts, 2005).

¹² A Jones and D Kelly, 'Defensing Silence? Time to Reconsider Whether Organisations are Silent or Deaf When Things Go Wrong' (2014) 23 *BMJ Quality & Safety* 709, 711-712.

willingness of individuals to effectively communicate concerns, and the willingness of organisations to listen and act.¹³

The third cause of organisational silence is what Hart and Hazelgrove term 'cultural censorship,' in which:

“... untoward events paradoxically are simultaneously recognized yet concealed, where a lack of consensus as to the contributing factors of an adverse event provides a convenient cloak for assigning it to the expected risks of medical practice, and where implicit bonds of transgression are formed and become culturally acceptable with respect to questionable practices that are shared by providers as a way of getting things done.”¹⁴

This form of organisational silence is arguably the most detrimental, as well as ethically and legally questionable. By concealing or normalizing such practices, patient care is jeopardised and opportunities for system redesign and learning are lost.¹⁵

Returning to Henriksen and Dayton definition, organisational silence is particularly problematic because significant problems within the organisation remain unresolved. When a serious incident occurs, it is only recognised in retrospect that the event could have been prevented. This leads to the unfortunate situation within a blame culture

¹³ K Henriksen and E Dayton, 'Organizational Silence and Hidden Threats to Patient Safety' (2006) 41(4) Health Services Research 1539, 1547; citing: A Edmondson, 'Learning from Mistakes Is Easier Said Than Done: Group and Organizational Influences on the Detection and Correction of Human Error' (1996) 32 Journal of Applied Behavioural Science 5-28; A Edmondson, 'Learning from Failure in Health Care: Frequent Opportunities, Pervasive Barriers' (2004) 13(Suppl II) Quality and Safety in Health Care ii3-ii9.

¹⁴ K Henriksen and E Dayton, 'Organizational Silence and Hidden Threats to Patient Safety' (2006) 41(4) Health Services Research 1539, 1541; citing: E Hart and J Hazelgrove, 'Understanding the Organizational Context for Adverse Events in the Health Services: The Role of Cultural Censorship' (2001) 10 Quality in Health Care 257-262.

¹⁵ See further: Chapter 6.3.3 'Social and Organisational Factors' examining the normalisation of error within healthcare organisations.

where individuals are held solely responsible for a patient safety incident, notwithstanding the multitude of latent factors that have contributed yet remained hidden.

Perfectionism in Healthcare

Another consequence of a culture of blame is the demand for perfection by both physicians themselves and society in general. Reflecting on human error in medicine, Leape has made the critical observation that perfectionism is inherent to the culture of medical practice; beginning in medical school and residency where 'error-free practice' is reinforced, errors are then viewed as a failure of one's character.¹⁶ In this regard, Wu describes physicians as the 'second victim' of medical error:

"Strangely, there is no place for mistakes in modern medicine. Society has entrusted physicians with the burden of understanding and dealing with illness. Although it is often said that "doctors are only human," technological wonders, the apparent precision of laboratory tests, and innovations that present tangible images of illness have in fact created an expectation of perfection. Patients, who have an understandable need to consider their doctors infallible, have colluded with doctors to deny the existence of error. Hospitals react to every error as an anomaly, for which the solution is to ferret out and blame an individual, with a promise that 'it will never happen again.' Paradoxically, this approach has diverted attention from the kind of systematic improvements that could decrease errors. Many errors are built into existing routines and devices, setting up the unwitting physician and patient for disaster. And, although patients are

¹⁶ L Leape, 'Error in Medicine' (1994) 272(23) JAMA 1851; D Cohen and M Rhydderch, 'Support for Tomorrow's Doctors: Getting it Right, Meeting Their Needs' (2013) 63(1) Occupational Medicine 2; M Peters, 'Perfectionism in Doctors' (2012) 344 BMJ 1674.

the first and obvious victims of medical mistakes, doctors are wounded by the same errors: they are the second victims.”¹⁷

Wu was the first to introduce the concept of the ‘Second Victim,’ and his description of physicians as the second victims of medical error is fundamental to understanding the pervasive effects of perfectionism in medicine, but more importantly, the far reaching consequences that a blame culture can have. It is important to note that the psychological consequences of error are not unique to physicians; all healthcare professionals who operate on the front line can be a ‘second victim.’ As Wu insightfully argued, “Nurses, pharmacists, and other members of the healthcare team are also susceptible to error and vulnerable to its fallout. Given the hospital hierarchy, they have less latitude to deal with their mistakes: they often bear silent witness to mistakes and agonies over conflicting loyalties to patient, institution, and team. They too are victims.”¹⁸ In support of this argument, Jones and Trieber have stated in relation to nursing:

“The present healthcare culture relies on nursing to, at times, do more than is humanly possible. Nurses are expected to multitask while doing very complex tasks in a chaotic, hurried fashion and yet to perform perfectly while doing so. This environment can be, and often is, toxic to nurses, leaving them exhausted, discouraged, and frustrated with their inability to provide adequate care for their patients. The stress, danger, and frustration that nurses experience on a daily basis has been identified as the single most variable causing nurses to leave the nursing profession.... What makes this

¹⁷ A Wu, ‘Medical Error: The Second Victim. The Doctor Who Makes the Mistake Needs Help Too.’ (2000) 320 BMJ 726.

¹⁸ *ibid* 727.

especially egregious for nurses is that they have so little control over their own work environment.”¹⁹

The circumstances which have been described by Jones and Trieber are relevant to understanding current healthcare culture, but they are also particularly relevant in the context of error causation. The causes of error are a fundamental component of patient safety theory, and will be examined in depth throughout chapter 6 of the thesis.

Paradoxically, attempting so-called ‘perfection’ can have a devastating effect on patient care. For example, the expectation of perfection from patients can contribute to defensive practice, in which a physician’s concern over liability leads to excessive diagnostics or treatment.²⁰ Moreover, where a physician views their patient as a potential adversary, communication between the two may become defensive.²¹

Defensive communication is antithetical to a safe and just culture because it creates barriers between the patient and the physician, leading to misinformation, a failure to follow requisite care plans, as well as increasing the probability of a patient choosing to litigate when an error has occurred.²² The potential consequences of error and the inherent feeling of personal responsibility on the part of healthcare professionals can

¹⁹ J Jones and L Treiber, ‘When Nurses Become the “Second Victim”’ (2012) 47(4) *Nursing Forum* 286, 289; citing: G Lafer, ‘Hospitals Speedups and the Fiction of a Nursing Shortage’ (2005) 30(4) *Labor Studies Journal* 27-46. See also: M Grissinger, ‘Too Many Abandon the “Second Victims” of Medical Errors’ (2014) 39(9) *Pharmacy and Therapeutics* 591.

²⁰ See generally: E Carrier et al., ‘High Physician Concern About Malpractice Risk Predicts More Aggressive Diagnostic Testing in Office-Based Practice’ (2013) 32(8) *Health Affairs* 1383; K DeVille, ‘Act First and Look up the Law Afterward?: Medical Malpractice and the Ethics of Defensive Medicine’ (1998) 19 *Theoretical Medicine and Bioethics* 569.

²¹ N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005) 102. Noting that physicians may come to view their patients as “angry adversaries and potential litigants.”

²² Both defensive communication and the necessity of patient cooperation are explored in depth within Chapter 2.3 ‘The Effect of Medical Malpractice Litigation on Patients and Healthcare Professionals’ and in Chapter 7.2.1 ‘Interventions Around the Patient.’

be physically and psychologically devastating.²³ Traditionally, very little support has been available as a result of cultural practices that deter openness and are heavy influenced by the possibility of disciplinary procedures and litigation.²⁴ In recommending ‘Second Victim Support Programs,’ MacLeod has argued, “Support programs may not be right for every medical error situation, nor may they be an appropriate resource for every staff physician. But they will send a clear and welcomed message to the entire staff that their health care organization embraces a culture of compassion and professional integrity.”²⁵ MacLeod’s comments are particularly relevant to the argument set out below: that efforts towards prevention will be ineffectual without organisational support advocating cultural change. It is worth reemphasising that in practice, a ‘blame culture’ extends beyond only healthcare professionals—all staff employed within the organisation are effected. Opportunities for progress and learning thus become reliant on hierarchical support and drive, as opposed to local unit-level initiatives. In other words, small and simple changes that could have a large impact on safety are not undertaken for fear of the consequences of not following the status quo. This is an unfortunate paradox because where those in the organisation fear speaking out, the need for change may not be communicated or recognised by those in a position to drive change. Certainly the law has a role to play in holding those at the blunt end (e.g. hospital boards) accountable for achieving specific safety standards, but it is the process taken to achieve those standards that can not be legislated and is reliant on staff participation and buy-in.

²³ S Scott et al., ‘The Natural History of Recovery for the Health Care Provider “Second Victim” After Adverse Patient Events.’ (2009) 18(5) *BMJ Quality & Safety* 325; L Joesten et al., ‘Assessing the Perceived Level of Institutional Support for the Second Victim After a Patient Safety Event’ (2015) 11(2) *Journal of Patient Safety* 73, 74-77.

²⁴ W Nelson, ‘Addressing the Second Victim in Medical Error’ (2008) 28(2) *Healthcare Executive* 56.

²⁵ L MacLeod, ‘“Second Victim” Causalities and How Physician Leaders Can Help’ (2014) 40(1) *Physician Executive* 8, 12. The need for effective support systems has also been highlighted by the National Quality Forum in the United States: National Quality Forum, *Safe Practices for Better Healthcare-2009 Update: A Consensus Report* (Washington: National Quality Forum, 2009).

Evolving from a culture dominated by fear to a just culture in healthcare can be challenging to achieve in practice, not least because it requires the collective beliefs of those within the organisation to reexamine their priorities and vulnerabilities, and also a willingness by organisation leaders and regulators to devote time and resources away from the status quo. The next section will examine the philosophy, development, and components of a just culture.

4.3 A Just Culture

Despite early enthusiasm for the adoption of a culture free from blame, the reality of clinical practice, and the legal framework within which it operates, have largely negated the blame-free culture and safety culture movements that began with the early work of James Reason²⁶ and the publication of *To Err is Human*.²⁷ In its place, the notion of a 'just culture' was introduced as a means of "balancing the 'no blame' systems approach to medical errors with the need for accountability—at the individual, managerial and organisational levels."²⁸

The dichotomy between holding individuals accountable for their actions, while maintaining an environment that supports open communication and learning, presents a challenge for healthcare regulators and the law—particularly within the current legal frameworks of the jurisdictions examined throughout this thesis. Indeed it would be difficult to adopt a system free from blame when the very foundations of our civil legal system rely so heavily on the apportionment of (monetary) liability to ensure accountability. While the philosophy behind a blame-free culture certainly has merit—i.e. that systemic improvement relies on organisational learning which is strictly

²⁶ J Reason, *Human Error* (New York: Cambridge University Press, 1990); J Reason, *Managing the Risks of Organizational Accidents* (Aldershot: Ashgate, 1997).

²⁷ Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999).

²⁸ R Wachter, 'Personal Accountability in Healthcare: Searching for the Right Balance' (2012) 22(2) *BMJ Quality & Safety* 176.

inhibited by fear—it does not adequately address the reality of clinical practice and healthcare delivery. As Boysen has argued, "...medical institutions cannot afford a blame-free culture: some errors do warrant disciplinary action."²⁹

For this reason, this thesis is predominantly concerned with reducing the *adversarial* culture within healthcare, as opposed to blame. To further elaborate on this point, it is useful to now briefly outline the characteristics of a safety culture before moving on to the hybrid and contemporary philosophy of a just culture.

A Culture of Safety

Early patient safety theory was largely based on the work and research of High Risk Organisations. As such, it is useful to consider an early definition of a 'culture of safety' as set out by the Advisory Committee on the Safety of Nuclear Installations:

"The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety and by confidence in the efficacy of preventive measures."³⁰

Extending this analysis further, Singer et al., have defined a culture of safety as, "the values shared among organization members about what is important, their beliefs

²⁹ P Boysen, 'Just Culture: A Foundation for Balanced Accountability and Patient Safety' (2013) 13 Ochsner Journal 400; citing: S Dekker, *Just Culture: Balancing Safety and Accountability*. (Burlington, VT: Ashgate Publishing, 2008). As Boysen further notes, "Finding a balance between the extremes of punishment and blamelessness is the goal of developing a just culture."

³⁰ Health and Safety Commission, *Organizing for Safety: Third Report of the Human Factors Study Group of ACSNI* (Sudbury: HSE Books, 1993); as taken from: V Nieva and J Sorra, 'Safety Culture Assessment: A Tool for Improving Patient Safety in Healthcare Organizations' (2003) 12(Suppl II) BMJ Quality & Safety ii17-18.

about how things operate in the organization, and the interaction of these with work unit and organizational structures and systems, which together produce behavioral norms in the organization that promote safety.”³¹ This definition is inclusive in that it acknowledges that cultural change requires adaptation of the values and beliefs of those within the organisation, and also adaptation of the organisational structures and systems to collectively promote safety. Alone, neither a change in values and beliefs, nor the development of organisational structures and systems will create cultural change. In this regard, Nieva and Sorra have stated, “A fundamental culture change is necessary to ensure that innovations introduced to improve patient safety actually achieve their potential.”³²

The challenges of cultural change within an organisation cannot be understated. Cultural reform requires not only the political will, judicial support, financial investment, and effective governance and regulatory structures, but also overcoming long established cultural norms.³³

At the organisational level, cultural reform which prioritises safety necessitates a strong commitment by leadership to mechanisms such as teamwork, evidence-based practice, communication, learning, transparency, consensus building, patient engagement and patient-centred care, accountability, system redesign and employee

³¹ S Singer et al., ‘Relationship of Safety Climate and Safety Performance in Hospitals’ (2009) 44 Health Services Research 399, 400.

³² V Nieva and J Sorra, ‘Safety Culture Assessment: A Tool for Improving Patient Safety in Healthcare Organizations’ (2003) 12(Suppl II) BMJ Quality & Safety ii17; M Dixon-Woods et al., ‘Culture and Behaviour in the English National Health Service: Overview of Lessons from a Large Multimethod Study’ (2014) 23 BMJ Quality & Safety 106. The authors found, *inter alia*, “Consistent achievement of high-quality care was challenged by unclear goals, overlapping priorities that distracted attention, and compliance-orientated bureaucratized management.”

³³ T James, ‘Fault and Blame in the NHS: Review and Replacement of the Clinical Negligence System in the UK’ in J Tingle et al. (eds), *Regulating Healthcare Quality: Legal and Professional Issues* (Edinburgh; New York: Butterworth-Heinemann, 2004) 59.

safety—all fundamental components of safety methodology.³⁴ In addition, the requirement of a psychologically safe work environment has increasingly been recognised throughout patient safety literature as integral to the prioritization of safety. A psychologically safe work environment has been defined by Derickson et al. as:

“Psychologically safe work environments prime employees to believe that they will not be penalized or resented for attempting to engage in team learning by asking questions, making suggestions, pointing out mistakes, or seeking feedback. Such environments allow employees to feel more secure in pointing out problems and making suggestions that benefit the organization. More specifically, psychologically safe health-care workplaces facilitate the reporting of actual and potential medical errors, by virtue of creating a nonpunitive environment where errors can be exposed and corrected without fear of gratuitous consequences. Such an environment is critical, given consistent findings that employees are reluctant to communicate negative information up the chain of command because of the

³⁴ C Sammer et al., ‘What is Patient Safety Culture? A Review of the Literature’ (2010) 42(2) *Journal of Nursing Scholarship* 156, 157-163; A Kachalia, ‘Improving Patient Safety Through Transparency’ (2013) 369(18) *NEJM* 1677-1679; V Roberts and M Perryman, ‘Creating a Culture for Health Care Quality and Safety’ (2007) 26(2) *Health Care Manager* 155; J Scott-Cawiezell et al., ‘Moving From a Culture of Blame to a Culture of Safety in a Nursing Home Setting’ (2006) 41(3) *Nursing Forum* 133; S Singer, ‘Identifying Organisational Cultures that Promote Patient Safety’ (2009) 34(4) *Health Care Manager Review* 219; C Vincent, *Patient Safety* (2nd edn, UK: Wiley-Blackwell, 2010) 269-289; D Mohr et al., ‘Does Employee Safety Matter for Patients Too? Employee Safety Climate and Patient Safety Culture in Health Care’ (12 June 2015) *Journal of Patient Safety* [epub ahead of print].

risks associated with disrupting the environment or being blamed for a mistake.”³⁵

The implementation of policies and attitudes that promote a psychologically safe work environment is a key component in the prioritisation of safety. This is because instilling cultural change that promotes safety over fear requires organisational dedication to transparency and information sharing. This means assurances that staff will not be penalised when safety risks are reported, and that dedicated resources to publicising how the risks have been remedied. Where healthcare professionals do not feel they can safely share information, the potential to learn, improve, and prevent is greatly reduced.

Although quantifying cultural change can be challenging, an analysis of the literature suggests that moving away from fear as a deterrent mechanism, and prioritising safety,

³⁵ R Derickson et al., ‘Psychological Safety and Error Reporting Within Veterans Health Administration Hospitals’ (2015) 11(1) *Journal of Patient Safety* 60; citing: A Tucker and A Edmondson, ‘Why Hospitals Don’t Learn from Failures: Organizational and Psychological Dynamics that Inhibit System Change.’ (2003) 45 *California Management Review* 55-72; F Walumbwa and J Schaubroeck, ‘Leader Personality Traits and Employee Voice Behavior: Mediating Roles of Ethical Leadership and Work Group Psychological Safety.’ (2009) 5 *Journal of Applied Psychology* 1275-1286; C Bond and E Anderson, ‘The Reluctance to Transmit Bad News: Private Discomfort of Public Display?’ (1987) 23 *Journal of Experimental Social Psychology* 176-187; A Edmondson, ‘Learning from Mistakes is Easier Said Than Done: Group and Organizational Influences on the Detection and Correction of Human Error.’ (1996) 32 *Journal of Applied Behavioural Science* 5-28; A Edmondson, ‘Psychological Safety and Learning Behavior in Work Teams.’ (1999) 44 *Administrative Science Quarterly* 350-383.

is significantly associated with improved patient outcomes.³⁶ For example, Pronovost et al. found a correlation between the implementation of a comprehensive unit-based safety program on two intensive care units and a reduction in both medication errors and the average length of patient stay. A key element of the program was identifying and addressing the unit staff's concerns.³⁷ Similarly, in a larger study of 179 hospitals in the United States, Mardon et al. found that hospitals that scored higher on factors that are inclusive of a safety culture (i.e. communication openness, feedback and communication about error, frequency of events reported, management support for patient safety, organisational learning and a nonpunitive response to error) had lower rates of in-hospital complications and adverse events.³⁸

Organisational support for safety improvement is fundamental, not least because the success of intervention will depend on it. Referring back to the example of perfectionism and 'second victim' support services, in a recent study by Joesten et al., the authors used surveys in a Boston hospital to assess the perceived level of institutional support for the second victim after an adverse incident. They found that only 10% to 30% of the respondents were aware of various support services or interventions offered; less than 32% agreed or strongly agreed that they could report

³⁶ L Hansen et al., 'Perceptions of Hospital Safety Climate and Incidence of Readmission' (2011) 46(2) Health Services Research 596. The authors concluded a hospital patient safety climate was associated with lower rates of patient readmission; M DiCuccio, 'The Relationship Between Patient Safety Culture and Patient Outcomes: A Systematic Review' (27 February 2014) Journal of Patient Safety 1 [epub ahead of print]. Similarly, DiCuccio concluded there was significant evidence over the previous ten year period to suggest a relationship between patient safety culture and patient outcome at both the hospital and nursing unit level. It is useful to note that in a study by Groves examining safety culture and the occurrence rate of pressure ulcers, falls, medication errors, nurse-sensitive outcomes, and post-operative outcomes; no significant relationship was found between cultural attributes and improved outcome. However, the author notes that this may be the result of conceptual disagreement amongst the studies as to the theoretical underpinnings of a safety culture: P Groves, 'The Relationship Between Safety Culture and Patient Outcomes: Results From Pilot Meta-Analyses' (2014) 36(1) Western Journal of Nursing Research 66, 78.

³⁷ P Pronovost et al., 'Implementing and Validating a Comprehensive Unit-Based Safety Program' (2005) 1(1) Journal of Patient Safety 33, 34-39.

³⁸ R Mardon et al., 'Exploring Relationships Between Hospital Patient Safety Culture and Adverse Events' (2010) 6(4) Journal of Patient Safety 226, 227-230.

concerns without fear of retribution or punitive action being taken; and most significantly, only 38% of the respondents experienced support from their manager or department chair, in contrast to 64% who experienced support from clinical colleagues.³⁹ The authors suggest that while the survey responses may indicate that managers are erring on the side of punitive, versus a colleague who will likely be more empathic, it also exemplifies the challenges of implementing a safety culture, particularly where there is a need to balance accountability with learning.⁴⁰ Owing to these challenges, it is now useful to examine in greater depth the concept of a just culture, and the role of accountability.

A Just Culture

Balancing accountability with learning is the goal of a just culture. Cultural reform within a healthcare environment requires political will, judicial support, financial investment, and effective governance and regulatory structures—primarily through the adoption and enforcement of legislation and regulations that encourage safety, while also ensuring individuals and organisations are held accountable for the care they provide. As Griffith notes,

“Just Culture refers to a values-supportive model of shared accountability. It’s a culture that holds organizations accountable for the systems they design and for how they respond to staff behaviors fairly and justly. In turn, staff are accountable for the quality of their choices and for reporting both their errors and system vulnerabilities. In an organization with a Just Culture, we focus on our systems yet do not lose sight of physicians,

³⁹ L Joesten et al., ‘Assessing the Perceived Level of Institutional Support for the Second Victim After a Patient Safety Event’ (2015) 11(2) *Journal of Patient Safety* 73, 74-75.

⁴⁰ *ibid* 77.

managers, pharmacists, clerks, or nurses as components within our system.”⁴¹

This definition takes into account the early notions of a safety culture, but also recognises that accountability is a fundamental component for ensuring safe care. While analysis throughout this thesis will centre largely on the argument that using civil liability as a sole means of holding individuals accountable does not deter negligence (which by definition is not intentional) but rather exacerbates it and fails to remedy the multitude of systemic factors that lead to the incident’s occurrence, this is not to suggest that individuals not be held accountable nor that patients not be compensated when an adverse incident occurs. As Griffith noted above, staff are held accountable for the quality of their choices, but protected by the organisation for attempting to improve the circumstances that contributed to their actions and choices. The important distinction in terms of a just culture is that accountability is appropriately directed and apportioned based on root cause. Accountability mechanisms, in practice, cannot and should not be mutually exclusive. In this regard, it is important to emphasise that accountability can be both a proactive and retrospective process, blame alternatively is retrospective and emotion driven. While again, I would argue they are often theoretical in practice (largely because the consequence of a failed accountability structure is blame), cultural attributes such as blame are the result of a collective attitude connected to the organisation’s understanding and enforcement of accountability and their accountability structures.⁴²

To further deconstruct the concept of a just culture, it is useful to consider the work of other high risk organisations and their contribution to healthcare. In 2007, the aviation industry established the EUROCONTROL *Just Culture Task Force*, which sought to “ ...

⁴¹ K Griffith, ‘The Growth of a Just Culture’ (2009) 9(12) Joint Commission Perspectives on Patient Safety 8.

⁴² M Paul, ‘Moving from Blame to Accountability’ (2016) < <https://thesystemsthinker.com/moving-from-blame-to-accountability/> > accessed: 07 July 2017.

promote, debate and discuss the legal questions relating to safety and justice, to foster and support dialogue between safety and judicial experts, and to develop relevant guidance material and policies in order to support the implementation and dissemination of a Just Culture concept.”⁴³ Fundamental to these efforts has been the implementation of Regulations (EU) No 691/2010⁴⁴ and No 996/2010⁴⁵, which sought to formally introduce the concept of a just culture, as well as provide a legislative basis inclusive of just culture principles in the investigation of air accidents and incidents. The regulations seek to address, “... balance between the objectives of the judiciary in determining whether criminal intent was involved, and the need of the aviation industry to be able to run a realtime self diagnostic system without unnecessary interference from the justice system.”⁴⁶ The balance between allowing the industry to conduct an open and transparent investigation, while ensuring the appropriate causes are determined and appropriate persons/bodies are ultimately held accountable is a hallmark of a just culture.

Lessons for healthcare have also been drawn from American Military Aviation and the US Coast Guard. Specifically, the American government commissioned the Department of Defense and the Agency for Healthcare Research and Quality “to translate the

⁴³ EUROCONTROL, ‘Just Culture’ <<http://www.eurocontrol.int/articles/just-culture>> accessed: 09 March 2016.

⁴⁴ European Council Regulation 691/2010 of 29 July 2010 laying down a performance scheme for air navigation services and network functions and amending Regulation (EC) No 2096/2005 laying down common requirements for the provision of air navigation services. [2010] L 201/1. The amended regulations are contained within: European Council Regulation 390/2013 of 3 May 2013 laying down a performance scheme for air navigation services and network functions Text with EEA relevance. [2013] OJ L 128; European Council Regulation 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007. [2014] OJ L 122.

⁴⁵ European Council Regulation 996/2010 of the European Parliament and of the the Council of 20 October 2010 on the investigation and prevention of accidents and incidents in civil aviation and repealing Directive 94/56/EC. [2010] L 295/35.

⁴⁶ EUROCONTROL, ‘Just Culture’ <<http://www.eurocontrol.int/articles/just-culture>> accessed: 09 March 2016.

principles of a just culture into a format applicable to the delivery of healthcare.”⁴⁷

Chief among their findings included the TeamSTEPPS (Strategies and Tools to Enhance Performance and Patient Safety).⁴⁸ In the context of accountability and competency based actions, the TeamSTEPPS protocol recommends appropriate outcomes based on five separate caregiver actions:

1. Impaired Judgment - discipline or suspension may be merited;
2. Malicious Action - may merit discipline, the commencement of legal proceedings, or suspension;
3. Reckless Action - may require discipline, retraining, and an obligation to teach lessons learned;
4. Risky Action - may merit coaching and an obligation to teach lessons learned; and
5. Unintentional Error - the caregiver is not held accountable but rather may be required to participate in a resulting investigation, and have an obligation to teach lessons learned.

Where the action is enabled by the system (i.e. the error is inherent in the system or the practice has become normalised), the organisation is held accountable retrospectively, but also held accountable going forward for proactive improvements stemming from the investigation process. Corrective actions may further include evaluation, coaching, suspension, or termination.⁴⁹

⁴⁷ P Boysen, 'Just Culture: A Foundation for Balanced Accountability and Patient Safety' (2013) 13 Ochsner Journal 403; citing: D Kirch and P Boysen, 'Changing the culture in medical education to teach patient safety.' (2010) 29(9) Health Affairs 1600-1604.

⁴⁸ P Boysen, 'Just Culture: A Foundation for Balanced Accountability and Patient Safety' (2013) 13 Ochsner Journal 404, 405; citing: Agency for Healthcare Research and Quality, 'TeamSTEPPS: Strategies and Tools to Enhance Performance and Patient Safety' <<http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/index.html>>

⁴⁹ *ibid*; citing: M Leonard and A Frankel, 'The Path to Safe and Reliable Healthcare.' (2010) 80(3) Patient Education Counseling 288-292.

Building on the TeamSTEPPS protocol, Leonard and Frankel further designed a three-step process, combining the above TeamSTEPPS with the NHS's algorithm for incident decision-making which asks four questions to deconstruct the caregivers actions and assign accountability, if necessary: was the harm deliberate, was the provider impaired, was the incident foreseeable due to a lack of following procedure, policies and protocols; and lastly, would another provider in the same position make the same error?⁵⁰ From this, the authors concluded that accountability can be determined by first analyzing the caregiver's actions under the framework of the TeamSTEPPS five measures. Second, considering whether another provider in the same position would make the same error, and lastly, determining whether the present system enabled the error and therefore requires redesign.⁵¹ Leonard and Frankel's contribution is particularly useful for acknowledging the role of the system in an individual's actions. One of the guiding principles of a just culture is that accountability must be justly and appropriately assigned—not merely in a vertical manner at the sharp end—and closely connected with the cause of the incident. This principle is clearly articulated by Berwick who notes:

“We distinguish three types of unnecessary risk of harm: risk of harm due to neglect or wilful misconduct; risk of harm due to failures in the system; and risk of harm from error. They are not the same.... Error and neglect or wilful misconduct warrant different responses. Even apparently simple human errors almost always have multiple causes, many beyond the control of the individual who makes the mistake. Therefore, it makes no sense at all to punish a person who makes an error, still less to criminalise it. The same is true of system failures that derive from the same kind of multiple unintentional mistakes. Because human error is normal and, by definition,

⁵⁰ *ibid* 405; citing: National Patient Safety Agency, 'Seven Steps to Patient Safety in General Practice.' <<http://www.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?allId.43743>>.

⁵¹ *ibid* 405; citing: M Leonard and A Frankel, 'The Path to Safe and Reliable Healthcare.' (2010) 80(3) *Patient Education Counseling* 288-292.

is unintended, well-intentioned people who make errors or are involved in systems that have failed around them need to be supported, not punished, so they will report their mistakes and the system defects they observe, such that all can learn from them. On the other hand, harm caused by neglect or wilful misconduct does warrant sanctions in health care, just as it does in other settings.”⁵²

Berwick’s emphasis on three separate types of unnecessary risk is useful for understanding the appropriate assignment of accountability in a just culture. While overlapping is of course possible, all three forms of risk warrant different responses. An excellent example that can potentially fall into all three of these categories is the improper administration of Vincristine, a widely used chemotherapeutic drug. When administered intrathecally, as opposed to intravenously, Vincristine has a 99% fatality rate. As a result of the inadvertent intrathecal administration of the drug, numerous healthcare professionals—throughout the world—have been held both criminally and civilly liable. Regardless of the very serious repercussions, as well as wide spread attention given to these cases, this error continues to unintentionally occur. Potential contributors include: staffing shortages resulting in fatigue, similar packaging to saline solution, and inadequate training.⁵³ The example of Vincristine is useful for illustrating misplaced accountability. Should the individuals who inappropriately administered the drug be held proportionately accountable? Yes. Has relying on civil and criminal liability to hold individuals accountable been a successful method of prevention thus

⁵² D Berwick, *A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England* (London: Department of Health, 2013) 12.

⁵³ D Hubbeling, ‘Criminal Prosecution for Medical Manslaughter’ (2010) 103 *Journal of the Royal Society of Medicine* 216, 217; K Saha, ‘Criminal Negligence: Another Unfortunate Incident of Intrathecal Vincristine Use’ (2003) 327 *BMJ* 697; World Health Organization, ‘Vincristine Sulphate’ <<http://www.who.int/patientsafety/activities/technical/vincristine/en/>> accessed: 19 June 2015. A systems approach looks beyond personal liability and examines all root causes. As one means of intervention, recent efforts have been made to fundamentally change the packaging of Vincristine through the use of forcing functions, thereby creating a barrier and making it impossible to administer the drug intrathecally.

far? Clearly not. Should organisations and product manufactures also be held accountable? Absolutely.

While the analysis throughout this thesis strongly advocates the need to move away from civil liability as the primary mechanism for enforcing accountability, this should not be taken as suggesting that an individual not be held accountable for their behaviour. Moreover, it is, in my opinion, the adversarial culture that is most detrimental as blame (and specifically blaming behaviour) is arguably a theoretical construction that can not be detached from accountability. As distinct from a blame culture that is managed by fear at the sharp end, a just culture strives to appropriately apportion accountability based on thorough investigation and root cause analysis. This means accountability for systemic failures, measurement, and improvement is acknowledged and directed towards those at the blunt end with the ability to direct resources and force change. I have, throughout this thesis, referred to this as non-linear accountability because, again, it can not be based simply on the standard and traditional linear management structure (i.e. top down). This principle can best be described as reciprocal accountability and is made possible through various legislative and regulatory mechanisms, including: clinical governance, organisational and professional regulation, and the civil law—all of which will be examined in greater detail below. Reciprocal accountability requires the organization take an active role in safety improvement, ensuring action is taken to correct systematic failings, best practices are being followed, and ensuring those responsible for patient care meet the requisite professional standards. As described by Morath and Turnbull:

“The concept of reciprocal accountability includes the leader’s accountability for creating a just culture. In a just culture, the leader draws a clear boundary between acceptable and unacceptable behavior. Individual malfeasance, impairment, illegal acts, intentional violation of known standards or procedures, disruptive or abusive behaviors, and the inability

to learn over time are all incompatible with trust and safety. They are barriers to safety and must be dealt with fairly, definitively, and in a timely manner....”⁵⁴

The concept of reciprocal accountability is particularly useful to understanding the law’s role in promoting a just culture. A question that often arises in the context of a safe/just cultural is: should organisations only attempt to reduce blaming behaviour when the care provided meets the legal standard of care? Certainly, individual responsibility—and liability—remain appropriate in situations such as those described by Morath and Turnbull, however, one could argue that the very act of distinguishing acceptable from unacceptable behaviour makes blame inevitable. However, taking a systems view, most errors are the result of complex human and system factors, this is why organisational (reciprocal) accountability is fundamental. Using fear as a tool for prevention is at best minimally effective because it does not prevent system errors, and as the above research has shown, it can result in organisational silence and the withholding of valuable information. As far back as 1989, Donald Berwick argued this point, noting that, “Fear of the kind engendered by the disciplinary approach poisons improvement in quality, since it inevitably leads to dissatisfaction, distortion of information, and the loss of the chance to learn.”⁵⁵ A litigious and adversarial culture relies on fear to deter behaviour. In this regard, the National Advisory Group on the Safety of Patients in England (lead by Prof. Donald Berwick, with contributions from, *inter alia*, Lucian Leape and James Reason), have stated that “Fear is toxic to both safety and improvement,” arguing that to improve safety and quality, healthcare systems must, “Abandon blame as a tool. Trust the goodwill and good intentions of the staff, and help them achieve what they already want to achieve: better care and the relief of

⁵⁴ J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 158-159.

⁵⁵ D Berwick, ‘Continuous Improvement as an Ideal in Health Care.’ (1989) 320 NEJM 53-56; as taken from: M Horstman and A Naik, ‘A “Just Culture” for Performance Measures’ (2015) 24 BMJ Quality & Safety 486.

human suffering. Misconduct can occur and it deserves censure. But, errors are not misconduct and do not warrant punishment.”⁵⁶ This statement clearly sets out the core philosophy behind a just culture: accountability, oversight, and censure are fundamental, however, they must be appropriately directed to be a tool in improvement, rather than “toxic to both safety and improvement.”

It would be easy to suggest blame should be removed from situations in which the law deems the conduct acceptable, however, it is also naive. This is because the distinction between blame and accountability is arguably theoretical. While the potential for disciplinary action, liability, and public condemnation likely all contribute to the fear of blame, it is the prospect of frivolous litigation, professional discipline, and scapegoating that is most detrimental. Individuals will naturally assume an investigation into causation will result in blame should their actions be considered complicit in any way. Even the investigation itself will likely be interpreted as blaming behaviour, notwithstanding the outcome. In essence, where negative repercussions can result from being found accountable for the incident, it would be impossible to remove the element of blame. Therefore, in my opinion, the correct response is to reduce the adversarial and litigious elements of a blame culture while maintaining the proper channels of accountability.

Legislation excluding liability from the disclosure of error and apologies has increasingly been enacted as a means of reducing the adversarial culture while still ensuring individuals are accountable to their patients for the care they provide.⁵⁷ The trend towards organisational support for disclosure policies has been advocated by Truog et al., who note:

⁵⁶ D Berwick, *A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England* (London: Department of Health, 2013) 4, 10.

⁵⁷ It should be noted that while the majority of jurisdictions have enacted legislation allowing physicians and healthcare organisations to disclose adverse incidents, apology laws are significantly less common. See further: Chapter 11 ‘Communication: Disclosure and Apology,’ and specifically Chapter 11.5 ‘The Decision to Apologise.’

“When optimal communication with patients and families in the aftermath of adverse events and medical errors is openly advocated as an institutional priority and responsibility, rather than as the sole province of the attending physician, improved disclosure practice will become an expectation throughout the health care systems, including as part of credentialing and privileging processes. Holding health care professionals accountable in these ways for adhering to organizational disclosure policies will send a powerful message that the expectation of improved practice in this domain of patient care is here to stay.”⁵⁸

In addition, increasing numbers of healthcare organisations have embraced healthcare mediation in cases of medical error as a mechanism by which to foster a just culture, engage patients, and provide organisational and professional accountability.

Healthcare mediation—in contrast to litigation—is uniquely suited to promoting a safety agenda because the mediation process embodies two of the hallmarks of a just culture: open channels of communication and accountability.⁵⁹ Likewise, the mediation process allows lessons to be learned from the event through the active participation of the plaintiff-patient, who may provide valuable insight into necessary changes. In this respect, healthcare mediation also embodies the principles of patient engagement and patient-centred care, another hallmark of a just culture and the patient safety movement. Engaging patients through active communication is fundamental to advancing safety and quality, while also holding the healthcare organisation and professionals accountable to the patient.⁶⁰ Interestingly, Sorra et al. found that healthcare organisations in which staff have a more positive perception of their

⁵⁸ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 132-133.

⁵⁹ See further: Chapter 12.3 ‘Healthcare Mediation.’

⁶⁰ See further: Chapter 7.2.1 ‘Interventions Around the Patient’ for an analysis of the role and importance of patient and family engagement.

hospital culture tended to have more positive assessments of care from their patients.⁶¹ Mechanisms such as clear and progressive legislation requiring comprehensive disclosure and mediation reduce the barriers to communication which are prominent and all-encompassing in a culture dominated by fear and blame. For this reason, chapters 11 and 12 of this thesis will extensively analyse American, English, and Canadian jurisprudence and legislation that has been influential in addressing these barriers and promoting a just culture.

Reducing medical error within healthcare requires thorough investigation, acknowledgment of unsafe processes, and a commitment to improvement. However, these requirements present a challenging dichotomy: in a culture that penalises any deviation short of perfection, the likelihood of thorough investigation and the acknowledgment of unsafe processes decreases. This is particularly problematic when the organisation has a top-down (linear) view of accountability. In contrast to a culture of blame that relies on the threat of punitive action to deter behaviour at the sharp end, and a culture of safety that excessively focuses on the system at the cost of effective oversight; a just culture recognizes this dichotomy and addresses it by ensuring accountability for past and future performance is appropriately directed (e.g. between the sharp end and the blunt end) and suited to the circumstances.

However, caution must be taken when shifting away from a safety culture doctrine to that of a just culture. As Driver has noted,

“The no-blame paradigm in patient safety grew out of a need to encourage open discussion about medical mistakes. Whereas shifting away from a purely no-blame approach may lead to greater adherence with safety practices, and one hopes fewer cases of preventable harm, it also risks

⁶¹ J Sorra et al., ‘Exploring Relationships Between Patient Safety Culture and Patient’s Assessments of Hospital Care’ (2012) 8(3) *Journal of Patient Safety* 131.

stifling the open discussions about medical errors that characterize learning organizations. Because of this, a movement in this direction should be undertaken carefully, starting first with a small number of well-established safety practices, and ensuring that robust education and system improvements precede and accompany the imposition of penalties for nonadherence.”⁶²

This chapter thus far has analysed in greater detail the components necessary for a just culture. Communication, mitigation, and compensation will also be examined in depth throughout chapters 10-12, and safety practices, including systemic improvement and review, will be extensively analysed throughout chapters 4-9. For the purposes of accountability in a just culture, the next section will consider the mechanisms for holding individuals, organisations, and governmental bodies accountable for safe care. While this topic is examined throughout later chapters in respect of the responsibility for systemic improvement, a question arises as to how best to hold individuals accountable for their performance, in light of the research that suggests the fear of punitive regulatory sanctions, liability, and blaming behaviour prevent organisational learning and improvement.⁶³ For this reason, it is useful to first consider the role of clinical governance, risk management and audit. Second, organisational and professional regulation will be examined in the context of a just culture. Lastly, the example of New Zealand will be considered as a jurisdiction whose compensation and accountability systems—on the face of it—are not premised on fault-based liability. The question will be answered: is fault-based monetary liability a prerequisite for accountability?

⁶² T Driver et al., ‘Responding to Clinicians Who Fail to Follow Patient Safety Practices: Perceptions of Physicians, Nurses, Trainees, and Patients’ (2014) 9 *Journal of Hospital Medicine* 99, 103.

⁶³ See further: Chapter 2 ‘The Role of Medical Malpractice Law and Litigation in the Reduction of Medical Error’

4.4 Accountability in a Just Culture

Historically, quality improvement within healthcare was viewed as inherent to the system and “sustained by the ethos and skills of the health professionals working within the organisation.”⁶⁴ The medical profession was self-regulatory in nature, owing to the specialised knowledge required to practice, and the unique position physicians held within society. However, with greater demand from the public for accountability and transparency, the balance between what Berwick refers to as “the romance of professional autonomy” versus the “tools of external accountability” have become fundamental to advancing quality and safety in healthcare.⁶⁵

This section will analyse three mechanisms used to ensure healthcare professionals are held accountable: clinical governance and audit; organisational and professional regulation; and the civil law. Beginning first with an analysis of the contribution of clinical governance, risk management, and audit in the promotion and maintenance of safe accountable care. Second, the equally fundamental contribution of organisational and professional regulation will be examined. Both governance and regulatory structures are essential to quality and safety improvement by ensuring clear avenues of accountability, transparency, and communication between the organisation, staff, and patients. As well, governance and regulatory structures contribute to quality and safety by ensuring staff are practicing at a standard consistent with best professional practices, and for ensuring continuous systemic improvement is undertaken in light of emerging best practices.⁶⁶ In the final section, New Zealand’s unique no-fault compensation system will be analysed as a means of examining whether monetary liability and blame are inescapable prerequisites for ensuring accountability.

⁶⁴ K Haynes, ‘Clinical Governance: a Means for Improving and Regulating Quality’ in J Tingle et al. (eds), *Regulating Healthcare Quality: Legal and Professional Issues* (Edinburgh; New York: Butterworth-Heinemann, 2004) 10; citing: L Donaldson and G Scally, ‘Clinical Governance and the Drive for Quality Improvement in the New NHS in England’ (1998) 317 *BMJ* 61-65.

⁶⁵ D Berwick, ‘Era 3 for Medicine and Health Care’ *JAMA* (03 March 2016) [e-pub ahead of print].

⁶⁶ Department of Health and Children (Ireland), *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance* (Dublin: Stationary Office, 2008) 61-62.

4.4.1 Clinical Governance, Risk Management, and Audit

Clinical Governance

Clinical governance is one mechanism by which to influence organisational culture and improve healthcare outcomes.⁶⁷ As Vanu Som asserts, “Through its integrated approach to quality improvement, clinical governance provides what amounts to a cultural change not least through its emphasis on multidisciplinary work, coordination, cooperation and teamwork.”⁶⁸ This section will first examine the origins and functions of clinical governance, with particular emphasis on the clinical governance structure within England’s National Health Service (NHS). In contrast to jurisdictions such as the United States, the NHS provides a unique example of streamlined healthcare quality improvement at a national level.⁶⁹ In the latter half of this section, the role of clinical audit and clinical risk management will be analysed in the context of accountability.

As stated above, quality and safety were traditionally seen as inherent to the healthcare system and maintained by the ethos and skills of those who worked within it.⁷⁰ The legal system and professional self-regulatory bodies were solely responsible for the regulation and management of appropriate skills and care.⁷¹ The concept of Clinical Governance as an integrated approach to quality improvement originated in the 1990’s as a means of politically demonstrating accountability throughout healthcare services,

⁶⁷ A Halligan, ‘Clinical Governance’ in M Powers, N Harris and A Barton (eds), *Clinical Negligence* (4th edn, Haywards Heath: Tottel, 2008) 44.

⁶⁸ C Vanu Som, ‘Developing the Human Resource Dimension of Clinical Governance’ in A Gray and S Harrison (eds), *Governing Medicine: Theory and Practice* (New York: Oxford University Press, 2004) 152.

⁶⁹ However, it is important to note that while the NHS provides the framework for Clinical Governance within England, the overall responsibility to ensure the principles are implemented locally remains with the individual NHS Trusts.

⁷⁰ G Scally and L Donaldson, ‘Clinical Governance and the Drive for Quality Improvement in the New NHS in England’ (1998) 317 *BMJ* 61.

⁷¹ For a detailed analysis of the traditional accountability structure, see further: A Halligan, ‘Clinical Governance’ in M Powers, N Harris and A Barton (eds), *Clinical Negligence* (4th edn, Haywards Heath: Tottel, 2008) 38.

as well as in response to the proliferation of corporate governance and patient safety theory.⁷² Speaking in both an International and Irish context, the Irish Commission on Patient Safety and Quality Assurance have noted,

“a central finding of many of the health system reviews of safety and quality failures that have been undertaken is that of weak systems of leadership, governance and accountability in healthcare, i.e. the view that ‘no-one was in charge’, with confused lines of responsibility and accountability between professional and managerial staff and often with parallel lines of responsibility for different professional groups within the one organisation.”⁷³

For this reason, clinical governance ideally functions as a framework which “...clearly describes responsibilities, delegated levels of authority, reporting relationships and accountability within the organisation. In particular, there must be clear assignment and documentation of responsibility within and between clinical teams involved in the care of individual patients.”⁷⁴ Additionally, clinical governance provides a mechanism for cultural change by advocating for continuous safety and quality improvement, continuing education and ethical practice, the use of best practice and audit to meet and raise standards of practice and patient outcome, and patient engagement.⁷⁵

Although not expressly in the context of clinical governance, all of these topics will be further analysed to varying degrees throughout the following chapters.

⁷² K Haynes, ‘Clinical Governance: a Means for Improving and Regulating Quality’ in J Tingle et al. (eds), *Regulating Healthcare Quality: Legal and Professional Issues* (Edinburgh; New York: Butterworth-Heinemann, 2004) 8-9.

⁷³ Department of Health and Children (Ireland), *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance* (Dublin: Department of Health, 2008) 61-62.

⁷⁴ *ibid* 93, 94.

⁷⁵ *ibid* 64.

England's National Health Service

By way of example, it is useful to now consider the Clinical Governance structure within the NHS. In England, clinical governance was first defined by the UK Department of Health in their 1998 Report *A First-Class Service: Quality in the New NHS* as,

“a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.”⁷⁶

At its core, clinical governance provides a mechanism by which to improve quality and safety through accountability, consolidation, and codification of healthcare services.⁷⁷ Effective clinical governance requires not only systemic change and support mechanisms, but cultural change as well.⁷⁸ As Vanu Som points out, “Clinical governance promotes an integrated approach to quality improvement which is different from the fragmented approaches of the past. It attempts to break the barriers of differentiated cultures to forge a wide consensus on quality improvement. It also makes every health staff member individually accountable for quality care. In a sense it thus brings together the managerial, organisational and clinical approaches to quality improvement.”⁷⁹ At its inception, the NHS clinical governance framework was composed of seven key components, or ‘The 7 Pillars,’ which included:

⁷⁶ Department of Health (UK), ‘Delivering Quality Standards’ in *A First-Class Service: Quality in the New NHS* (London: Department of Health, 1998) [3.2].

⁷⁷ G Scally and L Donaldson, ‘Clinical Governance and the Drive for Quality Improvement in the New NHS in England’ (1998) 317 *BMJ* 61, 62; V Harpwood, *Medicine, Malpractice and Misapprehensions* (Oxon: Routledge-Cavendish, 2007) 172.

⁷⁸ L Donaldson, ‘Clinical Governance: a Statutory Duty for Quality Improvement’ (1998) 52 *Journal of Epidemiology and Community Health* 73-74.

⁷⁹ C Vanu Som, ‘Developing the Human Resource Dimension of Clinical Governance’ in A Gray and S Harrison (eds), *Governing Medicine: Theory and Practice* (New York: Oxford University Press, 2004) 155-156.

1. Clinical Risk Management;
2. Education, Training and Continuing Professional and Personal Development;
3. Use of Information to Support Clinical Governance and Healthcare Delivery;
4. Clinical Audit;
5. Clinical Effectiveness and Research (Evidence-based Medicine and Guidelines);
6. Patient Involvement and Consultation;
7. Staffing and Staff Management.⁸⁰

Since its establishment, the NHS clinical governance structure has expanded and is now considered an 'umbrella' under which the various themes and components are included.⁸¹ In addition to the seven components listed above, the current NHS clinical governance framework also includes a focus on strategic capacity and capability, communication, leadership, as well as interdepartmental and multidisciplinary teamwork.⁸²

While the inclusion of the components on the revised list is beneficial, for clinical governance to be effective, attention must be paid to the role of organisational culture and its impact on the quality and safety improvement process. For example, cultural barriers such as a lack of openness and transparency, stifled innovation and employees feeling undervalued and inadequately rewarded are all barriers that will ultimately reduce the effectiveness and success of all other initiatives within the organisation.⁸³ As

⁸⁰ G Scally and L Donaldson, 'Clinical Governance and the Drive for Quality Improvement in the New NHS in England' (1998) 317 *BMJ* 61-65.

⁸¹ Flynn has critically argued that while the proliferation of mixed metaphors used to describe clinical governance (i.e. Umbrella, framework, model) indicates its inherent ambiguity, "The elasticity of the term clinical governance may be a factor which eventually contributes to its widespread acceptance...." R Flynn, "'Soft Bureaucracy'", *Governmentality and Clinical Government: Theoretical Approaches to Emergent Policy* in A Gray and S Harrison (eds), *Governing Medicine: Theory and Practice* (New York: Oxford University Press, 2004) 14.

⁸² E Chandrabharan and S Arulkumaran, 'Clinical Governance' (2007) 17(7) *Obstetrics, Gynaecology and Reproductive Medicine* 222, 223.

⁸³ R McSherry et al., 'Can Clinical Governance Act as a Cultural Barometer?' (2013) 109 (19) *Nursing Times* 12-15.

Haynes has argued, “Introduced in isolation, none of these dimensions will provide effective clinical governance. The key is to ensure they are connected and that the loop is closed, thereby providing a coherent and comprehensive programme. Success in achieving this will depend on strong and effective management and leadership who primary aim is to foster an open and participative ‘fair blame’ culture that emphasises both avoiding and learning from mistakes in equal measure.”⁸⁴ Clinical governance is a fundamental component of the accountability process because it provides the means for those within the organisation to work in collaboration, as opposed to the traditional silos of the past. In practice, the obvious concerns would arise as with any other bureaucratic organisation: time delays, poor communication, lack of trust, duplication of work, competing interests—all of which will jeopardise the enthusiasm of those striving for change, as well as the impact of attempted quality and safety improvement initiatives. Strong leadership and accountability structures, clearly defined objectives and expectations, and visible progression of results can aid in this.

In addition, effective clinical governance is intrinsically connected with clinical audit, managing clinical risk, and ensuring the professionals working within the system are accountable for monitoring the standards set out by the organisation and their respective professional bodies, all of which are examined below.

Clinical Risk Management and Clinical Audit

Clinical Risk Management and Clinical Audit are fundamental components of the clinical governance structure, seeking to recognise current risks and implement corrective action and continual monitoring.⁸⁵ Traditionally, clinical risk management

⁸⁴ K Haynes, ‘Clinical Governance: a Means for Improving and Regulating Quality’ in J Tingle et al. (eds), *Regulating Healthcare Quality: Legal and Professional Issues* (Edinburgh; New York: Butterworth-Heinemann, 2004) 12.

⁸⁵ A Block, ‘Disclosure of Adverse Outcomes and Apologizing to the Injured Patient’ in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 298.

was concerned solely with the reduction of financial risk resulting from legal liability.⁸⁶ However, a growing recognition of the connection between financial risk and quality and safety initiatives has led to an expansion of the role of clinical risk management. The theory behind current practices is that by improving clinical effectiveness and outcomes, economic loss can be reduced. This is achieved in a number of ways: through the identification, monitoring, reduction, and prevention of adverse outcomes; ensuring comprehensive, objective communication; altering current unsafe or risky practices through performance standards, protocols and guidelines; responding to and managing incident reports and legal claims; as well as ensuring organisational compliance.⁸⁷ Despite the numerous advances in the role of clinical risk management, Block makes the observation, “Most risk administrators find their time primarily directed toward risk control, rather than risk prevention, for an obvious reason: A lawsuit represents an actual loss.”⁸⁸ For clinical risk management to be effective in improving quality and safety, the management of clinical and financial risk must be holistic—with the guiding principle that prevention is more cost effective than mitigation.⁸⁹ One example where risk and prevention are increasingly recognised as interconnected is in the area of healthcare communication following an adverse incident—analysed extensively through chapters 10 to 12 of this thesis.

⁸⁶ V Harpwood, *Medicine, Malpractice and Misapprehensions* (Oxon: Routledge-Cavendish, 2007) 173-174; citing: L Wilson and P Goldschmidt, *Quality Management in Healthcare* (Sydney: McGraw-Hill, 1995). For an analysis of the rise of risk management systems in England, see generally: K Walshe, ‘The Development of Clinical Risk Management’ in C Vincent (ed), *Clinical Risk Management* (London: BMJ Books, 2001) 45-52.

⁸⁷ J Wilson and J Tingle, ‘Introduction to Clinical Risk Management and Modification’ in J Wilson and J Tingle (eds), *Clinical Risk Modification: A Route to Clinical Governance* (Oxford: Butterworth-Heinemann, 1999) 6; D Sale, *Understanding Clinical Governance and Quality Assurance: Making It Happen* (Hampshire: Palgrave Macmillan, 2005) 43; A Block, ‘Disclosure of Adverse Outcomes and Apologizing to the Injured Patient’ in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 301.

⁸⁸ A Block, ‘Disclosure of Adverse Outcomes and Apologizing to the Injured Patient’ in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 293.

⁸⁹ D Sale, *Understanding Clinical Governance and Quality Assurance: Making It Happen* (Hampshire: Palgrave Macmillan 2005) 41; J Price et al., ‘Principles of Clinical Risk Management’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 27.

Communication with patients that is open, effective, and transparent can be subsequently translated back into the system and used to inform safety and quality efforts going forward, while also reducing the probability and fear of litigation. In this way, clinical risk management has the ability to align with the objectives of a just culture by assuring accountability, transparency, quality and safety.

Closely connected with Clinical Risk Management and within the framework of Clinical Governance is Clinical Audit. Clinical audit has been defined by the UK's National Institute for Health and Care Excellence (NICE)⁹⁰ as a:

“... quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery.”⁹¹

Incident detection and reporting are intrinsic to the process of clinical audit.

Historically, the medical profession was skeptical of clinical audit and incident reporting systems out of fear for how the information collected would be used.⁹²

However, cultural interventions to redefine quality and safety processes as opportunities for learning and prevention (as opposed to liability and fault) have

⁹⁰ In April 2013, in accordance with the Health and Social Care Act 2012, the National Institute for Clinical Excellence became a Non Departmental Public Body; the name was formally changed to the National Institute for Health and Care Excellence to reflect a wider emphasis on developing guidance and quality standards in social care. See further: <www.nice.org.uk> accessed: 25 November 2014.

⁹¹ National Institute for Clinical Excellence, *Principles for Best Practice in Clinical Audit* (Oxon: Radcliffe Medical Press, 2002) 2.

⁹² V Harpwood, *Medicine, Malpractice and Misapprehensions* (Oxon: Routledge-Cavendish, 2007) 172; citing: I Kennedy, *Learning from Bristol: The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984–1995*. (London: The Stationery Office, 2001) [13].

contributed to the development and expansion of clinical audit and incident reporting.⁹³ Clinical audit is a fundamental component of the Clinical Governance structure because of its role in ensuring that the care provided, as well as the systems and processes implemented to improve safety, are meeting predefined international and local standards, and as such, achieving their desired effect. As the Irish Commission on Patient Safety and Quality Assurance have noted, “Driving quality improvement means being able to measure existing quality levels as well as being able to demonstrate the impact of quality improvement plans. This allows data driven decisions to be made, including potential impact on patient outcomes. A key issue is transparency of data to staff and the public alike.”⁹⁴ Clinical audit also holds organisations and individuals accountable to the public for the care they provide and for improvement going forward, specifically through benchmarking and reporting on performance standards, protocols, and guidelines necessary for safe clinical practice.

In practice, one of the most difficult challenges for those working within clinical governance, and specifically audit, has been setting the correct parameters for information collection and analysis. For example, Berwick has been critical of the overuse of mandatory measurement. In his recent publication contrasting the traditional practice within the medical profession of self-regulation, and current practices that seek to ensure accountability through external regulation, Berwick suggests that mandatory measurement should be reduced to only what matters (arguably subjective) but most important, mainly that required for learning. This, in turn, would reduce the “enormous amount of time wasted now on generating and responding to reports that help no one at all.”⁹⁵ Speaking further to the need for more

⁹³ See further: Chapter 9 ‘Incident Reporting and Analysis.’

⁹⁴ Health Service Executive, Quality and Patient Safety Division, *Report of the Quality and Safety Clinical Governance Development Initiative – Sharing our Learning* (Dublin: Stationary Office, 2014) 20.

⁹⁵ D Berwick, ‘Era 3 for Medicine and Health Care’ JAMA (03 March 2016) [e-pub ahead of print].

subjective measurement and accountability, particularly as it applies to a just culture, Horstman and Naik have argued:

“In a ‘Just Culture’ for quality, failure to meet performance measures would be an opportunity for improvement rather than punishment. Poorly performing hospitals and providers should be identified. If lapses in performance measures are due to inadequate training, resources or processes, punishing frontline staff, essential for correcting problems, is counterproductive. Poorly performing healthcare organisations should be given the latitude to report lapses and transparently describe the steps they will take to improve. This is not to say that accountability is removed from providers or institutions. As in patient safety, those who wilfully manipulate the system should be held accountable. However, we need to change the stakes for performance measures and build a culture where there is support for continuous improvement in addition to accountability.”⁹⁶

Clinical governance offers the multifaceted and multidisciplinary tool by which to coordinate and standardise quality and safety objectives throughout all levels of the organisation, as well as ensure continuous improvement, accountability, and transparency.⁹⁷ Effective clinical governance structures are particularly relevant in the collaboration of patient safety initiatives and risk management activities that reduce the barriers to healthcare communication. As Gallagher notes:

⁹⁶ M Horstman and A Naik, ‘A “Just Culture” for Performance Measures’ (2015) 24 *BMJ Quality & Safety* 486, 488.

⁹⁷ Department of Health (UK), *Integrated Governance Handbook: A Handbook for Executives and Non-Executives in Healthcare Organisations* (London: Department of Health, 2006) 10; J Gilmour, ‘Patient Safety and the Law in Canada’ in J Tingle and P Bark (eds) *Patient Safety, Law Policy and Practice* (Oxon: Routledge, 2011) 254. As Gilmour notes, “Hospitals and other health care organizations are often in a better position to implement change than practitioners, because they control many of the systemic factors affecting patient safety.”

“In many institutions, disclosure decisions are made by risk managers operating in ‘silos’ disconnected from those working on patient safety and quality. As a result, information gleaned from risk managers’ conversations about these events with caregivers may not be shared with the patient safety programs or communicated up the institutional chains of command. By recognizing disclosure as a key dimension of a transparent health care culture, institutions will stimulate improved communication and also promote greater reporting of unanticipated outcomes by caregivers to risk managers and patient safety programs. As previously unreported unanticipated outcomes are shared with patient safety experts, process improvements can be implemented to prevent recurrences and save lives. Sharing this information with senior executives and trustees will also create greater awareness of patient safety breakdowns among those who can commit the resources required to implement solutions.”⁹⁸

Gallagher’s comment is instructive not only in the context of disclosure or incident reporting, but in understanding the necessity for healthcare organisations to have in place structures that ensure both the healthcare organisation and the professionals working within it are held accountable for the care they provide, and the safety of the system it is provided in. To be effective, clinical governance structures must be established and enforced under clear legislative and regulatory frameworks, and work closely with professional regulators to ensure collaboration and support in meeting quality and safety objectives. The next section will examine in greater detail the importance of organisational and professional regulation, with particular regard to the practices in the United States and the United Kingdom.

⁹⁸ T Gallagher et al., ‘Disclosing Unanticipated Outcomes to Patients: The Art and Practice’ (2007) 3(3) *Journal of Patient Safety* 158, 159.

4.4.2 Organisational and Professional Regulation

Intrinsic to the work of clinical governance, audit and risk management is that of organisational and professional regulation. The Irish Commission on Patient Safety and Quality Assurance have defined 'regulation' as:

“... sustained and focused control exercised by a public agency over activities that are valued by a community, and in healthcare specifically as any set of influences or rules exterior to the practice or administration of medical care that imposes rules of behaviour.”⁹⁹

Organisational and professional regulation is fundamental to the accountability process, not least because it ensures external oversight—a necessary component of a just culture. The main mechanisms for organisational and professional regulation include: licensing (mandatory), accreditation (mandatory / voluntary), certification, and inspection.¹⁰⁰

To explain organisational regulation, it is useful to consider two examples: the voluntary process of accreditation in the United States, and the mandatory process required by the UK's National Health Service.

At an organisational level, in the United States, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is responsible for the accreditation and certification of healthcare organisations. Failing to maintain safety standards or to be engaged in continuing quality improvement, failure to disclose an unanticipated (sentinel) outcome to the patient, or the failure to report and remedy a sentinel event

⁹⁹ Department of Health and Children (Ireland), *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance* (Dublin: Department of Health, 2008) 105; citing: K Sutherland and S Leatherman, *Regulation and Quality Improvement. A Review of the Evidence*. (London: The Health Foundation, 2006).

¹⁰⁰ Department of Health and Children (Ireland), *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance* (Dublin: Department of Health, 2008) 105.

can all result in the revocation of accreditation.¹⁰¹ While the process of accreditation is voluntary, the United States require healthcare organisations be accredited as a condition of receiving medicare and medicaid funding.¹⁰² Additionally, accreditation has increasingly become a requirement for insurance reimbursement, and in some States, required to fulfil regulatory requirements.¹⁰³

Another interesting example of organisational regulation in the United States is that of Medicare's Value-Based Purchasing programme, which attempts to use institutional rather than personal accountability to improve safety standards, and is mandatory for organisations receiving medicare reimbursement. The programme was created in 2010 following the passage of the Patient Protection and Affordable Care Act (PPACA) with the objective of penalising hospitals who rate poorly in the area of safety, quality and patient reviews. Essentially, hospitals are reimbursed based on the quality of care provided, not quantity. While a dramatic improvement in outcomes has yet to be seen as a result of the program (possibly because it is still in its infancy), the United States Government Accountability Office note the program has been influential with respects to decreasing readmission rates, and improving patient experiences (according to self-reported measurement).¹⁰⁴ The benefit of such a system is that it ensures external oversight based on comparison to national quality standards. The programme also focuses on collective accountability with respects to the organisation and the healthcare

¹⁰¹ For the most recent version of the JCAHO Accreditation Standards, see further: Joint Commission on Accreditation of Healthcare Organizations, *2016 Hospital Accreditation Standards*. (Oakbrook Terrace, IL: Joint Commission Resources, 2015).

¹⁰² Department of Health and Children (Ireland), *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance* (Dublin: Department of Health, 2008) 120.

¹⁰³ Joint Commission on Accreditation of Healthcare Organizations, 'Benefits of Joint Commission Accreditation' (28 August 2015) <http://www.jointcommission.org/benefits_of_joint_commission_accreditation/> accessed: 22 March 2016.

¹⁰⁴ United States Government Accountability Office, Report to Congressional Committees, *Hospital Value-Based Purchasing: Initial Results Show Modest Effects on Medicare Payments and No Apparent Change in Quality-of-Care Trends*. (GAO-16-9, Washington: US Government Printing Office, October 2015) 13-16.

team—a principle strongly advocated by commentators such as Wachter, and Bell et al.

105

It is worth noting that external evaluation bodies (i.e. accrediting bodies, regulatory bodies and certification bodies) within the health and social care sector can also opt for an award of international accreditation through the International Society for Quality in Health Care. The ISQua offer accreditation of the organisation, standards, and surveyor training programme. Although voluntary, international quality accreditation offers the benefit of an established framework for systemic measurement so as to aid the organisation in gauging improvement with international benchmarking standards and best practice requirements – all tools they themselves can pass down within the accreditation, regulatory or certification process. International accreditation is another means of endorsing accountability and transparency by requiring the organisation to meet strictly pre-defined international safety and quality standards in the field of health and social care.¹⁰⁶

In the United Kingdom, all NHS hospitals and private healthcare providers must register with the Care Quality Commission, the body responsible for monitoring, inspecting and regulating health and social care services. The process is mandatory, and therefore differs from the voluntary accreditation process in the United States through the JCAHO. Accreditation is based on meeting the ‘fundamental standards’ set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. This includes, *inter alia*, the requirement that: individuals working within the

¹⁰⁵ R Wachter, ‘Personal Accountability in Healthcare: Searching for the Right Balance’ (2012) 22(2) *BMJ Quality & Safety* 176, 179; J Ferman, ‘Value-Based Purchasing Program Here to Stay: Payments will be Based on Performance.’ (2011) 26 *Health Executive* 76–78; S Bell et al., ‘Accountability for Medical Error: Moving Beyond Blame to Advocacy.’ (2011) 140 *Chest* 519–526.

¹⁰⁶ International Society for Quality in Health Care, ‘What is the International Accreditation Process (IAP)?’ <<http://www.isqua.org/accreditation-iap/what-is-the-iap>> accessed: 05 April 2016.

organisation are fit and proper;¹⁰⁷ that staffing levels are adequate;¹⁰⁸ that patients receive person-centred care¹⁰⁹ and are treated with dignity and respect;¹¹⁰ that care and treatment are safe, and avoidable harm or risk is prevented;¹¹¹ and that the organisation safeguards patients from abuse and improper treatment.¹¹² Moreover, NHS bodies have an obligation to ensure there is corporate and organisation wide commitment to creating an environment that fosters good professional practice.¹¹³ Regulation 17 requires the organisation have effective governance structures in place, including the ability to assess, monitor and drive improvement, conduct audit processes, seek feedback, and mitigate risk.¹¹⁴ Lastly, Regulation 20 allows the CQC to issue a warning, prosecute, or revoke accreditation of an NHS healthcare organisation for failure to act in an open and transparent manner, including requiring that truthful information be disclosed following an incident, or in some instances, requiring the provider apologise.¹¹⁵ The CQC is fundamental in ensuring healthcare organisations in the UK are held accountable for the safety and quality of the care they provide.

Lastly, an excellent example of a tool that can work in conjunction with licensing and supports proactive accountability processes is the use of the Irish Health Information Quality Authority's *National Standards for Safer Better Healthcare*.¹¹⁶ These standards

¹⁰⁷ Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, Regulation 4, 5, and 19.

¹⁰⁸ *ibid* Regulation 18.

¹⁰⁹ *ibid* Regulation 9.

¹¹⁰ *ibid* Regulation 10.

¹¹¹ *ibid* Regulation 12.

¹¹² *ibid* Regulation 13.

¹¹³ General Medical Council et al., *Effective Governance to Support Medical Revalidation: A Handbook for Boards and Governing Bodies* (London: General Medical Council, 2013) 4.

¹¹⁴ Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, Regulation 17.

¹¹⁵ *ibid* Regulation 20.

¹¹⁶ Health Information and Quality Authority, *A Guide to the National Standards for Safer Better Healthcare* (Dublin: HIQA, June 2012).

outline the basic principles and standards required at a national level, and encourage up to date, consistent, best practices throughout all of the social and healthcare services within Ireland (excluding mental health services). In particular, the forty-five standards fall under eight key themes, which include: person-centred care and support; effective care and support; safe care and support; better health and wellbeing; leadership, governance and management; workforce; use of resources; use of information. Subsequently, the HIQA have also developed service-specific standards in areas such as maternity services.¹¹⁷ Although still under deliberation, these standards are intended to be used as the basis for the licensing of all healthcare facilities in Ireland, both public and private.¹¹⁸

Professional Regulations

As examined above, medicine was traditionally a self-regulated profession. Owing to the increasing desire of the public for accountability and transparency, regulation of the medical profession is now the responsibility of Professional Regulatory Bodies, and conducted through the processes of Licensure/Registration, Certification and Re-certification, Credentialing, and Privileging. All require that the appropriate level of skill, knowledge and competence are met; however, licensure is generally dictated by legislation and is the minimum professional qualification necessary to practice medicine.¹¹⁹ Credentialing, alternatively, is a process by which the qualifications and experience of a physician are reviewed prior to employment. While not a statutory

¹¹⁷ Health Information and Quality Authority, *National Standards for Safer Better Maternity Services* (Dublin: HIQA, 2016).

¹¹⁸ It is important to note that within Ireland, the Health Information Quality Authority to date only has legislative authority over public hospitals and services funded by the Health Service Executive. Adoption of the standards by private facilities remains voluntary, however, there is currently legislation due to be introduced in the Dáil to give the HIQA legislative oversight of private facilities. See further: P Cullen, 'New Law to Bring Private Hospitals Under Remit of HIQA' *Irish Times* (Dublin, 20 June 2017) <<https://www.irishtimes.com/news/health/new-law-to-bring-private-hospitals-under-remit-of-hiqa-1.3126568>>

¹¹⁹ Department of Health and Children (Ireland), *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance* (Dublin: Department of Health, 2008) 124-125.

requirement, credentialing has become a fundamental risk management tool, and necessary for employment within many healthcare organisation.¹²⁰ Owing to its prominence and the increasingly transient nature of employment within Europe, the Irish Commission on Patient Safety and Quality Assurance have recommended the creation of an EU-wide credentialing system to allow for increased communication amongst European regulatory bodies.¹²¹

In the UK, the General Medical Council is responsible for registering physicians to practice at the beginning of their career within the NHS, ensuring continuing licensure requirements are met, and for taking action when the physician's fitness to practice is in question or there has been a significant departure from the principles set out in their guidance manual, *Good Medical Practice*.¹²² In contrast to the United States, the GMC maintain the official register for all registered physicians in the country, inclusive of disciplinary proceedings and lapses in licensure. The legal framework for fitness to practice procedures in the UK are set out within the Medical Act 1983 and the Fitness to Practise Rules 2004.¹²³

¹²⁰ *ibid* 140.

¹²¹ *ibid* 143-144. Noting, "The Commission concluded that a credentialing system potentially offers an important protection to patients in establishing a means by which the qualifications and competence of healthcare practitioners can be verified prior to and during employment. ... The Commission is of the view that, although there is currently some communication between comparable regulatory bodies throughout the EU, an EU-wide credentialing system would be of immense benefit to citizens across all member states."

¹²² For the most recent edition of the GMC's publication 'Good Medical Practice' (2013), see further: General Medical Council, 'Good Medical Practice' <<http://www.gmc-uk.org/guidance/index.asp>> accessed: 20 March 2016. For an explanatory memorandum explaining the investigation process, see further: General Medical Council, 'The GMC's Fitness to Practice Procedures' <http://www.gmc-uk.org/DC4541_The_GMC_s_Fitness_to_Practise_procedures.pdf_25416512.pdf> accessed: 20 March 2016.

¹²³ General Medical Council, 'Complaints and the Role of the GMC' <http://www.gmc-uk.org/concerns/complaints_and_role_of_the_gmc.asp> accessed: 20 March 2016; Medical Act 1983; Fitness to Practise Rules 2004.

In contrast to the UK, physicians in the United States are regulated at both the federal and state level. Federal regulation is overseen by the National Board of Medical Examiners, the Federation of State Medical Boards, US Department of Health and Human Services through the National Practitioner Data Bank, and the Healthcare Integrity and Protection Data Bank.¹²⁴ At the State level, each State is responsible for licensing new physicians through the State's Medical Board. Disciplinary proceedings are also held in accordance with State legislation and requirements.¹²⁵ For example, in New York, Physicians hold their license in accordance with the requirements of the New York State Department of Health, and the New York State Board for Medicine. Disciplinary proceedings are held and enforced by the New York State Board for Professional Misconduct.

Privileging is another mechanism by which to hold physicians accountable. In addition to their contractual obligations, physicians must be privileged to work within their respective healthcare organisations. This holds them accountable to any applicable bylaws and may dictate (depending on jurisdiction) their roles and responsibilities, privileging requirements, and the applicable disciplinary processes and penalties—all of which run concurrent to professional regulatory procedures. For example, a complaint that questions the competency of the physician may simultaneously be investigated by the hospital and the professional regulatory body for both the purposes of revoking the physician's privileges and license.

Owing to the severity and nature of the incident, discipline by the professional regulatory body and the healthcare organisation (by way of the applicable bylaws and contractual terms) can vary greatly depending on the circumstances. This may include:

¹²⁴ Department of Health and Children (Ireland), *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance* (Dublin: Department of Health, 2008) 124-125.

¹²⁵ A full list of the State Medical Boards can be found at: American Medical Association, 'State Medical Boards' <<http://www.ama-assn.org/ama/pub/education-careers/becoming-physician/medical-licensure/state-medical-boards.page>> accessed: 20 March 2016.

written reprimands, probation, requirements to undergo formal clinical or ethical training, as well as license suspension or revocation.¹²⁶ Where medical knowledge is in question, education to improve skills may be the most appropriate form of sanction. Similarly, an addiction problem may merit the requirement to undergo rehabilitation and probation, but may not necessitate the revocation of one's license. Referring to disciplinary proceedings conducted by the Texas Medical Board, Cardarelli and Licciardone note that the most common forms of violations by physicians include medical negligence, inappropriate prescription practices, and substance abuse.¹²⁷ Alternatively, a Canadian study by Alam et al., found that the most frequent violations for which Canadian physicians were disciplined included sexual misconduct, failure to meet a standard of care, and unprofessional conduct.¹²⁸ While all forms of violations require intervention, sanctions must be proportionate to be effective. This is necessary both subjectively and objectively—sanctions that are unduly harsh further perpetuate a culture of fear, blame, and secrecy; sanctions that are unduly mild are neither just, nor a deterrent.

In an effort to increase transparency, some jurisdictions publicly publish information related to professional medical misconduct and disciplinary proceedings. For example, the New York State Department of Health Office of Professional Medical Conduct publish the list of all physicians who have undergone disciplinary proceedings, the circumstances surrounding the proceedings, and the outcome.¹²⁹ Similarly, as a means of establishing transparency and accountability, the General Medical Council publish

¹²⁶ R Cardarelli and J Licciardone, 'Factors Associated With High-Severity Disciplinary Action by a State Medical Board: A Texas Study of Medical License Revocation' (2006) 106(3) *International Journal of Osteopathic Medicine* 153.

¹²⁷ *ibid*; citing: R Cardarelli et al., 'Predicting Risk for Disciplinary Action by a State Medical Board.' (2004) 100 *Texas Medicine Magazine* 84–90.

¹²⁸ A Alam et al., 'The Characteristics of Physicians Disciplined by Professional Colleges in Canada' (2011) 5(4) *Open Medicine* 166-172.

¹²⁹ See further: New York State Department of Health, 'Professional Misconduct and Physician Discipline' <<http://w3.health.state.ny.us/opmc/factions.nfs>> accessed: 20 March 2016.

annual reports, as well as a detailed figures showing the outcomes of fitness to practice complaints.¹³⁰

It is important to note that quality and safety is also addressed at a local level through professional forums. For physicians, internal review mechanisms such as peer review and M&M ('Morbidity and Mortality') Conferences allow clinical incidents to be scrutinised by peers within a non-judgmental, supportive, and confidential environment.¹³¹ Although beneficial from a learning perspective, peer-review and M&M conferences are based upon the traditional principles of self-regulation, making them ancillary to the aforementioned regulatory processes. Truog et al. describe this, noting that, "Peer review meetings have traditionally been highly confidential and tightly controlled. The idea of open discussions of professional practices, and particularly possible errors in practice, runs counter to this cultural bias."¹³² This has the unfortunate disadvantage (as compared to non-punitive root cause analysis) of continuing to foster a culture of perfection, as well as preventing organisation-wide learning and transparency.¹³³ Notwithstanding, confidential internal review mechanisms can be beneficial as opportunities for learning and mentorship, but should be conducted in conjunction with organisation-driven incident investigation and analysis processes.

¹³⁰ General Medical Council, 'Fitness to Practice Data' <<http://www.gmc-uk.org/concerns/24194.asp>> accessed: 20 March 2016.

¹³¹ See generally: N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005) 89; J Moskop et al. 'Emergency Physicians and Disclosure of Medical Errors.' (2006) 48(5) *Annals of Emergency Medicine* 523, 527

¹³² R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 42; M Edwards, 'Minimizing Bias in Clinical Peer Review' (2011) 37(6) *Physician Executive* 50. Discussing methods for mitigating outcome bias in clinical peer review.

¹³³ M Waite, 'To Tell the Truth: The Ethical and Legal Implications of Disclosure of Medical Error' (2005) 13 *Health Law Journal* 1, 24. Waite makes the critical observation that M&M conferences tend to focus largely on "the particular medical aspects of the treatment and condition as opposed to an examination of the error and its etiology."

The necessity of organisational and professional regulation cannot be understated, particularly in the context of ensuring a just culture where healthcare services must continually improve and accountability often falls disproportionately on the sharp end. Professional and organisational regulators are fundamental to the both the proactive and retrospective accountability process by contributing to the setting and monitoring of new and continuing educational standards; investigating, regulating, and imposing sanctions; and helping to achieve buy-in from the clinicians by also working as their advocates when necessary to maintain a just and proportionate system of accountability. Despite this, there continues to be a presumption within western healthcare systems that ensuring accountability and deterring negligent or reckless behaviour additionally requires the imposition of fault-based liability. While the necessity of compensation for patients and families following an adverse incident is not in dispute, a number of arguments can be made against the imposition of monetary liability as a mechanism for ensuring accountability. Arguably, the strongest of these arguments (and set out a number of times throughout this thesis) is that the threat of litigation creates a significant and detrimental barrier to healthcare communication, and prevents valuable lessons from being learned. While learning and accountability are in no way mutually exclusive, a blame culture (perpetuated by the threat of fault-based liability) can equally have a detrimental effect. For this reason, it is useful to examine the compensation system of New Zealand, a jurisdiction which—on the face of it—has separated compensation from accountability.

4.4.3 Necessity of Civil Litigation in the Accountability Process

This section is not intended to set out in detail the consequences of the civil and criminal law in healthcare. Referring back, the role of the civil and criminal law as well as the consequences of civil litigation on patients and physicians were examined in chapter 2. Rather, the intention of this section is to consider the necessity of civil litigation in the process of accountability. This is important because personal liability is closely linked with the detrimental effects of a culture of blame. The question this

section seeks to address is: is civil (fault-based) liability necessary to ensure individuals and organisations are held accountable? One need only consider the prevalence of the so-called ‘compensation culture’ that permeates western healthcare systems to know that civil liability is one of the primary mechanisms patients turn to when an adverse incident occurs. However, referring again to chapter 2, a review of the literature extensively analysed throughout that chapter strongly suggests that those filing a medical malpractice claim do so not only for the purposes of compensation, but also an explanation, an apology, or to make sure the incident ‘never happens again.’ While all of these remedies are fundamental to the accountability process, owing to the availability of the various clinical governance and professional regulatory mechanisms set out above, is personal liability necessary to hold physicians accountable? To answer this question, it is useful to consider the accountability structure in New Zealand, a country whose compensation system—on the face of it—is not premised on fault-based liability, but rather compensation based on outcome and not causation.

New Zealand’s No-fault Compensation Scheme

In 1972, the government of New Zealand enacted the Accident Compensation Act 1972.¹³⁴ The act sought to remove liability and provide compensation for work and non-work related injuries, including those caused by motor vehicle accidents.

Compensation was financed by employer/employee tax deductions, motor vehicle owners, and general taxation.¹³⁵ While the program includes the form of injuries listed above, for the purposes of this section, only medical injuries will be considered.

Prior to 1992, the criteria to file a claim resulting from medical injury lacked clear definition. To remedy this, the 1992 amendment expressly introduced the requirement to establish fault by requiring a compensatable injury be the result of ‘medical

¹³⁴ Accident Compensation Act 1972.

¹³⁵ C Flood, ‘New Zealand’s No-Fault Accident Compensation Scheme: Paradise or Panacea?’ (2000) 8(3) Health Law Review 3.

misadventure', defined as a "personal injury resulting from medical error or medical mishap."¹³⁶ The result of the 1992 reforms was to restrict compensation to those suffering an injury caused by 'medical misadventure' or 'medical error.' This introduced the requirement to find fault into a so-called 'no fault' system, and substantially limited the accessibility of the compensation process, in addition to limiting the willingness of physicians to openly engage with patients and disclose incidents.¹³⁷ The situation was reversed in 2005 following the passage of the Injury Prevention, Rehabilitation, and Compensation Amendment Act (No. 2) 2005, which replaced the term "medical misadventure" with "treatment injury" so as to remove the burden of establishing negligence when filing a claim. In this regard, Wallis has noted that following the 2005 reforms, eligibility for compensation was not restricted to medical error, but rather included all medical injuries. The current scheme allows for patient needs to be met subjectively. Claims are decided by the ACC's national claims unit, in consultation with the patient, physicians and independent clinical advisors. Entitlements fall in to four categories: treatment and rehabilitation, compensation for loss of earnings, lump-sum compensation, and support for dependents.¹³⁸ This, according to Wallis, "gave New Zealand's scheme some of the most liberal eligibility criteria in the world, and brought the compensation of medical injury into line with the overall 'no-fault' scheme. The changes also shifted the focus of the scheme away from

¹³⁶ The 1992-1998 amendments set out the definition of 'medical error' as: "the failure of a registered health professional to observe a standard of care and skill reasonably to be expected in the circumstances." Similarly requiring a finding out fault, 'medical mishap' was defined as: "an adverse consequence of treatment by, or at the direction of, a registered health professional, properly given, if – (a) the likelihood of the adverse consequence of the treatment occurring is rare; and (b) the adverse consequence of the treatment is severe." See: Accident Compensation Act 1998, section 36-37; as taken from: C Flood, 'New Zealand's No-Fault Accident Compensation Scheme: Paradise or Panacea?' (2000) 8(3) Health Law Review 3, 5.

¹³⁷ For an examination of the claims process prior to the 2005 Reforms which extended the scope of compensable injuries, see generally: P Davis et al., 'Compensation for Medical Injury in New Zealand: Does "No-Fault" Increase the Level of Claims Making and Reduce Social and Clinical Selectivity?' (2002) 27(5) Journal of Health Politics, Policy and Law 833-854.

¹³⁸ M Bismark and R Paterson, 'No-Fault Compensation in New Zealand: Harmonizing Injury Compensation, Provider Accountability, and Patient Safety' (2006) 25(1) Health Affairs 278, 280-281; citing: Accident Compensation Corporation, 'What Am I Entitled To?' (2005) <www.acc.co.nz/claimscare/entitlements>

identifying error (or fault) to providing assistance with treatment and rehabilitation.”

139

The 2005 amendment to the Accident Compensation Act provided a mechanism for patients to be compensated for medical injuries, notwithstanding if the care provided was done so negligently.¹⁴⁰ Essentially, the current legislation protects physicians from a claim of negligence being filed against them for injuries resulting from their medical practice. One exception is that a claim for punitive damages can be made where the injuries are the result of an act of bad faith, abuse of position, or the violation of the claimant’s rights. Punitive damages are sought in addition to a claim in compensation, and are allowed because they are not compensatory (which would violate the core principal of the act) but rather intended to punish inappropriate conduct.¹⁴¹

The ability to claim for punitive damages begs the question of whether New Zealand’s system is truly a ‘no-fault’ system. Addressing this, Bismark has noted in relation to a claim for putative damages in New Zealand, “... the courts have found that not even gross negligence warrants such damages unless there is some element of conscious or reckless conduct.”¹⁴² Therefore, it stands to reason that punitive damages as a mechanism for compensation are extremely limited, and unlikely an adequate resource for holding a clinician accountable or for having a large impact on the no-fault elements of the scheme. In the alternative, Bismark has noted, “in countries where litigation is the dominant avenue for obtaining redress for perceived problems with care, patients have little choice other than alleging negligence and suing for monetary

¹³⁹ K Wallis, ‘New Zealand’s 2005 “No-Fault” Compensation Reforms and Medical Professional Accountability for Harm’ (2013) 126 (1371) *New Zealand Medical Journal* 33, 34.

¹⁴⁰ The most recent version of the provisions is contained within the Accident Compensation Act 2010.

¹⁴¹ C Flood, ‘New Zealand’s No-Fault Accident Compensation Scheme: Paradise or Panacea?’ (2000) 8(3) *Health Law Review* 3, 4-5.

¹⁴² M Bismark and R Paterson, ‘No-Fault Compensation in New Zealand: Harmonizing Injury Compensation, Provider Accountability, and Patient Safety’ (2006) 25(1) *Health Affairs* 278, 279; citing: ‘A v. Bobtail’ (2003) 2 *New Zealand Law Review* 721.

damages, whatever the specific nature of their concern.”¹⁴³ Following the 2005 amendment, this clearly is not the case in New Zealand.

Bismark’s comment regarding the necessity of tort action is consistent with the literature cited throughout chapter 2 of this thesis, namely: in a highly litigious culture, a patient’s only option may be to initiate civil litigation as a means of compensating their loss and accessing information surrounding their care. This, in turn, further restricts a culture of openness between the healthcare organisation, clinicians, and patients because the threat of litigation over-shadows what ideally should continue to be a therapeutic relationship. This is particularly relevant in smaller tertiary care centres or jurisdictions where the patient may not have the option to be seen by an entirely independent physician or care team.

However, a question arises as to whether a no-fault system can adequately ensure accountability when a preventable error has occurred. While civil litigation may decrease the likelihood of a learning culture, so too does a lack of accountability. Healthcare organisations and professionals must be accountable for the care they provide, and also for continuous quality and safety improvement. Is monetary liability essential to achieving this? If we look to the New Zealand experience, the answer is no. Wallis has noted that the purpose of New Zealand’s compensation scheme was never to provide accountability, but rather to reduce the impact and incidence of injury.¹⁴⁴ This makes the scheme distinctly unique as compared to the jurisdictions examined throughout this thesis where compensation is at least perceived to be fundamental to the accountability process. Wallis has usefully distinguished this in the New Zealand context: “Under New Zealand’s regulatory system, in contrast to malpractice systems, compensation is determined according to *outcome* and may be awarded irrespective of

¹⁴³ M Bismark et al., ‘Accountability Sought by Patients Following Adverse Events from Medical Care: The New Zealand Experience’ (2006) 175(8) Canadian Medical Association Journal 889.

¹⁴⁴ K Wallis, ‘New Zealand’s 2005 “No-Fault” Compensation Reforms and Medical Professional Accountability for Harm’ (2013) 126 (1371) New Zealand Medical Journal 33, 34.

fault or negligence, while doctors are judged (under the HDC patient complaints system) according to *process* of care and may be held to account irrespective of injury.”

145

Essentially, this holds physicians accountable to practice at a level consistent with the civil law’s ‘standard of care’ but does not equate a deviation with financial compensation. This is not to suggest, however, that clinicians are not held fully accountable for their actions. In New Zealand, following the introduction of the Injury Prevention, Rehabilitation, and Compensation Amendment Act (No 2) 2005, the ACC was given the express legislative duty to report a ‘risk of harm to the public’ to the Medical Council, and the Health and Disability Commissioner (cited in the act as ‘the appropriate authorities.’)¹⁴⁶ This was done to address any potential gap in accountability that could result from not holding practitioners financially liable. The Health and Disability Commissioner is responsible for promoting patients’ rights and ensuring accountability. The commission provides patient advocacy, mediation, investigation, and dissemination of lessons learned. As well, as it pertains specifically to accountability, “the actions of organizations and individuals are considered, and the commissioner acts as a gatekeeper to disciplinary proceedings.”¹⁴⁷

This process is comparable to England, the United States, and Canada, where legislation is in place to report serious incidents (not solely related to medical error) to the professional regulatory body responsible for overseeing the licensing of medical practice (including competency, fitness to practice, and disciplinary tribunals), organisational regulatory bodies (responsible for accreditation), the healthcare organisation’s internal review and disciplinary procedures processes (e.g. clinical audit

¹⁴⁵ K Wallis, ‘New Zealand’s 2005 “No-Fault” Compensation Reforms and Medical Professional Accountability for Harm’ (2013) 126 (1371) *New Zealand Medical Journal* 33, 33-34.

¹⁴⁶ *ibid* 34.

¹⁴⁷ M Bismark and R Paterson, ‘No-Fault Compensation in New Zealand: Harmonizing Injury Compensation, Provider Accountability, and Patient Safety’ (2006) 25(1) *Health Affairs* 278, 281.

and risk management), the patient ombudsmen (where applicable), or in the case of very serious incidences: a criminal prosecutor.¹⁴⁸

Examining the effect of New Zealand's 2005 'no-fault' compensation reforms on medical professional accountability for harm, Wallis reviewed the overall trends in New Zealand's medical professional accountability processes from 2001–2010.¹⁴⁹ The author found that following the 2005 reforms, claims for compensation increased (unsurprisingly given that the definition was broadened) but claims to the Medical Council decreased. In response, Wallis argues, "The reforms thus increased the barrier between the compensation scheme and the Medical Council, and decreased accountability via compensation."¹⁵⁰ This, however, has been of benefit to both the medical community and patients, as compensation is easier to obtain for medical injuries, and clinicians are in a better position to assist patients in submitting a claim as it no longer requires an insinuation of wrongdoing nor potential disciplinary action (in many instances).¹⁵¹ Wallis also found that the decrease in reports sent to the Medical Council were offset by reports to the Health and Disability Commissioner, which provides an additional mechanism for accountability and means for informing patient safety efforts.¹⁵² It is important to note, however, that much like the other jurisdictions

¹⁴⁸ K Wallis, 'New Zealand's 2005 "No-Fault" Compensation Reforms and Medical Professional Accountability for Harm' (2013) 126 (1371) *New Zealand Medical Journal* 33. For example, the contractual obligation on NHS bodies to disclose information, failure of which can result in criminal prosecution. See further: sections 20(2)(a) and 20(3), Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

¹⁴⁹ *ibid.*

¹⁵⁰ *ibid* 40-41.

¹⁵¹ *ibid* 41.

¹⁵² *ibid* 41. Arguably, New Zealand's compensation scheme (following the 2005 Reforms) is likely a better indicator for the direction of patient safety efforts because the claims process allows for comprehensive data to be collected, ranging from minor incidents to sentinel incidents. This is because there is a reduction in legal and administrative burden, and cost, in seeking compensation as compared to traditional systems of tort compensation, and therefore greater reporting of incidents (specifically those lower in severity.) See further: K Wallis and S Dovey, 'No-fault Compensation for Treatment Injury in New Zealand: Identifying Threats to Patient Safety in Primary Care' (2011) 20 *BMJ Quality & Safety* 587-591.

examined within this thesis, learning for the clinicians and healthcare organisations in New Zealand occurs in the same manner as any other jurisdiction, i.e. accumulation of lessons learned via reporting, trending, and investigation.¹⁵³ Curiously, in the period following the 2005 amendment, Wallis found that fewer performance reviews and disciplinary proceedings were occurring. While this may, on the face of it, represent a decrease in accountability because of the legislation, Wallis suggests that it is more likely the removal of an insinuation of wrongdoing from compensation claims, as well as the administrative burden and cost contributed to the decrease, as the ACC continues to have authority to report medical malpractice and error to the appropriate disciplinary bodies.¹⁵⁴

From a public policy perspective, commentators have made the observation that the no-fault scheme reduced incentive for employers to invest in risk management or facilitate rehabilitation.¹⁵⁵ For example, in an examination of occupational fatality rates from eight OECD countries¹⁵⁶ to that of New Zealand during 2005-2008, Lilley et al. found that New Zealand ranked last in overall occupational safety performance, averaging twice as many occupational fatal injuries as Finland, Sweden, Norway and

¹⁵³ See further: Health Quality & Safety Commission, *Learning From Adverse Events: Adverse Events Reported to the Health Quality & Safety Commission 1 July 2014 to 30 June 2015* (Wellington: Health Quality & Safety Commission, 2015); Health Quality & Safety Commission, *From Knowledge to Action A Framework for Building Quality and Safety Capability in the New Zealand Health System* (Wellington: Health Quality & Safety Commission, October 2016).

¹⁵⁴ K Wallis, 'New Zealand's 2005 "No-Fault" Compensation Reforms and Medical Professional Accountability for Harm' (2013) 126 (1371) *New Zealand Medical Journal* 33, 42.

¹⁵⁵ C Flood, 'New Zealand's No-Fault Accident Compensation Scheme: Paradise or Panacea?' (2000) 8(3) *Health Law Review* 3, 6; citing: M Mills, 'The Case for ACC Reform' Labour Market Policy Group, Department of Labour, New Zealand, 4 [unpublished].

¹⁵⁶ The eight countries examined included: Australia, Finland, Norway, Sweden, Canada, France, Spain, and the United Kingdom.

the UK.¹⁵⁷ This argument is significant insofar as it purports to reinforce one of the primary objectives behind civil compensation—deterrence—and suggests that safety standards can only be met by holding an organisation or individual financially liable.

The problem with this argument is two-fold: first, any recourse to insurance would negate the defendant's personal liability, and therefore, the driving force would be the sanctions set out in the applicable legislation. In the case of physicians, this may include the loss of their license to practice medicine. For the hospital, the sanction could certainly be monetary, but the point is that it is not solely the plaintiff's monetary claim that may act as a deterrent. Second, if you apply the logic that the threat of monetary liability will increase compliance of safety legislation, it is reasonable then to assume that when the state is financially liable for compensating the injured patient, there will be stricter enforcement of that legislation. A similar argument is often made in regards vicarious liability. One then wonders, why in the above example there is a higher rate of occupational fatal injuries? On the face of it, this suggests that individuals and organisations are more likely to comply with safety standards if there is the potential for personal liability. While this may contribute, I would argue that the larger system cause is the lack of enforcement of safety legislation. Surely if the state is being held liable to compensate claimants, they would have a vested interest in enforcement? If the sanctions as set out in the legislation are being adequately enforced, then monetary liability should not be necessary.

¹⁵⁷ A limitation of this study is the lack of standardisation amongst the nine countries when comparing statistics specifically relating to the exclusion of certain economic activities, of the self-employed, and other excluded fatalities. This in turn may account for a marginal variance in the standardised (adjusted) occupational fatal injury incidence rates. See further: R Lilley, A Samaranayaka and H Weiss, *International Comparison of International Labour Organisation Published Occupational Fatal Injury Rates: How does New Zealand Compare Internationally? Commissioned Report for the Independent Taskforce on Workplace Health and Safety* (New Zealand: 15 March 2013) 29-32. <<http://hstaskforce.govt.nz/documents/comparison-of-ilo-published-occupational-fatal-injury-rates.pdf>> accessed: 11 January 2016.

Reflecting on the previous decade of the patient safety movement, commentators have argued that the pendulum swung too far in the direction of a no-blame culture, and that a more appropriate response was for accountability to be subjectively determined based on the circumstances of the incident. Such a balance is not without its challenges however. As Wachter notes, “With this recognition have come increasingly powerful efforts, including policy changes, to promote accountability, which have exposed a new tension: whether that accountability is best targeted at individual clinicians or the organisational leaders who establish the systems and enforce the policies.”¹⁵⁸ The example of New Zealand’s no-fault compensation system is useful in illustrating that accountability need not be reliant on the threat of monetary liability, but must nonetheless include clearly defined and enforceable sanctions. Whether those sanctions be targeted towards the blunt or sharp end of the spectrum is precisely at the heart of the just culture movement. My opinion would be that organisations must be accountable for enforcing all relevant safety legislation and jurisprudence, and individuals accountable for complying with it. As it applies to blame and accountability, that again in my opinion is largely theoretical because the two can not be separated in practice. The point is that accountability must be appropriately directed at those with the ability to affect change, and legislative sanctions must be enforceable without having to rely on individuals filing negligence claims. The fact that they appear not to be is a systemic failure which must be addressed, but which must not be used to negate the entire premise of a no-fault liability system.

4.5 Conclusion

This chapter sought to critically analyse the role of healthcare culture and accountability in the prevention of unsafe care. In the first and second sections, the fear of blame, liability and professional regulatory censure that combine to create a ‘culture of blame’ were examined. In contrast, the patient safety movement has sought to dispel

¹⁵⁸ R Wachter, ‘Personal Accountability in Healthcare: Searching for the Right Balance’ (2012) 22(2) *BMJ Quality & Safety* 176, 179.

the role of blame, by moving towards a 'just culture' that recognises human error as inevitable, and concentrates on prevention, accountability, transparency, learning, and mitigation when an incident does occur. The third section examined in greater depth the role of, and requirements for, accountability in a just culture. Beginning first with an analysis of the contribution of clinical governance, risk management, and audit in the promotion and maintenance of safe accountable care. Second, the equally fundamental contribution of organisational and professional regulation was examined. In the final section, New Zealand's unique no-fault compensation system was analysed as a means of examining whether monetary liability and blame are inescapable prerequisites for ensuring accountability.

By examining the detrimental effect that a collective fear of blame, liability, and professional regulatory censure contribute to creating a 'culture of blame,' it is possible to understand why such pervasive cultural beliefs persist and how they impact safety and quality improvement. In contrast, a just culture attempts to balance the need for accountability, while also promoting the hallmarks of a safety culture. Two important questions were considered throughout this chapter: first, can accountability really be detached from blame? And second, does holding an individual or organisation accountable for unsafe care require the use of the monetary liability? In regards the first, my analysis suggests that accountability and blame are arguably a theoretical distinction that cannot be separated in practice. That is not to suggest however that healthcare organisations or the law not attempt to reduce blaming behaviour which unlike proactive acceptability structures, is retrospective in nature and arguably emotion driven. In this respect, the second question is relevant. Is monetary liability necessary to ensure accountability? My analysis in this regard suggests no. If comprehensive regulatory structures are in place and the appropriate standards are determined by the applicable safety legislation and jurisprudence are being enforced, then accountability should not, and can not, need to rely solely on the litigation process, nor monetary liability.

Reforming the culture of a healthcare organisation to prioritise safe accountable care is fundamental to ensuring the longevity of the patient safety movement. Without cultural change, policies and practices with proven efficiency in one organisation may fail in another. However, this is not to suggest that organisational changes should be expedited. Indeed the consequences of policy change without cultural change can prove far more detrimental. As Khatri et al. state, “Without an alteration of the fundamental values, norms, and expectations of the organization, change remains superficial and short-lived in duration. Furthermore, failed attempts to change, unfortunately, frequently produce cynicism, frustration, loss of trust, and deterioration in morale among organizational members.”¹⁵⁹ The challenge for governments, healthcare organisations, and healthcare professionals is to implement patient safety initiatives, policy reform, and system redesign in a manner that incorporates safety methodology while ensuring accountability.

Achieving this ‘buy in’ for safety and quality improvement from the healthcare team is complicated, not least because the perceived threat of legal consequences can hamper any perceived benefit. Healthcare organisations may also be hesitant to hold physicians accountable to standards of best practice. For example, in contrast to the UK where physicians are employed within the NHS, physicians in the United States practice as independent contractors whose patients (depending on the speciality) may follow them should they decide to move to another institution. Wachter and Pronovost have noted that the result of this is a situation whereby healthcare organisations are reluctant to hold physicians accountable for fear they will move their practice (and the income for the institution that goes with it).¹⁶⁰ For this reason, it is fundamental that healthcare professionals and healthcare organisations are held accountable for safety through a variety of channels including civil legislation and jurisprudence, regulatory

¹⁵⁹ N Khatri et al., ‘From a Blame Culture to a Just Culture in Health Care’ (2009) 34(4) Health Care Management Review 312, 318.

¹⁶⁰ R Wachter and P Pronovost, ‘Balancing “No Blame” with Accountability in Patient Safety.’ (2009) 361 NEJM 1401–1406.

bodies, and by virtue of their contractual obligations. Incentivising safety and quality improvement may also be aided by, for example, linking non-punitive incident reporting to financial incentives, continuing professional development requirements, or payment reimbursements (such as the Medicare Value-Based Purchasing Programme.) Lastly, ensuring thorough and timely investigation is also fundamental so as to move away from sole consideration of human factors and factors outside one's control, to determining the root causes of an incident. This is because patient safety incidents (including medical errors) rarely occur in isolation. Even in situations of reckless or deliberate misconduct—where the individual for all intents and purposes is blameworthy—a question must still arise as to the level of culpability systemic failings may have had. The following two chapters of this thesis will deconstruct the causation of both systemic and human error—tools which are fundamentally necessary to the apportionment of accountability, and the ability to improve healthcare culture, communication, and ultimately, reduce medical error.

- Chapter 5 -

Human Factors vs The System

5.1 Introduction

The beginning of the Patient Safety Movement can be formally attributed to two seminal publications: *To Err Is Human* published by the Institute of Medicine in the United States and *An Organisation with a Memory* published by the Chief Medical Officer in England.¹ Both reports strongly criticised the high levels of preventable adverse events occurring within their respective jurisdictions, and the culture of blame which surrounded them. The reports argued, *inter alia*, that to improve quality and safety in healthcare, a deeper understanding of the systemic causes of medical error was required.

The doctrine of patient safety advocates a multidisciplinary and multifactorial approach to the prevention of adverse events. Patient safety theory seeks to change the culture in which clinical practice operates, and acknowledge the role of 'the system' in the causation of preventable adverse incidents, including medical error. As Halligan states, "To improve healthcare we need to reframe the issue, it is better systems of work that are required rather than better professionals. Great doctors do not make great healthcare. Great doctors interacting well with all of the other components of the healthcare systems make great healthcare."²

This chapter will critically compare the role of human factors and system factors in the causation of preventable patient safety incidents. Beginning with the person-centred

¹ Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999) 18; Department of Health (UK), *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS* (London: Department of Health, 2000) 5. See further: Chapter 3 'The Origins of the Patient Safety Movement.'

² A Halligan, 'Clinical Governance' in M Powers, N Harris and A Barton (eds), *Clinical Negligence* (4th edn, Haywards Heath: Tottel, 2008) 42.

approach which focuses on the role of human factors and the way in which individuals interact within their working environment, a comparison will be made to that of the systems-centred approach. Systems theory begins with the presumption that error is inevitable and as such, the goal is to engineer an error-tolerant system. In examining this principle, the second section will analyse the significant contribution of Reason's "Swiss Cheese" Model (SCM) in understanding the causal relationship between human factors and system-design. Criticisms of the SCM model, as well as the adapted Healthcare Error Proliferation model, will also be examined. The role of systems theory is significant to the discussion of the patient safety movement and the development of a just culture because it provides the foundation on which current strategies for quality and safety improvement are based.

5.2 Human Factors vs The System

Early research into medical error drew from the disciplines of physiology, neurophysiology, anthropology, psychology, sociology, medicine and psychiatry.³ This research focused largely on the role individual characteristics contributed to the causation of medical error. The patient safety movement sought to redefine the causes of error by recognising the predominant role of poorly designed systems, as opposed to the poorly performing individuals.⁴ Although novel within the domain of healthcare, theories of error causation focusing on systemic factors were being studied and applied within various high risk organisations (HROs) prior to its application in healthcare.⁵ For example, the work of the aviation and nuclear industries was highly influential to the promotion of system redesign and an understanding of systemic

³ M Jenicek, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011) 60; citing: J Jastrow (ed), *The Study of Human Error* (New York: D. Appleton-Century Company, 1936).

⁴ K Shojania and M Dixon-Woods, "'Bad Apples': Time to Redefine as a Type of Systems Problem?" (2013) 22 *BMJ Quality & Safety* 528.

⁵ M Chassin et al., 'The Ongoing Quality Improvement Journey: Next Stop, High Reliability' (2011) 30(4) *Health Affairs* 559.

causes of error.⁶ In examining the core methodology of HROs, the World Health Organization assert that, “High-risk organizations are obsessed with error and the possibility of future error. They accept that errors can and will occur, have internal systems that are ready to deal with errors, know when to request outside assistance, promote a culture that does not accept error and also realise that the first impression in any error is often misleading.”⁷ These core principles are intrinsic to the study of the patient safety movement, as current theories of accident causation and systems evolved largely from the methodology of these organisations. They are equally significant to the discussion of blame and the limitations of medical malpractice litigation, both examined throughout this latter chapters of this thesis.

In practice, research into the role of system factors and medical error causation is continually evolving and expanding. As Connor et al. highlight, “To date, most of the work in patient safety has been reactive. As the culture matures with increased information and trust, the emphasis will switch to a more proactive or generative approach.”⁸ Indeed, the necessity of proactive intervention was cited in the previous chapter as being fundamental within a just culture, in respect of the need for accountability in system redesign and intervention. Calls to improve the performance of healthcare systems on both a national and international level have also increased

⁶ See generally: A Kaissi, ““Learning” From Other Industries: Lessons and Challenges for Health Care Organizations’ (2012) 31(1) Health Care Manager 65; R Clay-Williams, ‘Military Rather than Civil Aviation Holds the Answers for Safer Healthcare’ (2013) 347 BMJ f5570; R Helmreich, ‘On Error Management: Lessons From Aviation’ (2000) 320 BMJ 781.

⁷ WHO World Alliance for Patient Safety, *Patient Safety Workshop: Learning from Error* (Geneva: World Health Organization, 2008) WHO/IER/PSP/2008.09. p7.

⁸ R Conner et al. (eds), ‘AORN Guidance Statement: Creating a Patient Safety Culture’ (2012) 1 Perioperative Standards and Recommended Practices 657-662. <<http://aornstandards.org/content/1/SEC41.short#C2691>> accessed: 03 June 2012.

over the previous decade.⁹ For example, internationally, the 2008 Tallinn Charter, called for European countries to “strengthen their health systems in terms of addressing patient safety and quality of care.”¹⁰ While the majority of clinical research thus far has come from an acute setting, a limitation to the expansion of patient safety research has been the ethical considerations of further study. As Jenicek states, “Ideally, cause-effect relationship and anything we do to control medical error are subject to experimental methodology, however limited our actions may be due to medical ethics or fortunately low frequency of medical error cases.”¹¹

As was examined in the previous chapter, one of the main challenges for the patient safety movement thus far has been gaining cultural acceptance for the belief that error can originate within the system. This is primarily due to the traditional presumption of human factors as the cause of error, reinforced by the legal system’s proclivity towards individual responsibility. As Howe and Walsh contend, “The virtual silence about real causation begets unending errors.”¹² Notwithstanding, legal, ethical, and procedural challenges may arise when distinguishing between human and system error for the purposes of accountability.¹³ For example, although the argument is often put forth that medical negligence litigation provides a deterrent function against negligent and

⁹ Patient Safety methodology has also been strongly advocated in common-law jurisdictions outside the scope of this thesis. For example, Australia has published an extensive framework for the implementation of patient safety methodology. See further: Australian Council for Safety and Quality in Health Care, *National Patient Safety Education Framework* (Australia: Australian Council for Safety and Quality in Health Care, 2005);

¹⁰ WHO Regional Office for Europe, *The Tallinn Charter: Health Systems for Health and Wealth* (Denmark: World Health Organization, 27 June 2008) <http://www.euro.who.int/__data/assets/pdf_file/0008/88613/E91438.pdf> accessed: 19 October 2013; WHO Regional Office for Europe, ‘Patient Safety’ (Denmark: World Health Organization, 2013) <<http://www.euro.who.int/en/health-topics/Health-systems/patient-safety/patient-safety>> accessed: 19 October 2013.

¹¹ M Jenicek, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011) 207.

¹² G Peters and B Peters, *Medical Error and Patient Safety: Human Factors in Medicine* (US: Taylor & Francais, 2008) 158.

¹³ See further: Chapter 4 ‘Healthcare Culture and Accountability.’

reckless physicians, this argument fails to adequately acknowledge the role of systemic error. Even an action which includes a claim of vicarious liability requires an individual tortfeasor to proceed.

To clarify, this chapter is vital to the analysis within this thesis because the premise on which the patient safety movement is based is that system errors set individuals up to fail. The threat of liability will hardly be an effective form of deterrence when the root cause originates outside the control of an individual and within the system. To understand further the role of systems engineering in preventing adverse events, it is now necessary to critically compare and define the role of human factors and system factors.

Human Factors

Human factors include the organisational, environmental, and individual cognitive, social, and personal factors that influence the way in which individuals interact with their working environment.¹⁴ For the sake of simplicity, human factors can alternatively be defined as “knowledge about human performance.”¹⁵ In examining the role human factors play in the occurrence of patient safety incidents, including medical error, Merry and McCall-Smith note:

“The prevailing failure in medicine (and other activities) to appreciate the need to engineer systems (in the widest sense) to facilitate human function and compensate for its weaknesses is no doubt one reason for the number of preventable adverse events which occur every day. There are exceptions, but in part this is the result of an attitude of denial of the limitations of human cognitive performance of a culture which too readily asserts that the

¹⁴ P Fortune et al. (eds), *Human Factors in the Healthcare Setting: A Pocket Guide for Clinical Instructors* (UK: Wiley-Blackwell, 2013) 6.

¹⁵ C Denham et al., ‘Are You Listening... Are You Really Listening?’ (2008) 4(3) *Journal of Patient Safety* 148.

solution lies in employing the right type of individuals and getting rid of others.”¹⁶

This is not to suggest that negligent or reckless care should be tolerated; indeed, the principle of reciprocal accountability within a just culture—and the advancement of safety and quality—require that organisations and individuals are accountable for the care they provide.¹⁷ As Morath and Turnbull have argued, “A safety culture is an accountable culture, and the overarching accountability is to those served.

Accountability is the specific translation of responsibility. Whereas responsibility involves the authority and ability to make decisions and act independently, accountability entails the requirement of responsibility for specific conduct, behaviour, and duties. Mechanisms of accountability help create a culture of patient safety.”¹⁸

Understanding why human error occurs must include the recognition that human cognitive performance has limitations.¹⁹ In this regard, it has been said that “Human error in medicine, and the adverse events that may follow, are problems of psychology

¹⁶ A Merry and A McCall-Smith, *Errors, Medicine and the Law* (Cambridge: Cambridge University Press, 2001) 96.

¹⁷ K Henriksen and E Dayton, ‘Organizational Silence and Hidden Threats to Patient Safety’ (2006) 41(4) *Health Services Research* 1539, 1543-1544; citing: D Marx, *Patient Safety and the Just Culture: A Primer for Health Care Executives. Report Prepared for MERS-TM* (New York: Columbia University, 2001). The authors note: “While a systems approach to patient safety focuses on situational factors and latent conditions, individual accountability is in no way relegated to lesser importance. Even in the best designed, most fault tolerant systems, individuals do foolish things and commit preventable harmful errors. In a just culture, individuals are still accountable for their own behavior and grossly negligent behavior is subject to disciplinary action, even though the intent is to create an atmosphere where individuals feel safe to openly report and learn from unintended mistakes.” See also: K Shojania and M Dixon-Woods, “‘Bad Apples’: Time to Redefine as a Type of Systems Problem?” (2013) 22 *BMJ Quality & Safety* 528–531; J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 158-159.

¹⁸ J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 157.

¹⁹ A Merry and A McCall-Smith, *Errors, Medicine and the Law* (Cambridge: Cambridge University Press, 2001) 96.

and engineering, not of medicine.”²⁰Addressing these limitations and designing interventions within the system is key to quality and safety improvement.

Traditionally, however, the approach to error management and prevention has focused largely on addressing the psychological precursors to error, rather than seeking to understand the context within which it occurred. The ‘person-centred’ approach to error management was described within *An Organisation with a Memory*:

“Its associated counter-measures are aimed at individuals rather than situations and these invariably fall within the ‘control’ paradigm of management. Such controls include disciplinary measures, writing more procedures to guide individual behaviour, or blaming, naming and shaming. Aside from treating errors as moral issues, it isolates unsafe acts from their context, thus making it very hard to uncover and eliminate recurrent error traps within the system. Though attractive from a managerial and legal perspective, as the predominant approach it is ill-suited to the healthcare domain – or to any other sphere which has high-technology elements. It is important to emphasise that this does not mean that individuals should never be held accountable for their actions.”²¹

This critique of the ‘person-centred’ approach is significant because it emphasises the importance of context when understanding human error. Additionally, it provides recognition that counter-measures designed solely to address human error have thus far been unsuccessful. In contrast to the human factors approach, the ‘systems

²⁰ J Senders, ‘Medical Devices, Medical Errors, and Medical Accidents’ in: M Bogner (ed), *Human Error in Medicine*. (Hillsdale, NJ: Lawrence Erlbaum Associates, 1994) 159–177; as taken from: R Wears et al., ‘The Medicalization of Patient Safety’ (2005) 1(1) *Journal of Patient Safety* 4.

²¹ Department of Health (UK), *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS* (London: The Stationery Office, 2000) [3.6] 20-21.

approach' "... takes a holistic stance on the issues of failure."²² The key features of the systems approach within healthcare will now be analysed.

Systems Theory

Prior to the introduction of systems theory, medical error was believed to be the result of a "... natural culmination of series of events or circumstances, which invariably occur in a fixed and logical order...."²³ In contrast, the systems approach begins on the presumption that error is inevitable and as such, the goal is to engineer an error-tolerant system. The concept of an 'error-tolerant' system has been defined by Morath and Turnbull as: "a system in which errors do not cause irreversible effects because system interfaces support the immediate detection of errors and allow practitioners to take corrective action to recover from errors."²⁴

Fundamental to the systems approach is an emphasis on system vulnerabilities and redesign. The system is seen to be composed of "multicausal variables that interact to create the conditions in which harm can reach a patient."²⁵ A systems approach to error necessitates a detailed analysis of the circumstances that lead to its occurrence, as the systemic causes may not be readily apparent in the aftermath of an incident. As was described in *An Organisation with a Memory*, "Errors are seen as being shaped and provoked by 'upstream' systemic factors, which include the organisation's strategy, its culture and the approach of management towards risk and uncertainty."²⁶ For this

²² *ibid* [3.7] 21-22.

²³ J Reason et al., *Revisiting the << Swiss Cheese >> Model of Accidents* (Bruxelles; France: Eurocontrol Experimental Center, 2006) 17; citing: H Heinrich, *Industrial Accident Prevention* (New York: McGraw-Hill, 1931); M Bogner, 'Stretching the Search for the "Why" of Error: The Systems Approach' (2002) 27 *Journal of Clinical Engineering* 110-115.

²⁴ J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 47.

²⁵ *ibid* 45.

²⁶ Department of Health (UK), *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS* (London: The Stationery Office, 2000) [3.7] 21-22.

reason, clinical audit, incident reporting and detailed incident analysis are fundamental components to identifying systemic flaws, and implementing appropriate system barriers.²⁷

Systems theory (and patient safety theory) centers around the presumption that human error is inevitable, therefore, counter measures directed at the system will ultimately be more effective at reducing the occurrence of patient safety incidents than those directed at individual practices or persons.²⁸ Measures directed at system redesign are extensive and have progressed since the beginning of the patient safety movement. For example, 'human factors engineering' is an interdisciplinary approach to evaluating and improving safety. The main goal of human factors engineering is to design user-centred technology which takes account of human limitations, ultimately ensuring the optimal relationship between the system and those who work within it.²⁹ In practice, all errors are the result of both human and system factors. As Jenicek notes, "The balance between human and system error may vary from one specialty to another. ... However, any error may be thought of as a system error with varying proportions of human and other system components depending on the workplace, medical specialty, and setting of clinical and community care."³⁰ Essentially, human factors engineering involves designing systems that make patient safety incidents and medical error impossible by intervening on the chain of causation before an incident occurs.

It is important to note, however, that the study and acceptance of the systems approach has been incremental. An example of this is the reporting of diagnostic error over

²⁷ See further: Chapter 9 'Incident Reporting and Analysis.'

²⁸ World Health Organization (Report by the Secretariat), *Quality of Care: Patient Safety* (23 March 2002) A55/13. [9].

²⁹ M Jenicek, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011) 191; citing: V Gawron et al., 'Medical Error and Human Factors Engineering' (2006) 21(1) *American Journal of Medical Quality* 57-67.

³⁰ M Jenicek, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011) 209.

errors previously thought to be more amendable to the system. As Wachter comments, “physicians may have been more reluctant to discuss diagnostic errors than other types of errors because they viewed diagnostic errors as being more closely associated with their own cognitive failings than errors that feel more ‘system-ish.’”³¹ To overcome the pervasive belief that medical error is solely the result of cognitive failings, a systems approach requires transparency, and the acknowledgement that preventable patient safety incidents and medical error occur notwithstanding attempts at perfect performance. In understanding the causal relationship between human and system-design, it is now necessary to consider the contribution of Reason’s “Swiss Cheese” model.

5.3 Reason’s “Swiss Cheese” Model (SCM)

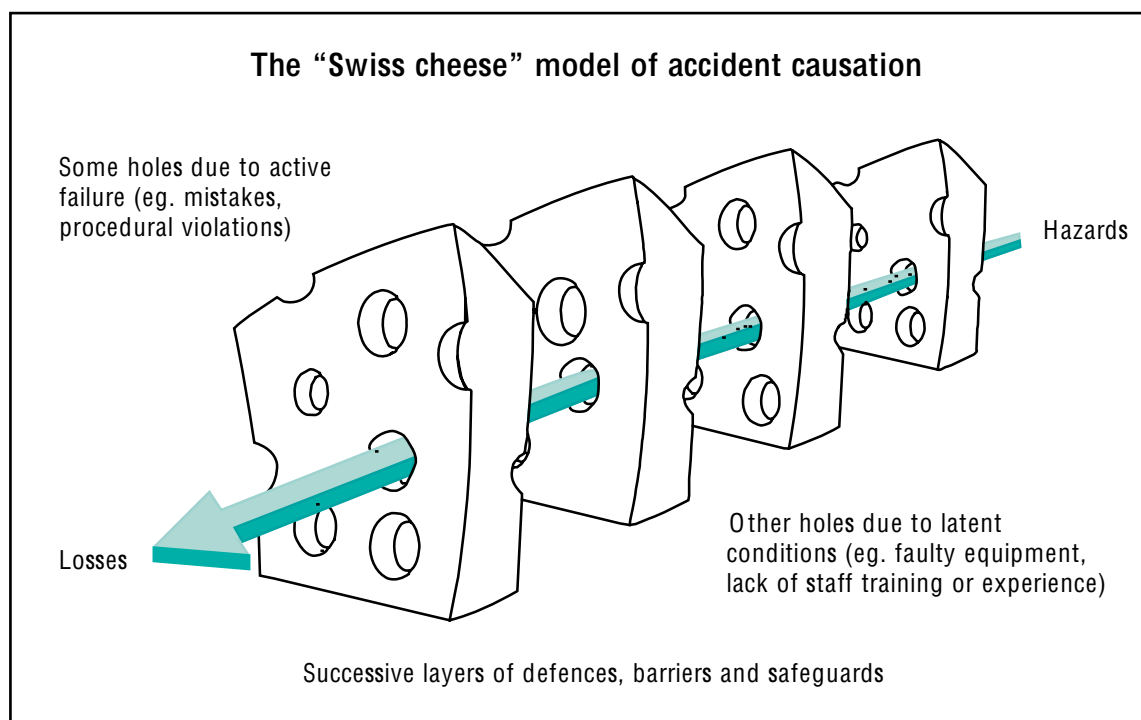


Figure 1. The “Swiss Cheese” Model³²

³¹ R Wachter, ‘Entering the Second Decade of the Patient Safety Movement: The Field Matures’ (2009) 169(20) JAMA Internal Medicine 1894, 1895.

³² Figure 1. The “Swiss Cheese” Model. As taken from: Department of Health (UK), *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS* (London: The Stationery Office, 2000) [3.11] 23.

The “Swiss Cheese” Model (SCM), created by James Reason, began with the intention to provide “an essentially cognitive psychological account of the nature, varieties, and the mental sources of human error.”³³ It has since become a tool for the description of accident causation. The SCM lists the successive layers of defenses, barriers and safeguards within an organisation (‘slices of cheese’); adding to it ‘holes’ of vulnerability at various organisational levels.³⁴ It is useful to note that not all sources of vulnerability will end in a patient safety incident. As Morath and Turnbull suggest, “More often than not, the vulnerabilities are deflected from the path toward an accident, either because the failure results in no harm or because normal defenses—organizational, human, or technological—successfully defend against the failure reaching a patient.”³⁵ Developing and implementing mechanisms of intervention to act as barriers between error and patient harm is a primary objective of the patient safety movement.

Functions of the “Swiss Cheese” Model

Since its publication, the “Swiss Cheese” Model has been adapted into both retrospective and prospective models to suit the subjective factors of the industry to which it is being applied. According to Reason, the SCM has three general purposes: as a conceptual framework, as a means of communication, and as a means of analysis.³⁶

The first purpose for the SCM is its use as a ‘conceptual framework.’ As Reason argues:

³³ J Reason et al., *Revisiting the << Swiss Cheese >> Model of Accidents* (Bruxelles; France: Eurocontrol Experimental Center, 2006) 4.

³⁴ J Reason, ‘Human Error: Models and Management’ (2000) 320(7237) *BMJ* 768–770.

³⁵ J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 52.

³⁶ J Reason et al., *Revisiting the << Swiss Cheese >> Model of Accidents* (Bruxelles; France: Eurocontrol Experimental Center, 2006) 9-10.

“The SCM is a heuristic explanatory device for communicating the interactions and concatenations that occur when a complex well-defended system suffers a catastrophic breakdown. In particular, it conveys the fact that no one failure, human or technical, is sufficient to cause an accident. Rather, it involves the unlikely and often unforeseeable conjunction of several contributing factors arising from different levels of the system. It also indicates what defines an *organizational accident*, namely the concurrent failure of several defences, facilitated, and in some way prepared, by sub-optimal features of the organisation design.”³⁷

In essence, the conceptual framework of the SCM can be described as a “normative organisation model” with layers of barriers added at the sharp end. This is most evident in the case of detailed and subjective forms of the SCM.³⁸ However, Reason notes that while “accident investigation for natural reasons starts with the proximate events, including barriers and defences that somehow failed to meet their objectives,” the positioning of the barriers at the sharp end is largely symbolic as failed barriers occur at every level within the organisation.³⁹

The second purpose for the SCM is its use as a means of communication. Reason makes the observation that, “... the strong point of the SCM as a communication tool is that it has been instrumental in developing the understanding of accidents as the outcome of failures at several stages, as a (complex) combination of active failures and latent conditions, rather than as the result of isolated events at the sharp end. It is thus

³⁷ *ibid* 9.

³⁸ *ibid* 17.

³⁹ J Reason et al., *Revisiting the << Swiss Cheese >> Model of Accidents* (Bruxelles; France: Eurocontrol Experimental Center, 2006).

a powerful vehicle for explanations.”⁴⁰ However, this is not to suggest that accidents are the consequence of a specific sequence of events or failures. Rather, the SCM allows causation to be illustrated and put into the context of the system as a whole, as opposed to a singular and linear event.

Lastly, the third potential purpose for the SCM is its use as a basis for analysis. For this purpose, Reason contends that, “The model has also been applied to proactive process measurement—the repeated assessment of a limited set of ‘vital signs’ that collectively give some indication of the current state of ‘safety health’ and the factors that are most in need of remediation.”⁴¹

Given the dynamic and complex nature inherent in healthcare services, the SCM—as both a conceptual framework and means of communication—has become a valuable tool within the patient safety movement for illustrating the complex causes of patient safety incidents. As Dekker identifies, “The layers of defence are not static or constant, and not independent of each other either. They can interact, support or erode one another. The “Swiss Cheese” analogy is useful to think about the complexity of failure, and conversely, about the effort it takes to make and keep a system safe. It can also help structure your search for distal contributors to the mishap.”⁴² Dekker’s observation is useful in understanding the theoretical premise of the SCM. While the illustration of the SCM suggests that the layers of defense are independent of one another, in practice, each level of the healthcare system works in combination. For example, a misdiagnosis may be the result of a delay in pathology or radiology reports, inadequate staffing levels, lack of proper patient identification, or a technological failure. All of these are influenced by both active (human) factors and latent (system)

⁴⁰ *ibid* 16.

⁴¹ *ibid* 10.

⁴² S Dekker, *The Field Guide to Human Error Investigations*. (Aldershot: Ashgate, 2002) 119-120; as taken from: J Reason et al., *Revisiting the << Swiss Cheese >> Model of Accidents* (Bruxelles; France: Eurocontrol Experimental Center, 2006) 12.

factors occurring at various levels of the organisation. Ideally, each level should also have the appropriate defenses, barriers and safeguards in place to defend against failure.⁴³

While a strength of the SCM is its ability to adapt to the idiosyncrasies of the organisation and the complex causes leading to and resulting in error; the SCM has also been criticised in terms of its operative effects. The main criticisms include issues of specificity, methods of application of the 'human factors' within the model, and barriers in assessing the conditions surrounding patient safety incidents and an effective safety management strategy going forward. These criticisms will now be analysed.

The first criticism concerns issues of specificity within the model. Luxhøj and Kauffeld have critically argued that the SCM is "insufficiently specific regarding the nature of the holes in the cheese and their inter-relationships."⁴⁴ The authors contend that the model "... does not account for the detailed interrelationships among causal factors. Without these distinct linkages, the results are too vague to be of significant practical use."⁴⁵ Likewise, Dekker makes the observation that the SCM does not explain, "where the holes are or what they consist of, why the holes are there in the first place, why the holes change over time, both in size and location, how the holes get to line up to produce an accident."⁴⁶ However, in addressing the issue of specificity within the SCM,

⁴³ For a detailed analysis of active and latent failure, see further: Chapter 6.2 'Identifying Medical Error.'

⁴⁴ J Luxhøj and K Kauffeld, 'Evaluating the Effect of Technology Insertion into the National Airspace System' (2003) 5 *The Rutgers Scholar*; as taken from: J Reason et al., *Revisiting the << Swiss Cheese >> Model of Accidents* (Bruxelles; France: Eurocontrol Experimental Center, 2006) 12.

⁴⁵ *ibid.*

⁴⁶ S Dekker, *The Field Guide to Human Error Investigations*. (Aldershot: Ashgate, 2002) 119-120; as taken from: J Reason et al., *Revisiting the << Swiss Cheese >> Model of Accidents* (Bruxelles; France: Eurocontrol Experimental Center, 2006) 12.

Reason has argued that the model was intended as a generic tool, details of specificity are inherently subjective and to be based on individual investigations.⁴⁷

The method by which 'human factors' are chosen and applied in the context of the SCM has also drawn criticism. In cautioning against the use of hindsight when using the SCM retrospectively, Shorrock et al. note, "From a safety management perspective, the key point is to identify, as well as possible, the potential contributors to a multi-factorial process. Here hindsight can be of benefit, although it should be used with care."⁴⁸ The second criticism raised by Shorrock et al. is that the misapplication of both human and system factors within the SCM can shift the blame from the sharp end to the blunt end; as well, "highlighting management problems may hide very real human factors issues like the impact of emotion on performance, or hamper the research needed to better understand human fallibility."⁴⁹ Given the role of both human and system factors in the causation of error, Shorrock's point is a legitimate one. However, the intention of the SCM is to highlight *all* relevant factors. While this may only be possible through extensive epidemiological analysis (for example, root cause analysis), the SCM is at minimum a starting point towards a greater understanding of the causation of preventable patient safety incidents.⁵⁰

The third criticism raised is that causal connections between latent conditions and adverse events cannot easily be identified, particularly prior to an adverse incident occurring. Likewise, where the SCM may identify human factors as the cause of the

⁴⁷ J Reason et al., *Revisiting the << Swiss Cheese >> Model of Accidents* (Bruxelles; France: Eurocontrol Experimental Center, 2006) 9; citing: S Shappell and D Wigeon, *The Human Factors Analysis and Classification System*, Office of Aviation Medicine, Federal Aviation Administration (US Department of Transportation, 2000) DOT/FAA/AM-00/7. p 2.

⁴⁸ S Shorrock et al., 'Who Moved My (Swiss) Cheese?' (2005) (Jan/Feb) *Aircraft & Aerospace* 31-33; as taken from: J Reason et al., *Revisiting the << Swiss Cheese >> Model of Accidents* (Bruxelles; France: Eurocontrol Experimental Center, 2006) 13.

⁴⁹ *ibid.*

⁵⁰ See further: Chapter 9.3 'Incident Analysis.'

specific accident scenario, this may not explain the accident from a safety management perspective, nor the correct safety management strategy going forward.⁵¹ This is a legitimate criticism given that not all latent factors can or will result in adverse circumstances. Reason argues in response that prevention strategies can be based on identified latent factors where the latent factors are *de facto* not conducive to safety. For example, an often cited latent factor is staff under-scheduling and fatigue. While fatigue will not always result in an adverse incident, it certainly increases the chances of such an incident occurring.⁵² For this reason, Reason argues that in terms of safety management, effective prevention policies—as well as further intrinsic information into the cause of the accident—can be based on an analysis of latent conditions, in addition to all of the information taken from reporting, analysis and application to the SCM.⁵³

It is worth noting that the most recent version of the “Swiss Cheese” Model, the Mark III, reformed elements of the original model. Most prominently, the Mark III included a deemphasis on the normative organisational model, and on the role of human failures at the sharp end. The Mark III version also reduced the emphasis on ‘hazards’ and replaced it with an emphasis on ‘barriers.’ Reason suggests that, “This may be taken as representing the view that it is more efficient to prevent accidents by strengthening system barriers than by eliminating causes.”⁵⁴ Finally, in acknowledging criticisms raised over the potential misapplication of human factors, the Mark III version does not refer to human or managerial failures or factors, but rather organisational factors.⁵⁵

⁵¹ J Reason et al., *Revisiting the << Swiss Cheese >> Model of Accidents* (Bruxelles; France: Eurocontrol Experimental Center, 2006) 13; citing: S Shorrocks et al., ‘Who Moved My (Swiss) Cheese?’ (2005) (Jan / Feb) *Aircraft & Aerospace* 31-33.

⁵² See further: Chapter 8 ‘Case Study: Resident Duty Hours.’

⁵³ J Reason et al., *Revisiting the << Swiss Cheese >> Model of Accidents* (Bruxelles; France: Eurocontrol Experimental Center, 2006) 13.

⁵⁴ *ibid* 17.

⁵⁵ *ibid* 13.

Having examined the theory and development of the SCM, it is now instructive for the purposes of understanding the complexity of medical error to consider the Healthcare Error Proliferation Model.

The Healthcare Error Proliferation Model

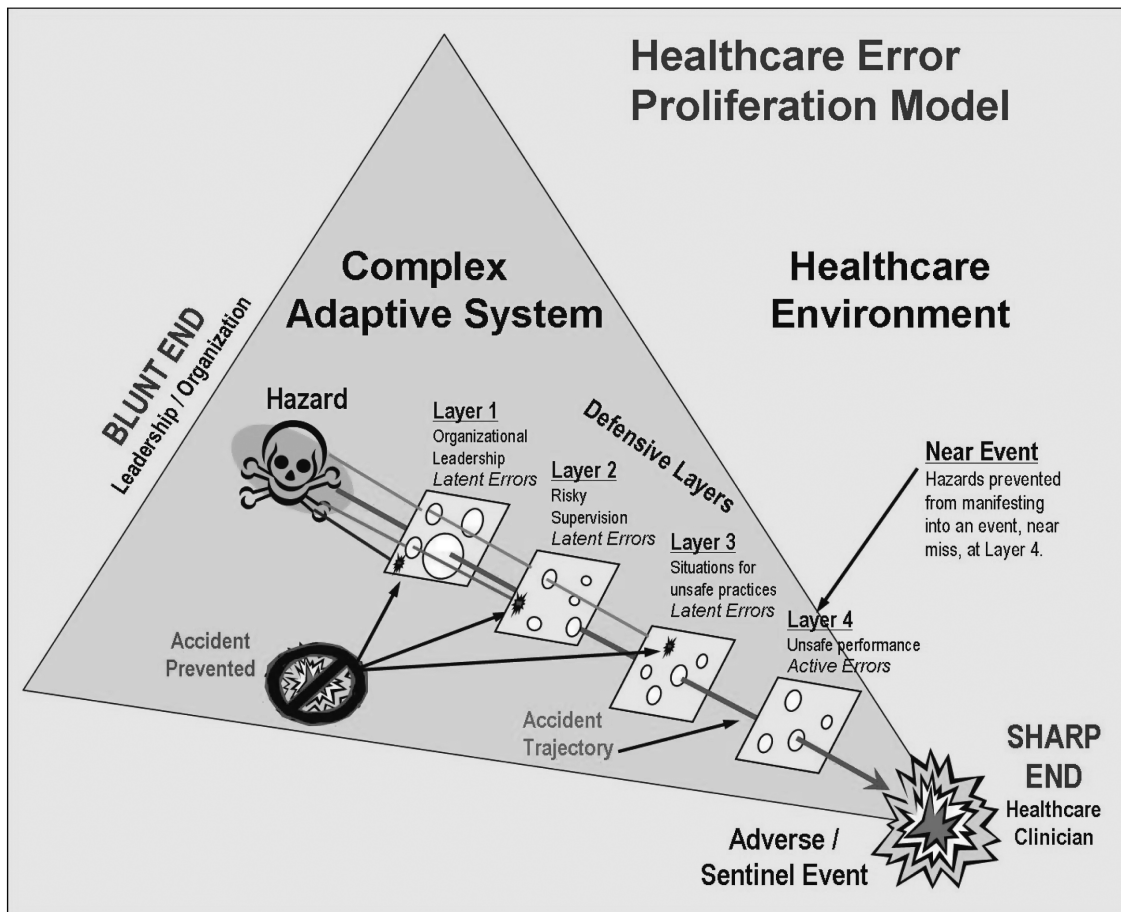


Figure 2. The Healthcare Error Proliferation Model⁵⁶

The Healthcare Error Proliferation Model is an adaptation of Reason’s SCM which incorporates the fundamental elements of the SCM and applies them to the healthcare environment. Palmieri et al., suggest that within healthcare, the first layer representing the policies and procedures of those in the organisation’s leadership are the most

⁵⁶ Figure 2. The Healthcare Proliferation Model. As taken from: P Palmieri et al., ‘The Anatomy and Physiology of Error in Adverse Health Care Events’ in T Grant et al., (eds) *Patient Safety and Health Care Management* (2008) 7 *Advances in Health Care Management* 33-68.

challenging to alter because "... the current 'blame and shame' person approach is frequently derived from an attribution like process."⁵⁷ The second layer of defense, termed "Risky Supervision," consists of management at various levels of the organisation. The authors suggest that, "managers, both clinical and administrative, are directly responsible for organizing, implementing, and evaluating policies and procedures to guide the safe supervision and management of the complex adaptive care delivery system."⁵⁸ The third layer of defense is 'Situations for Unsafe Practices.' This includes substandard conditions and practices, and can result from imperfect environmental conditions and situations.⁵⁹ Lastly, the fourth layer of defense represents 'Situations for Unsafe Performance.' While the causes of adverse events at the sharp end are complex and vast, in this regard, the authors argue that, "To prevent adverse events that result directly from unsafe acts requires blocking holes or trapping hazards that result from within the clinician's controlled defensive layer."⁶⁰ A common example of a fourth layer barrier would be the introduction of forcing functions, which prevent a particular action.

Both the "Swiss Cheese" Model and the Healthcare Error Proliferation Model are useful tools for explaining the context in which preventable safety incidents occur. The Healthcare Error Proliferation Model has distinct advantages to the SCR when used within a healthcare setting as conceptual framework and means of communication. Specifically, the acknowledgement that healthcare environments function within a 'complex adaptive system' in which the factors affecting patient care can vary greatly based on the unit or the healthcare professionals involved. In addition, this model clearly illustrates the various blunt end levels of the healthcare system in which latent

⁵⁷ P Palmieri et al., 'The Anatomy and Physiology of Error in Adverse Health Care Events' in T Grant et al., (eds) *Patient Safety and Health Care Management* (2008) 7 *Advances in Health Care Management* 33, 48.

⁵⁸ *ibid* 51.

⁵⁹ *ibid* 51-52.

⁶⁰ *ibid* 56.

factors lie dormant. Recognition of this has been an important element of the patient safety movement and future research into systems theory should focus largely on intervention barriers that can be implemented at the blunt end.

While both the SCM and the Healthcare Error Proliferation model are useful tools for understanding and communicating the conceptual framework for error causation, they are less effective at retrospectively identifying the causes of an incident. In this respect, epidemiological analysis (such as root cause analysis) is more effective as a means of identifying causation because it offers the distinct advantage of including detailed methodology for conducting an incident analysis. Notwithstanding, these models can aid in educating healthcare professionals and the public as to the various sources of latent hazards occurring within the system. Educating healthcare professionals as to the human and system factors that contribute to preventable patient safety incidents will likely also have the advantage of increasing incident reporting, and moving towards a just culture—both objectives of the patient safety movement.⁶¹

5.4 Conclusion

This chapter has analysed the role that human factors and system factors have in the causation of patient safety incidents. In contrast to traditional theories of error causation that focused primarily on individual responsibility and human factors; patient safety theory stresses that, “The pursuit of human error does not aid but rather impedes our understanding of how complex systems fail and the ways in which human clinicians contribute to or detract from safety.”⁶² To illustrate the division between human factors at the sharp end and latent factors at the blunt end, the third section of this chapter analysed Reason’s “Swiss Cheese” Model and the Healthcare Error Proliferation model as tools for understanding and communicating the

⁶¹ See further: Chapter 9 ‘Incident Reporting Systems and Analysis.’

⁶² J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 59.

complexity of system failure. The Healthcare Error Proliferation Model is a particularly effective tool in translating Reason's principles to the clinical environment, given its acknowledgement that the healthcare environment operates within a 'complex adaptive system.' For safety and quality improvement—including the prevention of error—organisational latent factors must be addressed by those with the ability to “address the problems-behind-the-problems...”⁶³ In practice, this means those at the blunt end must encourage a culture that recognises preventable patient safety incidents as intrinsic to healthcare delivery, but in turn, actively seeks to prevent latent factors from resulting in harm at the sharp-end. The role of systems theory is significant to the discussion of the patient movement because it provides the foundation on which current intervention strategies for quality and safety improvement are based.

⁶³ K Henriksen and E Dayton, 'Organizational Silence and Hidden Threats to Patient Safety' (2006) 41(4) Health Services Research 1539, 1550.

- Chapter 6 -

The Nature of Medical Error

6.1 Introduction

Within healthcare, the term 'medical error' has numerous definitions. For example, the Institute of Medicine's report *To Err is Human* defines medical error as: "... the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)."¹ Alternatively, the World Health Organization have defined medical error as "An adverse event or near miss that is preventable with the current state of medical knowledge."² Despite their differences, what is consistent between these two definitions is that medical error is preventable.

Having examined in the previous chapter the role of human and system factors that operate at the blunt and sharp ends of the healthcare spectrum; this chapter will extend that analysis by examining in detail the role that human and system failure have in the causation of medical error. Medical errors, by their very nature, are most closely connected to active failure at the sharp end. For this reason, the first section will identify and examine the many diverse causes of active failure that result in preventable incidents, specifically medical error. For the purposes of categorisation, active errors will be described first using the generic error-modeling system (GEMS) which divides error into three broad categories: knowledge-based, rule-based, and skill-based.³ In addition, medical errors will be examined according to their cognitive basis; namely error as a result of a slip, lapse, mistake or violation.

¹ Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999) 18; citing: J Reason, *Human Error* (Cambridge: Cambridge University, 1990).

² World Health Organization, *Glossary of Patient Safety Concepts and References* (January 2009) <http://www.who.int/patientsafety/taxonomy/icps_technical_annex2.pdf> accessed: 16 March 2015.

³ M Jenicek, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011) 33; citing: J Reason, *Human Error* (Cambridge: Cambridge University Press, 1990).

In the second section, factors that contribute to the occurrence of both active and latent failure will be critically examined. Beginning first with work environment factors that inhibit safe care, including: the normalisation of deviance, diffusion of responsibility, division of labour and the 'work-around.' Second, individual factors that leave the system vulnerable will be examined. These include: bias, fundamental attribution error, the use of heuristics and maintaining the status quo. Lastly, in contrast to social factors related to individuals within a clinical setting, organisational factors primarily related to the philosophies and decisions originating at the blunt end will be identified, including: unchallenged beliefs, the 'good provided fallacy' and neglect of the interdependencies.⁴ From a patient safety perspective, understanding the diverse causes of active and latent factors that contribute to error is essential for the development of a just culture, the epidemiological analysis of patient safety incidents, and for designing blunt and sharp end intervention strategies.

6.2 Identifying Medical Error

This section will critically compare the methods by which error is defined and classified. By way of introduction, it is useful to note at the onset that patient safety theory categorises error by both the type of error, and by where it originates within the organisation. Referring back to Reason's "Swiss Cheese" model, the 'sharp end' is comprised of those who provide direct patient care and is most closely connected to 'active failure' involving human factors. This is distinct from the "blunt end" which includes those who are primarily responsible for policy decisions and oversight. The blunt end is generally identified with 'system-produced error' characterised by latent failures. This distinction is recognised by Firth-Cozen and Sandars, who point out, "Active failures are usually associated with human factors. Occasionally there can be a sudden and unexpected failure of equipment but this is rare. These active failures contribute to most threats to patients. However, latent failures are 'errors waiting to

⁴ K Henriksen and E Dayton, 'Organizational Silence and Hidden Threats to Patient Safety' (2006) 41(4) Health Services Research 1539, 1548-1550.

occur' and are associated with the healthcare system. These latent failures are the root cause of most active failures."⁵

In defining and classifying error, it is necessary to begin with an examination of the types of error. Specifically, active failures occurring at the sharp end, as distinct from latent failure at the blunt end. For the sake of clarity, the following is written on the basis that the 'sharp end' and the 'blunt end' function as separate entities. However, this distinction is largely theoretical as clinical, organisational, and financial processes are inherently interdependent in practice.⁶

6.2.1 Active Failure and the Sharp End

The sharp end encompasses the work environment, care team, and individual healthcare professionals within the care delivery process. This is where expertise is applied and preventable patient safety incidents, including active errors, are directly experienced.⁷ Active errors can include decisions, actions or inactions which precede a patient safety incident.⁸ For the purposes of categorisation, active errors will be described first using the generic error-modeling system (GEMS) which divides error into three broad categories: knowledge-based, rule-based, and skill-based.⁹ Second, errors will be categorised according to their cognitive basis, specifically: error as a result of a slip, lapse, mistake, or violation.

⁵ J Firth-Cozen and J Sandars, 'The Nature of Error' in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 4.

⁶ J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 49.

⁷ *ibid* 47.

⁸ J Sandars, 'The Theory and Evidence Base for Clinical Risk Management' in K Haynes and M Thomas (eds), *Clinical Risk Management in Primary Care* (Oxon: Radcliffe, 2005) 57.

⁹ M Jenicek, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011) 33; citing: J Reason, *Human Error* (Cambridge: Cambridge University Press, 1990).

Knowledge, Rule and Skill-based Error

i. Knowledge-Based Error

Knowledge-based medical errors are based on the healthcare professionals knowledge of the particular process. Knowledge-based errors include those in which faulty reasoning, inexperience, or poor evidence is used and results in a preventable patient safety incident. A knowledge-based error can occur despite the correct skills being applied and executed according to proper rules.¹⁰ Knowledge-based errors can be prevented by improving clinical knowledge and supervision, as well as through the use of safety checklists (e.g. the WHO Surgical Safety Checklist) and practice guidelines.¹¹ Accountability for a knowledge-based error can fall to either the sharp or blunt end depending on the specific circumstances, and legislation requiring the aforementioned (i.e. checklists) can be influential in practice.

ii. Rule-Based Error

Rule-based errors are those errors which involve the misinterpretation of a specific rule, failure to apply a rule designed to prevent error, or applying a poorly designated rule.¹² A useful example of this is when an incorrect diagnosis (possibly as a result of a knowledge-based error) results in the use of an inappropriate treatment plan or medication (rule-based error.) Again, accountability for such an error will depend on the specific circumstances and may be directed at both the blunt or sharp end and incorporate clinical audit and education.

¹⁰ *ibid*; J Sandars, 'The Theory and Evidence Base for Clinical Risk Management' in K Haynes and M Thomas (eds), *Clinical Risk Management in Primary Care* (Oxon: Radcliffe, 2005) 57.

¹¹ J Aronson, 'Medication Errors: Definitions and Classification' (2009) 67(6) *British Journal of Clinical Pharmacology* 599, 603.

¹² J Sandars, 'The Theory and Evidence Base for Clinical Risk Management' in K Haynes and M Thomas (eds), *Clinical Risk Management in Primary Care* (Oxon: Radcliffe, 2005) 57.

iii. Skill-Based Error

Skill-based errors are errors that result from “absent-mindedness”¹³ and are caused most often by slips or lapses (examined below). As Jenicek explains, skill-based errors “take place without conscious control... and highlight integrated patterns of behavior.”¹⁴ An example of a skill-based error includes the wrong site administration of a medication.

Mistakes, Lapses, Slips and Violations

At the sharp end, active failures can be further identified by type; these include identification by means of a mistake, lapse, slip, or violation. Violations are rare and deliberate attempts not to follow rules;¹⁵ whereas mistakes, slips or lapses can include errors of commission or omission, and are far more common. While all three usually begin with an investigation as to the culpability of the individual at the sharp end, it is vital that the blunt end be equally accountable for failure to implement effective intervention strategies where known risks exist. Hospital accreditation requirements can be useful in this regard in ensuring adequate standards are met and followed. As well, legislation that holds hospital governing bodies accountable for safety, and threatening organisations with the prospect of vicariously liability can also be influential.

i. Mistakes

A mistake can be defined as an error in “action, calculation, opinion, or judgment.”¹⁶ Mistakes are most common in knowledge or rule-based activities, and can be the result

¹³ *ibid.*

¹⁴ M Jenicek, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011) 33; citing: J Reason, *Human Error* (Cambridge: Cambridge University Press, 1990).

¹⁵ J Firth-Cozen and J Sandars, ‘The Nature of Error’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 5.

¹⁶ M Jenicek, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011) 179.

of, *inter alia*: inexperience, poor planning, time pressures, or fatigue. An example of a mistake in a clinical context could include prescribing two medications that, when taken together, have the possibility of inducing an adverse reaction.

ii. Lapse

Lapses generally occur in skill-based activities and are caused by a failure in memory (i.e. “a lapse in memory.”)¹⁷ Given the nature of this form of error, prevention strategies include the use of standardised protocol, and best practice guidelines.¹⁸ An example of a lapse can include unknowingly omitting a step from a task. In this regard, safety checklists can be beneficial in confirming all appropriate steps have been completed.

iii. Slips

Similar to lapses, ‘slips’ generally occur while performing skill-based activities. According to Morath and Turnbull, “Distractions create fertile environmental conditions for slips. A distraction may be an external stimulus in the environment (such as noise or interruptions) or an internal stimulus (a nagging worry; focused concentration on an upcoming task or event; a psychological state such as fatigue).”¹⁹ Unlike lapses, slips are generally unknown until after the event occurs.²⁰ Writing 100ml instead of the intended dosage of 10ml is a common but potentially fatal example of a slip. As with mishaps, computer programs designed to interrupt human error can be useful in preventing this form of error.

¹⁷ J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 60; M Jenicek, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011) 179.

¹⁸ J Firth-Cozen and J Sandars, ‘The Nature of Error’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 5.

¹⁹ J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 60.

²⁰ J Firth-Cozen and J Sandars, ‘The Nature of Error’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 4-5.

6.2.2 Latent Failure and the Blunt End

It was recognised in the UK's Report *An Organisation with a Memory* that to improve the rate of error within the healthcare system, the conditions under which the system operates must be changed so as to make them 'less error-provoking.' In this regard, they contend: "Errors are seen as being shaped and provoked by 'upstream' systemic factors, which include the organisation's strategy, its culture and the approach of management towards risk and uncertainty."²¹ In contrast to direct patient care described previously as the 'sharp end'; the 'blunt end' includes, *inter alia*, the work of management, government, and regulators. Decisions made at the blunt end (for example, 'upstream' systemic factors) contribute to preventable incidents by producing hidden latent conditions that increase the likelihood of an active failure occurring.²² Jenicek notes that system-produced error and harm are the result of an accumulated failure of "various human, chemical, physical, technological, and environmental factors in their nature, constellation, and interaction."²³ As with active failure, latent failures can occur through acts of commission or omission, and may lie dormant and unnoticed for long periods before hazardous conditions at the sharp end emerge.²⁴ When designing systems to be resistant to latent conditions, Lowe argues that organisations must "design out latent conditions that contribute to error and create better and safer systems of healthcare delivery."²⁵ Doing so, however, requires an understanding of not only how preventable incidents occur, but why. For this reason,

²¹ Department of Health (UK), *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS* (London: Department of Health, 2000) [3.7] 20-21.

²² J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 48.

²³ M Jenicek, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011) 209.

²⁴ V Lachman, 'Patient Safety: The Ethical Imperative' (2008) 20(2) *Journal of the Dermatology Nursing Association* 134; J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 51.

²⁵ C Lowe, 'Accidents Waiting to Happen: The Contribution of Latent Conditions to Patient Safety' (2006) 15(Supp 1) *BMJ Quality & Safety* i72, i75.

the next section will analyse the latent and active factors that contribute to error and weaken existing defence barriers.

6.3 Causes of Medical Error

Medical errors do not occur in isolation but rather are the result of both latent and active failures. As Henriksen and Dayton note, “While the active errors that humans make may appear to have a random quality, many of these errors occur in systematic and predictable ways.”²⁶ The following section will critically analyse factors that contribute to the occurrence of active and latent failure; ultimately weakening existing barriers of defence within the system. These factors are categorised under the headings: Work Environment Factors, Individual Factors, and Social and Organisational Factors.

6.3.1 Work Environment Factors

Healthcare professionals, in an effort to deal with the complexities of patient care, often develop coping strategies for effectively managing an excessive workload. Although the consequence of pragmatism, these coping strategies can reduce the effectiveness of system barriers designed to prevent error. This section will consider the role of four workplace factors that inhibit safe care, specifically: the normalisation of deviance, diffusion of responsibility, division of labour, and the ‘work-around’.

i. Normalisation of Deviance

The normalisation of deviance can be defined as, “the acceptance of, or failure to recognize, faulty and risk-prone processes because they are so familiar, pervasive, and entrenched in the work environment. This results in failure to attend to problematic conditions.”²⁷ Failing to attend to problematic conditions is antithetical to quality and

²⁶ K Henriksen and E Dayton, ‘Organizational Silence and Hidden Threats to Patient Safety’ (2006) 41(4) Health Services Research 1539, 1541.

²⁷ J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 66.

safety improvement. However, healthcare professionals may resort to such practices in an effort to effectively manage the complexities of patient care. A useful example of this was the tragic events at Mid-Staffordshire NHS Foundation Trust, in which systemic problems were consistently left unaddressed.²⁸ There are many reasons for the normalisation of deviance, as Macrae has argued, "... many healthcare staff are used to working within systems that are deeply imperfect— where time is pressured, required equipment may not always be available and clinical demand can at times exceed the resources available."²⁹ Where these shortcomings are not questioned—but rather become the norm—the normalisation of deviance can have a devastating effect. According to Banja, the most common reasons for this include: believing the rules are inefficient or counterproductive and do not apply to the specific situation; a lack of knowledge as to the correct rules or standards; as a result of the complexity of the work environment itself or complex technology; organisational silence in which workers are afraid to intervene; or where leadership deliberately withhold or dilute information about systematic problems.³⁰ Addressing the normalisation of deviance requires organisational responsibility for fostering an atmosphere that allows healthcare professionals to question and report deviant practices without fear of blame or censure.³¹

²⁸ R Francis, *Report of the Mid-Staffordshire NHS Foundation Trust Public Inquiry: Volume 3* (London: The Stationery Office, 2013).

²⁹ C Macrae, 'Early Warnings, Weak Signals and Learning from Healthcare Disasters' (2014) 23 *BMJ Quality & Safety* 440, 441. See further: Chapter 3.3 'England.'

³⁰ K Banja, 'The Normalization of Deviance in Healthcare Delivery' (2010) 53(2) *Business Horizons* 139, 142-144.

³¹ M Price, 'When Doing Wrong Feels So Right: Normalization of Deviance' (07 March 2015) *Journal of Patient Safety* 1-2. [Epub ahead of print].

ii. Diffusion of Responsibility

The concept of ‘diffusion of responsibility,’ also known as the ‘bystander effect,’ originates from the school of sociology.³² In healthcare, diffusion of responsibility refers to a situation in which there is a collective lack of responsibility for specific tasks or duties (such as a safety issue) or alternatively a lack of accountability when an incident occurs.³³ Diffusion of responsibility does not mean a deliberate decision not to take responsibility, but rather a situation in which it is believed by all involved that the responsibility has already been assumed by another person. This phenomenon is most common when specific tasks are not individually assigned. Engaging healthcare professions in teams and assigning accountability for specific tasks is a way of addressing this behaviour.³⁴

iii. Division of Labour

‘Division of labour’ refers to the allocation of specific tasks according to occupation and skill set. The division of labour is certainly not unique to healthcare, however, the increasing complexity of clinical settings, coupled with staff shortages and increased workload make the division of labour a potential barrier to quality and safety. This is recognised by Claridge and Sandars, who state, “This inevitably creates difficulties, with greater potential for errors to occur, because of the requirement to coordinate, collaborate and cooperate.”³⁵ The division of labour can also contribute to the

³² J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 68.

³³ T Claridge and J Sandars, ‘Patient Safety Culture’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 21.

³⁴ K Henriksen and E Dayton, ‘Organizational Silence and Hidden Threats to Patient Safety’ (2006) 41(4) *Health Services Research* 1539, 1547.

³⁵ T Claridge and J Sandars, ‘Patient Safety Culture’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 21.

aforementioned diffusion of responsibility. Similarly, assigning accountability for specific tasks is a way of addressing this behaviour.³⁶

iv. The 'Work-Around'

The 'work-around' can be defined as "... those work patterns an individual or a group of individuals create in order to accomplish a crucial work goal within a system of dysfunctional work processes that prohibits the accomplishment of that goal or makes it difficult."³⁷ The difficulty with counteracting a work-around pattern is that in one sense, it is created as a result of necessity. Effective performance within the workplace depends on one's ability to effectively adapt to the resources within that environment. However—referring back to the "Swiss Cheese" Model—Reason theorized that error does not occur as the result of a single isolated factor, but rather due to a multitude of human and system failures. The work-around can contribute to error because while the initial 'dysfunctional work process' may be seen as the first hole in the "Swiss Cheese," the work-around may create the second.

Examples of work environment factors that lead to error are endless. In a general sense, active/latent conditions that are antecedent to error include, "inadequate training, unworkable procedures, denigration of preventative maintenance and quality standards, poor or inadequate technology, information overload, unrealistic time pressure, understaffing, and fatigue."³⁸ Furthermore, financial pressures, management and regulatory structures, advancing technology,³⁹ inappropriate uses of medicine

³⁶ K Henriksen and E Dayton, 'Organizational Silence and Hidden Threats to Patient Safety' (2006) 41(4) Health Services Research 1539, 1547. In this regard, Henriksen and Dayton argue, "When people are made accountable for specifiable actions, they can monitor and self-manage their own performance."

³⁷ J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 52.

³⁸ *ibid* 49.

³⁹ *ibid* 46-47.

technologies, deficient execution skills, systematic failures,⁴⁰ poor working conditions and communication failure⁴¹ can also contribute to work environment factors that create the ideal circumstances for error.

6.3.2 Individual Factors

Individual factors such as inexperience or communication issues are commonly recognised contributors to error.⁴² This section will examine individual factors not so commonly recognised that are equally significant contributors to error and leave the system vulnerable. Existing literature has identified four prominent individual factors that will be examined in greater detail below, these include: bias, fundamental attribution error, the use of heuristics, and maintaining the status quo.⁴³

i. Bias

In the context of medical error, bias or ‘cognitive bias’ can be defined as a pattern of deviation in judgment which can effect both reasoning and conclusions.⁴⁴ Two important examples of bias include hindsight bias and outcome bias. Outcome bias is the “... influence of outcome knowledge on evaluations of decision quality...”⁴⁵

⁴⁰ M Jenicek, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011) 7-8.

⁴¹ M Donaldson and B Raik, ‘Preventing Errors’ in E Siegler et al. (eds), *An Introduction to Hospitals and Inpatient Care* (NY: Springer, 2003) 296; citing: Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999).

⁴² See further: Chapter 11 ‘Communication: Disclosure and Apology.’

⁴³ M Jenicek, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011) 180; A Artino Jr. et al., ‘Broadening Our Understanding of Clinical Quality: From Attribution Error to Situated Cognition’ (2012) 91(2) *Clinical Pharmacology and Therapeutics* 167; J Marewski and G Gigerenzer, ‘Heuristic Decision Making in Medicine’ (2012) 14(1) *Dialogues in Clinical Neuroscience* 77, 79; K Henriksen and E Dayton, ‘Organizational Silence and Hidden Threats to Patient Safety’ (2006) 41(4) *Health Services Research* 1539, 1544.

⁴⁴ M Jenicek, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011) 180; citing: K Henriksen and H Kaplan, ‘Hindsight Bias, Outcome Knowledge and Adaptive Learning’ (2003) 12(Suppl II) *BMJ Quality & Safety* ii46-ii50.

⁴⁵ *ibid.*

Although similar, hindsight bias may be more difficult to identify. Morath and Turnbull argue there are two parts to hindsight bias: first, “Observers of past events exaggerate what other people should have been able to anticipate in foresight.”⁴⁶ Second, “Observers of past events are unaware of the great influence that knowing the outcome has had on their perceptions.”⁴⁷ As with outcome bias, hindsight bias has the ability to negatively impact incident reporting and error investigations as the likelihood of hindsight bias increases with the severity of the consequences.⁴⁸ Likewise, hindsight bias can perpetuate a culture of blame in which individuals fear disclosing preventable incidents and error out of concern that their actions will attract regulatory censure or liability.⁴⁹ Incident analysis is an important step in overcoming hindsight bias as the consequence of the error is less significant during an epidemiological analysis than the factors that lead to its occurrence.⁵⁰

ii. Fundamental Attribution Error

Originating within the domain of social psychology, ‘fundamental attribution error’ is defined as the tendency to overestimate the influence of personal characteristics and underestimate the influence of situational factors.⁵¹ While pervasive in all areas of clinical care, Croskerry notes, “Cultural differences exist in terms of the respective weights attributed to dispositional and situational causes.”⁵² In this regard, fundamental attribution errors are particularly common within a blaming culture as

⁴⁶ J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 63.

⁴⁷ *ibid* 64.

⁴⁸ J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005).

⁴⁹ See further: Chapter 4 ‘Healthcare Culture and Accountability.’

⁵⁰ See further: Chapter 9.3 ‘Incident Analysis.’

⁵¹ A Artino Jr. et al., ‘Broadening Our Understanding of Clinical Quality: From Attribution Error to Situated Cognition’ (2012) 91(2) *Clinical Pharmacology and Therapeutics* 167.

⁵² P Croskerry, ‘The Importance of Cognitive Errors in Diagnosis and Strategies to Minimize Them’ (2003) 78(8) *Academic Medicine* 775, 777.

active factors at the sharp end are more closely scrutinised than contributing latent factors. In illustrating this tendency, the seminal report *An Organisation with a Memory* noted, “Human error is commonly blamed for failures because it is often the most readily identifiable factor operating in the period just prior to an adverse event. Yet two important facts about human error are often overlooked. First, the best people can make the worst mistakes. Second, far from being random, errors fall into recurrent patterns.”⁵³

iii. Heuristics

Marewski and Gigerenzer have identified three forms of decision making involving the use of heuristics. The first is the optimization model which assumes “that decision makers will collect and evaluate all information, weight each piece of it according to some criterion, and then combine the pieces to maximize the chances of attaining their goals.”⁵⁴ The second and most commonly practiced within healthcare is that of the heuristics-and-biases framework. It considers optimisation as the ‘normative yardstick’ while also acknowledging that “humans commit systematic errors when judging probabilities and making decisions.”⁵⁵ The third form of decision making is simply the use of ‘heuristics’, defined as “a simple decision strategy that ignores part of the available information and focuses on the few relevant predictors.”⁵⁶

In advocating for the use of heuristics in clinical practice, Marewski and Gigerenzer argue that heuristics have the advantage of being simpler to execute, understand, and communicate as compared to the optimisation or heuristics-and-bias models of clinical

⁵³ Department of Health (UK), *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS* (London: The Stationery Office, 2000) [3.8].

⁵⁴ J Marewski and G Gigerenzer, ‘Heuristic Decision Making in Medicine’ (2012) 14(1) *Dialogues in Clinical Neuroscience* 77, 79

⁵⁵ *ibid*; citing: D Kahneman et al. (eds), *Judgment Under Uncertainty: Heuristics and Biases*. (Cambridge, UK: Cambridge University Press; 1982)

⁵⁶ J Marewski and G Gigerenzer, ‘Heuristic Decision Making in Medicine’ (2012) 14(1) *Dialogues in Clinical Neuroscience* 77-89.

decision-making.⁵⁷ While there are advantages to the use of heuristics in clinical decision making, there are also disadvantages. Where clinicians continue to repeat an inherently risky behaviour based on previous experience, and an inherent error in that behaviour remains uncorrected, a patient safety issue arises and becomes difficult to resolve.⁵⁸

iv. The Status Quo

Henriksen and Dayton argue that within the healthcare industry, the ‘sins of commission’ carry a heavier penalty than the ‘sins of omission.’⁵⁹ As a result, the fourth individual factor that can contribute to error is maintaining the status quo. Maintaining the status quo includes ‘omission bias,’ in which healthcare professionals on the frontline have a tendency towards inaction.⁶⁰ ‘Omission Bias’ can be defined as, “The tendency toward inaction and rooted in the principle of nonmaleficence. In hindsight, events that have occurred through the natural progression of a disease are more acceptable than those that may be attributed directly to the action of the physician.”⁶¹ This is a particularly important point in the context of blame. Referring back to Reason’s “Swiss Cheese” model, omission bias occurs at both the blunt and sharp end, however, it is a latent factor and therefore does not attract the same attention as active

⁵⁷ *ibid* 80-81, 85; citing: J Rieskamp and P Otto, ‘SSL: A Theory of How People Learn to Select Strategies’ (2006) 135 *Journal of Experimental Psychology* 207–236; J Steurer et al., ‘Legal Concerns Trigger Prostate-Specific Antigen Testing’ (2009) 15 *Journal of Evaluation in Clinical Practice* 390–392; J Marewski and L Schooler, ‘Cognitive Niches: An Ecological Model of Strategy Selection’ (2011) 118 *Psychological Review* 393-437. The authors argue that this is due to the different mechanisms used in deciding which heuristic to employ; for example, relying on basic cognitive capacities within the specific environment or the social and individual learning processes that have contributed to individual decision making. These factors can be inherently subjective and can change depending on time and place.

⁵⁸ K Henriksen and E Dayton, ‘Organizational Silence and Hidden Threats to Patient Safety’ (2006) 41(4) *Health Services Research* 1539, 1542.

⁵⁹ *ibid* 1544.

⁶⁰ See: “Table 1 ‘Cognitive Dispositions to Respond (CDRs) That May Lead to Diagnostic Error’ in P Croskerry, ‘The Importance of Cognitive Errors in Diagnosis and Strategies to Minimize Them’ (2003) 78(8) *Academic Medicine* 775, 777.

⁶¹ *ibid*.

failure. Despite this, the consequences of inaction—as with the normalisation of deviance—can be disastrous, and accountability must fall to both the sharp and blunt ends to report, intervene, and correct.

6.3.3 Social and Organisational Factors

Lastly, to understand the factors that contribute to medical error, it is necessary to consider the social and organisational factors that occur within a healthcare setting.

Social Factors

Henriksen and Dayton argue that the three most prevalent social factors contributing to preventable adverse incidents (including medical error) include: conformity, microclimates of mistrust, and the diffusion of responsibility. ‘Conformity’ occurs when individuals conform their judgments and beliefs to those of others to gain acceptance and/or identity. This behaviour is particularly prevalent when a knowledge differential exists within the group.⁶² In a clinical context, ‘microclimates of mistrust’ are the result of variations at a local level that can lead to distrust within the unit as a result of social factors such as failures in communication, undefined roles or conformity within the subgroups.⁶³ Lastly, the concept of diffusion of responsibility has been considered previously. However, for the purposes of error causation and social factors, the diffusion of responsibility within the clinical setting is again relevant as it explains how seemingly obvious duties can be neglected where a presumption exists that others have attended to such responsibilities.⁶⁴ Henriksen and Dayton observe that the “key point here is when individuals harbor less doubt and are more secure in their own roles, they are more likely to transcend individual concerns and speak up

⁶² K Henriksen and E Dayton, ‘Organizational Silence and Hidden Threats to Patient Safety’ (2006) 41(4) Health Services Research 1539, 1545; citing: E Aronson, *The Social Animal* (8th edn, New York: Worth Publishers, 1999).

⁶³ *ibid.*

⁶⁴ *ibid.*; citing: E Aronson, *The Social Animal* (8th edn, New York: Worth Publishers, 1999) 1546.

regarding higher-order organizational concerns.”⁶⁵ Therefore, it is essential that governance and hierarchy structures be firmly established, and responsibilities and accountability be clearly delegated.

Organisational Factors

In contrast to social factors related to individuals within a clinical setting, organisational factors are primarily related to philosophies and decisions originating at the blunt end. Organisational factors that contribute to medical errors include: unchallenged beliefs, the ‘good provided fallacy,’ and neglect of the interdependencies.⁶⁶

i. Unchallenged Beliefs

‘Unchallenged beliefs’ denote a situation in which organisations make decisions to justify their past decisions, even where there is evidence to the contrary of the benefit. Henriksen and Dayton suggest that this may be the result of the time, cost, and effort already put into a particular course of action. Additionally, if the organisation is one that punishes decisions that lead to unfavourable outcomes, an ineffective program may continue to be supported with the hope that it will eventually be successful.⁶⁷ Failing to challenge existing courses of action is antithetical to quality and safety improvement. In this regard, Clinical Audit (a function of the Clinical Governance structure) is useful in countering this, as it enables current processes to be analysed against evidence-based practices.⁶⁸

⁶⁵ *ibid*; citing: E Aronson, *The Social Animal* (8th edn, New York: Worth Publishers, 1999) 1547.

⁶⁶ *ibid*; citing: E Aronson, *The Social Animal* (8th edn, New York: Worth Publishers, 1999) 1548 - 1550.

⁶⁷ *ibid* 1549; citing: B Staw, ‘Knee-Deep in the Big Muddy: A Study of Escalating Commitment to a Chosen Course of Action’ (1976) 16 *Organizational Behavior and Human Performance* 27-44; B Staw, ‘The Escalation of Commitment to a Course of Action’ (1981) 6 *Academy of Management Review* 577-587.

⁶⁸ See further: Chapter 4.4.2 ‘Organisational and Professional Regulation.’

ii. 'Good Provider Fallacy'

The 'good provider fallacy' suggests that within healthcare, there is a tendency to value employees who maintain the status quo and acquiesce to organisational silence. While taking initiative may be encouraged, advocating change and appearing disruptive are not. In contrast, Henriksen and Dayton argue that the perceived qualities of the 'good worker' must be challenged:

“Providers are needed who will help the organization learn. It is time for managers to value providers who ask disruptive, penetrating, or otherwise embarrassing questions without viewing them as trouble-makers or whiners. It is time for managers to value providers who present evidence contrary to the view that things are alright, who create cognitive dissonance that serves as an impetus for change, and who step out of their accustomed roles to help solve the problem-behind-the-problem. And foremost, it is time managers and their leaders value these same qualities among themselves.”⁶⁹

Henriksen and Dayton's argument is very much in line with patient safety initiatives such as incident reporting. For an organisation to learn and improve, healthcare professionals must be incentivised to call attention to that which they believe is inefficient, inappropriate, or unsafe. Holding organisations accountable by way of stringent accreditation requirements, legislation, and the threat of vicarious liability for failure to remedy and meet best practice standards can be influential in encouraging this practice.

⁶⁹ K Henriksen and E Dayton, 'Organizational Silence and Hidden Threats to Patient Safety' (2006) 41(4) *Health Services Research* 1539, 1550; citing: A Tucker and A Edmondson, 'Why Hospitals Don't Learn from Failures: Organizational and Psychological Dynamics That Inhibit System Change' (2003) 45 *California Management Review* 55-72; A Edmondson, 'Learning from Failure in Health Care: Frequent Opportunities, Pervasive Barriers' (2004) 13 (Suppl II) *Quality and Safety in Health Care* ii3-ii9; R Wears, *Oral Remarks at The SEIPS Short Course on Human Factors Engineering and Patient Safety—Part I* (Madison, WI: University of Wisconsin-Madison, 2004).

iii. Neglect of the Interdependencies

The final organisational factor that can contribute to unsafe care and medical error is a 'neglect of the interdependencies.' Henriksen and Dayton assert that within healthcare organisations, a complex system of interdependencies exists; made up of technology, personnel, work processes, and external influences.⁷⁰ The neglect of these interdependencies through short term solutions can consequently leave the system vulnerable. It is the attention to, and understanding of, the complexities of the system that is fundamental to understanding the nature and prevention of error.⁷¹

This section has identified and analysed the complex work environment, individual, social and organisational factors that—through both the sharp end and blunt end—contribute to occurrence of medical error. Understanding these complexities is vital when attempting to design and implement system barriers to prevent latent errors from reaching the sharp end.

6.4 Conclusion

From a patient safety perspective, understanding the complex causes of medical error is fundamental for at least two reasons. First, within a culture of blame, medical error is often associated with the legal standards of individual fault, negligence, or recklessness. Where the standard of care has been met, however, the negative association to the act of an error may be more a result of semantics than cause. As Sandars suggests, "The word 'error' is a rather emotionally laden term, implying blame rather than simply representing any aspect of performance and the fact that this is often highly 'context bound,' where performance is influenced by the nature of the

⁷⁰ K Henriksen and E Dayton, 'Organizational Silence and Hidden Threats to Patient Safety' (2006) 41(4) Health Services Research 1539, 1550; citing: P Schyve, 'Systems Thinking and Patient Safety' in K Henriksen et al. (eds), *Advances in Patient Safety: From Research to Implementation. Volume 2: Concepts and Methodology* (Rockville: Agency for Healthcare Research and Quality, 2005) 1-4.

⁷¹ K Henriksen and E Dayton, 'Organizational Silence and Hidden Threats to Patient Safety' (2006) 41(4) Health Services Research 1539, 1550.

task and the circumstances and environment in which that task is being undertaken.”⁷² Recognising that medical error is not solely related to falling below the legal standards of care—but rather a result of diverse factors—is essential for moving towards a just culture. Second, understanding the diverse factors that lead to error is necessary in encouraging those at the sharp end to report incidents, and those on the blunt end to investigate their root cause. Intervention strategies based on the sharp and blunt end will be analysed in detail within the following chapter.

This chapter identified and critically explored the role of human and system failures in the causation of medical error. Medical errors, by their very nature, are most closely connected to active failure at the sharp end. For this reason, the first section addressed the many diverse causes of active failure that result in medical error. Deconstruction and categorisation is necessary to ensure accountability is appropriately directed, and intervention strategies effectively designed and implemented. The second section sought to contextualise medical error by examining work environment and individual factors that result from the coping strategies of healthcare professionals attempting to navigate through a complex system. Lastly, in contrast to social factors related to individuals within a clinical setting, organisational factors stemming from the blunt end that contribute to medical error were identified. Only by recognising and addressing these diverse active and latent factors can medical error be acknowledged as a symptom of a larger systemic problem and opportunities for improvement implemented.

⁷² J Sandars, ‘The Theory and Evidence Base for Clinical Risk Management’ in K Haynes and M Thomas (eds), *Clinical Risk Management in Primary Care* (Oxon: Radcliffe, 2005) 57; citing: J Reason, *Human Error* (Cambridge: Cambridge University, 1990).

- Chapter 7 -

Safety Interventions: Preventing Patient Safety Incidents and Medical Error

7.1 Introduction

The World Health Organization have defined 'Patient Safety Solutions' as, "any system design or intervention that has demonstrated the ability to prevent or mitigate patient harm stemming from the processes of health care."¹ This section will identify and critically analyse examples of current best practices for system redesign and intervention that can be used within healthcare organisations to reduce medical error, and ultimately, improve safety and quality. As has been argued thus far within this thesis, system redesign and workplace interventions will be ineffective without first addressing the cultural values of the organisation. In this regard, Donaldson and Raik expressed the opinion that,

"Where errors occur, individuals must be held responsible for their actions. Nonetheless, accountability is not the same as making systems safer. Redesigning care processes reduces errors more effectively than blaming individuals. There are many opportunities for individuals to prevent error. Some actions are clinically oriented and have considerable evidence to support them.... Others are broader in focus or address the work environment."²

¹ World Health Organization, 'Patient Safety: What are Patient Safety Solutions?' (World Health Organization, 2013) <http://www.who.int/patientsafety/implementation/solutions/patientsafety/solutions_explained/en/index.html> accessed: 24 June 2013. See also: WHO Collaborating Centre for Patient Safety Solutions (International Steering Committee), *Nine Patient Safety Solutions* (Geneva: World Health Organization, April 2007) <<http://www.ccforspatientsafety.org/Patient-Safety-Solutions/>> accessed: 31 May 2012.

² M Donaldson and B Raik, 'Preventing Errors' in E Siegler et al. (eds), *An Introduction to Hospitals and Inpatient Care* (NY: Springer, 2003) 297.

It is important to note that within the field of patient safety, the study of medical error prevention is generally limited to nonexperimental or quasi-experimental research, owing to strict ethical considerations.³ For this reason, near-miss reporting and epidemiological analysis (examined in the previous chapter) is vital to the development of strategies for system redesign and intervention. Given the multifactorial nature of incident and error causation, no ‘one size fits all’ approach can be used to improve patient safety. Rather, implementing a diverse range of strategies subject to the current weaknesses within the organisation is essential.

Intervention strategies can be ranked according to their effectiveness at preventing patient safety incidents, forming a “safety spectrum.”⁴ In the first section, intervention at the level of the patient and caregiver will be analysed. Specifically, this section will focus on the importance of patient and family engagement, patient and family-centred care, and patient education in the context of safety and quality improvement. This will be followed by an examination of interventions at the level of the caregiver. In contrast to intervention at the patient level which is idiosyncratic, intervention at the caregiver level is designed to standardise and simplify processes that commonly result in patient safety incidents and medical error. In particular, the use of checklists, teamwork, and accountable care units will be examined. Subsequently, intervention strategies designed for the workplace and system-level will be analysed. Workplace interventions include those which can alter the behaviour created by that environment. Examples of workplace interventions include implementing cultural change, improving the rate of incident reporting, and reducing workplace fatigue. Similarly, system level interventions are designed to reduce patient safety incidents by intervening on both human and system failure. This section will also critically examine specific examples of workplace and system interventions strategies, which if

³ M Jenicek, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011) 215.

⁴ H Woodward et al., ‘What Have We Learned About Interventions to Reduce Medical Errors?’ (2010) 31 *Annual Review of Public Health* 479, 480-481.

implemented, can improve quality and safety. In the second section, the prevention of adverse drug events will be analysed. Preventing adverse drug events is multifaceted, as such, this section will examine intervention strategies that can be applied at both the blunt and sharp end. This section is useful in understanding how a specific patient safety incident can be targeted within the organisation and prevented. This chapter is vital to understanding the scope and context of patient safety methodology.

7.2 Safety Interventions

Safety interventions are designed with one purpose: to prevent patient safety incidents and patient harm. The appropriate form of intervention to improve safety will depend on the level at which it is applied. As Woodward notes:

“... error-reduction strategies can be ranked by their effectiveness in decreasing the probability of error and harm, forming a safety spectrum. The strongest strategies build forcing functions into tools and procedures, making it difficult for an error or adverse event to occur. Intermediate strategies include standardizing work processes. The weakest strategies focus on education aimed at changing individual behavior...”⁵

This section will begin by analysing interventions at the level of the patient and caregiver. Although individual behaviour is the most difficult to intervene on (as Woodward identified above), patient safety incidents are the result of numerous failed barriers but only take one successful barrier to prevent. For this reason, it is necessary to examine intervention strategies at all levels—both at the blunt and sharp end. In the second section work-place and system level intervention strategies higher on the safety spectrum will be analysed.⁶

⁵ *ibid.*

⁶ The list of subheadings used within this chapter are largely influenced by H Woodward et al., ‘What Have We Learned About Interventions to Reduce Medical Errors?’ (2010) 31 Annual Review of Public Health 479, 480-490.

7.2.1 Interventions around the Patient

Healthcare has traditionally been dominated by a culture of paternalism and dogmatism in which minimal emphasis was placed on involving patients in their care.⁷ Over the past two decades, the Patient Safety Movement has vigorously promoted a culture inclusive of patient engagement and patient-centred care.⁸

Patient Engagement and Patient-Centred Care

Patient and family engagement has become a critical factor in the improvement of quality and safety by shaping priorities for policy development, reducing healthcare related costs and disparities in healthcare access and outcomes.⁹ Carman et al., have defined ‘patient and family engagement’ as:

“... patients, families, their representatives, and health professionals working in active partnership at various levels across the health care system — direct care, organizational design and governance, and policy making— to improve health and health care.”¹⁰

⁷ WHO World Alliance for Patient Safety, *Patient Safety Workshop: Learning from Error* (Geneva: World Health Organization, 2008) WHO/IER/PSP/2008.09. p12; ‘Communication During Patient Hand-Over’ in WHO Collaborating Centre for Patient Safety Solutions (International Steering Committee), *Nine Patient Safety Solutions* (Geneva: World Health Organization, April 2007) < <http://www.ccforspatientsafety.org/common/pdfs/fpdf/presskit/PreambleandSolutions.pdf> > accessed: 19 May 2012.

⁸ For example, the significance of patient-centred care was recognised by the Institute of Medicine as a key element of high quality care. Institute of Medicine (Committee on Quality of Health Care in America), *Crossing the Quality Chasm : A New Health System for the 21st Century*. (Washington: National Academy Press, 2001).

⁹ D Khodyakov, ‘Patient Engagement in the Process of Planning and Designing Outpatient Care Improvements at the Veterans Administration Health-Care System: Findings from an Online Expert Panel’ (23 February 2016) *Health Expectations* 2 [e-pub ahead of print]; K McDonald et al., ‘The Patient Is In: Patient Involvement Strategies for Diagnostic Error Mitigation’ (2013) 22(Supp 2) ii33-ii39; D Lavalley et al., ‘Incorporating Patient-Reported Outcomes Into Health Care To Engage Patients And Enhance Care’ (2016) 35(4) *Health Affairs* 575-582; M Solomon, ‘The Ethical Imperative And Moral Challenges Of Engaging Patients And The Public With Evidence’ (2016) 35(4) *Health Affairs* 583-589.

¹⁰ K Carman et al., ‘Patient and Family Engagement: A Framework for Understanding the Elements and Developing Interventions and Policies’ (2013) 32(2) *Health Affairs* 223, 224.

In contrast, the Institute of Medicine have defined patient-centred care as, “a partnership among practitioners, patients, and their families (when appropriate) to ensure that decisions respect patients’ wants, needs, and preferences and that patients have the education and support they need to make decisions and participate in their own care.”¹¹ Going one step further, Donald Berwick has argued that patient-centred care should be defined as, “The experience (to the extent the informed, individual patient desires it) of transparency, individualization, recognition, respect, dignity, and choice in all matters, without exception, related to one’s person, circumstances, and relationships in health care.”¹² Although Berwick himself admits such a view is extreme and likely to be met with objection from the medical profession, he reasons that patient-centred care must be seen as an element of quality care itself, not only for its potential to improve health status and outcome. Thus, a more liberal approach is appropriate to move patient-centred care in to the realm of actually achieving quality improvement.¹³ Notwithstanding the distinction, for the purposes of this analysis, the term patient-centred care can be distinguished from patient engagement, insofar as it largely concerns incorporating the subjective factors related to the patient’s own care. While this is certainly a fundamental element of patient engagement (which will be examined further below), the concept of patient engagement additionally incorporates the partnership of patients and their families with not only the care team, but also the healthcare organisation, governance structures, and system and policy design—all integral to quality and safety improvement.

In further examining the components of patient engagement, including patient-centred care, Carman et al., have usefully set out a three prong framework for developing patient engagement interventions and strategies. In the authors’ view, patient

¹¹ Institute of Medicine, *Envisioning the National Health Care Quality Report*. (Washington: National Academies Press, 2001) 7.

¹² D Berwick, ‘What “Patient-Centered” Should Mean: Confessions of an Extremist’ (2009) 28(4) *Health Affairs* 555, 560.

¹³ *ibid* 563.

engagement is characterised by the flow of information between patients, their healthcare providers, and the organisation. In practice, the flow of information can range from patient involvement with limited power or decision-making authority to shared power, responsibility, and active partnership in the proactive management of their health.¹⁴ The flow of information is multidimensional, incorporating three theoretically separate levels of engagement: direct care, organisational design and governance, and policy making. Again, all levels of engagement strongly incorporate the principles examined throughout this thesis, and in practice, are highly interdependent. For example, with respect to direct care, patient engagement requires that patients are actively informed and involved in their care and treatment plans—essentially working in partnership with their healthcare team versus the more traditional and paternalistic role of the patient as a bystander. A component of this is ‘patient activation’, a relatively new term in the literature that represents a patient’s knowledge, skill and confidence in managing their care.¹⁵ This concept is closely related (arguably intrinsically) to the principle of informed consent, however, it goes one step further in considering both skill and confidence—all of which are related to the more prominent concept of health literacy. The use of interactive systems and shared-decision making tools to improve communication between the patient and physician is a key method of enhancing patient-engagement at the level of direct care and immediately impacts potential lapses in communication. Examples of such systems and tools include mobile health applications and full access to medical records.¹⁶

¹⁴ K Carman et al., ‘Patient and Family Engagement: A Framework for Understanding the Elements and Developing Interventions and Policies’ (2013) 32(2) *Health Affairs* 223, 224-225.

¹⁵ *ibid* 223; J James, ‘Health Policy Briefs: Patient Engagement’ (14 February 2013) <http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=86> accessed: 07 April 2016; J Hibbard et al., ‘What the Evidence Shows about Patient Activation: Better Health Outcomes and Care Experiences; Fewer Data on Costs’ (2013) 32(2) *Health Affairs* 207-214; K Carman et al., ‘Understanding An Informed Public’s Views On The Role Of Evidence In Making Health Care Decisions’ (2016) 35(4) *Health Affairs* 566-574.

¹⁶ C Tang et al., ‘Interactive Systems for Patient-Centered Care to Enhance Patient Engagement’ (2016) 23 *Journal of the American Medical Informatics Association* 2–4.

Carman et al., suggest that patient engagement at the level of organisational design and governance integrates the patients' values, experiences, and perspectives into the design and governance of healthcare organisations.¹⁷ Patient advocacy by way of a designated Patient Advocate, or by having patient representation on Governance Boards, can be hugely beneficial in this regard. In addition, patient advocates also offer an invaluable resource for attending to patient complaints and queries at the first instance. While latter chapters of this thesis explore more contentious and complex disputes, patient advocates can offer an early line of communication between patients and their healthcare providers—offering not only the ability to mitigate the dispute early, but also feed back the information for quality improvement purposes. On a larger scale, patient participation in the design and evaluation of quality improvement processes, staff training, and patient advocacy are all examples of patient-engagement at the organisational design and governance level.¹⁸ Lastly, patient-engagement must also be incorporated at the policy level. This includes patient involvement and collaboration at the national, state/regional, and local levels with respects to policy research, design, and implementation.¹⁹

Limitations with respect to patient engagement exist however. For example, cognitive decline and low health literacy can reduce the ability of patients to participate. Similarly, organisations that do not incorporate patient engagement and patient-centred principles into their overall quality improvement philosophy and objectives may be less inclined to implement such policies or continually audit and improve them. Healthcare professionals may also be hesitant, owing to time constraints, pre-

¹⁷ K Carman et al., 'Patient and Family Engagement: A Framework for Understanding the Elements and Developing Interventions and Policies' (2013) 32(2) *Health Affairs* 223, 225-226.

¹⁸ K Carman et al., 'Patient and Family Engagement: A Framework for Understanding the Elements and Developing Interventions and Policies' (2013) 32(2) *Health Affairs* 223, 225-226.

¹⁹ *ibid* 226; S Woolf et al., 'Authentic Engagement Of Patients And Communities Can Transform Research, Practice, And Policy' (2016) 35(4) *Health Affairs* 590-594.

existing cultural bias, or a lack of training in patient-engagement strategies.²⁰ Despite this barriers, in a study concerning patient engagement in outpatient care design decision-making within the American Veteran Affairs Hospital System found that medical experts strongly favoured patient consultation as the preferred method of engagement; specifically through surveys, focus groups, and advisory councils.²¹ While the views of the respondents did not go so far as to favour full engagement (i.e. full partnership), the results showing a desire to engage with patients are encouraging and signify a move away from a traditionally paternalistic culture. Lastly, Carman et al., note that the broader social and political environment can profoundly influence the willingness of patients to become involved, and healthcare organisations and professionals to actively engage. Again, collaboration at the national, state / regional, and local levels with respects to policy research, design, and implementation is fundamental—as is legislation, regulations and directives to support patient engagement. These include the incorporation of patient advisory councils into healthcare policy and design, and legislation to encourage shared decision making.²²

In a broader context, another limitation that can reduce the effectiveness of patient engagement efforts is being unable to effectively evaluate them. Barello et al., have noted that despite the prominence of literature that emerged from 2002-2012 regarding the importance of patient-engagement, few attempts to find empirical markers of

²⁰ J James, 'Health Policy Briefs: Patient Engagement' (14 February 2013) <http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=86> accessed: 07 April 2016.

²¹ D Khodyakov, 'Patient Engagement in the Process of Planning and Designing Outpatient Care Improvements at the Veterans Administration Health-Care System: Findings from an Online Expert Panel' (23 February 2016) *Health Expectations* 2 [e-pub ahead of print].

²² K Carman et al., 'Patient and Family Engagement: A Framework for Understanding the Elements and Developing Interventions and Policies' (2013) 32(2) *Health Affairs* 223, 227; D Veroff et al., 'Enhanced Support for Shared Decision Making Reduced Costs of Care for Patients with Preference-Sensitive Conditions' (2013) 32(2) *Health Affairs* 285-293; F Légaré, 'Shared Decision Making: Examining Key Elements and Barriers to Adoption into Routine Clinical Practice' (2013) 32(2) *Health Affairs* 276-284; M Tai-Seale et al., 'Enhancing Shared Decision Making Through Carefully Designed Interventions That Target Patient And Provider Behavior' (2016) 35(4) *Health Affairs* 605-612.

patient-engagement have been conducted, thereby reducing the ability to enable data comparison and evaluation.²³ Future research should explore this further.

Having examined the broader principle of patient engagement, it is now useful to further examine the role of patient-centred care in the process of patient engagement. Patient-centred care is reinforced by the doctrine of informed consent and the provision of patient safety rights, which seeks to strengthen patient-clinician relationships, promote communication, and further patient engagement.²⁴ In this regard, it is illustrative to define the premise behind 'patient safety rights' as set out by the World Health Organization:

“... patient safety rights are shaped as realistic and informed expectations; that promote information on risks, involvement in decision making, and choice is provided at a level of details which are accessible; that patients are trained to be knowledgeable and vigilant in the same time, for maximum safety compliance, within and outside health care settings; that safety becomes a shared responsibility, with the patient co-producer of health.”²⁵

Promoting policies that increase patient engagement and embrace a doctrine of patient-centred care inclusive of patient safety rights through clinical practices, organisational policies, and legislation is one method by which to improve quality and safety. An

²³ S Barelo et al., 'Patient Engagement as an Emerging Challenge for Healthcare Services: Mapping the Literature' (2012) *Nursing Research and Practice* 1, 5.

²⁴ R Epstein and R Street Jr., 'The Values and Value of Patient-Centered Care' (2011) 9(2) *Annals of Family Medicine* 100, 101; Z Berger et al., 'Promoting Engagement by Patients and Families to Reduce Adverse Events in Acute Care Setting: A Systematic Review' (2014) 23 *BMJ Quality & Safety* 548; WHO Regional Office for Europe, *Patient Safety and Rights: Developing Tools to Support Consumer Health Literacy* (Denmark: World Health Organization, 2010) <http://www.euro.who.int/__data/assets/pdf_file/0018/133128/e94739.pdf> accessed: 20 May 2012.

²⁵ WHO Regional Office for Europe, *Patient Safety and Rights: Developing Tools to Support Consumer Health Literacy* (Denmark: World Health Organization, 2010) 2. <http://www.euro.who.int/__data/assets/pdf_file/0018/133128/e94739.pdf> accessed: 20 May 2012.

example of a safety intervention based on the principles of patient-centred care is improving the communication between patient and physicians, as well as patient education—both strongly advocated throughout later chapters of this thesis.

Engaging and educating patients to be both knowledgeable and vigilant in the course of their care is one of the defining objectives of the patient safety movement. However, the realities of patient care can often create barriers to meeting this objective, for example: time constraints can pose a significant challenge to patient education, particularly in the course of explaining complex health conditions or treatments.²⁶ Additionally, efforts to educate patients will be unsuccessful where there is a communication failure at the onset. From a patient perspective, the most common causes of communication failure with their physician or nurse include: a failure to adequately listen or be attentive; a lack of interest or compassion; a lack of time or availability; the use of medical terminology; and the incomprehensible flow and presentation of information.²⁷ Likewise, for healthcare professionals, communication can also be impaired by patient characteristics. In this regard, Bartlett et al., found that patients with communication difficulties—such as language barriers and disabilities—were three times more likely to experience a preventable adverse event.²⁸ Issues may

²⁶ T Konrad et al., 'It's About Time: Physicians' Perceptions of Time Constraints in Primary Care Medical Practice in Three National Healthcare Systems.' (2010) 48(2) *Medical Care* 95.

²⁷ WHO World Alliance for Patient Safety, *Patient Safety Workshop: Learning from Error* (Geneva: World Health Organization, 2008) WHO/IER/PSP/2008.09. p12; M Beyer et al., 'Communication and Patient Safety' in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 17.

²⁸ G Bartlett et al., 'Impact of Patient Communication Problems on the Risk of Preventable Adverse Events in Acute Care Settings' (2008) 178(12) *Canadian Medical Association Journal* 1555, 1559. The authors note, "... patients with communication problems were 3 times more likely to experience a preventable adverse event than patients without such problems. These events were mainly drug related or caused by poor clinical management. Almost half of the events were associated with some level of disability or multiple hospital admissions, with one-third of the patients who experienced preventable adverse events requiring readmission to hospital." See also: C Roberts, "'Mince' or 'Mice'? Clinical Miscommunications and Patient Safety in a Linguistically Diverse Society' in B Hurwitz and A Sheikh (eds), *Health Care Errors and Patient Safety* (UK: Wiley-Blackwell, 2009) 112-128.

also arise where cultural bias exists, or social and cultural backgrounds differ.²⁹ This is further sustained by the increasing reliance on healthcare professionals from other countries.³⁰ Additionally, patients may use, "... concealing, masking, cloaking, disguising, or head nodding to cover their communication limitations" making it difficult to accurately judge their level of comprehension.³¹

A useful example of a patient-centred safety intervention is the prevention of polypharmacy related adverse drug events. Improving the aforementioned communication barriers and educating patients is fundamental to this process, and intrinsic to the goals of patient engagement and patient-centred care. Polypharmacy—a practice in which multiple pharmaceuticals are prescribed—has been cited as one of the main factors that contribute to the risk of adverse drug events in older adults.³² As Woodward notes, "[t]his situation arises through such mechanisms as increased adverse drug reactions, drug-drug interactions, and prescription errors. Complex and demanding regimes also reduce adherence, resulting in preventable morbidity, mortality, and hospital admissions."³³ In a study examining the current prescription regimes of 630 elderly patients in long-term care within Ireland and Northern Ireland, Byrne found that of the 630 patients, half were prescribed between eight and fourteen

²⁹ G Peters and B Peters, *Medical Error and Patient Safety: Human Factors in Medicine* (US: Taylor & Francis, 2008) 151; M Beyer et al., 'Communication and Patient Safety' in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 17.

³⁰ 'Communication During Patient Hand-Overs' in WHO Collaborating Centre for Patient Safety Solutions (International Steering Committee), *Nine Patient Safety Solutions* (Geneva: World Health Organization, April 2007) < <http://www.ccforspatientsafety.org/common/pdfs/fpdf/presskit/PreambleandSolutions.pdf> > accessed: 19 May 2012.

³¹ G Peters and B Peters, *Medical Error and Patient Safety: Human Factors in Medicine* (US: Taylor & Francis, 2008) 150; J Ellins and A Coulter, 'The Patient's Role in Preventing Errors and Promoting Safety' in B Hurwitz and A Sheikh (eds), *Health Care Errors and Patient Safety* (UK: Wiley-Blackwell, 2009) 166-178.

³² See further below: Chapter 7.3 'Intervening on Adverse Drug Events.'

³³ H Woodward et al., 'What Have We Learned About Interventions to Reduce Medical Errors?' (2010) 31 *Annual Review of Public Health* 479, 481; citing: S Frazier, 'Health Outcomes and Polypharmacy in Elderly Individuals: An Integrated Literature Review' (2005) 31(9) *Journal of Gerontological Nursing* 4-11.

drugs. Moreover, almost one-fifth of the 630 patients were receiving three or more potentially inappropriate medications.³⁴ While technology such as e-prescribing and medication safety alerts are arguably the most effective form of prevention given the complexity of polypharmacy;³⁵ patient and caregiver-based interventions that include both education and behaviour strategies can be useful as patients are less likely to follow their doctor's advice when they do not understand it or disagree.³⁶ Likewise, in an acute care setting, educating patients as to their care plan, including them in rounds (i.e. ACU bedside rounds), and having them repeat back the information given is also helpful in allowing them to manage their care after being discharged.³⁷ Although related to surgical informed consent, a study by Prochazka et al. confirmed the effectiveness of the 'repeat back' procedure, finding that when patients repeat back the information they were given prior to surgery, their ability to understand the procedure and provide informed consent increased.³⁸ Additionally, Weissman recommends including questions for patients related to adverse events in post-discharge interviews as patients may report events not previously documented that may impact their care plan going forward.³⁹

³⁴ S Byrne et al., *An Evaluation of the Inappropriate Prescribing in Older Residents in Long Term Care Facilities in the Greater Cork and Northern Ireland Regions Using the STOPP and Beers' Criteria*. (Ireland: Centre for Ageing Research and Development Ireland, 2011); M Houston, 'Drugs Mixture Poses Serious Risks to Health' *Irish Times* (Dublin, 12 April 2011) <<http://www.irishtimes.com/news/health/drugs-mixture-poses-serious-risks-to-health-1.570160>>.

³⁵ S Phansalkar et al., 'A Review of Human Factors Principles for the Design and Implementation of Medication Safety Alerts in Clinical Information Systems.' (2010) 17(5) *Journal of the American Medical Informatics Association* 493.

³⁶ G Peters and B Peters, *Medical Error and Patient Safety: Human Factors in Medicine* (US: Taylor & Francis, 2008) 143; citing: R Blendon et al., 'Common Concerns amid Diverse Systems: Health Care Experiences in Five Countries' (2003) 22(3) *Health Affairs* 117–121.

³⁷ K O'Leary et al., 'Hospitalized Patients' Understanding of Their Plan of Care' (2010) 85(1) *Mayo Clinic Proceedings* 47.

³⁸ A Prochazka et al., 'Patient Perceptions of Surgical Informed Consent: Is Repeat Back Helpful or Harmful?' (2014) 10(3) *Journal of Patient Safety* 140.

³⁹ J Weissman, 'Comparing Patient-Reported Hospital Adverse Events with Medical Record Review: Do Patients Know Something That Hospitals Do Not?' (2008) 149(2) *Annals of Internal Medicine* 100.

Polypharmacy is just one example of the many areas of patient care in which engaging, communicating with, and educating patients can reduce the occurrence of medical errors and in turn, improve the quality and safety of care. For this reason, the principle of patient engagement and patient-centred care is one of the primary objectives of the patient safety movement, and integral to this thesis.

7.2.2 Interventions Around the Caregiver

In contrast to interventions at the patient level which are idiosyncratic, interventions at the caregiver level are designed to standardise and simplify processes that commonly result in patient safety incidents, including medical error. This section will examine the role of checklists, teamwork, and accountable care units in the process of preventing patient safety incidents.

Checklists

Originating from the field of aviation, ‘checklists’ are one method by which to “detect a potential error before it leads to harm.”⁴⁰ Owing to variation in clinical practice and outcomes, checklists and pre-printed orders are intended to standardise processes and counteract the human factors that contribute to error.⁴¹ Arguably, the most universally adopted checklist within healthcare is that of the Surgical Safety Checklist. Developed by the World Health Organization in 2009, the Surgical Safety Checklist seeks to standardise preoperative, intraoperative and postoperative care.⁴² The 2009 study by

⁴⁰ World Health Organization, ‘Patient Safety Checklists’ <<http://www.who.int/patientsafety/implementation/checklists/en/>> accessed: 10 March 2015.

⁴¹ H Woodward et al., ‘What Have We Learned About Interventions to Reduce Medical Errors?’ (2010) 31 Annual Review of Public Health 479, 487. In this regard, Woodward notes, the “[s]tandardization of procedures in medicine is universally poor and results in variation in clinical practice and outcomes.”; B Hilligoss and S Moffatt-Bruce, ‘The Limits of Checklists: Handoff and Narrative Thinking’ (2014) 23 BMJ Quality & Safety 528. The authors suggest that caution should be taken with intervention strategies that rely heavily on the paradigmatic mode (such as checklists), arguing that “... to build more resilient systems of care, we must supplement current improvement efforts with approaches that honour the strengths and challenges of narrative thinking.”

⁴² World Health Organization, ‘Patient Safety Checklists’ <<http://www.who.int/patientsafety/implementation/checklists/en/>> accessed: 10 March 2015.

Haynes et al. entitled 'A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population' examined the introduction of the WHO Surgical Safety Checklist into the operating rooms of eight hospitals throughout the world. The study recorded the first thirty days of hospitalisation following operation; specifically the rate of complications, including death.⁴³ Safety measures within the Surgical Checklist included, *inter alia*, ensuring the correct identity of the patient and site, thorough preoperative site marking, and oral confirmation in the operating room.⁴⁴ The authors concluded that use of the Surgical Safety Checklist was associated with significant improvement in surgical outcome. In particular, after the introduction of the Checklist, postoperative complication rates fell by 36% on average and the rate of fatality was reduced from 1.5% to 0.8%.⁴⁵ In conclusion, the authors noted, "whereas the evidence of improvement in surgical outcomes is substantial and robust, the exact mechanism of improvement is less clear and most likely multifactorial. Use of the checklist involved both changes in systems and changes in the behavior of individual surgical teams."⁴⁶ This finding reinforces the need to develop and implement multi-factorial intervention strategies. Similarly, a 2010 study on the use of surgical team training and checklists within 74 Veteran Affairs hospitals in the United States, observed an 18% reduction in mortality rates over a one year period.⁴⁷ It is worth noting, however, that a 2014 study by Urbach et al. focusing on the use of the Surgical Checklist within Ontario hospitals demonstrated an alternative finding, insofar as no significant reductions in operative

⁴³ A Haynes et al., 'A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population' (2009) 360 NEJM 491. Hospitals involved in the study were located in the cities of: Toronto, Canada; New Delhi, India; Amman, Jordan; Auckland, New Zealand; Manila, Philippines; Ifakara, Tanzania; London, England; and Seattle, Washington.

⁴⁴ *ibid* 497.

⁴⁵ *ibid* 496.

⁴⁶ *ibid* 496-497.

⁴⁷ J Neily et al., 'Association Between Implementation of a Medical Team Training Program and Surgical Mortality' (2010) 304(15) JAMA 1683.

complications or mortality were found.⁴⁸ In this regard, the authors note that in studies showing a substantial reduction in complications and mortality, the use of the Surgical Safety Checklist was combined with extensive team training or checklists that covered care from the preoperative stage to discharge.⁴⁹

In light of the aforementioned studies, the study by Urbach et al. is arguably the most instructive. While checklists are an important intervention in preventing frontline skill-based errors (i.e. slips and lapses), without team training, their ability to reduce adverse surgical events is limited. For this reason, the next section will examine the use of teamwork and training in the context of incident prevention.

Teamwork: Communication and Training

Effective and comprehensive communication between healthcare professionals is essential to reducing medical error, and ultimately, quality and safety improvement. The nature of a clinical setting, particularly an acute care setting, relies heavily on the ability of healthcare professionals to effectively communicate and work in teams. Ineffective communication, in the alternative, hinders continuity of care, increases organisational silence, and prevents the effective resolution of conflict.⁵⁰ In this regard, the Irish Health Information and Quality Authority have strongly emphasised the importance of team communication, noting, “Communication at all times should follow a structured format so that there is no confusion over exactly what is required of each team or individual. Effective multi-disciplinary and multi-professional team

⁴⁸ R Urbach et al., ‘Introduction of Surgical Safety Checklists in Ontario, Canada’ (2014) 370 NEJM 1029. The authors further note that surgical safety checklists may be less effective in practice because of the “Hawthorne Effect” in which people perform better during observation.

⁴⁹ *ibid* 1037; citing: L Bliss et al., ‘Thirty-Day Outcomes Support Implementation of a Surgical Safety Checklist.’ (2012) 215 *Journal of the American College of Surgeons* 766; Y Young-Xu et al., ‘Association Between Implementation of a Medical Team Training Program and Surgical Morbidity.’ (2011) 146 *JAMA Surgery* 1368; J Neily et al., ‘Association Between Implementation of a Medical Team Training Program and Surgical Mortality’ (2010) 304(15) *JAMA* 1683.

⁵⁰ M Beyer et al., ‘Communication and Patient Safety’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 18; citing: National Patient Safety Agency (UK) <www.npsa.nhs.uk>.

working is an essential component of reliable, safe care and the contemporaneous transfer of information between individual professionals and teams – both documented in the notes and verbally, is essential.”⁵¹ This is a principle strongly integrated into the development of the Accountable Care Units, particularly as it applies to safety wall-walks and bedside rounds. It must be emphasised that the following strategies will not improve team communication without the overall organisational adoption of a just culture, including an emphasis on the value of teamwork. This was emphasised within the seminal publication, *An Organisation with a Memory*, in which teamwork was cited as one of the seven factors critical to the delivery of safe care.⁵²

Improving teamwork and communication skills is multifaceted. This section will examine two methods by which team communication can be enhanced. The first will consider a unit-based intervention, specifically, techniques to improve communication between healthcare professionals during handovers. The second will analyse team training as a means of improving communication and harmonisation.

Patient Handovers

Patient Handovers, or transitions of care, involve the process of transferring patient-specific information from one healthcare professional to another, or between healthcare

⁵¹ Health Information and Quality Authority, *Investigation into the Safety, Quality and Standards of Services provided by the Health Service Executive to Patients, Including Pregnant Women, At Risk of Clinical Deterioration, Including Those Provided in University Hospital Galway, and as Reflected in the Care and Treatment Provided to Savita Halappanavar* (Dublin: HIQA, 7 October 2013) 188; citing: Australian Commission on Safety and Quality in Health Care, *The OSSIE Guide to Clinical Handover Improvement*. (Sydney: Australian Commission on Safety and Quality in Health Care, 2010); Royal College of Obstetricians and Gynecologists, *Improving Patient Handover. Good Practice No 12* (London: Royal College of Obstetricians and Gynecologists, 2010).

⁵² Department of Health (UK), *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS* (London: Department of Health, 2000) [3.14] p24. The seven factors cited within the report that are critical to the delivery of safe care include: Institutional Context, Organisational and Management Factors, Work Environment, Team Factors, Individual (Staff) Factors, Task Factors and Patient Characteristics.

professionals and patients or their families.⁵³ Certainly having one primary physician responsible for the overall care management (often called the ‘most responsible physician/clinician’ (MRP)) is vital for ensuring both continuity of care and accountability. However, handovers are of course necessary when transferring over direct patient care or when obtaining a specialist consult (particularly in an acute care setting.) Comprehensive handover procedures are fundamental to ensuring continuity of care, however, a number of barriers can prevent the effective handover of information, resulting from both human and system factors. Potential barriers include: time pressures, cultural and language differences, low health literacy, staffing shortages, and “lack of information technology infrastructure and interoperability.”⁵⁴ While the proficiency of information technology and staffing shortages are the responsibility of the blunt end to improve, effective intervention that applies human factors principles can be used to improve barriers at the sharp end. For example, the use of interpreters before the administration of a drug or when recommending a care plan can reduce language barriers.⁵⁵ As well, educating patients (examined above) can improve health literacy so as to improve communication between the care team and patient.⁵⁶

For healthcare professionals on the frontline, a number of methods have been suggested for improving handover communication. First, the Joint Commission have strongly advocated the adaptation of the “SBAR” (Situation, Background, Assessment,

⁵³ ‘Communication During Patient Hand-Overs’ in WHO Collaborating Centre for Patient Safety Solutions (International Steering Committee), *Nine Patient Safety Solutions* (Geneva: World Health Organization, April 2007) < <http://www.ccforspatientsafety.org/common/pdfs/fpdf/presskit/PreambleandSolutions.pdf> > accessed: 19 May 2012.

⁵⁴ *ibid.*

⁵⁵ B Armor and C Bulkley, ‘English as a Second Language is a Risk for an Adverse Drug Event’ (2014) 10(4) *Journal of Patient Safety* 231-232.

⁵⁶ H Koh et al., ‘A Proposed Health Literate Care Model Would Constitute A Systems Approach To Improving Patients’ Engagement in Care (2013) 32(2) *Health Affairs* 357. The authors examine the relationship between health literacy and care received, as well as propose a model for improving health literacy amongst patients so as to improve health outcomes.

and Recommendation) technique, commonly used within High Risk Organisations.⁵⁷ The SBAR technique provides a standardised template by which to communicate information, ensuring accuracy and consistency in the information given and feedback required.⁵⁸ This is particularly appropriate in a multi-disciplinary context in which time constraints may create a barrier to communication. Second, the ‘bedside handover’ (discussed above) is a strategy advocated by the Institute of Medicine as a means of improving patient care and helping healthcare professionals develop patient-centred techniques. This requires that handovers occur quite literally at the ‘best side’ of the patient. A distinct advantage to this technique is the opportunity to engage the patient and have them confirm information or ask questions relating to their care.⁵⁹

⁵⁷ V Arora et al., ‘A Theoretical Framework and Competency-Based Approach to Improving Handoffs’ [2008] 17(1) *Quality and Safety in Health Care* 11-14, 13; citing: K Haig et al., ‘SBAR: A Shared Mental Model for Improving Communication Between Clinicians’ (2006) 32 *Joint Commission Journal on Quality and Safety* 167–75; M Leonard et al., ‘The Human Factor: The Critical Importance of Effective Teamwork and Communication in Providing Safe Care’ (2004) 13 (Suppl 1) *BMJ Quality & Safety* i85–90. See also: Joint Commission, ‘Transitions of Care: The Need For a More Effective Approach to Continuing Patient Care’ (June 2012) <http://www.jointcommission.org/assets/1/18/hot_topics_transitions_of_care.pdf> accessed: 11 March 2015.

⁵⁸ M Riebschleger and I Philibert, ‘Chapter 9: New Standards for Transitions of Care: Discussion and Justification’ in I Philibert et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME 2011) 58; citing: I Philibert, ‘Use of Strategies From High-reliability Organisations to the Patient Hand-off By Resident Physicians: Practical Implications’ [2009] 18(4) *BMJ Quality & Safety* 261–266. See also: C Denham, ‘SBAR for Patients’ (2008) 4(1) *Journal of Patient Safety* 38.

⁵⁹ Institute of Medicine (Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety), *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*. C Ulmer et al. (eds), (Washington: National Academies Press, 2008) 274; citing: J Singer and J Dean, ‘Emergency Physician Intershift Handovers: An Analysis of our Transitional Care’ [2006] 22(10) *Pediatric Emergency Care* 751-754; K Alvarado, ‘Transfer of Accountability: Transforming Shift Handover to Enhance Patient Safety’ [2006] 9(Supp) *Healthcare Quarterly* 75-79, 78.

Further recommendations that can improve team communication and continuity of care include: the use of “precise, unambiguous, face-to-face communication;”⁶⁰ using uniform language or terminology;⁶¹ structured and standardised procedures (i.e. SBAR technique);⁶² reducing interruptions;⁶³ and using interactive questions (i.e. the ‘read-back’ technique).⁶⁴ Lastly, the use of electronic sign-out systems has also been advocated as a means of providing “structured, easy-to-access databases of patient information and creating formatted checklists of tasks that need to be considered for patient treatment.”⁶⁵ This method is supported by the research of Ryan et al., who found that the use of electronic handover systems in a surgical setting, as compared to paper-based handovers, reduced the patient’s length of stay in-hospital and provided better continuity of care.⁶⁶

⁶⁰ ‘Communication During Patient Hand-Overs’ in WHO Collaborating Centre for Patient Safety Solutions (International Steering Committee), *Nine Patient Safety Solutions* (Geneva: World Health Organization, April 2007) < <http://www.ccforspatientsafety.org/common/pdfs/fpdf/presskit/PreambleandSolutions.pdf> > accessed: 19 May 2012; citing: D Solet et al., ‘Lost in Translation: Challenges and Opportunities During Physician-to-Physician Communication During Patient Handoffs’ (2005) 80(12) *Academic Medicine* 1094–1099.

⁶¹ Institute of Medicine (Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety), *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*. C Ulmer et al. (eds), (Washington: National Academies Press, 2008) 271; citing: V Arora, ‘Communication Failures in Patient Sign-Out and Suggestions for Improvement: A Critical Incident Analysis’ [2005] 14(6) *Quality and Safety in Health Care* 401-407.

⁶² *ibid* 268.

⁶³ *ibid* 275.

⁶⁴ V Arora et al., ‘A Theoretical Framework and Competency-Based Approach to Improving Handoffs’ [2008] 17(1) *Quality and Safety in Health Care* 11-14, 13; citing: K Haig et al., ‘SBAR: A Shared Mental Model for Improving Communication Between Clinicians’ (2006) 32 *Joint Commission Journal on Quality and Safety* 167–75; M Leonard et al., ‘The Human Factor: The Critical Importance of Effective Teamwork and Communication in Providing Safe Care’ (2004) 13 (Suppl 1) *BMJ Quality & Safety* i85–90.

⁶⁵ Institute of Medicine (Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety), *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*. C Ulmer et al. (eds), (Washington: National Academies Press, 2008) 272.

⁶⁶ S Ryan et al., ‘Impact of a New Electronic Handover System in Surgery’ (2011) 9(3) *International Journal of Surgery* 217.

A practical strategy for implementing unit-based team work and patient engagement principles—inclusive of many of the aforementioned recommendations—is the incorporation of Accountable Care Units (ACU). ACUs have gained prominence as a means of addressing fragmented hospital care at a unit-level. ACUs are structured around four core features: (1) Unit Level Nurse and Physician Co-Leadership, (2) Unit Level Performance Reporting, (3) Structured Interdisciplinary Bedside Rounds, and (4) Unit-Based Teams. In practice, ACUs reduce fragmented care by assigning patients to small teams of physicians and nurses based on geographical location. In addition to having one designated primary care physician/ hospitalist (the “most responsible physician”) with overall responsibility. ACUs also offer an invaluable opportunity to engage the patient and family directly at the bedside, including them in care pathway planning, and allowing them to engage and assist the multi-disciplinary team responsible for their care. Additionally, safety wall-walks are an important component of the ACUs and accountable care in general. Safety wall-walks ensure all team members are aware of the standards sought and required of them, and holds the practitioners and organisation accountable by making the required standards, accomplishments, and failures visible. Although limited, evidence to date has shown a reduction in both length of hospital stay and mortality through the use of Accountable Care Units.⁶⁷

⁶⁷ J Stein et al., ‘Reorganizing a Hospital Ward as an Accountable Care Unit’ (2015) 10(1) *Journal of Hospital Medicine* 36-40.

Team Training

Team training is another method aimed at reducing the occurrence of medical error by improving communication and teamwork.⁶⁸ Team training can be defined as “a set of tools and methods that form an instructional strategy, which provide team members with the opportunity to practice skills and receive feedback in a rich learning environment.”⁶⁹ Generally, team training combines two separate practices: classroom based practices which focus on awareness, and simulator-based training which focuses on skills and feedback.⁷⁰ An example of a team training program is the Medical Team Training program (MTT) implemented throughout the Veterans Affairs Hospitals in the United States. MTT is based on the principles of Crew Resource Management, a practice developed by the aviation industry as a means of improving cockpit safety.⁷¹ The MTT program is unique in that, in addition to classroom and simulator-based training, the program also includes training in peer-to-peer communication (i.e. handover procedures), the SBAR technique and interdisciplinary patient-centred

⁶⁸ For an extensive review of the literature concerning the impact of team training on clinical performance, see further: J Schmutz and T Manser, ‘Do Team Processes Really Have an Effect on Clinical Performance? A Systematic Literature Review’ (2013) 110(4) *British Journal of Anaesthesia* 529. The authors concluded that a review of the literature supported the use of team training as a means of improving performance; however, further research is needed to develop adequate tools by which to measure the training methods used and clinical outcomes.; S Weaver et al., ‘Team-Training in Healthcare: A Narrative Synthesis of the Literature’ (2014) 24 *BMJ Quality & Safety* 359; C Vincent, *Patient Safety* (2nd edn, UK: Wiley-Blackwell, 2010) 341- 370.

⁶⁹ E Salas et al., ‘Does Team Training Work? Principles for Health Care’ (2008) 15 *Academic Emergency Medicine* 1002, 1003.

⁷⁰ D Baker et al., ‘Medical Team Training Programs in Health Care’ in K Henriksen et al. (eds), *Advances in Patient Safety: From Research to Implementation. Volume 4: Programs, Tools, and Products* (Rockville: Agency for Healthcare Research and Quality, 2005).

⁷¹ For an analysis of Crew Resource Management applied in a healthcare setting, see further: A Shea-Lewis, ‘Teamwork: Crew Resource Management in a Community Hospital’ (2009) 31(5) *Journal for Healthcare Quality* 14; M Oriol, ‘Crew Resource Management: Applications in Healthcare Organizations’ (2006) 36(9) *Journal of Nursing Administration* 402; E McConaughy, ‘Crew Resource Management in Healthcare: The Evolution of Teamwork Training and MedTeams’ (2008) 22(2) *The Journal of Perinatal & Neonatal Nursing* 96; S Taylor-Adams et al., ‘Safety Skills for Clinicians: An Essential Component of Patient Safety’ (2008) 4(3) *Journal of Patient Safety* 141; G Haller et al., ‘Effect of Crew Resource Management Training in a Multidisciplinary Obstetrical Setting’ (2008) 20(4) *International Journal for Quality in Health Care* 254-263; E Salas et al., ‘What Crew Resource Management Training Will Not Do for Patient Safety: Unless...’ (2007) 3(2) *Journal of Patient Safety* 62.

briefings (rounds).⁷² These techniques have the ability to reduce error by incorporating multidisciplinary and interdisciplinary communication training in addition to practical skills-based training within the clinical setting. As Weaver concludes, “The critical element defining team-training is that the learning activity focuses on developing, refining and reinforcing knowledge, skills or attitudes that underlie effective teamwork behaviours such as communication, coordination and collaboration.”⁷³ Team training is an effective multidisciplinary strategy to improve quality and safety. However, without also addressing workplace and system-related factors, incidents will continue to occur notwithstanding the best efforts of those involved. For this reason, it is now instructive to examine workplace and system factors in greater detail.

7.2.3 Interventions Around the Workplace and System

Workplace interventions involve strategies that are designed to alter the behaviour created by the particular environment.⁷⁴ The most common example is the process of moving from a culture of blame to a just culture. Interventions designed to improve workplace (cultural) factors generally concentrate on those environmental factors that increase the likelihood of error. For example, improving the rate of incident reporting, reducing workplace fatigue,⁷⁵ addressing staffing levels, and improving multidisciplinary and interdisciplinary communication.⁷⁶ However, putting in place interventions that create lasting cultural change within an organisation provides for its own unique challenges. As Woodward argues, cultural change “... involves

⁷² E Dunn et al., ‘Medical Team Training: Applying Crew Resource Management in the Veterans Health Administration’ (2007) 33(6) *Joint Commission Journal on Quality and Patient Safety* 317, 320.

⁷³ S Weaver et al., ‘Team-Training in Healthcare: A Narrative Synthesis of the Literature’ (2014) 23 *BMJ Quality & Safety* 359, 360.

⁷⁴ H Woodward et al., ‘What Have We Learned About Interventions to Reduce Medical Errors?’ (2010) 31 *Annual Review of Public Health* 479, 488-489.

⁷⁵ See further: Chapter 8 ‘Case Study: Resident Duty Hours.’

⁷⁶ H Woodward et al., ‘What Have We Learned About Interventions to Reduce Medical Errors?’ (2010) 31 *Annual Review of Public Health* 479, 488; citing: R Friedman et al., ‘The Intern and Sleep Loss’ (1971) 285(4) *NEJM* 201. See also: K Volpp et al., ‘Mortality Among Patients in VA hospitals in the First 2 Years Following ACGME Resident Duty Hour Reform.’ (2007) 298(9) *JAMA* 984.

modification of ingrained behavior and intangible factors such as organizational leadership, vision, and strategy.”⁷⁷

Although outside the scope of this thesis, it is useful to note that in addition to clinical governance and patient safety methodology (such as that cited within this chapter), further initiatives have gained prominence in the field of healthcare safety and quality improvement with respect to the work environment. For example, Lean methodologies were originally pioneered by Toyota and can be defined as a “ ... set of operating philosophies and methods that help create maximum value for patients by reducing waste and waits.”⁷⁸ Similarly, Six-Sigma was pioneered by Motorola and seeks to reduce variation in work-flow processes.⁷⁹ Common to both Lean and Six-Sigma (and Lean Sigma—a hybrid of both) is a focus on streamlining, and the removal of non-value added activities. Both are tied closely to the organisation’s financial objectives.⁸⁰ Although elements of the Lean/Six-Sigma philosophy are also present within patient safety theory—and arguably have similar results—the core principle driving Lean/Six-Sigma processes is that of improving efficiency.⁸¹ In contrast, patient safety theory is

⁷⁷ *ibid* 487; citing: M Connor et al., ‘Creating a Fair and Just Culture: One Institution’s Path Towards Organizational Change.’ (2007) 33(10) *Joint Commission Journal on Quality and Patient Safety* 617-624.

⁷⁸ A Lawal et al., ‘Lean Management in Health Care: Definition, Concepts, Methodology and Effects Reported’ (2014) 3 *Systematic Reviews* 103. See generally: T Joosten et al., ‘Application of Lean Thinking to Health Care: Issues and Observations’ (2009) 21(5) *International Journal for Quality in Health Care* 341; D Kimsey, ‘Lean Methodology in Health Care’ (2010) 92(1) *Association of Preoperative Nurses Journal* 53.

⁷⁹ See generally: B Nakhai and J Neves, ‘The Challenges of Six Sigma in Improving Service Quality’ (2009) 26(7) *International Journal of Quality & Reliability Management* 663; H Koning et al., ‘Lean Six Sigma in Healthcare’ (2006) 28(2) *Journal for Healthcare Quality* 4.

⁸⁰ For a discussion of the advantages and disadvantages of Lean and Six-Sigma methodology, see further: W Martin, ‘Quality Models: Selecting the Best Model to Deliver Results’ (2007) 33(3) *Physician Executive* 24.

⁸¹ C Pexton, ‘One Piece of the Patient Safety Puzzle: Advantages of the Six Sigma Approach’ (Jan/Feb 2005) *Patient Safety & Quality Healthcare*. <<http://psqh.com/janfeb05/sixsigma.html>> accessed: 05 May 2015. As Pexton notes, “While the link may be more obvious between patient safety and true clinical projects, such as reducing hospital acquired infections or preventing medication errors, benefits can also be drawn from operational projects that seek to remove inefficiency from the system and improve the bottom line.”

primarily concerned with improving safety and quality through prevention. However, there are common elements. For example, the removal of a non-standard drug from a unit drug cart is an important safety barrier and can be seen as being both efficient (Lean/Six-Sigma), and reduces the potential to administer an incorrect dose (patient safety).

Another work environment intervention that has received considerable attention is that of 'Pay for Performance.' Pay for performance is an initiative in which physicians receive incentive pay for exceeding performance standards and criteria.⁸² Proponents of pay for performance initiatives argue its use encourages the use of evidence-based processes of care, and ultimately increases efficiency while decreasing healthcare spending.⁸³ Alternatively, opponents have argued that the pay for performance initiative is problematic due to the "limited set of clinical practice parameters to assess quality."⁸⁴ Moreover, the focus on efficiency measures can lead to distraction from

⁸² For a discussion of the cultural and ethical implications of Pay for Performance programs on the medical community, see further: L Fink, 'Pay for Performance - A Clash of Cultures' (2006) 32(4) *Physician Executive* 34; R Thompson, 'Is Pay for Performance Ethical?' (2005) 31(6) *Physician Executive* 60. See also: R Werner and R Adams Dudley, 'Making the "Pay" Matter in Pay-For-Performance: Implications For Payment Strategies' (2009) 28(5) *Health Affairs* 1498; R Werner et al., 'The Effect of Pay-For-Performance In Hospitals: Lessons For Quality Improvement' (2011) 30(4) *Health Affairs* 690.

⁸³ S Calikoglu et al., 'Hospital Pay-For-Performance Programs in Maryland Produced Strong Results, Including Reduced Hospital-Acquired Conditions' (2012) 31(12) *Health Affairs* 2649. For example, the authors found a decrease of 15.26% in the rate of hospital-acquired infection over a two year period between 2007-2010, resulting in an overall cost savings of \$110.9 million USD.; T Doran and M Roland, 'Lessons From Major Initiatives To Improve Primary Care In The United Kingdom' (2010) 29(5) *Health Affairs* 1023. The authors note that while the income and morale of General Practitioners increased and quality of care improved, the long term success of the program with respects to patient outcomes remain unclear.

⁸⁴ L Snyder et al., 'Pay-for-Performance Principles that Promote Patient-Centered Care: An Ethics Manifesto' Position Paper for the American College of Physicians Ethics, Professionalism and Human Rights Committee (2007) 147 *Annals of Internal Medicine* 792

comprehensive patient care (in particular, with respects to elderly and acutely ill patients) and a reduction in team work.⁸⁵

Alternatively, the following specific system level interventions are designed to reduce medical error by intervening on both active and latent failure. The most prominent form of intervention is through the use of information technology. For example, in the discipline of patient safety, medication and error monitoring, incident reporting and epidemiological analysis are all strategies aided by advances in IT support that have become vital to the reduction of patient safety incidents. As the philosophy behind both workplace and system-level intervention has been previously examined throughout this thesis,⁸⁶ this section will now examine specific strategies that can be applied to intervene at both the blunt and sharp end.

Workplace and System Intervention Strategies⁸⁷

- (a) *User-Centred Design*: The role of technology in healthcare and patient safety cannot be understated. Alarms and monitors are common safety strategies in all high-risk industries; however, as Firth-Cozen and Sandars observe, “a paradox is that procedures that become highly reliant on technology can increase error

⁸⁵ J Bernstein, ‘Not By Bread Alone: Shortcomings of the Pay-For-Performance Approach’ (2014) 472 *Clinical Orthopaedics and Related Research* 405; D Berwick, ‘The Toxicity of Pay for Performance’ (1995) 4(1) *Quality Management in Healthcare* 27; L Snyder et al., ‘Pay-for-Performance Principles that Promote Patient-Centered Care: An Ethics Manifesto’ Position Paper for the American College of Physicians Ethics, Professionalism and Human Rights Committee (2007) 147 *Annals of Internal Medicine* 792; C Damberg et al., ‘Taking Stock of Pay-For-Performance: A Candid Assessment From The Front Lines’ (2009) 28(2) *Health Affairs* 517; C Damberg et al., ‘Taking Stock of Pay-For-Performance: A Candid Assessment From The Front Lines’ (2009) 28(2) *Health Affairs* 517; M Roland et al., ‘Does Pay for Performance in Hospitals Save Lives?’ (2014) 23(4) *BMJ Quality & Safety* 346; A Ryan et al., ‘Medicare’s Flagship Test Of Pay-For-Performance Did Not Spur More Rapid Quality Improvement Among Low-Performing Hospitals’ (2012) 31(4) *Health Affairs* 797.

⁸⁶ For an examination of the philosophy behind workplace and system-level factors, see further Chapter 4 ‘Healthcare Culture and Accountability,’ Chapter 5 ‘Human Factors vs The System,’ and Chapter 9 ‘Incident Reporting and Analysis.’

⁸⁷ This section has been largely influenced by the work of Donaldson and Raik. See further: M Donaldson and B Raik, ‘Preventing Errors’ in E Siegler et al. (eds), *An Introduction to Hospitals and Inpatient Care* (NY: Springer, 2003) 299-303.

because the operators still have human infallibility and may choose to ignore prompts or misinterpret information, especially if there is malfunction of the technology.”⁸⁸ To prevent this, technology used within a clinical setting should be designed for the end-user, with safeguards that incorporate both human strengths and weaknesses.⁸⁹ An example of this includes built-in functions, which assist the user in correctly using the equipment at varying levels that ultimately make it difficult—if not impossible—to use incorrectly.⁹⁰ Having those on the frontline participate in purchasing decisions (based on practical experience) can also aid in selecting the most appropriate technology for the end user.⁹¹

- (b) *Standardise and Simplify Processes and Equipment:* This includes the standardisation of procedures, equipment, and medicines. Where it is not possible to standardise, all efforts should be made to differentiate as clearly as possible.⁹² Closely connected to standardisation is the simplification of key processes. At the local level, Donaldson and Raik suggest simplification can include limiting the number of handoffs, reducing the variety of dose strengths available on drug carts, or automatic dispensing of pharmaceuticals.⁹³ Standardisation and simplification reduces the need to rely on memory and therefore can be beneficial in preventing slips and lapses that result during skill-based activities.

⁸⁸ J Firth-Cozen and J Sandars, ‘The Nature of Error’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 7.

⁸⁹ M Donaldson and B Raik, ‘Preventing Errors’ in E Siegler et al. (eds), *An Introduction to Hospitals and Inpatient Care* (NY: Springer, 2003) 299. See generally: A Dabbs et al., ‘User-Centered Design and Interactive Health Technologies for Patients’ (2010) 27(3) *Computers, Informatics, Nursing* 175. The authors describe the development process for the creation of patient-centred technology.

⁹⁰ *ibid* 300.

⁹¹ C Nemeth et al., ‘Between Choice and Chance: The Role of Human Factors in Acute Care Equipment Decisions’ (2009) 5(2) *Journal of Patient Safety* 114.

⁹² M Donaldson and B Raik, ‘Preventing Errors’ in E Siegler et al. (eds), *An Introduction to Hospitals and Inpatient Care* (NY: Springer, 2003) 299.

⁹³ *ibid* 300.

- (c) *Attend to Safety Conditions:* An emphasis on safety in the workplace includes the incorporation of human factors and systems thinking, both of which were examined in greater depth previously. In particular, attention should be paid to hours of work, staffing ratios, and sources of distraction.⁹⁴ Likewise, it is important to avoid reliance on vigilance. As Donaldson and Raik argue, “Individuals cannot remain vigilant for long periods of inaction, it is unreasonable to expect them to do so.” Limiting shift hours and using safety checklists can aid in preventing errors resulting from a reliance on vigilance.⁹⁵
- (d) *Compensating for Slips, Lapses, and Mistakes:* In some instances, safety interventions are most appropriately directed at the action of performing a particular task, as opposed to altering the task. To do this, it is necessary to first categorise the type of error and then apply the appropriate type of intervention. For example, when designing to avoid slips, lapses, or mistakes appropriate interventions include: ‘forcing functions’ that prevent an action without a corresponding deliberate act; ‘constraining functions’ that interrupt automatic actions; and ‘redundancy functions’ that may include the requirement for a second person’s signature or barcoding.⁹⁶
- (e) *Involve Patients in Their Care:* Arguably, one of the most fundamental and practical patient safety solutions is to engage patients and involve them in their care. While closely connected to the issue of patient autonomy and informed consent, from a patient safety perspective, the quality and comprehensiveness of the information given is more significant than the quantity.⁹⁷ In addition to

⁹⁴ *ibid.*

⁹⁵ *ibid.*

⁹⁶ J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 61-62.

⁹⁷ G Bartlett et al., ‘Impact of Patient Communication Problems on the Risk of Preventable Adverse Events in Acute Care Settings’ (2008) 178(12) *Canadian Medical Association Journal* 1555.

information relevant to the patient's medication and condition, Donaldson and Raik note that patients should also be given written information which provides them enough information to self-monitor and follow-up should complications occur.⁹⁸ Other examples of patient and family involvement shown to reduce the rate of error in an acute care setting include involving patients in infection control, handovers and transfer processes, as well as pre-operative and surgical site marking processes.⁹⁹

- (f) *Anticipate the Unexpected, Design for Recovery, and Team Training:* Donaldson and Raik have argued that notwithstanding design, all technology has the potential to introduce new errors, even when its purpose is the prevention of error.¹⁰⁰ Therefore, steps must be taken to anticipate the unexpected. Designing for recovery allows for the mitigation of error. Practical patient safety examples of this may include, "keeping antidotes for high-risk drugs up-to-date and easily accessible and having standardized, well-rehearsed procedures in place for responding quickly to adverse events."¹⁰¹ Additionally, team training and simulation training are now considered best practice within an acute care setting and have had significant rates of success in the promotion of patient safety and the prevention of patient safety incidents.¹⁰²

- (g) *Improve Access to Accurate, Timely Information:* As healthcare services evolve, so must the resources to safely provide it. As such, improving access to accurate and

⁹⁸ M Donaldson and B Raik, 'Preventing Errors' in E Siegler et al. (eds), *An Introduction to Hospitals and Inpatient Care* (NY: Springer, 2003) 301.

⁹⁹ S Winokur and K Beauregard, 'Patient Safety: Mindful, Meaningful, and Fulfilling' (2005) 22(1) *Frontiers of Health Services Management* 17, 25.

¹⁰⁰ M Donaldson and B Raik, 'Preventing Errors' in E Siegler et al. (eds), *An Introduction to Hospitals and Inpatient Care* (NY: Springer, 2003) 301-302.

¹⁰¹ *ibid* 302.

¹⁰² *ibid* 301-302; A King et al., 'Errors As Allies: Error Management Training in Health Professions Education' (2013) 22 *BMJ Quality & Safety* 516.

timely information is fundamental for the improvement of safety and quality. Information at the 'point of patient care' is critical. This may include medication history, multi-disciplinary team notes, clinical care pathways (examined below), colour-coded wristbands/bar codes for allergies and patient identification information.¹⁰³ Decision Support Systems and computerized health records have also become a key tool for improving safety by providing timely information relating to the decision-making process.¹⁰⁴

- (h) *Use of Clinical Care Pathways:* Clinical pathways, or care maps, are methods of patient care management that organise the care a patient will receive through the use of evidence-based practices and the coordination of a multidisciplinary care team's responsibilities, while under the direction of a designated 'most responsible physician' (MRP). Clinical pathways ensure that the appropriate resources are in place and that all members of the care team are working towards the same treatment outcome. As Blesser notes, "The aim of a clinical pathway is to improve the quality of care, reduce risks, increase patient satisfaction and increase the efficiency in the use of resources."¹⁰⁵

- (i) *Clinical Practice Guidelines:* Clinical Practice Guidelines has been defined by the Institute of Medicine as, "... statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options."¹⁰⁶ Clinical practices guidelines are a useful tool for quality and safety improvement as they

¹⁰³ *ibid* 302-303.

¹⁰⁴ G Peters and B Peters, *Medical Error and Patient Safety: Human Factors in Medicine* (US: Taylor & Francais, 2008) 157.

¹⁰⁵ L Blesser et al., 'Defining Pathways' (2006) 14(7) *Journal of Nursing Management* 553.

¹⁰⁶ Institute of Medicine, *Clinical Practice Guidelines We Can Trust* (Washington: Institute of Medicine, March 2011) 1.

increase consistency in the provision of care; as well as in the recording, collection and reporting of critical data.¹⁰⁷

In recognising that ‘To Err is Human,’ the intervention strategies listed above have one clear purpose: intersecting the path between clinical care and harm. By reducing system-related barriers, the opportunity for error is reduced. Thus far, this chapter has considered safety interventions that intervene on behaviour without a reliance on deterrence mechanisms, and are designed for implementation at multiple levels within the organisation. By way of example, the next section will examine a specific category of patient safety incidents: adverse drug events.

7.3 Intervening on Adverse Drug Events (ADEs)

In one of the first significant studies of adverse events, the 1984 *Harvard Practice Study*, found that 4% of all hospitalised patients in New York State suffered an adverse event. The leading cause of these, accounting for 19.4% of adverse events, was the use of drugs.¹⁰⁸ An adverse drug event is defined as “an injury resulting from medical intervention related to a drug.”¹⁰⁹ It is important to highlight at the onset that adverse drug events are not the resulting side-effects of a drug, but rather encompass all other adverse events which result from the drug’s use or administration.¹¹⁰ In this regard, the

¹⁰⁷ Health Information and Quality Authority, *Investigation into the Safety, Quality and Standards of Services Provided by the Health Service Executive to Patients, Including Pregnant Women, At Risk of Clinical Deterioration, Including Those Provided in University Hospital Galway, and as Reflected in the Care and Treatment Provided to Savita Halappanavar* (Dublin: HIQA, 7 October 2013) 177.

¹⁰⁸ T Brennan et al., ‘Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I’ (1991) 324 NEJM 370; L Leape et al., ‘The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II’ (1991) 324 NEJM 377.

¹⁰⁹ D Bates et al., ‘Incidence of Adverse Drug Events and Potential Adverse Drug Events: Implications for Prevention. ADE Prevention Study Group.’ (1995) 274(1) JAMA 29; World Health Organization, *Glossary of Patient Safety Concepts and References* (January 2009) 4 <http://www.who.int/patientsafety/taxonomy/icps_technical_annex2.pdf> accessed: 16 March 2015.

¹¹⁰ WHO World Alliance for Patient Safety, *Patient Safety Workshop: Learning from Error* (Geneva: World Health Organization, 2008) WHO/IER/PSP/2008.09. p14.

1995 study by Bates et al. is instructive. The authors, in examining the occurrence of adverse drug events in an acute care setting, found that of all adverse drug events which occurred, 28% were preventable. Significantly, this occurred most often at the ordering stage (56%), followed by administration (34%), transcription (6%) and dispensing (4%).¹¹¹

It is also noteworthy, particularly in the context of understanding human and system factors, that medication errors make up only a small percentage of preventable adverse drug events.¹¹² Therefore, prevention strategies that 'blame and shame' individuals who error will be ineffective. Rather, strategies for the prevention of adverse drug events (including medication errors) must be considered holistically, incorporating both the human and system factors that have contributed to their occurrence. This is not to suggest individuals and organisations not be held accountable when an ADE occurs, rather that prevention is always preferable to post incident mitigation.

Strategies for the Prevention of Adverse Drug Events

Due to variances within clinical care settings, this section will consider the human and system factors that contribute to adverse drug events in the context of prevention strategies. To do this, the recommendations of the American Hospital Association (AHA) and The Institute for Safe Medication Practices (ISMP) are particularly instructive. In their joint publication, the AHA and ISMP list ten key elements for the safe use of medicines.¹¹³ Each element incorporates the associated human and system factors that contribute to ADEs.

¹¹¹ D Bates et al., 'Incidence of Adverse Drug Events and Potential Adverse Drug Events: Implications for Prevention. ADE Prevention Study Group.' (1995) 274(1) JAMA 29, 31-33.

¹¹² *ibid.* Significantly, Bates et al. found that medication errors account for only 1% of all preventable adverse drug events.

¹¹³ American Hospital Association et al., *Pathways for Medication Safety: Looking Collectively at Risk* (Chicago: Health Research and Educational Trust, 2002) [2.3.4] <<http://www.ismp.org/tools/pathwaysection2.pdf>> accessed: 09 July 2013. See also: M Cohen, 'Causes of Medication Errors' in M Cohen (ed), *Medication Errors* (Washington: American Pharmaceutical Association, 2007) 56-58.

- (a) *Patient Information* - Ensuring current patient information is readily available electronically for physicians, nurses and pharmacists is fundamental to the prevention of adverse drug events. One strategy for ensuring this is the use of Computerized Physician Order Entry (CPOE) Systems that incorporate bar-coding.¹¹⁴ The use of CPOE systems has been shown to reduce the rate of serious medication errors by up to 81%.¹¹⁵ For example, COPE systems provide for medication-related alerting which prevents, *inter alia*, prescribing two interacting drugs.¹¹⁶ Bar-coded name bracelets and colour-coded allergy bracelets are another tool that can be used to ensure that vital patient information is readily available.¹¹⁷
- (b) *Drug Information* - Similar to patient information, up to date electronically available drug information is another tool to improve safety. This is useful in preventing knowledge-based errors, transcription errors, and also can alert clinicians to current guidelines for prescribing.¹¹⁸ Where possible, having in-

¹¹⁴ A Agrawal, 'Medication Errors: Prevention Using Information Technology Systems' (2009) 76(6) *British Journal of Clinical Pharmacology* 681, 682; J Anderson, 'A Systems Approach to Preventing Adverse Drug Events.' (2003) 92 *Studies in Health Technology and Informatics* 95. Anderson argues that the prevention of ADEs requires the systemic implementation of information technology designed to investigate and prevent ADEs.

¹¹⁵ D Bates et al., 'The Impact of Computerized Physician Order Entry on Medication Error Prevention,' (1999) 6(4) *Journal of the American Medical Informatics Association* 313; E Fortescue et al., 'Prioritizing Strategies for Preventing Medication Errors and Adverse Drug Events in Pediatric Inpatients.' (2003) 111 (4 Pt 1) *Pediatrics* 722. Similarly, Fortescue et al. found the use of COPE systems reduced the rate of medication errors by 76%.

¹¹⁶ S Phansalkar et al., 'A Review of Human Factors Principles for the Design and Implementation of Medication Safety Alerts in Clinical Information Systems.' (2010) 17(5) *Journal of the American Medical Informatics Association* 493; J Westbrook et al., 'Effects of Two Commercial Electronic Prescribing Systems on Prescribing Error Rates in Hospital In-Patients: A Before and After Study.' (2012) 9(1) *PLoS Medicine* e1001164.

¹¹⁷ American Hospital Association et al., *Pathways for Medication Safety: Looking Collectively at Risk* (Chicago: Health Research and Educational Trust, 2002) [2.3.4].

¹¹⁸ V Jylhä et al., 'Preventable Adverse Drug Events and Their Causes and Contributing Factors: The Analysis of Register Data.' (2011) 23(2) *International Journal for Quality in Health Care* 187. The authors found that the majority of information management errors mainly occurred at the prescription and transcription stage, relating specifically to documentation, copying data, or contraindicated prescriptions.

hospital pharmacists available for consultation and medication screening is also advisable.¹¹⁹ This was highlighted in a study comparing strategies for adverse drug event prevention, in which Fortescue et al. found the integration of ward-based clinical pharmacists reduced medication errors by 78%.¹²⁰

- (c) *Communication Related to Medications* - Eliminating communication barriers is necessary at all levels for quality and safety improvement. With respects to medications, the use of CPOE systems is an effective tool to improve communication. Disallowing unsafe communication, such as the use of abbreviations or nonemergency verbal orders is strongly recommended.¹²¹

- (d) *Drug Labeling, Packaging, and Nomenclature* - The World Health Organization have cited “Look-alike, sound alike” medication names are one of the most common causes of medication errors and adverse drug events. Drug packaging, location, and names—including brand and generic—are common sharp end causes of error.¹²² Mechanisms for intervention include: ensuring medications are labelled until the time they are administered;¹²³ minimising the use of verbal orders and requiring the printing of drug names and dosages; double checking the purpose of the medication; as well as including both the generic and brand name in

¹¹⁹ American Hospital Association et al., *Pathways for Medication Safety: Looking Collectively at Risk* (Chicago: Health Research and Educational Trust, 2002) [2.3.5].

¹²⁰ E Fortescue et al., ‘Prioritizing Strategies for Preventing Medication Errors and Adverse Drug Events in Pediatric Inpatients.’ (2003) 111 (4 Pt 1) *Pediatrics* 722.

¹²¹ American Hospital Association et al., *Pathways for Medication Safety: Looking Collectively at Risk* (Chicago: Health Research and Educational Trust, 2002) [2.3.5].

¹²² WHO Collaborating Centre for Patient Safety Solutions (International Steering Committee), *Nine Patient Safety Solutions* (Geneva: World Health Organization, April 2007) < <http://www.ccforspatientsafety.org/Patient-Safety-Solutions/> > accessed: 31 May 2012.

¹²³ American Hospital Association et al., *Pathways for Medication Safety: Looking Collectively at Risk* (Chicago: Health Research and Educational Trust, 2002) [2.3.7].

written orders.¹²⁴ Again, COPE Systems may assist with the aforementioned strategies.

- (e) *Drug Standardisation, Storage, and Distribution* - Examples of interventions at the system level that can prevent active medication errors at the sharp end include: standardising medicines in terms of dosages (for example unit-dose form) or limiting available doses to reduce intermingling; ensuring high-alert medications are separately stored; reducing the number of medicines not commonly required on unit drug carts; purchasing premixed medications (such as IV solutions) where possible, and the use of electronic drug dispensers.¹²⁵

- (f) *Medication Delivery Device Acquisition, Use, and Monitoring* - Although medication delivery devices generally incorporate user-centred design, healthcare organisations can increase safety further by limiting the variety of devices so as to promote familiarity and ensuring procedures are in place for independent review in the case of potential device-related errors.¹²⁶

- (g) *Environmental Factors* - Environmental factors related to patient safety incidents and medical error have been examined above and similarly apply to adverse drug events. These include: attention given to staffing levels, workload, and

¹²⁴ WHO Collaborating Centre for Patient Safety Solutions, 'Look-Alike, Sound-Alike Medication Names' (Geneva: World Health Organization, 2007) <<http://www.who.int/patientsafety/solutions/patientsafety/PS-Solution1.pdf>> accessed: 09 March 2015.

¹²⁵ American Hospital Association et al., *Pathways for Medication Safety: Looking Collectively at Risk* (Chicago: Health Research and Educational Trust, 2002) (Chicago: Health Research and Educational Trust, 2002) [2.3.8]; WHO Collaborating Centre for Patient Safety Solutions, 'Look-Alike, Sound-Alike Medication Names' (Geneva: World Health Organization, 2007) <<http://www.who.int/patientsafety/solutions/patientsafety/PS-Solution1.pdf>> accessed: 09 March 2015; M Donaldson and B Raik, 'Preventing Errors' in E Siegler et al. (eds), *An Introduction to Hospitals and Inpatient Care* (NY: Springer, 2003) 303.

¹²⁶ American Hospital Association et al., *Pathways for Medication Safety: Looking Collectively at Risk* (Chicago: Health Research and Educational Trust, 2002) [2.3.9].

potential sources of interruption.¹²⁷ An interesting example of this in the context of drug delivery are “Do Not Disturb” vests, worn by nurses while in the process of drug administration. Advocates of the “Do Not Disturb” vest argue its use prevents interruptions by alerting others that drug administration is in progress.¹²⁸ However, critics suggest its use can adversely impact other patient safety objectives. For example, in a study looking at the use of red vests that stated on the front “I Am Administering Medication-Please Do Not Interrupt Me”, Palese et al. found that patients perceived the message as directed at them, thereby inhibiting communication. Although the authors suggest their benefit still outweighs the risk of negative patient perception; attention should be given to the colour, words, and location of the message so as to minimise negative perceptions.¹²⁹

- (h) *Staff Competency and Education* - The AHA and ISMP note that, “Although staff education is a weak error-reduction strategy by itself, it can play an important role when it’s combined with system-based error-reduction strategies.” As such, the primary recommendation for staff competency is the inclusion of a comprehensive training program involving orientation for new staff, and continuing professional development for the safe use of medication.¹³⁰

¹²⁷ M Raban and J Westbrook, ‘Are Interventions to Reduce Interruptions and Errors During Medication Administration Effective?: A Systematic Review’ (2014) 23 *BMJ Quality & Safety* 414. Following a systematic review, the authors found limited evidence of the effectiveness of a single intervention strategy to reduce interruptions, recommending that, “Policy makers should proceed with great caution in implementing such interventions until controlled trials confirm their value.”

¹²⁸ M Federwisch et al., ‘The Sterile Cockpit: An Effective Approach to Reducing Medication Errors?’ (2014) 114(2) *American Journal of Nursing* 47, 49.

¹²⁹ A Palese et al., “‘I Am Administering Medication-Please Do Not Interrupt Me’: Red Tabards Preventing Interruptions as Perceived by Surgical Patients’ (12 June 2015) *Journal of Patient Safety* [epub ahead of print].

¹³⁰ American Hospital Association et al., *Pathways for Medication Safety: Looking Collectively at Risk* (Chicago: Health Research and Educational Trust, 2002) [2.3.11].

Specialised training is also necessary for those administering high-risk medications, such as those required for chemotherapy.¹³¹

- (i) *Patient Education* - Educating and engaging patients in their care can play an important role in the prevention of adverse drug events. Specific strategies within an acute care setting include: encouraging patients and caregivers to ask questions, offering programs for pharmacist counselling of high-risk patients, and having patients identify themselves in multidisciplinary care rounds and prior to drug administration.¹³²

- (j) *Quality Processes and Risk Management* - Incident reporting and analysis will be extensively analysed in the following chapter.¹³³ However, for the purpose of adverse drug event prevention, the AHA and ISMP strongly advocate the creation and support of legal and cultural interventions that allow for the open discussion of error, confidential blame-free incident reporting, disclosure of adverse drug events (including medication errors) to patients,¹³⁴ and psychological counselling for healthcare professions involved in serious error causing harm.¹³⁵

A number of reflections can be gleaned from the above findings. From a patient safety perspective, preventing the occurrence of adverse drug events and medication errors is paramount. Notwithstanding, barriers continue to exist that impede this goal. For

¹³¹ WHO World Alliance for Patient Safety, *Patient Safety Workshop: Learning from Error* (Geneva: World Health Organization, 2008) WHO/IER/PSP/2008.09. p14.

¹³² American Hospital Association et al., *Pathways for Medication Safety: Looking Collectively at Risk* (Chicago: Health Research and Educational Trust, 2002) [2.3.12].

¹³³ See further: Chapter 9 'Incident Reporting and Analysis.'

¹³⁴ See further: Chapter 11 'Communication: Disclosure and Apology.'

¹³⁵ American Hospital Association et al., *Pathways for Medication Safety: Looking Collectively at Risk* (Chicago: Health Research and Educational Trust, 2002) [2.3.13].

example, medication errors frequently result from confusing packaging and labelling instructions. In this regard, the WHO recommend improvement to the design of medicine packaging so as to ensure labels are clear, visible, and include unique identifiers.¹³⁶ While there is evidence to support this patient safety initiative, there is a significant limitation: the ability to improve the packaging of medicines is in most instances limited to the manufacturer or legislation, consideration by either being an onerous task and limited to political will and financial incentives.

Another example of both a safety intervention and barrier is that of the “five rights” method. Lachman has argued that the vast majority of nursing errors related to medication administration have resulted from the deviation of one of the ‘five rights.’¹³⁷ This method requires that prior to the administration of medication, healthcare professionals verify that it is the right patient, medication, dosage, route, and time. However, commentators have argued that the ‘five rights’ place an overemphasis on the abilities of the individual (human factors) and does not address the components of the systems that are critical to the reduction of error (system factors).¹³⁸ Lastly, the use of computerized physician order entry systems (CPOE) are increasingly being used as a tool for improving the safety and quality in patient care; however, issues have arisen as to new errors being created concerning workflow,

¹³⁶ WHO World Alliance for Patient Safety, *Patient Safety Workshop: Learning from Error* (Geneva: World Health Organization, 2008) WHO/IER/PSP/2008.09. p14; WHO Collaborating Centre for Patient Safety Solutions, ‘Look-Alike, Sound-Alike Medication Names’ (Geneva: World Health Organization, 2007) <<http://www.who.int/patientsafety/solutions/patientsafety/PS-Solution1.pdf>> accessed: 09 March 2015.

¹³⁷ V Lachman, ‘Patient Safety: The Ethical Imperative’ (2008) 20(2) *Journal of the Dermatology Nursing Association* 134. See generally: A Brady and S Fleming, ‘A Literature Review of the Individual and Systems Factors that Contribute to Medication Errors in Nursing Practice’ (2009) 17 *Journal of Nursing Management* 679.

¹³⁸ M Cohen, ‘Causes of Medication Errors’ in M Cohen (ed), *Medication Errors* (Washington: American Pharmaceutical Association, 2007) 55.

software complications and malfunction systems.¹³⁹ These three examples illustrate the challenges of implementing safety barriers within such a complex and multifaceted environment.

7.4 Conclusion

Intervening on latent and active factors that contribute to medical error is fundamental to quality and safety improvement. The concept of the 'safety spectrum' is useful in understanding how multiple layers of intervention can be used to decrease the opportunity of harm passing from the blunt end to the sharp end.¹⁴⁰ In this regard, system level intervention that makes incidents and error impossible are the most effective and most necessary. For example, designing technology that anticipates the limitations of the end-user has the distinct advantage of creating a barrier between human error and the patient. However, as the report *To Err is Human* explicitly made clear: even perfect systems are designed and used by humans, and thus, can be used imperfectly.¹⁴¹ Complicated, seemingly inefficient or malfunctioning technology can result in work-arounds that decrease its effectiveness.¹⁴² For this reason, applying

¹³⁹ D Massive et al., 'Computerized Physician Order Entry in the Critical Care Environment: A Review of Current Literature' (2011) 26(3) *Journal of Intensive Care Medicine* 165; J Coleman, 'Missed Medication Doses in Hospitalised Patients: A Descriptive Account of Quality Improvement Measures and Time Series Analysis' (2013) 25(5) *International Journal for Quality in Health Care* 564; J Firth-Cozen and J Sandars, 'The Nature of Error' in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 7.

¹⁴⁰ H Woodward et al., 'What Have We Learned About Interventions to Reduce Medical Errors?' (2010) 31 *Annual Review of Public Health* 479, 480-481.

¹⁴¹ Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999).

¹⁴² H Woodward et al., 'What Have We Learned About Interventions to Reduce Medical Errors?' (2010) 31 *Annual Review of Public Health* 479, 488; citing: J Ash et al., 'Some Unintended Consequences of Information Technology in Health Care: The Nature of Patient Care Information System-Related Errors' (2004) 11 *Journal of the American Informatics Association* 104-112; J Nebreker et al., 'High Rates of Adverse Drug Events in a Highly Computerized Hospital' (2005) 165(10) *JAMA Internal Medicine* 1111-1116; A Rule et al., 'New Technology, New Errors: How To Prime an Upgrade of an Insulin Infusion Pump' (2007) 33(3) *Joint Commission Journal on Quality and Patient Safety* 155-161; E Patterson et al., 'Compliance with Intended Use of Bar Code Medication Administration in Acute and Long-Term Care: An Observational Study' (2006) 48(1) *Human Factors* 15-22.

multiple intervention strategies at all levels is necessary as the greater number of barriers within the pathway of an incident, the less chance of it reaching the patient. Applying intervention strategies that on their own are lower on the safety spectrum, such as those that involve patient education or team communication training, can reinforce safe practices, improve cultural barriers, and provide an additional layer of safety intervention.

This chapter has critically analysed intervention strategies that can be applied within a clinical setting to prevent patient safety incidents. In the first section, interventions at the level of the patient and caregiver were analysed. Specifically, strategies that can be applied directly at the frontline were examined, including patient engagement and patient-centred care, patient education, the use of checklists, and teamwork. This was followed by an examination of workplace and system-level intervention strategies. This section sought to provide a comprehensive list of intervention strategies that can be applied at various levels of the healthcare system, preventing both latent and active factors from reaching the sharp end. Lastly, the second section illustrated how organisations can target and prevent a specific category of patient safety incidents: adverse drug events.

In the context of implementing safety interventions, the following chapter will examine in greater depth the practical consequences of cultural norms by considering the example of resident duty hours, their role in medical practice, and the challenges of reducing them—notwithstanding the wealth of evidence to suggest a significant benefit for the reduction of medical error.

- Chapter 8 -

Case Study: Resident Duty Hours

8.1 Introduction

In 1971, Friedman et al. conducted their seminal study entitled 'The Intern and Sleep Loss' in which the authors found that residents made twice as many errors reading a standardised electrocardiogram after being awake for twenty-four hours, as compared with their rested colleagues.¹ Similarly, in examining the practical effects of duty-hours worked by residents, Landrigan et al. compared interns on both the traditional work schedule of twenty-four hours or more, and a reduced hour schedule with shifts less than twenty-four hours.² Strikingly, the Interns working twenty-four hours or more were found to have made 35.9% more serious medical errors as well as 20.8% more serious medication errors than those working less than twenty-four hours. The authors concluded, "Eliminating extended work shifts and reducing the number of hours interns work per week can reduce serious medical errors...."³ A third study by Barger et al. found there to be a 300% increase in fatigue related errors by first year residents, after working five shifts of 24 hours or more.⁴ Equally as troubling, the consequences of fatigue can continue outside of the workplace. For example, in a 2005 study, Barger et al. considered the risk of extended work shifts of thirty-two hours and the effects on driving. Focusing solely on first year residents, the authors found that residents were 2.3 times more likely to be involved in a motor vehicle accident and 5.9 times more likely to be involved in a near miss.⁵ Despite the very clear consequences of workplace

¹ R Friedman et al., 'The Intern and Sleep Loss' (1971) 285(4) NEJM 201–203.

² C Landrigan et al., 'Effect of Reducing Interns' Work Hours on Serious Medical Errors in Intensive Care Units' (2004) 351(18) NEJM 1838.

³ *ibid.*

⁴ L Barger et al., 'Impact of Extended-Duration Shifts on Medical Errors, Adverse Events, and Attentional Failures.' (2006) 3(12) PLoS Medicine 487.

⁵ L Barger et al., 'Extended Work Shifts and the Risk of Motor Vehicle Crashes Among Interns' (2005) 352(2) NEJM 125.

fatigue well borne out by the literature, regulation of medical and surgical resident duty hours—by the courts, legislation or professional standards and guidelines—continues to be a significant challenge to implement. This, in turn, provides a useful example of implementing a culture of safety.⁶

This chapter will explore the consequences of workplace fatigue by using a specific methodological tool: the case study. In particular, developments towards the regulation of resident duty hours in the United States, Canada, and the European Union will be critically compared. Beginning in the first section with an examination of how the tragic 1984 death of Libby Zion resulted in State legislation and brought to a national and international stage the consequences of resident fatigue. The implementation of the 2003 and 2011 Accreditation Council for Graduate Medical Education *Common Duty Hour Standards*, which limited the number of hours residents within the United States could be continuously scheduled for duty, will also be examined.⁷ The second section will analyse the use of collective bargaining agreements in Canada and the arbitration case of *McGill University Health Centre v Association des Résidents de McGill*.⁸ This case set precedent within the province of Québec by acknowledging the dangers of excessive duty hours for both residents and patients. The third section will consider legislative and judicial developments within Europe. Specifically, the European Working Time Directive and the 2015 Irish case of *European Commission v Ireland*⁹ which excluded ‘training hours’ from the definition of working time set out within the Directive. The final section will critically analyse the impact of the resident duty hour

⁶ See generally: P Fortune et al. (eds), *Human Factors in the Healthcare Setting: A Pocket Guide for Clinical Instructors* (UK: Wiley-Blackwell, 2013) 61-70, for a discussion of the consequences of fatigue and stress on clinical performance.

⁷ I Philibert et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME, 2011).

⁸ *McGill University Health Centre v Association des Résidents de McGill* (Arbitration Board, Québec, Canada. 07 June 2011. Grievance No. 4-CUSM-0809-01) [1].

⁹ Case C-87/14 *European Commission v Ireland* [2015] ECLI:EU:C:2015:449.

restrictions, and explore the main arguments against their further reduction. In particular, that a further reduction will increase the number of handovers between residents, thereby disrupting continuity of care and creating a risk to patient safety. Ultimately, an argument will be put forth for their reduction in light of both worker and patient safety. This chapter is relevant in the context of safety and quality improvement because it clearly illustrates the extraordinary challenges of cultural change and safety intervention when legislative intervention is absent, and when governments and regulatory organisations are reluctant to reform the status quo.

8.2 The United States

This section will examine how the 1984 death of Libby Zion—a consequence of fatigue—resulted in both legislation and federal policy change over the past three decades in the United States. Libby Zion’s death highlighted both the practice, and the consequences of medical and surgical resident duty work-hours.

The Death of Libby Zion

On the night of the 4th March 1984, Libby Zion, an 18-year old patient, was admitted to the emergency room at New York Hospital.¹⁰ Upon being admitted, an emergency room physician described her as presenting with a “fever, agitation and strange jerking motions of her body.”¹¹ It was disclosed to the admitting physician that she been taking the prescription antidepressant Phenelzine.¹² Throughout the course of the night, Zion was put under the care of the attending physician, a resident and an intern; each of whom had been working in excess of eighteen hours by the time she was admitted.

¹⁰ Although not relevant to the following section, it is worth noting that New York Hospital has since become New York Presbyterian Hospital.

¹¹ B Lerner, ‘A Case That Shook Medicine’ *Washington Post* (Washington DC, 28 November 2006) <<http://www.washingtonpost.com/wp-dyn/content/article/2006/11/24/AR2006112400985.html>>.

¹² C Lee, ‘Federal Regulation of Hospital Resident Work Hours: Enforcement With Real Teeth’ (2006) 9(1) *Journal of Health Care Law & Policy* 162, 175; B Lerner, ‘A Case That Shook Medicine’ *Washington Post* (Washington DC, 28 November 2006) <<http://www.washingtonpost.com/wp-dyn/content/article/2006/11/24/AR2006112400985.html>>.

The resident assigned to her prescribed Meperidine, hydration, and observation. In the hours that followed, Zion's condition worsened and she became more agitated. As a result, nurses on the ward consulted her attending residents who—by phone—ordered physical restraints and prescribed Haloperidol to control the agitation. Although Zion did fall asleep, she went into cardiac arrest soon after and died as a result of a fatally high temperature.¹³

The facts and cause surrounding the death of Libby Zion were both legally and politically contentious.¹⁴ While initially determined to be caused by an infection;¹⁵ it is now widely accepted that Zion's death was the result of Serotonin Syndrome. As Boyer and Shannon, explain, "[t]he death of an 18-year-old patient named Libby Zion in New York City more than 20 years ago, which resulted from coadministration of Meperidine and Phenelzine, remains the most widely recognized and dramatic example of this preventable condition."¹⁶ Although Zion's death could have been prevented by avoiding the coadministration of Meperidine and Phenelzine, it was essentially only one of a number of latent and active failures that allowed the incident to occur. This, in essence, is precisely the type of situation envisioned by the authors of *To Err is Human*: multiple causes originating within the system but with the consequences disproportionately falling on the individuals at the sharp end of the spectrum. The

¹³ C Lee, 'Federal Regulation of Hospital Resident Work Hours: Enforcement With Real Teeth' (2006) 9(1) *Journal of Health Care Law & Policy* 162, 176; citing: Report of the Fourth Grand Jury for the April / May Term of 1986 Concerning the Care and Treatment of a Patient and the Supervision of Interns and Junior Residents at a Hospital in New York County 2; D Asch and R Parker, 'The Libby Zion Case: One Step Forward or Two Steps Backward?' (1988) 318 *NEJM* 771.

¹⁴ See further: L Andrews, 'I Was Juror No. 6, the Lone Dissenter in the Libby Zion Case' *New York Times* (New York, 21 February 1995) <<http://www.nytimes.com/1995/02/21/opinion/1-i-was-juror-no-6-the-lone-dissenter-in-the-libby-zion-case-219095.html>>. ; B Lerner, 'A Life-Changing Case for Doctors in Training' *New York Times* (New York, 14 August 2011) <http://www.nytimes.com/2009/03/03/health/03zion.html?_r=0>.

¹⁵ I Philibert and C Taradejna, 'Chapter 2: A Brief History of Duty Hours and Graduate Education' in I Philibert et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME, 2011) 6.

¹⁶ E Boyer and M Shannon, 'The Serotonin Syndrome' (2005) 352(11) *NEJM* 1112..

legal developments resulting from her death that ultimately lead to a reduction in resident duty hours in New York State, will now be examined.

Libby Zion Trial/ Grand Jury Inquiry

In *Zion v New York Hospital*,¹⁷ the family of Libby Zion brought medical malpractice proceedings for wrongful death against New York Hospital and four of the physicians involved in her care. This included the emergency physician, resident, and intern directly involved in her care the night of her death, as well as her primary care physician. The jury found in the plaintiff's favour against three of the four defendant physicians; however, both the defendant hospital and emergency room physician were not found to have been negligent. Additionally, the jury concluded Zion had contributed to the events by failing to inform the defendant physicians of her alleged history of cocaine use. Notwithstanding, the trial judge dismissed the finding of contributory negligence and set damages at \$375,000 against the three defendant physicians.¹⁸

In addition to the civil case, a grand jury was convened to consider murder charges against the physicians involved in her death.¹⁹ The grand jury found, *inter alia*, that there was insufficient evidence sounding the cause of death. As a result, no criminal indictments were filed against the physicians involved or New York Hospital.²⁰ However, the grand jury were critical of the duty hours worked, and supervision

¹⁷ *Zion v New York Hospital* [1992] N.Y. App. Div. 590 N.Y.S.2d 188.

¹⁸ C Lee, 'Federal Regulation of Hospital Resident Work Hours: Enforcement With Real Teeth' (2006) 9(1) *Journal of Health Care Law & Policy* 162, 179 (footnote 137); B Lerner, 'A Case That Shook Medicine' *Washington Post* (Washington DC, 28 November 2006) <<http://www.washingtonpost.com/wp-dyn/content/article/2006/11/24/AR2006112400985.html>>.

¹⁹ B Lerner, 'A Case That Shook Medicine' *Washington Post* (Washington DC, 28 November 2006) <<http://www.washingtonpost.com/wp-dyn/content/article/2006/11/24/AR2006112400985.html>>.

²⁰ C Lee, 'Federal Regulation of Hospital Resident Work Hours: Enforcement With Real Teeth' (2006) 9(1) *Journal of Health Care Law & Policy* 162, 177; citing: Report of the Fourth Grand Jury for the April / May Term of 1986 Concerning the Care and Treatment of a Patient and the Supervision of Interns and Junior Residents at a Hospital in New York County 2.

received, by the medical residents involved in Zion's care. In particular, they were critical of the fact that both the junior resident and intern who had been working in the emergency room that night had already worked eighteen hours by the time Zion was admitted.²¹ The grand jury ultimately recommended,

"The State Department of Health should promulgate regulations to limit consecutive working hours for interns and junior residents in teaching hospitals."²² In response to this recommendation, then New York Health Commissioner David Axelrod established the New York State Department of Health Ad Hoc Committee on Emergency Services, colloquially known as the 'Bell Commission.'²³

The Bell Commission and New York State Law

The Bell Commission were tasked with reviewing the Recommendations of the Grand Jury report from the Libby Zion case. In regards resident duty hours, the Bell Commission's final report to the New York State Department of Health (NYSDOH) recommended, *inter alia*, imposing a twenty-four hour consecutive limit for residents, averaging eighty hours over a four-week period, as well as a requirement that senior

²¹ *ibid* 178.

²² Report of the Fourth Grand Jury for the April / May Term of 1986 Concerning the Care and Treatment of a Patient and the Supervision of Interns and Junior Residents at a Hospital in New York County 2; as taken from: C Lee, 'Federal Regulation of Hospital Resident Work Hours: Enforcement With Real Teeth' (2006) 9(1) *Journal of Health Care Law & Policy* 162, 178.

²³ I Philibert and C Taradejna, 'Chapter 2: A Brief History of Duty Hours and Graduate Education' in I Philibert et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME, 2011) 6; New York State Department of Health Ad Hoc Committee on Emergency Service, *Report on the New York State Ad Hoc Advisory Committee on Emergency Services: Supervision and Residents' Working Conditions* (New York: 1987).

physicians more closely supervise residents within the hospital.²⁴ However, the report unfortunately omitted the inclusion of a duty-free intershift period which had previously been considered.²⁵ As Lee notes, following their issuance, “the Bell Commission recommendations received extensive political support throughout New York State. As a result of political and public pressure, in addition to its own public hearings and consultations with national and state leaders in medical education, the NYSDOH promulgated regulations adopting the Commission’s recommended reforms.”²⁶

The following year, the New York State legislature amended the New York Health Code, taking into consideration the Bell Commission’s recommendations. Section 405.4 of Title 10 of the New York Codes, Rules and Regulations included, *inter alia*, a provision that residents shall not be scheduled to work for more than twenty-four consecutive hours²⁷ and the restriction that “the scheduled work week shall not exceed an average of eighty hours per week over a four week period.”²⁸ In addition to the recommendations of the Bell Commission, the Regulations also included the requirement that: “scheduled on-duty assignments be separated by not less than eight non-working hours. Post-graduate trainees shall have at least one twenty-four period

²⁴ I Philibert and C Taradejna, ‘Chapter 2: A Brief History of Duty Hours and Graduate Education’ in I Philibert et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME, 2011) 6.

²⁵ C Lee, ‘Federal Regulation of Hospital Resident Work Hours: Enforcement With Real Teeth’ (2006) 9(1) *Journal of Health Care Law & Policy* 162, 181; citing: New York State Department of Health Ad Hoc Committee on Emergency Service, *Report on the New York State Ad Hoc Advisory Committee on Emergency Services: Supervision and Residents’ Working Conditions* (New York: 1987) 6.

²⁶ *ibid* 182; D Asch and R Parker, ‘The Libby Zion Case: One Step Forward or Two Steps Backward?’ (1988) 318 *NEJM* 771, 773.

²⁷ New York Codes, Rules and Regulations tit. 10, § 405.4(b)(6)(ii)(b).

²⁸ New York Codes, Rules and Regulations tit. 10, § 405.4(b)(6)(ii)(a).

of scheduled non-working time per week.”²⁹ Despite being contested the following year in the *Hospital Association of New York State v Axelrod* [1990], the Supreme Court of New York for Albany County ultimately upheld Regulation 10 NYCRR §405.4.³⁰ In accordance with Section 405.4, the primary enforcement mechanism of the Regulations was through New York State Department of Health citations and fines.³¹ However, following investigation and findings of defects and low compliance, the New York State government enacted the Health Care Reform Act of 2000. The Act increased penalties, enforcement mechanisms, and transparency.³²

Although an achievement at the State level, enacting similar legislation on a federal level has been considerably more challenging. In an effort to regulate the work-hours and supervision of residents federally throughout the United States, the Patient and Physician Safety and Protection Act of 2001 and 2002 were introduced in the House of Representatives “to amend title XVIII of the Social Security Act to reduce the work hours and increase the supervision of resident-physicians to ensure the safety of patients and resident-physicians themselves.”³³ Although the legislation failed to gain support at the time, a second attempt was made in 2005 when the Act was reintroduced in the House of Representatives.³⁴ This too, rather unfortunately, continued to lack support by legislators, and as a result has remained in the committee

²⁹ New York Codes, Rules and Regulations tit. 10, § 405.4 tit. 10, § 405.4(b)(6)(iv); C Lee, ‘Federal Regulation of Hospital Resident Work Hours: Enforcement With Real Teeth’ (2006) 9(1) *Journal of Health Care Law & Policy* 162, 182.

³⁰ *Hospital Association of New York State v Axelrod* [1989] N.Y. Sup. Ct. 546 N.Y.S.2d 531, [1990] N.Y. App. Div. 565 N.Y.S.2d 243.

³¹ C Lee, ‘Federal Regulation of Hospital Resident Work Hours: Enforcement With Real Teeth’ (2006) 9(1) *Journal of Health Care Law & Policy* 162, 182; citing: J Whetsell, ‘Changing the Law, Changing the Culture: Rethinking the “Sleepy Resident” Problem’ (2003) 12 *Annals of Health Law* 23, 54.

³² F McDonald, ‘Working to Death: The Regulation of Working Hours in Health Care’ (2008) 30(1) *Law & Policy* 108, 130; citing: H Lawrence, ‘The Impact of Residents’ Work Hour Restrictions’ [2003] 3 *Current Women’s’ Health Reports* 487-491.

³³ Physician Safety and Protection Act 2001, HR 3236, 107th Cong.; Patient and Physician Safety and Protection Act 2002, S. 2614, 107th Cong. (2002).

³⁴ Patient and Physician Safety and Protection Act 2005, Bill HR 1228, 109th Cong.

stage and not been enacted.³⁵ As federal legislation thus far has been unsuccessful, alternative sources of oversight in the United States, specifically those of the Accreditation Council for Graduate Medical Education *Duty Hour Standards*, will now be analysed.

The ACGME Common Duty Hour Standards

Historically, at the federal level, review of medical residency programs was provided by the American Medical Association. The Accreditation Council for Graduate Medical Education (ACGME) was created in 1981 and has since been responsible for the Accreditation of post-MD medical training programs within the United States.³⁶

Despite the events that took place in the wake of Lion Zion's death, and the critical finding by the New York grand jury of the consequences of excessive duty hours and legislation at both a state and federal level, it was not until the publication of the *To Err is Human*³⁷ that the issue of resident duty hours was addressed by the ACGME. As Philibert and Taradejna note,

“Three developments convinced the ACGME in 2002 of the need for a more comprehensive set of duty-hour standards for all specialties. The first is a

³⁵ Patient and Physician Safety and Protection Act 2005, Bill HR 1228, 109th Cong. Sponsor: Rep. John Conyers Jr. [D-MI14]. Status: This bill was introduced on March 10, 2005, in a previous session of Congress, but was not enacted. (Referred to Committee) <<http://thomas.loc.gov/cgi-bin/bdquery/z?d109:hr1228>> accessed: 09 November 2012.

³⁶ I Philibert and C Taradejna, 'Chapter 2: A Brief History of Duty Hours and Graduate Education' in I Philibert et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME, 2011) 5. Noting, "The ACGME was organized in 1981 by transitioning the LCGME to an unincorporated entity with 5 member organizations (the AMA, the American Board of Medical Specialties, the American Hospital Association, the Association of American Medical Colleges, and the Council of Medical Specialty Societies."

³⁷ Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999).

changing health care delivery system, with increasingly ill patients and the resulting greater demands on residents. Second, there is a growing public opinion that long duty hours compromise patient safety and resident well-being. The members of the Work Group were concerned that governments could decide to regulate residents' duty hours if the medical education community failed to address these issues. Third, research has resulted in better data about the effects of sleep deprivation on residents' clinical and educational performance."³⁸

Although *To Err is Human* did not specifically address the issue of resident work hours, Philibert and Taradejna have further noted, "its release prompted the ACGME Board of Directors and its Strategic Initiatives Committee to explore sources of errors in the resident education environment, with reviews of the literature and other sources again suggesting limitation of resident hours and enhancing supervision as important strategies to enhance safety in teaching settings."³⁹

The resulting 2003 *ACGME Common Duty Hour Standards* provided a mechanism for standardisation throughout the United States by way of accreditation requirements for all medical teaching facilities. The ACGME argued that, in contrast to legislation, the requirements allowed for "greater flexibility and sensitivity to specialty

³⁸ I Philibert et al., 'New Requirements for Resident Duty Hours' [2002] 288(9) JAMA 1112-1114, 1112; citing: Accreditation Council for Graduate Medical Education, *Report of the ACGME Work Group on Resident Duty Hours* (Chicago: ACGME, 2002).

³⁹ I Philibert and C Taradejna, 'Chapter 2: A Brief History of Duty Hours and Graduate Education' in I Philibert et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME, 2011) 8; citing: Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999) 64.

considerations....”⁴⁰ In a model similar to that implemented in New York State, the 2003 ACGME Standards included the requirement that residents duty hours may not exceed twenty-four hours in duration and were limited to eighty hours per week, averaged over a four week period.⁴¹

Five years later, the Institute of Medicine specifically addressed the issue of resident duty hours. The report, *‘Resident Duty Hours: Enhancing Sleep, Supervision, and Safety’*⁴² reiterated the consequences of fatigue on human performance.⁴³ In addition, the report identified the potential for fatigue to cause increased errors in handovers, as well as emphasised the need for increased supervision to account for the disruption in continuity of care.⁴⁴ In following the recommendations of the Institute of Medicine, ACGME published *‘The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development.’*⁴⁵ The 2011 ACGME Standards reinforced the duty hour requirement that hours must not exceed eighty per week,

⁴⁰ I Philibert et al., ‘The 2003 Common Standards and Their Effect’ in I Philibert et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME, 2011) 14.

⁴¹ Accreditation Council for Graduate Medical Education, ‘Resident Duty Hours in the Learning and Working Environment: Comparison of 2003 and 2011 Standards’ <<http://www.acgme.org/acgmeweb/Portals/0/PDFs/dh-ComparisonTable2003v2011.pdf>> accessed: 11 October 2012.

⁴² Institute of Medicine (Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety), *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*. C Ulmer et al. (eds), (Washington: National Academies Press, 2008).

⁴³ *ibid* 191. See further: R Jags et al., ‘Residents Report on Adverse Events and Their Causes’ [2005] 165(22) *Archives of Internal Medicine* 2607; C Landrigan et al., ‘Effect of Reducing Interns’ Work Hours on Serious Medical Errors in Intensive Care Units’ [2004] 351(18) *NEJM* 1838; S Lockley et al., ‘Effects of Health Care Provider Work Hours and Sleep Deprivation on Safety and Performance’ [2007] 33(11 Suppl) *Joint Commission Journal on Quality and Patient Safety* 7.

⁴⁴ *ibid* 266-268; citing: L Horowitz et al., ‘Development and Implementation of an Oral Sign-Out Skills Curriculum’ [2007] 22(10) *Journal of General Internal Medicine* 1470; A Vidyarthi et al., ‘Managing Discontinuity in Academic Medical Centers: Strategies for a Safe and Effective Resident Sign-Out’ (2006) 1(4) *Journal of Hospital Medicine* 257.

⁴⁵ I Philibert et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME, 2011).

averaging over four weeks. However, where the previous guideline for first year residents permitted them to be scheduled to a maximum of twenty-four hours of continuous duty, the 2011 guidelines reduced this to a maximum of sixteen hours.⁴⁶ The 2011 Standards also included provisions requiring enhanced supervision; increased education about fatigue, handovers and teamwork; as well as limits on the number of patients a resident could have at one time.⁴⁷

Despite the enthusiasm surrounding the implementation of duty hour restrictions, enforcement has created new challenges. While the accreditation requirements are self-regulatory in nature, failure of a post-MD medical training program to comply with the 2011 Standards can result in the loss of accreditation and as such, a loss of government funding.⁴⁸ This, however, has led to work-arounds to compensate for the decreased hours residents are available. As Philibert et al. explain,

“... much of the large-scale change and innovation to adapt to the duty hour limits did not materialize. A small number of programs reengineered their patient care and education systems, but most used schedule changes,

⁴⁶ Accreditation Council for Graduate Medical Education, ‘Duty Hours: ACGME Standards’ (ACGME, 1 July 2011) 17. <<http://www.acgme.org/acgmeweb/GraduateMedicalEducation/DutyHours.aspx>> accessed: 11 October 2012.

⁴⁷ T Whalen and W Walsh, ‘Chapter 11: Going Beyond Duty Hours: A Focus on Patient Safety’ in I Philibert et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME, 2011) 69.

⁴⁸ F McDonald, ‘Working to Death: The Regulation of Working Hours in Health Care’ (2008) 30(1) *Law & Policy* 108, 124; citing: B Bell, ‘Reconsideration of the New York State Laws Rationalizing the Supervision and the Working Conditions of Residents’ (2003) 20 *Einstein Journal of Biology and Medicine* 36-40; L Altman and D Grady, ‘Hospital Accreditor will Strictly Limit Hours of Residents’ *New York Times* (New York, 13 June 2002).

substitution of residents' clinical work with mid-level practitioners or hospitalists, and an increase in faculty clinical load."⁴⁹

Before examining the impact of the implementation of ACGME duty hours standards on current practice in the United States, it is illustrative to first consider the history and development of residents duty hours in Canada and the European Union.

8.3 Canada

In contrast to the United States where resident duty hours are nationally regulated through accreditation, Canada has not introduced federal legislation, national oversight through accreditation, or national guidelines regulating the duty hours of medical or surgical residents.⁵⁰ With the exception of the province of Québec, duty hours are negotiated individually by province or territory, and generally by way of collective agreement.⁵¹ For example, in Manitoba, duty hours are limited to a weekly total of eighty-nine hours, averaged over a four week period.⁵² Similarly, the Professional Association of Residents in the Maritime Provinces (Nova Scotia, New Brunswick and Prince Edward Island) negotiated an annual and gradual reduction of duty hours in their agreement; the current agreement restricts the maximum number of

⁴⁹ I Philibert et al., 'The 2003 Common Standards and Their Effect' in I Philibert et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME, 2011) 17.

⁵⁰ A Woods, 'Medical Residents Needs Shorter Work Shifts, Many Say.' *The Toronto Star* (Toronto; Montreal, 30 September 2012). <http://www.thestar.com/news/canada/2012/09/30/medical_residents_needs_shorter_work_shifts_many_say.html>

⁵¹ Canadian Association of Interns & Residents, 'Canadian Patient and Physician Safety and Wellbeing: Resident Duty Hours' Position Paper on Resident Duty Hours (Ottawa: April 2012) 2.

⁵² PARIM and Winnipeg RHA. *Collective Agreement*. 1 July 2014 to 30 June 2018. [Art 13.02 (d)]. <<http://www.parim.org/wp-content/uploads/2015/06/PARIM-Collective-Agreement-2014-2018-OSB.pdf>> accessed: 05 June 2016.

hours to ninety per week, averaged over four weeks. This is down from ninety-five hours per week in 2008.⁵³

In contrast to the difficulties faced in the United States in enacting legislation or ensuring compliance with the ACGME's Standards, collective agreements have the advantage of negotiation and subjectivity, while pursuing both public and private interests.⁵⁴ In addition to Canada, both New Zealand and Australia also regulate duty hours through collective agreement, with the primary focus being occupational health and safety.⁵⁵ For the purposes of this analysis, the distinction between motivating factors is significant. As was examined above, the introduction of the ACGME Standards occurred in light of patient safety concerns following the publication of *To Err is Human*.⁵⁶ In contrast, the reduction of duty hours in Canada, New Zealand, Australia, and the European Union, has primarily been out of concern for the health and safety of the residents involved. This dichotomy can be seen in the following example of litigation brought within the province of Québec.

⁵³ PARI-MP. *Collective Agreement*. 1 July 2011 to 30 June 2014. [Art 17(b)]. <www.cdha.nshealth.ca/system/files/sites/834/documents/professional-association-residents-maritime-provinces.pdf> accessed: 05 June 2016. Although the current collective agreement has expired, all provisions remain in place until a new agreement is reached.

⁵⁴ F McDonald, 'Working to Death: The Regulation of Working Hours in Health Care' (2008) 30(1) *Law & Policy* 108, 117-118. However, McDonald has made the critical observation that collective agreements are most successful in countries that provide for socialised healthcare. As she notes, "In these countries, legislative frameworks centralized publicly funded health services within structural frameworks at the local, regional, or national level. Further, the regulatory traditions within the health sectors of these countries were based on accommodations with professional groups, in particular physicians."

⁵⁵ *ibid* 118; citing: New Zealand Resident Doctors' Association, *Collective Agreement* (Auckland: 2007); Australian Medical Association, *National Code of Practice—Hours of Work, Shiftwork and Rostering for Hospital Doctors* (Kingston ACT, Australia: Australian Medical Association Ltd, 2005). New Zealand negotiates collective agreements nationally. Australia, much like Canada, also use collective agreements but they too vary from State to State.

⁵⁶ Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999).

Québec

Prior to 2011, in accordance with the terms of their collective agreement, medical and surgical residents in Québec were required to work duty hours of twenty-four hour periods, to a maximum of seventy-two hours per week, averaged over four weeks.⁵⁷

In March of 2009, the president of the Association des Résidents de McGill⁵⁸ filed a grievance contesting the terms of their agreement on the basis that the twenty-four hour call duty requirement “constitutes an unacceptable condition of employment which jeopardizes the health, safety and physical integrity of patients and the residents themselves.”⁵⁹ It was argued that this condition of employment violated the Canadian Charter of Rights and Freedoms⁶⁰ and the Quebec Charter of Human Rights and Freedoms.⁶¹ The grievance sought to have the duty hour requirement reduced from twenty-four hours to sixteen.⁶²

The Arbitration ruling, delivered the 07 June 2011, declared clause 12.14 to be in violation of section 7 of the Canadian Charter, and section 1 and 46 of the Québec Charter. ⁶³ In reaching this finding, the Arbitrator stated:

⁵⁷ *McGill University Health Centre v Association des Résidents de McGill* (Arbitration Board, Québec, Canada. 07 June 2011. Grievance No. 4-CUSM-0809-01) [1].

⁵⁸ The *Association des Résidents de McGill* represents medical and surgical residents from McGill University, Montréal, Canada.

⁵⁹ *McGill University Health Centre v Association des Résidents de McGill* (Arbitration Board, Québec, Canada. 07 June 2011. Grievance No. 4-CUSM-0809-01) [1].

⁶⁰ Hereinafter: the “Canadian Charter.”

⁶¹ Hereinafter the “Quebec Charter.”

⁶² *McGill University Health Centre v Association des Résidents de McGill* (Arbitration Board, Québec, Canada. 07 June 2011. Grievance No. 4-CUSM-0809-01) [1]. The current collective agreement can be accessed at: Fédération des Médecins Résidents du Québec, *Collective Agreement* (2011-2015) <<http://www.fmrq.qc.ca/files/documents/e2/17/2013-03-19-fmrq-guide-interpretation-de-l-entente-2010-2015-va-finale-modifi-e.pdf>> accessed: 05 June 2016. Although the current collective agreement has expired, all provisions remain in place until a new agreement is reached.

⁶³ *McGill University Health Centre v Association des Résidents de McGill* (Arbitration Board, Québec, Canada. 07 June 2011. Grievance No. 4-CUSM-0809-01) [174-175].

[131] "... It has been established to my satisfaction that the call duty schedule in an establishment of a duration of 24 hours is dangerous for resident health and leads in many of them to physical, and even mental problems. Some are less affected than others, but many of them suffer from problems of attention, concentration, memory and extreme fatigue. Not only does such a schedule jeopardize their health, but it also indirectly endangers the health of patients, who may become victims of medical errors."⁶⁴

Following this ruling, clause 12.14 was ruled inoperative and resident duty hours in the province of Québec may no longer exceed 16 hours per day.⁶⁵

The necessity of the Association des Résidents de McGill to have had to pursue arbitration in order to effect a change in duty hours is a useful example of the difficulty in adapting both policy and cultural change where neither legislation, nor regulations are in place. As McDonald observes, "Courts often act in a policy capacity only when those in a position to enact a regulatory change appear to ignore an issue of significant public interest, such as safety."⁶⁶

Both the Canadian Medical Association⁶⁷ and the Canadian Association of Interns & Residents⁶⁸ have strongly advocated to federally adopt the sixteen hour maximum

⁶⁴ *ibid* [131].

⁶⁵ *ibid* [176].

⁶⁶ F McDonald, 'Working to Death: The Regulation of Working Hours in Health Care' (2008) 30(1) *Law & Policy* 108, 117; citing: W Viscusi, 'Overview' in W Viscusi (ed), *Regulation through Litigation* (Washington: AEI-Brookings Joint Center for Regulatory Studies, 2002); M Mello et al., 'Fostering Rational Regulation of Patient Safety' (2005) 30(3) *Journal of Health Politics, Policy and Law* 375- 426.

⁶⁷ P Sullivan, 'Resident training: How many hours is too many?' (Canadian Medical Association, 8 May 2012) <<http://www.cma.ca/resident-training-hours-too-many>> accessed: 12 November 2012. As Sullivan notes, "The duty-hours issue reached the floor of General Council during the CMA's 2011 annual meeting, when delegates passed a resolution supporting better management of duty hours not only to ensure patients and provider safety but also to "promote an optimal learning experience" for residents."

⁶⁸ Canadian Association of Interns & Residents, 'Canadian Patient and Physician Safety and Wellbeing: Resident Duty Hours' Position Paper on Resident Duty Hours (Ottawa: April 2012) 2.

established in the province of Québec. To date, however, it remains to the individual unions within the provinces and territories to oversee and negotiate resident duty hours.

8.4 The European Working Time Directive

In the context of resident duty hours, a once promising example of the legislative process preemptively intervening to improve workplace and patient safety can be seen in the European Working Time Directive.

As compared to the aforementioned jurisdictions, the European Union first addressed the issue of maximum working hours nearly twenty-five years ago. In 1993, the European Working Time Directive was the first Directive passed by the European Union that sought to reform occupational health and safety laws. While the Health Sector was included within the Directive, it was not the sole focus of reforms and did not expressly address the maximum hours per week medical and surgical residents could be required to work.⁶⁹ Consequently, in 2000, the EU amended the Working Time Directive to include groups which had previously been excluded from the Directive in 1993. European Council Directive 2000/34/EC added to the original Directive 'Doctors in Training,' requiring a transitional limitation period for duty hours of fifty-eight hours per week beginning in 2004, and ultimately reducing to a maximum of forty-eight hours by the end of the transitional period in 2009.⁷⁰ In 2003, both the 1993 and 2000 Directives were consolidated by European Council Directive 2003/88/EC.⁷¹

⁶⁹ F McDonald, 'Working to Death: The Regulation of Working Hours in Health Care' (2008) 30(1) Law & Policy 108-140; citing: European Council Directive 93/104/EC of 23 November 1993 concerning certain aspects of the organization of working time. [1993] OJ L307/18.

⁷⁰ European Council Directive 2000/34/EC of 22 June 2000 amending European Council Directive 93/104/EC concerning certain aspects of the organization of working time to cover sectors and activities excluded from that Directive. [2000] OJ L195/41, Article 6.

⁷¹ European Council Directive 2003/88/EC of the European Parliament and of the Council of 4 November 2003 concerning certain aspects of the organisation of working time. [2003] OJ L 2003/299.

While the Directive has been a positive step towards reducing excessive working hours, limitations exist. For example, a recent decision of the European Court of Justice ruled that the ‘protected training time’ for non-consultant hospital doctors (NCHD, a.k.a. residents) in Ireland was not included within the forty-eight hour limit set out in the Directive.⁷² The unsuccessful argument before the court was that, “the training activities of NCHD are an integral part of their employment in that they must carry out those activities under the terms of their employment contracts.”⁷³ In other words, by not combining training hours with time spent treating patients, neither the maximum working time periods, nor the minimum rest periods dictated by the Directive were being followed.

The court strongly distinguished the time spent working under contract with the NCHD’s employer (the Health Service Executive) from the training obligations set out by the NCHD’s training organisations (bodies not connected directly with the state.) Despite opposition from commentators and members of the medical community, this decision definitively established the parameters of the definition of ‘working time’ as not including the training hours of NCHD when required by a separate body to the employer.

Culliton has argued that by not including training hours, the limited definition does not reflect the original intention of the act: the protection of workers, and in a medical

⁷² Case C-87/14 *European Commission v Ireland* [2015] ECLI:EU:C:2015:449. The 1993 and 2000 European Council Directive was implemented in Ireland via the European Communities (Organisation of Working Time) (Activities of Doctors in Training) Regulations 2004, S.I. No. 494/2004, as amended by the 2010 Regulation, S.I. No. 533/2010.

⁷³ Case C-87/14 *European Commission v Ireland* [2015] ECLI:EU:C:2015:449. [24].

context, the protection of patients.⁷⁴ This is particularly problematic given that Ireland, on the face of it, appears to be complying with the 48 hour limit, but only when training hours are excluded.⁷⁵ Owing to this limitation in the legislation, it would now fall to the Irish government to independently enact legislation that expressly combines working hours with training hours for the purpose of enforcement—a highly unlikely scenario given it was the Irish government who successfully defended the current position at the ECJ. Alternatively, the union representing NCHDs, the Irish Medical Organisation, could attempt a renegotiation of NCHD contracts. However, this too would arguably be in vain given the express ruling by the court, and their consequently weakened bargaining position.

8.5 Impact of the Duty Hour Restrictions

The Libby Zion case in New York State, and the contractual dispute in Québec, provide useful examples of the judicial system intervening to reform unsafe work practices. The same could be said of the legislative process intervening by way of the European Working Time Directive, however, the recent ECJ decision arguably limited its effectiveness with respect to enforcing safe limits on NCHD hours. Where specific legislation has not been enacted at the state or federal level, or (as is the case with resident duty hours) the specific safety issue falls outside of existing health and safety legislation, litigation by way of vicarious liability may be the last option available to force healthcare organisations to alter their practices. Vicarious liability ultimately holds the organisation accountable for the tortious acts or omissions of their employees (including to an extent, independent contractors.) In some instances, as with the Zion

⁷⁴ G Culliton, 'HSE: EWTD Obligations "Unaffected"' Irish Medical Times (Dublin, 17 July 2015) <<http://www.imt.ie/news/2015/07/hse-ewtd-obligations-unaffected.html>>; Case C-87/14 *European Commission v Ireland* [2015] ECLI:EU:C:2015:192, Opinion of the Advocate General. For commentary regarding Irish NCHD working hours prior to the European Court of Justice's decision, see further: S Lynch, 'State facing fines up to €100m after finding on doctors hours' Irish Times (Dublin, 19 March 2015) <<http://www.irishtimes.com/news/health/state-facing-fines-up-to-100m-after-finding-on-doctors-hours-1.2145306>>.

⁷⁵ G Culliton, 'HSE: EWTD Obligations "Unaffected"' Irish Medical Times (Dublin, 17 July 2015) <<http://www.imt.ie/news/2015/07/hse-ewtd-obligations-unaffected.html>>.

case, these acts and omissions are the result of systemic defeats that were influential in the tort occurring (i.e. over scheduling of residents causing excess fatigue, poor communication within the hierarchy structure, etc.) While beneficial in theory, there are a number of disadvantages to using vicarious liability (and litigation for that matter) as a tool to promote safety. First, litigation by its very nature is retrospective. Indeed, litigation was only initiated in the Zion case after the negligent act had occurred. Second, a court cannot force a healthcare organisation or the legislature to institute specific quality and safety policies. Civil courts are, primarily, restricted to compensating the claimant by holding the defendants financially liable. This is due to the constitutional limitations within the separation of powers doctrine which restrict the court's ability to force policy change when it does not conflict with existing legislation. Indeed, it was only owing to the contractual nature of the dispute, and a liberal interpretation of the Canadian/ Québec Charters, that the arbitration case of *McGill University Health Centre v Association des Résidents de McGill* lead to policy change in Québec.⁷⁶ While healthcare organisations, accreditation and regulatory bodies are all capable of implementing policy change, the example of resident duty hours clearly demonstrates how competing interests can limit the extent such bodies may be willing to do so, unless (again) required via legislation that expressly limits such practices.

Much of the current debate surrounding resident duty hours has focused on the scheduled hours of continuous duty that have become customary and culturally acceptable within healthcare. The current regulations in the United States were introduced out of concern for patient safety, in contrast to Canada and the European Union who reduced duty hours out of concern for worker safety. Notwithstanding these theoretical differences, the result has largely been the same: resident duty hours (including training time) within these jurisdictions continue to average twenty-four

⁷⁶ *McGill University Health Centre v Association des Résidents de McGill* (Arbitration Board, Québec, Canada. 07 June 2011. Grievance No. 4-CUSM-0809-01).

continuous hours, to a maximum of eighty per week. Certainly the arbitration ruling from Québec is an exception to be aspired to, however the judgement stemmed from a specific contractual dispute between the two parties within that specific province. All other Canadian provinces, as well as the United States and Europe, remain regulated by federal/state laws, contractual terms, and accreditation policies that are clearly inconsistent with the literature set out earlier in this chapter regarding the dangers of fatigue.⁷⁷

Despite the acknowledgement that working while fatigued can result in a higher number of medical errors, it is interesting then the primary arguments against further reducing duty hours have focused primarily on the welfare of patients. In this regard, regulators have argued that a further reduction in duty hours will increase the number of handovers between residents, thereby disrupting continuity of care and creating a risk to patient safety. As the IOM have stated, “Although fewer duty hours or appropriately placed rest periods may help to reduce fatigue in residents, they raise serious concerns for continuity of care.”⁷⁸ In reference to the introduction of the 2003 ACGME Standards, and the increased frequency of handovers, Riebschleger and Philibert point out, “A consequence of the regulation of duty hours is that the responsibility for each patient may be transferred between 2 or more physicians 2 to 3

⁷⁷ R Friedman et al., ‘The Intern and Sleep Loss’ (1971) 285(4) NEJM 201–203. Finding that residents made twice as many errors reading a standardized electrocardiogram after being awake for twenty-four hours as compared with their rested colleagues.; C Landrigan et al., ‘Effect of Reducing Interns’ Work Hours on Serious Medical Errors in Intensive Care Units’ (2004) 351(18) NEJM 1838. Finding that Interns working twenty-four hours or more were found to have made 35.9% more serious medical errors as well as 20.8% more serious medication errors than those working less than twenty-four hours.

⁷⁸ Institute of Medicine (Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety), *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*. C Ulmer et al. (eds), (Washington, DC: National Academies Press, 2008) 268; citing: L Horowitz et al., ‘Development and Implementation of an Oral Sign-Out Skills Curriculum’ [2007] 22(10) *Journal of General Internal Medicine* 1470-1474; A Vidyarthi et al., ‘Managing Discontinuity in Academic Medical Centers: Strategies for a Safe and Effective Resident Sign-Out’ [2006] 1(4) *Journal of Hospital Medicine* 257-266.

times during a 24-hour period.”⁷⁹ Similar concern was seen following the enactment of legislation in New York State in 1989. As Bloch argued, “These scheduling changes, intended to enhance the quality of patient care, in fact distance the intern from the patient. ... Clichés like ‘continuity of care’ gain real meaning here.”⁸⁰ The concern over continuity of care is certainly legitimate given the consequences of communication failures in the process of patient handovers. This was highlighted by the Joint Commission on the Accreditation of Healthcare Organizations who, in 2005, conducted an evaluation reviewing more than 3000 root-causes of previously reported error data. It was determined that communication failures resulted in seventy percent of sentinel events in accredited healthcare facilities with at least half of the communication failures occurring during patient handovers.⁸¹ As it applies to duty hour restrictions and fatigue, in a study by Volpp et al. sought to determine if the restrictions on duty hours introduced in the 2003 ACGME Standards were associated with changes in mortality within Veteran Affairs Hospitals.⁸² The authors found that while a significant improvement in mortality was seen across medical patients, surgical patient mortality was unaffected. One reason suggested for the variation was potential differences between medical and surgical residents in mechanisms for handovers and continuity of care.⁸³ This study suggests that the consequences of fatigue may outweigh the

⁷⁹ M Riebschleger and I Philibert, ‘Chapter 9: New Standards for Transitions of Care: Discussion and Justification’ in I Philibert et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME, 2011) 57.

⁸⁰ A Bloch, ‘The Post-Bell Commission Residency: Sleep vs. Care’ [1989] 261 JAMA 3243, 3243-3244; as taken from: C Lee, ‘Federal Regulation of Hospital Resident Work Hours: Enforcement With Real Teeth’ (2006) 9(1) *Journal of Health Care Law & Policy* 162, 184-185.

⁸¹ Institute of Medicine (Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety), *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*. C Ulmer et al. (eds), (Washington, DC: National Academies Press, 2008) 267; citing: Joint Commission International Center for Patient Safety, *Improving Hand-Off Communications: Meeting National Patient Safety Goal 2E*. [2006] 6 *Patient Safety* 9-15.

⁸² K Volpp et al., ‘Mortality Among Patients in VA hospitals in the First 2 Years Following ACGME Resident Duty Hour Reform’ (2007) 298(9) JAMA 984, 984.

⁸³ *ibid* 990-991.

consequences to continuity of care, particularly when procedures can be implemented to improve handover communication.

Closely connected to the concern over continuity of care is the very legitimate and practical argument that the healthcare system cannot accommodate a reduction in resident duty hours in light of the widespread international shortage of physicians.⁸⁴ In this situation, it is understandable (although still unacceptable from a safety perspective) that healthcare organisations and governments would continue to allow residents to work hours that would be prohibited in other professions. While it would be ideal for legislation to be enacted that restricts the total number of working hours (including protected training time) to those considered optimal for safety, it is also naïve. Therefore, rather than forcing physicians to work harder and longer, new solutions will have to be found. Referring back to Philibert's observations on the effect of the 2003 and 2011 ACGME standards, healthcare organisations have compensated for the reduction in resident hours by substituting the work previously done by residents with mid-level practitioners or hospitalists, and increasing faculty clinical workload.⁸⁵ While this raises its own questions about fatigue in mid-level practitioners and hospitalists, the primary concern is there are simply not enough physicians to care for the number of patients using healthcare services. Although the widespread problem of physician shortages is outside the scope of this thesis, it is worth noting that in a study by Freed et al. considering the reduction in pediatric resident duty hours, the authors concluded that, "Changes in work hours for pediatric residents appear to have an impact on workforce planning within pediatric hospitals. Decreases in available resident work hours will create an increasing demand, primarily for nonresident physicians,

⁸⁴ F McDonald, 'Working to Death: The Regulation of Working Hours in Health Care' (2008) 30(1) Law & Policy 108, 135.

⁸⁵ I Philibert et al., 'The 2003 Common Standards and Their Effect' in I Philibert et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME, 2011) 17.

[Pediatric Nurse Practitioners] PNPs, and [Neonatal Nurse Practitioners] NNPs.”⁸⁶ Therefore, one suggestion for overcoming the issue of increased workload resulting from the reduction of resident duty hours may be for governments and healthcare organisations to increase the number of Nurse Practitioners employed within units that rely heavily on medical and surgical residents. In a similar vain, greater integration of hospital pharmacists to reduce some of the physician workload may be of benefit.⁸⁷ Lastly, it nearly goes without saying that significant investment in local medical education enrolment and international recruitment is required, although also a challenge given the limited resources that generally exist for healthcare. Further research should explore alternate strategies for dealing with this very serious dilemma.

While concern about continuity of care is certainly legitimate, the main question is: is it a greater risk to patient care than the potential consequences of resident fatigue? As was examined in the previous chapter, a number of intervention strategies have been designed to improve handover communication and thereby improve continuity of care.⁸⁸ For example, the use of electronic sign-out systems has been advocated as a means of providing “structured, easy-to-access databases of patient information and creating formatted checklists of tasks that need to be considered for patient treatment.”⁸⁹ The consequences of fatigue, however, are more difficult to intervene on and prevent. In this regard, Whalen and Walsh have argued:

⁸⁶ G Freed et al., ‘Resident Work Hour Changes in Children’s Hospitals: Impact on Staffing Patterns and Workforce Needs’ (2012) 130(4) *Pediatrics* 700-704.

⁸⁷ American Hospital Association et al., *Pathways for Medication Safety: Looking Collectively at Risk* (Chicago: Health Research and Educational Trust, 2002) [2.3.5].

⁸⁸ See further: Chapter 7.2.2 ‘Interventions Around the Caregiver’ regarding intervention strategies to improve handover procedures and continuity of care.

⁸⁹ Institute of Medicine (Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety), *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*. C Ulmer et al. (eds), (Washington, DC: National Academies Press, 2008) 272.

“Standards and regulations to promote patient safety and resident alertness for the learning process traditionally have focused on the number of hours worked. ... However, focusing predominantly on duty hours neglects much of the science about sleep and performance that may influence multiple human factors. The concept of ‘fatigue’ extends beyond sleep status and views other factors. This concept recognizes that the performance effect of sleep loss on performance is more complex than a linear association with hours without sleep and is influenced by the time of day and its effect on circadian rhythm, as well as the length and complexity of the test or task, and whether it is self-paced or performed at a pace that is externally dictated.”⁹⁰

Whalen and Walsh’s comments are particularly instructive for understanding why—from both a patient safety and worker safety perspective—a further reduction to resident work hours is necessary, inclusive of adequate rest periods and time spent in training.

Referring back to the case of Libby Zion, to conclude that ‘but for’ the negligent actions of the three residents to coadminister Meperidine and Phenezine, her death would not have occurred—is factual but incomplete. Indeed, the direct cause of her death was the coadministration of Meperidine and Phenezine.⁹¹ However, it was the latent factors that allowed the incident to occur that are most instructive for prevention.⁹² Primary among these were a lack of supervision, limited communication between multiple caregivers, the prescribing of two incompatible drugs; coupled with time pressures,

⁹⁰ T Whalen and W Walsh, ‘Chapter 10: New Standards Addressing Fitness for Duty, Alertness Management, and Fatigue Mitigation’ in I Philibert et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME, 2011) 62.

⁹¹ E Boyer and M Shannon, ‘The Serotonin Syndrome’ (2005) 352(11) NEJM 1112.

⁹² *ibid.*

large patient loads and ultimately, fatigue. Indeed this is the exact situation envisioned by the philosophy 'To Err is Human' and the report that bears its name. Since Zion's death in 1984, current technology such as Computerized Physician Order Entry Systems and the incorporation of pharmacists at the unit level are now used to intervene on polypharmacy related incidents. In addition, increasing supervision requirements, team communication training, and reduced patient loads have all become standard methods by which to improve safety. But to understand the impact of fatigue on human error first requires the recognition that human cognitive performance has limitations.⁹³ Fatigue—being both a symptom and a cause of latent and active failure—only adds to those already inherent limitations. Instead of relying solely on intervention techniques to reduce fatigue related error, it is equally necessary to reduce the conditions that cause fatigue, beginning with legislating for the reduction of excessive resident duty hours.

8.6 Conclusion

The case studies within this chapter illustrate the extraordinary challenges of cultural change within healthcare. Following the events that took place on the 4th March 1984, the initial response of the Zion family and the State was to bring malpractice proceedings and file criminal charges, respectively. This was then followed by the Bell Commission's recommendations, the amendment of the New York Health Code⁹⁴ and ultimately, the adoption of Health Care Reform Act of 2000. Despite recognition that excessive duty hours were a danger to the safety of patients, and the great lengths taken in New York, it was not until 2003 that resident duty hours were regulated at a national level within the United States. Alternatively, the European Working Time Directive was certainly a progressive step forward, but failed to anticipate the cultural idiosyncrasies inherent within the training of physicians. Lastly, in Canada, it was only

⁹³ A Merry and A McCall-Smith, *Errors, Medicine and the Law* (Cambridge: Cambridge University Press, 2001) 96.

⁹⁴ New York Codes, Rules and Regulations tit. 10, § 405.4(b)(6)(ii)(b).

the contractual nature of the dispute that lead to change—and only within the province of Québec.

Excessive resident duty hours continue to be a cultural norm, despite the evidence examined within this chapter that strongly suggests they are a danger to the safety of workers and patients. As it applies to fatigue, it could be argued that reducing the number of duty hours based on a risk to patient safety, in contrast to worker safety, is largely a distinction without a difference. Safe patient care, in principle, must take into account the health of those providing it. Notwithstanding, a barrier to reform has been the interpretation of the ethical duty owed to patients within differing jurisdictions. This has been insightfully contrasted by McDonald, who notes:

“One perspective considers that a professional’s obligations to patients can best be served if the professional is mindful of his or her physical limitations. The other perspective, common in the United States, appears to be that the patient’s interests are best served through continuity in care, no matter what physical or psychological burden this places on the health provider.”⁹⁵

McDonald’s comment clearly illustrates the dissension that can surround mechanisms for safety intervention. As Woodward notes, “Perhaps the greatest obstacle, even when proven interventions exist, is successful implementation. Barriers to implementation include costs, institutional resistance, nervousness about the consequences, and the swift development of workarounds.”⁹⁶ Indeed, all of the barriers Woodward lists have been persuasively argued in the United States, Canada, and Ireland in an effort to maintain the status quo.

⁹⁵ F McDonald, ‘Working to Death: The Regulation of Working Hours in Health Care’ (2008) 30(1) Law & Policy 108, 133.

⁹⁶ H Woodward et al., ‘What Have We Learned About Interventions to Reduce Medical Errors?’ (2010) 31 Annual Review of Public Health 479, 491.

The obstacles experienced within these jurisdictions illustrate the importance of judicial intervention, and the availability of sanctions as a tool in the safety process. Certainly one could argue that a failure to enforce health and safety standards can be remedied by way of damages, fines, or the loss of accreditation. The problem in the case of resident duty hours, however, has less to do with deterrents and sanctions, and more to do with the prevailing cultural norms that allow these practices to continue. Fines and a loss of accreditation are available sanctions, but only when the number of hours exceeds the current limits. With the exception of Québec, duty hours within these jurisdictions remain at a level inconsistent with worker and patient safety, notwithstanding contractual or regulatory compliance.

The need for collaborative regulation amongst the medical community, legislature, and external regulators is clear. However, short of pressure from the public and a significant cultural change amongst the medical community and stakeholders, it is difficult to see how change will be possible without significant legislative intervention that recognises fatigue as systemic. Chapters 10-12 of this thesis will extend analysis of the challenges of cultural change in the context of healthcare communication, and examine in greater depth contemporary methods in which legislation can be used to evoke change.

- Chapter 9 -

Incident Reporting and Analysis

9.1 Introduction

Building on the previous chapters that identified latent and active factors that contribute to unsafe conditions and weakened system barriers; this chapter will critically analyse the role of incident reporting systems and analysis in both response to error, and their role in prevention. In their seminal publication *To Err is Human*, the Institute of Medicine strongly called for the implementation of mandatory and voluntary incident reporting systems as part of comprehensive strategy in the promotion of patient safety.¹ Although challenges persist, the effective operation of incident reporting systems and epidemiological analysis is fundamental to reducing medical error within the healthcare system.

The primary purpose of both mandatory and voluntary incident reporting is to discover underlying system defeats and—through analysis—prevent their reoccurrence.² In addition, mandatory reporting systems seek to hold healthcare organisations and professionals accountable to the public for the care they provide. Balancing accountability with organisational learning is key to achieving a just culture, and ultimately safety and quality improvement. Accountability systems are necessary to ensure serious incidents are investigated and accountability is appropriately, and justly, directed. However, mandatory accountability systems can also impose barriers to incident reporting such a fear of liability or punishment. Learning systems, alternatively, support reporting by ensuring confidentiality, but their voluntary nature

¹ Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System*. L Kohn, J Corrigan and M Donaldson (eds), (Washington: National Academy Press, 1999).

² WHO World Alliance for Patient Safety, *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems: From Information to Action* (Geneva: World Health Organization, 2005) WHO/EIP/SPO/QPS/05.3. p28.

may result in an underrepresentation of the true number of incidents occurring within the healthcare organisation.³

This chapter will begin by analysing the key elements of incident reporting system, namely: the role and purpose of incident reporting in healthcare, the difference between mandatory and voluntary reporting systems, and the necessity of confidentiality. In addition, examples of incident reporting systems from the United States, England, and Canada will be examined. The second section will critically argue that for incident reporting to be effective, detailed analysis of incident reports and feedback to those reporting is fundamental. The importance of a responsive reporting system has been identified by the WHO, who note, "... a reporting system must produce a visible, useful response by the receiver to justify the resources expended in reporting, or, for that matter, to stimulate individuals or institutions to report. The response system is more important than the reporting system."⁴ In examining incident analysis and feedback, the example of root-cause analysis will be outlined. Root-cause analysis seeks to identify the causation of patient safety incidents, and specifically, the latent and active failures that contribute to their occurrence. Lastly, the third section will identify and critically explore the primary barriers to incident reporting, including: organisational culture, time pressures, the administrative burden of reporting, and lack of adequate response and feedback from the organisation. Countermeasures to reduce barriers to incident reporting will also be suggested.

³ S Weingart, 'What Can Hospitalized Patients Tell Us About Adverse Events? Learning from Patient-Reported Incidents' (2005) 20 *Journal of General Internal Medicine* 830, 834; citing: D Bates, 'A 40-year-old Woman who Noticed a Medication Error' (2001) 285 *JAMA* 3134-3140; L Pizzi et al., 'Other Practices Related to Patient Participation' in K Shojania et al., (eds), *Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment* (No. 43. Rockville: US Agency for Healthcare Research and Quality, 2001) 575-578.

⁴ WHO World Alliance for Patient Safety, *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems: From Information to Action* (Geneva: World Health Organization, 2005) WHO/EIP/SPO/QPS/05.3. p12.

9.2 Key Elements of Incident Reporting Systems

The reporting of patient safety incidents is fundamental to the improvement of quality and safety in healthcare. In practice, the key elements of an individual incident reporting system will vary depending on its objective. Reportable incidents are generally categorised by severity of the incident, incident type, or a combination of both.⁵ For the most serious of incidents, mandatory reporting may be indicated as a means of ensuring accountability to the public. In the alternative, voluntary reporting systems provide the opportunity for organisational learning based on large scale reporting of patient safety incidents, including near-misses. It should be noted at the onset that while organisational learning is certainly a priority in a just culture, in the context of reporting systems, this is distinct from public accountability.⁶ Reported events are generally categorized by event, risk, or causation. This can include categorisation based on the type of error, patient outcome, the equipment involved, underlying human and system factors, or by the stage in the care process in which the incident occurred.⁷ For incident reporting systems to be effective, confidentiality and analysis are essential. From a patient safety perspective, the ultimate goal of both mandatory and voluntary reporting systems is to understand current risks to the safety of patients, their cause, contributory factors, and to disseminate the lessons learned as widely as possible to prevent reoccurrence.

⁵ European Commission Patient Safety and Quality of Care Working Group, *Key Findings and Recommendations on Reporting and Learning Systems for Patient Safety Incidents Across Europe* (Denmark: European Commission, May 2014) 24.

⁶ See further: Chapter 4.3 'A Just Culture' regarding reciprocal accountability.

⁷ WHO World Alliance for Patient Safety, *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems: From Information to Action* (Geneva: World Health Organization, 2005) WHO/EIP/SPO/QPS/05.3. p23.

Mandatory and Voluntary Reporting Systems

Events that require mandatory disclosure can range from the unanticipated death of patient, a wrong-site surgery, serious medication errors, or where gross negligence or professional misconduct have taken place and lead to patient harm.⁸ Mandatory reporting systems are generally enacted in accordance with legislation or accreditation requirements, and are indicated for the most serious of incident (i.e. those involving serious disability or death.)⁹ Mandatory reporting is intended to hold healthcare professionals and organisations accountable to the public for the care they provide by requiring the disclosure of serious incidents to specific regulatory bodies capable of investigating further, releasing the appropriate amount of confidential information to the public, and comparing statistics gathered from various institutions.¹⁰ Additionally, mandatory reporting holds organisations accountable to best practice standards for the investigation and correction of root causes.

Where the care provided is particularly concerning or unsafe, disciplinary procedures including legal or regulatory censure may be merited in an attempt to improve performance or conditions.¹¹ It is important to note at the onset that reporting for the purposes of safety improvement is separate and distinct from the discipline process. While a quality investigation may alert the appropriate bodies to the need for disciplinary proceedings, the information collected in a quality investigation can not be used for disciplinary purposes. One incident may give rise to separate investigations

⁸ J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 127.

⁹ Z Robinson Wolf and R Hughes, 'Error Reporting and Disclosure' in R Hughes (ed), *Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Volume 2* (Rockville: Agency for Healthcare Research and Quality, 2008) 337.

¹⁰ J Sandars, 'The Theory and Evidence Base for Clinical Risk Management' in K Haynes and M Thomas (eds), *Clinical Risk Management in Primary Care* (Oxon: Radcliffe, 2005) 53.

¹¹ See further: Chapter 4.4.2 'Organisational and Professional Regulation'; WHO World Alliance for Patient Safety, *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems: From Information to Action* (Geneva: World Health Organization, 2005) WHO/EIP/SPO/QPS/05.3. p15.

and separate avenues for attaching privilege. Legislation (discussed below) must clearly outline these separate purposes and avenues.

In contrast, voluntary reporting systems operate at both a national and local level; focusing primarily on learning, transparency, and identifying system defects that lead to patient safety incidents. This occurs through both the wide-scale screening of multiple reports, and the in-depth analysis of individual incident reports. Voluntary reporting systems ultimately seek to prevent reoccurrence and improve the culture within the healthcare organisation. As described by Morath and Turnbull, “The implementation of a voluntary blameless reporting system is a deep cultural intervention in an organization that legitimizes transparency of system vulnerability, nurtures an ‘alert field,’ and empowers front-line providers to expose risks. In turn, the front line learns to expect responses from managers at the blunt end to support the work of improvement.”¹² This statement is significant because it highlights two essential components of a voluntary reporting system: that the system be ‘blameless’ and be responsive. For this to be accomplished, the confidentiality of the reporter must be ensured and the risk of punitive action removed. Both the requirement of confidentiality and non-punitive reporting, as well as the necessity of ‘responsiveness’ will be analysed in greater detail below.

A question that often arises with respects to voluntary and mandatory reporting is: what type of incident merits mandatory reporting? In a perfect system, for the purposes of quality and safety improvement, all incidents (including near-misses) would be reported to a non-punitive reporting system, analysed in detail, with lessons gathered to improve systemic flaws and translated into legislation and guidelines to prevent similar incidents from ever occurring again. However, the reality of healthcare makes such a situation entirely impractical, owing to the extraordinary time and financial pressure healthcare organisations and professionals are under. Furthermore,

¹² *ibid* 123.

on a practical note, Berwick has been critical of the overuse of mandatory measurement, arguing that mandatory measurement should be reduced to only what matters (arguably subjective) but most important, mainly that required for learning. This, he suggests, would reduce the “enormous amount of time wasted now on generating and responding to reports that help no one at all.”¹³

This concern was similarly noted by the National Patient Safety Foundation, cautioning against the over-collection of data:

“Measurement is foundational to advancing improvement. It helps clarify goals, establish a shared sense of purpose, and confirm that organizations are heading in the right direction over time. However, measurement also carries the potential for unintended negative effects. Inaccurate measurement obscures the true state of affairs, leading either to ill-advised complacency or efforts disproportionately targeted on minor problems. The quantity of measures now required by different regulatory bodies can distract attention from important goals, and the task of collecting and analyzing data is overwhelming.”¹⁴

For this reason, and based on current best practices, mandatory reporting is (and indeed should be) limited to the most serious of incidents. For example, those defined as sentinel within the framework of the JCAHO sentinel event policy.¹⁵ This is in no way to suggest that individuals and organisations should not be held accountable for

¹³ D Berwick, ‘Era 3 for Medicine and Health Care’ JAMA (03 March 2016) [e-pub ahead of print].

¹⁴ National Patient Safety Foundation, *Free from Harm: Accelerating Patient Safety Improvement Fifteen Years after To Err Is Human*. (Boston: National Patient Safety Foundation, 2015) 18.

¹⁵ A sentinel event is defined by the Joint Commission as: “... a Patient Safety Event (not primarily related to the natural course of the patient’s illness or underlying condition), that reaches a patient and results in any of the following: Death, Permanent harm or Severe temporary harm and intervention required to sustain life.” Joint Commission, ‘Sentinel Event Policy and Procedure’ <http://www.jointcommission.org/Sentinel_Event_Policy_and_Procedures/> accessed: 18 February 2015.

incidents that fall outside of this limited range of the most serious incidents, nor that these incidents should not be voluntarily reported (including near-misses). As examined above, accountability and safety improvement in the context of incident reporting are mutually exclusive, the latter being confidential and solely for the purpose of system improvement and audit. Rather, in my opinion, it would be unreasonable and disadvantageous to place further onerous burdens (ie. mandatory reporting of all incidents) on healthcare professionals during a time of significant staff shortages and financial restraints. A useful example of this is the excessive duty hours required to be worked by medical residents, analysed in the previous chapter. Indeed, one of the primary arguments for requiring medical residents to work excessive duty hours is based on the limited number of physicians, as well as the challenges of providing continuity of care. By adding to already time-consuming obligations for paperwork, physicians inevitably have less time for patient care. As Berwick noted above, it would be difficult and disadvantageous to process the volume of data that would be provided if all incidents (including near-misses) were mandatorily required.

Accordingly, the voluntary reporting of minor incidents (falling below the threshold of sentinel events) and near-misses should be both encouraged and incentivised. Although not customary, possible incentives may include the use of financial incentives for voluntarily submitted reports, or by linking reporting and recommendations made to continuing professional development requirements.

An interesting question arises from the above, namely: whether mandatory or voluntary systems of error reporting and disclosure are more effective (and acceptable to the public)? This, again, comes back to the persistent problem of limited staffing resources for both the completion of incident reports and the analysis of the root causes and wide-scale trending. In an ideal system, all incidents would be subject to the transparency that a mandatorily reported (sentinel) incident attracts—but this is neither practical nor realistic. When a healthcare professional feels psychologically safe to

report an incident and reporting becomes a cultural norm and expectation, this ideally leads to an overall high level of participation in the voluntary system, and trending opportunities. Again, with the exception of significant incidents requiring extensive analysis, the value of reporting lies in its ability to show trends which can then be analysed and proactively responded to on a large scale with the appropriate interventions. Whether this is acceptable to the public or not is debatable, but it does satisfy the first step in what I would argue is one of the principle obligations of an organisation: to demonstrate accountability in the correction of systemic error.

Confidential and Non-Punitive Reporting

In the document *Draft Guidelines for Adverse Event Reporting and Learning Systems*, the World Health Organization stated,

“The most important characteristic for success of a patient safety reporting system is that it must be non-punitive. Neither reporters nor others involved in the incidents can be punished as a result of reporting. For public systems, this requirement is the most difficult to achieve, since the public often assumes an individual is to blame, and there can be strong pressure to punish the ‘culprit’. While perhaps temporarily emotionally satisfying, this approach is doomed to fail. People will not report any errors they can hide. It is important for national systems to protect reporters from blame. The best way to do this is by keeping the reports confidential.”¹⁶

This quote emphasises two fundamental concepts: that the reporting system be non-punitive and that the reports received remain confidential. Similar to the disclosure of error to patients; the fear of disciplinary proceedings, embarrassment, and potential litigation can prevent effective incident reporting. As Paterick et al. note in reference to

¹⁶ WHO World Alliance for Patient Safety, *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems: From Information to Action* (Geneva: World Health Organization, 2005) WHO/EIP/SPO/QPS/05.3. p50.

the United States, “As long as physicians perceive that they are at risk for sanctions, malpractice claims, and unpredictable compensation of injured patients as determined by the United States’ tort law system, legislative or regulative reform is unlikely to affect the underreporting of medical errors, and patient safety cannot benefit from the lessons derived from past medical errors and near misses.”¹⁷ Although the authors refer to the United States, the same is true within all jurisdictions that use tort law as a deterrent. One way in which the United States federal government has attempted to incentivise reporting is by enacting legislation that attaches privilege to ‘Patient Safety Work Product,’ in accordance with the Patient Safety and Quality Improvement Act 2005.¹⁸ As noted in chapter 3, the Act was a major milestone for the patient safety movement, and in the adoption and acceptance of incident reporting systems. The Act federally designated patient safety work product as privileged, and therefore inadmissible in civil, criminal, or administrative proceedings, or from disclosure under the Freedom of Information Act. Section 7 of the Act defines ‘Patient Safety Work Product’ as: “... any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements— (i) which—

(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

(II) are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or (ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.”¹⁹

¹⁷ Z Paterick et al., ‘The Challenges to Transparency in Reporting Medical Errors’ (2009) 5(4) *Journal of Patient Safety* 205.

¹⁸ Patient Safety and Quality Improvement Act 2005, SS 544, HR 3205, Public Law 109-41.

¹⁹ Patient Safety and Quality Improvement Act 2005, S 544, HR 3205, Public Law 109-41, section 7.

While the act is certainly a fundamental step forward, wide scale acceptance of reporting also requires cultural reform. In this respect, healthcare organisations must develop an "... atmosphere of trust in which openness and frankness in identifying and reporting problems, or potential problems, is encouraged and rewarded."²⁰ Ensuring a psychologically safe work environment, inclusive of just culture principles, can aid in reducing this barrier. In particular, the necessity of confidentiality was identified in a study by Derickson et al. who found, perhaps unsurprisingly, that physicians are significantly more likely to report preventable incidents when in a psychologically safe work environment in which the fear of punitive action is removed and feedback is welcomed.²¹ Education is also fundamental to achieving reporting goals. Those responsible for reporting must be equipped with a basic understanding of confidentiality and privilege. This includes an explanation on how that information will be used once collected and what is privileged and confidential. Supplying this information on a designated and standardised intake form is one small yet practical way in which to establish consistency and comfort in the reporting process. Educating staff to de-identify the information when possible upon entry into the database may also be beneficial, so as to provide for confidentiality but not anonymity, as further information may be required.²² It is important to emphasise that the requirement of confidentiality and privilege will not eliminate legal liability or regulatory scrutiny for the events which have taken place, merely that the report itself remains confidential within the organisation and cannot be produced as evidence should legal proceedings result from the event.²³

²⁰ National Steering Committee on Patient Safety (CA), *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care* (Ottawa: 2002) 15. <http://www.royalcollege.ca/portal/page/portal/rc/common/documents/advocacy/building_a_safer_system_e.pdf> accessed: 29 November 2014.

²¹ R Derickson et al., 'Psychological Safety and Error Reporting Within Veterans Health Administration Hospitals' (2015) 11(1) *Journal of Patient Safety* 60.

²² J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 134.

²³ J Sandars, 'The Theory and Evidence Base for Clinical Risk Management' in K Haynes and M Thomas (eds), *Clinical Risk Management in Primary Care* (Oxon: Radcliffe, 2005) 53.

From the perspective of the organisation, the confidential nature of the reports can present a dichotomy between accountability and learning. Ensuring accountability while supporting learning and quality improvement requires that separate investigations are conducted according to their purpose. Within the healthcare organisation, it is necessary to create an ‘information firewall’ between safety and quality improvement mechanisms and accountability mechanisms. This is highlighted by the Canadian Medical Protection Association, who state, “By separating the professional accountability process from the quality improvement process, health professionals will be more likely to provide a quality improvement committee their opinions, and in appropriate instances, hypothesize as to how certain processes could be changed to improve the system.”²⁴ The necessity of a firewall has also been cited by the European Commission’s Patient Safety and Quality of Care Working Group, who notes: “Reporting systems should be independent of any authority with the power to punish the reporter or organisation and having a stake in the outcome. Maintaining a ‘firewall’ between the reporting agency and the disciplinary agency in a governmental system can be difficult, but it is essential, if trust in reporting is to be maintained.”²⁵

Separately investigating reportable incidents is a way to accomplish this. At a local level, risk management systems are a fundamental component of the Clinical Governance structure and have the authority to investigate incidents on behalf of the organisation for the purposes of accountability.²⁶ While the material facts from a quality improvement investigation may be used within the risk management investigation, all observations and conclusions are strictly privileged for the purposes of quality improvement. In this respect, one of the most important roles of legislation is

²⁴ Canadian Medical Protective Association, *Reporting and Responding to Adverse Events: A Medical Liability Perspective* (Ottawa: Canadian Medical Protective Association, 2009) 5.

²⁵ European Commission Patient Safety and Quality of Care Working Group, *Key Findings and Recommendations on Reporting and Learning Systems for Patient Safety Incidents Across Europe* (Denmark: European Commission, May 2014) 15.

²⁶ See further: Chapter 4.4.2 ‘Organisational and Professional Regulation.’

in protecting privileged information and facilitating a firewall—both with respects to separate groups of investigation, and the legal protection separating the information where some overlaps may be inevitable. Following an investigation, mechanisms for holding individuals and organisations accountable such as licensing, accreditation, and legal liability can be utilised by the appropriate bodies, in accordance with the relevant legislation and regulatory requirements.²⁷ Essentially, quality and safety improvement requires separate investigation with the objective of understanding causation, and providing recommendations and guidelines for prevention.

For the purposes of both public accountability, and quality and safety improvement, some healthcare organisations and governmental bodies provide the results of individual investigations, or quarterly and annual reports. Engaging reporters and providing feedback is fundamental to the viability of a reporting system. For this reason, the WHO have cited the response system as being more important than the reporting system.²⁸ For example, the Joint Commission and the NHS (described below) publish data quarterly of voluntarily reported incidents.²⁹ In addition, both publish safety alerts, guidelines and recommendations based on the wide-scale occurrence of particular adverse incidents. Although rare, where the events have been particularly egregious, a more detailed report may be necessary as a means of demonstrating organisational accountability. Such as in the case of the ‘Bristol Inquiry’ in England, a thorough explanation of the events and circumstances that occurred, as well as

²⁷ For example, in England, serious incidents—particularly those involving the death of a patient—must be reported in accordance with the Health and Safety at Work Act 1974. See further: NHS Commissioning Board, *Serious Incident Framework* (March 2013) <www.england.nhs.uk/wp-content/uploads/2013/03/sif-guide.doc> accessed: 20 February 2015. See also: Chapter 4.4.2 ‘Organisational and Professional Regulation.’

²⁸ National Patient Safety Agency (UK), *Act on Reporting: Five Actions to Improve Patient Safety Reporting* (London: NHS Confederation, 2008)

²⁹ For example, see: Joint Commission, ‘Seminal Event Data’ (2014) <http://www.jointcommission.org/sentinel_event.aspx> accessed: 08 February 2015.

recommendations for prevention of future incidents, was published independent of governmental or local investigations.³⁰

Examples of Incident Reporting Systems

The importance of incident reporting has been emphasised on both an international and national scale. For example, building on the work of the World Health Organization,³¹ the Council of the European Union stated unequivocally in their 2009 European Council Recommendation on Patient Safety that: “Member States should set up, maintain or improve comprehensive reporting and learning systems so that the extent and causes of adverse events can be captured in order to develop efficient solutions and interventions.”³² Following on from the 2009 Recommendations, and based on practical experience in the development and operations of the existing reporting systems of the EU Member States (and Norway), the European Commission’s Patient Safety and Quality of Care Working Group published their 2014 report: *Key Findings and Recommendations on Reporting and Learning Systems for Patient Safety Incidents Across Europe*.³³ Amongst their many recommendations, the Working Group strongly encouraged Member States to, *inter alia*, incorporate mechanisms within their National or Local systems that allowed reporting by patients and families;³⁴ ensure reporting systems are blame-free, confidential, and contain a fire-wall between learning and censure processes;³⁵ that incident analysis be performed by

³⁰ I Kennedy, *Learning from Bristol: The Report of the Public Inquiry into Children’s Heart Surgery at the Bristol Royal Infirmary 1984–1995*. (London: The Stationery Office, 2001).

³¹ WHO World Alliance for Patient Safety, *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems: From Information to Action* (Geneva: World Health Organization, 2005) WHO/EIP/SPO/QPS/05.3.

³² European Council Recommendation on Patient Safety, *Including the Prevention and Control of Healthcare Associated Infections* [2009] (2009/C 151/01).

³³ European Commission Patient Safety and Quality of Care Working Group, *Key Findings and Recommendations on Reporting and Learning Systems for Patient Safety Incidents Across Europe* (Denmark: European Commission, May 2014).

³⁴ *ibid* 27-28.

³⁵ *ibid* 15, 28-30.

credible experts in a timely manner;³⁶ and the absolute necessity of ensuring feedback and evidence of change.³⁷ While the report did not discuss the analysis of incidents or how learning can best be achieved, it was useful in setting out the advantages and disadvantages of current reporting systems within the Member States, as well as providing recommendations for best-practices in the implementation of the 2009 Recommendations.

Both the Council in 2009 and Working Group in 2014 strongly recommended that patients be informed and empowered in the reporting process, and have available an accessible and comprehensible system for complaints and redress.³⁸ The incorporation of patients is welcome, owing to the unique and significant role patient feedback can have in the quality improvement process, as well as in the design and delivery of services. One unfortunate feature of the 2009 European Council Recommendations is that they do not have the power to mandate actions like a Directive from the European Union would. This is unfortunate because the lack of uniformity in reporting systems reduces their value for information sharing. While the majority of National Healthcare systems in the EU already have in place mechanisms for reporting serious events, from a patient safety / audit perspective, uniformity amongst all member states would be an invaluable opportunity. This, in some respects, is similar to the JCAHO sentinel event system in which organisations accredited by JCAHO are mandatorily required to report sentinel events (ie. wrong site surgery and medication errors.)³⁹ However, unlike JCAHO accredited institutions that are required to have similar regulatory structures and uniform reporting standards, a mandatory reporting system within the EU would

³⁶ *ibid* 44.

³⁷ *ibid* 30-32.

³⁸ European Council Recommendation on Patient Safety, *Including the Prevention and Control of Healthcare Associated Infections* [2009] (2009/C 151/01); European Commission Patient Safety and Quality of Care Working Group, *Key Findings and Recommendations on Reporting and Learning Systems for Patient Safety Incidents Across Europe* (Denmark: European Commission, May 2014).

³⁹ Joint Commission, 'Sentinel Event Policy and Procedure' <http://www.jointcommission.org/Sentinel_Event_Policy_and_Procedures/> accessed: 18 February 2015.

require an extraordinary system of information sharing and collaboration amongst countries with difference legislation (particularly in the area of privilege and disclosure), accreditation requirements, and even languages. Though undeniably desirable, such an endeavour would require significant political and financial investment which may prove too complicated and burdensome to achieve. Future research should examine overcoming such challenges.

It is now instructive to consider a selection of specific reporting systems based on jurisdiction and objective. In the United States, one example of a large scale voluntary non-governmental incident reporting system is the Joint Commission's Sentinel Event Reporting System. Although the system is voluntary, accredited healthcare institutions in the United States are strongly encouraged to report sentinel events to the Joint Commission, to the extent that their accreditation may be called into question where the sentinel event is not reported or there is a failure to implement safety based reforms. The information collected is investigated by the Joint Commission and the 'lessons learned' disseminated throughout all JCAHO accredited institutions to raise attention, offer recommendations, and produce national best practice guidelines.⁴⁰

In England, the National Reporting and Learning System (NRLS) was established in 2003 following the publication of *An Organisation with a Memory*.⁴¹ NHS Trusts are responsible for local reporting and governance; with overall responsibility for the system falling to NHS England.⁴² The NRLS is unique insofar as it provides for both

⁴⁰ A sentinel event is defined by the Joint Commission as: "... a Patient Safety Event (not primarily related to the natural course of the patient's illness or underlying condition), that reaches a patient and results in any of the following: Death, Permanent harm or Severe temporary harm and intervention required to sustain life." Joint Commission, 'Sentinel Event Policy and Procedure' <http://www.jointcommission.org/Sentinel_Event_Policy_and_Procedures/> accessed: 18 February 2015.

⁴¹ Department of Health (UK), *Building a Safer NHS for Patients: Implementing an Organisation with a Memory* (London: Department of Health, 2001).

⁴² The National Patient Safety Agency was responsible for the NRLS prior to its abolition in 2012, in accordance with section 281 of the Health and Social Care Act 2012.

voluntary and mandatory reporting depending on the severity of the incident. Patient safety incidents, including never-events,⁴³ can be voluntarily reported by healthcare staff via their organisation's local risk management system or the NRLS directly. Both patients and the public can also report patient safety incidents directly to the NRLS.⁴⁴ To maintain confidentiality, incident reports are anonymised upon entry into the system.⁴⁵ For serious incidents requiring further investigation, mandatory reporting by NHS Trusts has been required since the 01 April 2010. Serious incidents requiring notification include, *inter alia*, serious injury or death of patient, allegations of abuse or events which prevent the NHS or trust from running safely and properly.⁴⁶ Although the NRLS does not investigate individual reports, quarterly data reports are issued summarising the results of patient safety incidents reported and recommendations for prevention.⁴⁷

⁴³ The NHS routinely update their list of "Never Events," defined as incidents which are "unacceptable and eminently preventable." For each, guidelines are provided. See: Department of Health (UK), *The "Never Events" List 2012/2013* (London: Department of Health, 2012) <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215206/dh_132352.pdf> accessed: 19 February 2015.

⁴⁴ Patient Safety Incidents are defined within the NHS as, "any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS-funded healthcare." See: National Health Service, 'Report a Patient Safety Incident' <<http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/>> accessed: 22 February 2015.

⁴⁵ Anonymisation takes place both before submission to the NRLS by the individual healthcare organisation and upon receipt of the report. See: European Commission Patient Safety and Quality of Care Working Group, *Key Findings and Recommendations on Reporting and Learning Systems for Patient Safety Incidents Across Europe* (Denmark: European Commission, May 2014) 29. <http://ec.europa.eu/health/patient_safety/docs/guidelines_psqcwg_reporting_learning_systems_en.pdf> accessed: 19 February 2015.

⁴⁶ See further: Regulations 16-18 of the Care Quality Commission (Registration) Regulations 2009 in accordance with the Health and Social Care Act 2008. While notification by Trusts to the CQC is mandatory, reporting the incidents to the National Reporting and Learning System meets this requirement. See further: Care Quality Commission, 'Notifications Required by the Health and Social Care Act 2008: Guidance for English NHS providers' (July 2013) <http://www.cqc.org.uk/sites/default/files/documents/statutory_notifications_for_nhs_bodies_-_provider_guidance_v6.pdf> accessed: 20 February 2015; National Patient Safety Agency, 'National Framework for Reporting & Learning from Serious Incidents Requiring Investigation' <www.nrls.npsa.nhs.uk/patientsafetydirect> accessed: 20 February 2015.

⁴⁷ National Health Service, 'NRLS Quarterly Data Workbook' (22 October 2014) <<http://www.nrls.npsa.nhs.uk/resources/collections/quarterly-data-summaries/?entryid45=135304>> accessed: 08 February 2015.

Lastly, in addition to the collection of information by national and local reporting systems, international organisations have also played a key role in the collection and analysis of safety incidents. For example, the International Medication Safety Network was established based on the Salamanca Declaration in 2006.⁴⁸ From the 12 original participating countries that signed the declaration, the IMSN now works in collaboration with 27 countries and the World Health Organization. The IMSN have been influential in a number of areas based on medication incidents voluntarily reported directly by healthcare professionals to their reporting system, as well as incidents reported to the reporting systems within the participating countries. Specifically, the IMSN have published guidelines and created specific continuing education curriculums in the areas of Pharmacovigilance and Medication Errors, Safer Medicines Naming and Safer Packaging and Labelling.⁴⁹ One organisation that works in collaboration with the IMSN is the Canadian Medication Incident Reporting and Prevention System (CMIRPS) which offers healthcare professions the opportunity to voluntarily report a 'medication incident' involving a medication mistake or complication leading to a medication mistake.⁵⁰ A valuable component of the CMIRPS is the consumer-focused website SafeMedicationUse.ca which allows patients and the public to complete voluntary and confidential medication incident reports.⁵¹ As with the NHS National Reporting and Learning System, facilitating patient reporting is a valuable tool for quality and safety improvement because patients can provide useful insight into new symptoms or adverse consequences that may not be directly

⁴⁸ International Medication Safety Network, 'Salamanca Declaration to Promote Safe Medication Practices Globally' <http://www.intmedsafe.net/wp-content/uploads/2013/12/Salamanca_Declaration_INSMPC.pdf> accessed: 05 April 2016.

⁴⁹ International Medication Safety Network, <www.intmedsafe.net/> accessed: 04 April 2016.

⁵⁰ This is distinct from an adverse drug reaction which can be voluntarily submitted to the Canadian Vigilance Program by Healthcare Professionals and Patients. See: Health Canada, 'Canada Vigilance Program' <<http://www.hc-sc.gc.ca/dhp-mps/medeff/vigilance-eng.php>> accessed: 18 February 2015. For an analysis of incident reporting systems in Canada, see further: A Butt, 'Medical Error in Canada: Issues Related to Reporting of Medical Error and Methods to Increase Reporting' (2010) 7(1) *McMaster University Medical Journal* 15.

⁵¹ Health Canada, 'SafeMedicationUse.ca' <<http://www.safemedicationuse.ca>> accessed: 18 February 2014.

observed, tested in a clinical setting, or recorded in the patient's medical record.⁵²

Denham has emphasised the value of patient input, noting, "The hospital's deepest resource of care information is patients and their families; this is because these people have the ability to share core root cause information, from symptom to outcome, that can drive the quality and safety of care in hospitals."⁵³

The reporting systems described above all provide an accessible means by which healthcare organisations, professionals, and the public can bring attention to both latent and active failure contributing to unsafe care. Without analysis however, the data gained from reporting is unlikely to lead to systemic change or recommendations for prevention. For this reason, it is necessary to examine the process of incident analysis.

9.3 Incident Analysis

Healthcare organisations use numerous methods to gain information for quality and safety improvement. This can include, *inter alia*, medical chart review, surveillance, patient complaints, or malpractice claim analysis.⁵⁴ Although these forms of incident detection can be beneficial insofar as they provide an extensive source of data concerning events of varying severity, collection of each is highly labour intensive which limits the number of incidents that can be detected or investigated. Moreover,

⁵² J Etchegaray et al., 'Structuring Patient and Family Involvement in Medical Error Event Disclosure and Analysis' (2014) 33(1) *Health Affairs* 46; S Weingart, 'What Can Hospitalized Patients Tell Us About Adverse Events? Learning from Patient-Reported Incidents' (2005) 20 *Journal of General Internal Medicine* 830; Z Robinson Wolf and R Hughes, 'Error Reporting and Disclosure' in R Hughes (ed), *Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Volume 2* (Rockville: Agency for Healthcare Research and Quality, 2008) 336.

⁵³ C Denham et al., 'Are You Listening... Are You Really Listening?' (2008) 4(3) *Journal of Patient Safety* 148, 151.

⁵⁴ A Block, 'Disclosure of Adverse Outcomes and Apologizing to the Injured Patient' in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 288-289; WHO World Alliance for Patient Safety, *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems: From Information to Action* (Geneva: World Health Organization, 2005) WHO/EIP/SPO/QPS/05.3. p30-34.

these forms of incident detection can underestimate the extent of the problem due to varying standards of documentation, concern about liability, the exclusion of privileged communications, or a lack of oversight.⁵⁵ Alternatively, voluntary incident reporting submitted directly for the purposes of quality and safety improvement is a valuable means of gaining large amounts of data from various sources. Without analysis, however, the primary function of reporting—learning—can not be accomplished. For this reason, incident analysis is a fundamental component of an incident reporting system.

As described previously, investigation and incident analysis are separated based on their purpose. For the purposes of accountability and liability, local risk management systems are responsible for investigating serious incidents. At the same time, a safety and quality investigation should occur with the intention of detecting the ‘root cause’ of the adverse incident, identifying all factors relevant to its occurrence, and potential strategies for improvement and intervention going forward.⁵⁶

The most frequently used method of incident analysis is the epidemiological analysis model which includes root-cause analysis.⁵⁷ The World Health Organization have defined root-cause analysis as, “... the systematic analysis of all the factors which

⁵⁵ S Weingart, ‘What Can Hospitalized Patients Tell Us About Adverse Events? Learning from Patient-Reported Incidents’ (2005) 20 *Journal of General Internal Medicine* 830, 834; citing: D Bates, ‘A 40-year-old Woman Who Noticed a Medication Error’ (2001) 285 *JAMA* 3134-3140; L Pizzi et al., ‘Other Practices Related to Patient Participation’ in K Shojania et al., (eds), *Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment* (No. 43. Rockville: US Agency for Healthcare Research and Quality, 2001) 575-578.

⁵⁶ D Hetzler et al., ‘Conflict Management in Hospital Systems: Not Just For Leadership’ (2011) 5 *American Journal of Mediation* 65, 68.

⁵⁷ European Commission Patient Safety and Quality of Care Working Group, *Key Findings and Recommendations on Reporting and Learning Systems for Patient Safety Incidents Across Europe* (Denmark: European Commission, May 2014) 45-46. <http://ec.europa.eu/health/patient_safety/docs/guidelines_psqcwg_reporting_learningsystems_en.pdf> accessed: 19 February 2015.

predisposed to, or had the potential to prevent, an error.”⁵⁸ Root-cause analysis seeks to identify the sources of system error, and the behaviours that have contributed to the occurrence of a patient safety incident, including near-misses. At its core, root-cause analysis is a multidisciplinary process, chronologically linking together all information relevant to the event, including (but not limited to) interviews with the patient and clinicians involved, incident reports, internal/external reviews, and patient medical charts. Patients and caregivers may also be involved in the analysis process.⁵⁹ An investigation is then conducted and the information is broken down to identify the various factors leading to the occurrence of the adverse incident or near-miss. A useful example of this is the Joint Commission’s *Framework for Conducting a Root Cause Analysis and Action Plan*. Root-cause analysis questions are categorised based on relevant human and system factors: staffing levels, environmental, and external factors, as well as the organisation’s cultural practices.⁶⁰ Root-cause analysis aims to retrospectively identify systemic and human factors that can ultimately be integrated into a strategy for prevention.⁶¹

Preventing the reoccurrence of patient safety incidents is one of the primary objectives of the patient safety movement. Providing feedback from the collection and analysis of

⁵⁸ World Health Organization, *Patient Safety Workshop: Learning from Error* (Geneva: World Health Organization, 2008) WHO/IER/PSP/2008.09. p18.

⁵⁹ T Zimmerman and G Amori, ‘Including Patients in Root Cause and System Failure Analysis: Legal and Psychological Implications’ (2007) 27(2) *Journal of Healthcare Risk Management* 27. The authors argue that the involvement of patients, caregivers, and patient advocates in post-event analysis offers increased transparency and a greater role in safety improvement.

⁶⁰ Joint Commission, ‘Framework for Conducting a Root Cause Analysis and Action Plan’ (22 March 2013) <http://www.jointcommission.org/Framework_for_Conducting_a_Root_Cause_Analysis_and_Action_Plan/> accessed: 23 February 2015.

⁶¹ See generally: A Hettinger et al., ‘An Evidence-Based Toolkit for the Development of Effective and Sustainable Root Cause Analysis System Safety Solutions’ (2013) 33(2) *Journal of Healthcare Risk Management* 11; A Lee et al., ‘Using Root Cause Analysis to Reduce Falls with Injury in Community Settings’ (2012) 38(8) *Joint Commission Journal on Quality and Patient Safety* 366. The authors describe an interesting example of root-cause analysis within a long term care setting to identify risk factors and strategies for the prevention of fall rates.

reported incidents is key to furthering this objective. This was emphasised by the European Commission's Patient Safety and Quality of Care Working Group who suggest, "The most important function of a reporting system is to use the results of data analysis and investigations to improve healthcare directly and help healthcare professionals to do safer work."⁶² The importance of credible and timely feedback, based on expert evaluation, cannot be understated. One of the major barriers to incident reporting is the failure of organisations to conduct analysis, provide feedback, and implement changes leading to improvement. As Claridge and Sanders assert:

"Many incident reporting systems have faltered when it is apparent that the organization has not taken note of the comments and produced changes in the way that it performs. This requires the organization to have a willingness to learn from these incidents, no matter how trivial or at variance with its planned actions, and the changes have to be made demonstrable to the workers in the organization. It has to be seen that something has been done."⁶³

This is a significant barrier for at least two reasons. First, voluntary reporting systems rely on the contribution of healthcare professionals; when feedback is not received, reporters can become discouraged from reporting incidents without an visible benefit. Second, the valuable lessons used to prevent future similar incidents will be lost without proper analysis and feedback. Owing to the gravity of low levels of incident reporting, the next section of this chapter will critically analyse the primary barriers faced by healthcare professionals when reporting patient safety incidents.

⁶² European Commission Patient Safety and Quality of Care Working Group, *Key Findings and Recommendations on Reporting and Learning Systems for Patient Safety Incidents Across Europe* (Denmark: European Commission, May 2014) 11. <http://ec.europa.eu/health/patient_safety/docs/guidelines_psqcwg_reporting_learningsystems_en.pdf> accessed: 19 February 2015.

⁶³ T Claridge and J Sandars, 'Patient Safety Culture' in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 22.

9.4 Barriers to Incident Reporting

Despite efforts to make incident reporting systems efficient and confidential, a number of practical barriers continue to prevent healthcare professionals from reporting patient safety incidents and near-misses. As evidenced by an analysis of the literature, barriers to incident reporting can be categorised under two main headings: cultural barriers and administrative barriers.

Cultural Barriers to Incident Reporting

The culture of a healthcare organisation plays a significant role in the willingness of healthcare professionals to report the occurrence of a patient safety incident. Cultural barriers and concerns related to liability can severely undermine the success of an incident reporting system and reduce opportunities to learn. As Nobel and Pronovost have argued, when healthcare professionals fear reporting, an 'epidemiological bias' is created, insofar as only minor errors are reported at the expense of the analysis of more serious errors.⁶⁴ The occurrence of an adverse incident can invoke a wide range of reactions; regardless of whether error or negligence were involved, the severity of a potential finding of liability can contribute to feelings of denial, blame, or distancing oneself from the incident. Even when a healthcare professional accepts responsibility for the incident, the potential consequences, particularly when it involves error, can be more than enough to prevent reporting.⁶⁵

In a 2005 study based on physician interviews, Waring found that the predominant barrier to incident reporting was associated with a fear of blame and liability from the

⁶⁴ D Nobel and P Pronovost, 'Underreporting of Patient Safety Incidents Reduces Health Care's Ability to Quantify and Accurately Measure Harm Reduction' (2010) 6(4) *Journal of Patient Safety* 247.

⁶⁵ J Benbasset et al., 'Physicians' Attitudes Towards Litigation and Defensive Practice: Development of a Scale.' (2001) 27(2) *Behavioural Medicine* 52-61

public, press, and regulatory bodies.⁶⁶ This belief is reinforced by a failure on the part of the healthcare organisation to ensure confidentiality and support for those reporting.⁶⁷ As Robinson Wolf and Hughes have argued, “Health care leaders who do not protect reporters of errors from negative consequences reinforce this fear, as does the criminalisation of fatal health care mistakes. Fear of these negative consequences can lead to reporting errors only when a patient is harmed or when the error could not be ‘covered up’....”⁶⁸ The gravity of a finding of fault cannot be understated; legal and professional consequences can include liability in tort law, professional disciplinary action or in the extreme, criminal liability. Likewise, the psychological consequences of a finding of fault can range from shame and guilt, to damage to one’s professional reputation and self-esteem.⁶⁹ Unsurprisingly, Waring’s research specifically identified the practical effects of cultural barriers to incident reporting, noting that clinicians were inclined not to report adverse events where there was a concern that increased openness could lead to questions of competence or reprimand⁷⁰ or when error was normalised by the “perceived inevitability of error and its acceptance in medical

⁶⁶ J Waring, ‘Beyond Blame: Cultural Barriers to Medical Incident Reporting’ (2005) 60(9) *Social Science & Medicine* 1927, 1934. Noting, “All doctors involved in the research made reference to the “blame thing” or a “blame culture” when expressing their apprehensions about incident reporting. It was evident from the way doctors discussed blame that it was perceived to involve the unfair or inappropriate allocation of responsibility for poor performance or outcomes, and possibly the unwarranted recourse to reprisals and punishment.”

⁶⁷ J Weissman et al., ‘Error Reporting and Disclosure Systems: Views from Hospital Leaders’ (2005) 293 *JAMA* 1359. Noting that the perception exists amongst physicians and hospital leaders that mandatory, nonconfidential reporting encourages lawsuits.

⁶⁸ Z Robinson Wolf and R Hughes, ‘Error Reporting and Disclosure’ in R Hughes (ed), *Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Volume 2* (Rockville: Agency for Healthcare Research and Quality, 2008) 338; citing: M Kapp, ‘Medical Error versus Malpractice.’ (1997) 1 *DePaul Journal of Health Care Law* 750-72; R Hughes and E Ortiz, ‘Medication Errors: Why They Happen, and How They Can Be Prevented.’ (2005) 105(3) *American Journal of Nursing* 14-20; J Holbrook, ‘The Criminalization of Fatal Medical Mistakes.’ (2003) 327 *BMJ* 1118-1119; L Leape et al. ‘Systems Analysis of Adverse Drug Events. ADE Prevention Study Group.’ (1995) 274(1) *JAMA* 35-43.

⁶⁹ A Wu, ‘Medical Error: The Second Victim. The Doctor Who Makes the Mistake Needs Help Too.’ (2000) 320 *BMJ* 726.

⁷⁰ J Waring, ‘Beyond Blame: Cultural Barriers to Medical Incident Reporting’ (2005) 60(9) *Social Science & Medicine* 1927, 1934. Noting, “As such it is not just the fear of blame that inhibits medical reporting but also the desire to protect the symbolic façade of professional competence, and the identity and status of the physicians with the patient.”

culture.”⁷¹ The nature of retrospective analysis is not without its disadvantages. The potential for hindsight bias creates a legitimate barrier for those voluntarily reporting.⁷² From a patient safety perspective, the occupational barriers resulting from the culture of a healthcare organisation are equally significant to cultural factors related to liability. This is affirmed by Leape, who notes, “The worst punishments are often self-inflicted: shame and guilt. The expectation of perfect performance is deeply ingrained in doctors and nurses, beginning in schools and then with continual reinforcement in everyday practice. Shame results when we fail, which we inevitably do. Not surprisingly, physicians and nurses often will not admit errors - to themselves or others. They don’t report errors they can hide.”⁷³ This passage is instructive for the promotion of incident reporting, insofar as it emphasises the need to acknowledge and improve complex occupational factors, in addition to cultural factors related to a fear of liability and regulatory sanctions. A challenge that presents itself in this context is when the error arguably merits discipline. While information reported for the purposes of quality improvement is privileged, this only means the quality report cannot be used or shared for the purposes of discipline. In practice, a reported event will still alert the organisation to the occurrence of an incident. Depending on severity, the organisation may already be aware of the incident and investigating it, and be under mandate to report to the appropriate governing body. The patient also may be legally and ethically entitled to have disclosed to them the facts surrounding the event. In circumstances that are less serious and merit voluntary but not mandatorily reporting,

⁷¹ *ibid* 1932. Warring describes the “normalisation of error” as a situation in which, “... some common mistakes are regarded as routine and normal within the context of medical work, and in consequence these events are not perceived as problematic or worth reporting.” See further: Chapter 6 ‘The Nature of Medical Error.’

⁷² J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 121. Hindsight bias is defined by the authors as, “... the human tendency to assign blame to a human being as the cause when things do not work out for the patient.”

⁷³ L Leape, ‘Reporting of Medical Errors: Time for a Reality Check’ (2001) 179 *Western Journal of Medicine* 156-161; as taken from: T James, ‘Fault and Blame in the NHS: Review and Replacement of the Clinical Negligence System in the UK’ in J Tingle et al. (eds), *Regulating Healthcare Quality: Legal and Professional Issues* (Edinburgh; New York: Butterworth-Heinemann, 2004) 61.

it is understandable that a healthcare professional will fear repercussions from reporting. It is in this situation that the previous chapters of this thesis gain real meaning. Healthcare professionals must be confident that any discipline that results will be just and appropriate to the circumstances, an objective only possible when rules and regulations are transparent, predefined, appropriate, and proportionate. For example, where there has been a privacy violation, the appropriate sanction may be to take a course on patient privacy, as opposed to the far more serious sanction of suspension. It is also necessary to ensure sanctions coincide with principles of a just culture, and that there is not the appearance of bias or a conflict of interest when imposing sanctions.

To be clear, this chapter has considered voluntary reporting that is intended for the purposes of quality improvement and not accountability (i.e. discipline).

Organisations, in practice, have an obligation once notified to act and address error and conflict. This may, again, mean using the facts derived from the quality report to separately investigate for the purposes of accountability. The key is in ensuring disciplinary proceedings are just and proportionate. It is understandable that in practice healthcare professionals would be concerned about reporting, but buy in can be aided where the organisation's culture supports and rewards information sharing, and rules and regulations are (as above) transparent, predefined, appropriate, and proportionate. Confidential reporting systems, organisational support structures, and clear and transparent accountability structures are fundamental components of a just culture, and a means by which to address cultural reporting barriers.

Bureaucratic and Administrative Barriers to Incident Reporting

The success of an incident reporting system is dependent on the willingness of healthcare professionals to submit incident reports. Like cultural barriers, bureaucratic and administrative procedures can also create a number of barriers discouraging incident reporting. For a reporting system to be effective, healthcare professionals must

view the reporting system as constructive.⁷⁴ This requires that feedback and analysis are provided in a timely and credible manner, ultimately offering lessons for the promotion of quality and safety improvement. This point was addressed by the European Commission's Patient Safety and Quality of Care Working Group, who point out that, "If a healthcare provider reports an incident without knowing where the report ends, or whether any action is taken, there is a risk that they will — after a number of attempts — cease reporting incidents, even if this is mandatory. To avoid this risk, it is essential to gather information regarding incidents and analyse the data. It is important to publish data and data analysis to highlight developments across different years."⁷⁵ Overcoming this barrier requires that adequate resources are put in place to facilitate analysis. In turn, analysis and feedback must prioritise learning. Summary data and recommendations for improvement should be published to provide evidence of this. One suggestion for increasing the likelihood of the above recommendations being implemented is to link the utilisation of resources to accreditation requirements in the same way process of care standards are incorporated into the awarding of accreditation.

A second administrative barrier can result from variation in patient safety information and classification,⁷⁶ discrepancies as to what information should be reported (including the failure to recognise areas of risk) and who is responsible for reporting.⁷⁷ This point was demonstrated by Waring's research in which he found physicians relied heavily

⁷⁴ D Cooke et al., 'Using a Survey of Incident Reporting and Learning Practices to Improve Organizational Learning at a Cancer Care Center' (2007) 16 *Quality and Safety in Health Care* 342–348.

⁷⁵ European Commission Patient Safety and Quality of Care Working Group, *Key Findings and Recommendations on Reporting and Learning Systems for Patient Safety Incidents Across Europe* (Denmark: European Commission, May 2014) 40. <http://ec.europa.eu/health/patient_safety/docs/guidelines_psqcwg_reporting_learningsystems_en.pdf> accessed: 19 February 2015.

⁷⁶ R Thomson et al., 'Towards an International Classification for Patient Safety: A Delphi Survey' (2009) 21(1) *International Journal for Quality in Health Care* 9–17.

⁷⁷ A Block, 'Disclosure of Adverse Outcomes and Apologizing to the Injured Patient' in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 289.

on the nursing staff to report incidents, arguing it was an administrative function of their professional duties.⁷⁸ Standardisation of the required information, as well as specific reporting guidelines could aid in addressing this barrier.⁷⁹ In addition, healthcare professionals may view incident reporting as inefficient and unworthy of the time and effort required, particularly where reporting takes time away from patient care.⁸⁰ This is particularly problematic in regards near-miss reporting. It is understandable that physicians, already overburdened by professional responsibilities, may be disinclined from spending additional time on reporting near-misses. However, research has shown that near-miss reporting can provide immense benefits to safer practice. For example, Barach and Small found that near-misses occur between 3 and 300 times more often than adverse events.⁸¹ Given their frequency, these findings are significant because they demonstrate the value in data collected from near-miss reporting, and offer the opportunity to analyse large amounts of data with fewer barriers in collection (i.e. the fear of liability.)

As it relates to bureaucratic and administrative barriers, voluntary incident reporting can be encouraged by standardising incident reporting platforms, ensuring credible

⁷⁸ J Waring, 'Beyond Blame: Cultural Barriers to Medical Incident Reporting' (2005) 60(9) *Social Science & Medicine* 1927, 1933-1934.

⁷⁹ M Ong et al., 'Automated Categorisation of Clinical Incident Reports Using Statistical Text Classification' (2010) 19 *BMJ Quality & Safety* e55. The authors recommend the use of statistical text classification techniques to increase efficiency through the automatic categorisation of clinical incident reports.

⁸⁰ J Waring, 'Beyond Blame: Cultural Barriers to Medical Incident Reporting' (2005) 60(9) *Social Science & Medicine* 1927, 1932-1933; Z Robinson Wolf and R Hughes, 'Error Reporting and Disclosure' in R Hughes (ed), *Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Volume 2* (Rockville: Agency for Healthcare Research and Quality, 2008) 350; citing: N Elder et al. 'Barriers and Motivators for Making Error Reports from Family Medicine Offices: A Report from the American Academy of Family Physicians National Research Network' (2007) 20 *Journal of the American Board of Family Medicine* 115-123; C Uribe et al., 'Perceived Barriers to Medical-Error Reporting: An Exploratory Investigation.' (2002) 47(4) *Journal of Healthcare Management* 263-280; B Wakefield et al., 'Organizational Culture, Continuous Quality Improvement, and Medication Administration Error Reporting.' (2001) 16(4) *American Journal of Medical Quality* 128-134.

⁸¹ P Barach and S Small, 'Reporting and Preventing Medical Mishaps: Lessons from Non-Medical Near Miss Reporting' (2000) 320 *BMJ* 759.

feedback is given both in summary and following more detailed analysis, a strong commitment to reporting by senior leadership and regulators, as well as emphasising the quality and safety improvement (and decreased liability) that can result from the incident reporting and analysis.

9.5 Conclusion

This chapter has argued that incident reporting is a fundamental step in quality and safety improvement, particularly in its ability to draw attention to latent systemic factors through incident analysis. The primary objective of both mandatory and voluntary incident reporting systems must be to improve quality and safety through organisational learning and system improvement. This is not to suggest that healthcare organisations and professionals should not be held accountable to the public. As was examined in the first section, serious incidents require investigation as a means of ensuring safe care, and mandatory reporting systems are designed to ensure that level of accountability.⁸² Voluntary reporting systems, alternatively, offer a valuable means by which to engage healthcare professionals and the public in the furtherance of organisational learning. However, incident reporting in itself is insufficient to promote large scale learning and change. As was examined within the second section, emphasis is needed on incident analysis, measurement, and safety improvement programs.⁸³ When analysed, incident reports can provide valuable insight into systemic failure and are instructive for the creation of recommendations, guidelines, and system redesign.⁸⁴ Lastly, the third section of this chapter examined cultural and administrative barriers to incident reporting. In particular, this section examined in detail the reluctance to

⁸² J O'Hagan and D Persaud, 'Creating a Culture of Accountability in Health Care' (2009) 29(2) Health Care Manager 124. The authors note, "Accountability encompasses the procedures and processes by which one party justifies and takes responsibility for its activities such as for achieving organizational goals."

⁸³ C Vincent, 'Incident Reporting and Patient Safety' (2007) 334 BMJ 51.

⁸⁴ WHO World Alliance for Patient Safety, *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems: From Information to Action* (Geneva: World Health Organization, 2005) WHO/EIP/SPO/QPS/05.3. p12-13.

voluntarily submit incident reports as a result of time constraints, a lack of feedback or faith that action will be taken, and the fear of legal or professional regulatory censure.⁸⁵ As Warring observed, the primary barrier among these was associated with a fear of blame and liability from the public, press, and regulatory bodies.⁸⁶ Addressing this barrier requires those reporting to have confidence in the confidentiality process and the organisation, and a clear understanding of any potential repercussions. The organisation, in turn, must be dedicated to providing credible and timely feedback. In addition, emphasise on near-miss reporting was discussed for its benefit to safety improvement as there is limited fear of blame or liability for an incident that was prevented. As Morath and Turnbull insightfully point out, “A near miss is alarming, but it does not carry the same sense of failure and emotional content as an incident which harms a patient. This presents fewer barriers to learning because blame and fear of legal retribution are usually absent. A near miss provides two distinct opportunities for learning. The first resides in the lessons that can be gleaned from the accident that almost happened; the second resides in the interventions that prevented it.”⁸⁷ Increasing the rate of incident reporting, including near-misses, requires those leading the organisation to prioritise incident reporting, analysis, and safety. By offering incentives, emphasising its value in terms of education and the reduced occurrence of patient safety incidents, and ultimately, the reduction of liability (since one is not liable

⁸⁵ A Baba-Akbar Sari et al., ‘Sensitivity of Routine System for Reporting Patient Safety Incidents in an NHS Hospital: Retrospective Case Note Review’ (2007) 334 *BMJ* 79, 81; citing: C Uribe et al., ‘Perceived Barriers to Medical-Error Reporting: An Exploratory Investigation.’ (2002) 47 *Journal of Healthcare Management* 263-279; S Evans et al., ‘Attitudes and Barriers to Incident Reporting: A Collaborative Hospital Study.’ (2006) 15 *BMJ Quality & Safety* 39-43; M Kingston et al., ‘Attitudes of Doctors and Nurses Towards Incident Reporting: A Qualitative Analysis.’ (2004) 181 *Medical Journal of Australia* 27-28; T Walsh and P Beatty, ‘Human Factors Error and Patient Monitoring.’ (2002) 23 *Physiological Measurement* R111-132; J Firth Cozens, ‘Barriers to Incident Reporting’ (2002) 11 *BMJ Quality & Safety* 7.

⁸⁶ J Waring, ‘Beyond Blame: Cultural Barriers to Medical Incident Reporting’ (2005) 60(9) *Social Science & Medicine* 1927, 1934.

⁸⁷ J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 135.

for an incident that was prevented) incident reporting will become a cultural norm, as opposed to a burden or liability risk.

- Chapter 10 -

Communication:

Bridging the Patient-Physician Relationship

10.1 Introduction

Improving healthcare communication is fundamental to the improvement of safety and quality. It is not a specific intervention strategy in itself, but rather must be woven into the policies, procedures, and routines of all of those whose work impacts the healthcare system. This chapter will argue that in both the course of clinical care and in response to medical errors causing harm, improving communication between a physician, patient and family, and the healthcare organisation has the potential to improve patient and physician well-being, compliance and moral, as well as reduce the occurrence of medical error, litigation, and healthcare culture. However, quality and safety initiatives to improve healthcare communication and reduce communication barriers have proven challenging to implement, primarily due to the threat of litigation and a fear of unjust censure. For this reason, this chapter will begin by examining the challenges of communication in the wake of medical error. Following on, the second section will consider the psychological consequences of medical error and the impact of such on patients and physicians, particularly as it relates to communication between the parties. This analysis is not limited to only patient communication, open and factual communication with the organisation by physicians and staff is also an essential component for safety improvement. The third section will consider the benefits and barriers to constructive communication. Lastly, the fourth and fifth sections will examine the use of in-hospital communication programs and internal dispute mechanisms designed to enable physician-patient communication. The objective of this chapter is to examine the role and benefits of healthcare communication in the pursuit of reducing medical malpractice litigation and medical error. In this respect, this chapter will consider both the response to medical error, and strategies for improving patient safety.

10.2 Communication in the Wake of Medical Error

Although the seriousness of the injury may be an influencing factor in the decision to initiate a medical malpractice claim—particularly where there are significant costs attached to follow up care or where a death has occurred—commentators argue that it is the communication following an unanticipated patient safety incident that is the single most determinate factor in a patient’s decision to initiate legal proceedings.¹ The fear of liability created by the legal system’s adversarial approach can severely inhibit physician-patient communication.² As Berlinger argues, “Physicians may think of themselves as less powerful than injured patients and their families if they have been taught to view such patients and families as angry adversaries and potential litigants. But in the physician-patient relationship, the physician is always the more powerful actor, whether or not she is comfortable with that role. The injured patient, moreover, has been rendered more, not less, vulnerable as the result of his injury.”³ Reducing this dissonance within the physician-patient relationship through communication—both

¹ M Beyer et al., ‘Communication and Patient Safety’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 16. The author argues that, “The decision to make a claim appears to be related to how well the doctor had communicated with the patient and relatives, including explanation about the risks associated with investigation and treatment. If an adverse event does occur, effective communication can also reduce the likelihood of complaints and litigation.”; E Zonana, ‘Getting Healthier: A Proposal for Improving Medical Malpractice Mediation’ (2001) 5 *American Journal of Mediation* 9, 20-21; M Greenberg et al., RAND Institute for Civil Justice, *Is Better Patient Safety Associated with Less Malpractice Activity? Evidence from California* (CA: RAND Corporation, 2010) 2; citing: G Hickson et al., ‘Factors That Prompted Families to File Medical Malpractice Claims Following Perinatal Injuries’ (1992) 267(10) *JAMA* 1359–1363; G Hickson et al., ‘Patient Complaints and Malpractice Risk’ (2009) 282(22) *JAMA* 2951–2957; C Vincent et al., ‘Why Do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action’ (1994) 343(8912) *Lancet* 1609–1613. See also: N Meruelo, ‘Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.’ (2008) 29 *Journal of Legal Medicine* 285, 289; A Block, ‘Disclosure of Adverse Outcomes and Apologizing to the Injured Patient’ in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 293; citing: M Tragin et al., ‘Physician Demographics and Risk of Medical Malpractice’ (1992) 93 *American Journal of Medicine* 541.

² H Morreim, ‘Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank’ (2012) 27(1) *Ohio State Journal on Dispute Resolution* 109, 116; citing: C Liebman and C Hyman, ‘Medical Error Disclosure, Mediation Skills, and Malpractice Litigation: A Demonstration Project in Pennsylvania.’ (2005) 61-65.<www.pewtrusts.org/our_work_report_detail.aspx?id=24398>

³ N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005) 102.

before and after an incident—is critical when responding to and attempting to prevent medical error. For the purposes of this chapter, the focus will be on the response.

Traditionally, communication (in the form of disclosure of error or apologies) was viewed by the medical community—and indeed perpetuated by their legal counsel and insurance companies⁴—as evidence of liability.⁵ Defensive communication occurred by way of an initial denial or concealment of information until compelled by way of the discovery process.⁶ This led to the unfortunate, yet prevalent, situation of litigation being used as a last resort due to frustration, fear, or a desire for information and closure.⁷ The situation is often further aggravated when the patient-physician

⁴ A Block, 'Disclosure of Adverse Outcomes and Apologizing to the Injured Patient' in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 287.

⁵ N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005) 53; N Meruelo, 'Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.' (2008) 29 *Journal of Legal Medicine* 285, 293; citing: E Galton, 'Mediation of Medical Negligence Claims' (2000) 28 *Capital University Law Review* 321, 323-24; J Fraser Jr., 'Technical Report: Alternative Dispute Resolution in Medical Malpractice' (2001) 107 *Journal of Pediatrics* 602, 603-04. See also: J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 149. See further: Chapter 11 'Communication: Disclosure and Apology.'

⁶ N Meruelo, 'Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.' (2008) 29 *Journal of Legal Medicine* 285, 289; citing: H Farber and M White, 'Medical Malpractice: An Empirical Examination of the Litigation Process' (1991) 22 *Rand Journal of Economics* 199, 216. Meruelo notes that, "Plaintiffs are willing to sue because they value information gathering as worth the costs of suing." See also: A Merry and A McCall-Smith, *Errors, Medicine and the Law* (Cambridge: Cambridge University Press, 2001) 221; A Howe and P Walsh, 'The Impact on Patients and Healthcare Professionals' in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 41.

⁷ J Wilson and J Tingle, 'Introduction to Clinical Risk Management and Modification' in J Wilson and J Tingle (eds), *Clinical Risk Modification: A Route to Clinical Governance* (Oxford: Butterworth-Heinemann, 1999) 10-11; E Zonana, 'Getting Healthier: A Proposal for Improving Medical Malpractice Mediation' (2001) 5 *American Journal of Mediation* 9, 20-21.

relationship was poor to begin with.⁸ For example, research by Farber and White found that physicians who had never been sued, "... were viewed by their patients as 'concerned, accessible, and willing to communicate,' but physicians who had been sued frequently were often viewed by their patients as 'hurried, uninterested, and unwilling to listen and answer questions.'"⁹

Central to my analysis—and indeed, the premise on which this thesis is based—is the argument that all efforts should be put towards prevention; however, when an incident has occurred, all efforts should then be directed towards learning and mitigation. Improving communication and reducing healthcare communication barriers between healthcare professionals and patients is fundamental to prevention, learning, and ultimately, mitigation following an incident. By addressing the factors that result in a patient's decision to initiate a malpractice claim, as well as improving the physician-patient communication, quality and safety can ultimately be improved. Owing to the significance of effective healthcare communication, particularly following medical error, it is now useful to examine the role of communication in the clinical setting, which will provide the foundation for the following chapters in which the legal and ethical obligation to disclose information to patients following an incident will be analysed.

Although the fear of litigation is often cited as the primary factor restricting communication—particularly in the nondisclosure of medical error—external

⁸ E Zonana, 'Getting Healthier: A Proposal for Improving Medical Malpractice Mediation' (2001) 5 *American Journal of Mediation* 9, 22; citing: S Fielding, *The Practice of Uncertainty: Voices of Physicians and Patients in Medical Malpractice Claims* (Connecticut: Auburn House, 1999) 109. See also: N Meruelo, 'Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.' (2008) 29 *Journal of Legal Medicine* 285, 289; citing: G Hickson et al., 'Obstetricians' Prior Malpractice Experience and Patients' Satisfaction with Care' (1994) 272 *JAMA* 1583, 1587.

⁹ N Meruelo, 'Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.' (2008) 29 *Journal of Legal Medicine* 285, 289; citing: H Farber and M White, 'Medical Malpractice: An Empirical Examination of the Litigation Process' (1991) 22 *Rand Journal of Economics* 199, 216.

pressures such as budgetary constraints, workload, fatigue, time pressures, and cultural differences can equally restrict effective communication.¹⁰ Likewise, internal pressures may also contribute to inadequate communication. This can include misunderstandings as a result of bias and prejudgments originating from the use of heuristics, differing personalities, or cultural differences.¹¹ Such a situation is further aggravated by internal conflict between staff members. As Rabinovich-Einy notes, “Often, communication problems among staff expand to the external realm, generating disputes between staff and a patient or her family. In other instances, such problems are rooted in an external dispute and present an extension of such conflict.”¹² This is significant because both internal and external disputes that are not effectively resolved can become latent factors that contribute to both an incident occurring, and the decision to litigate after. While the conflict itself may not constitute a legal cause of action, the result may nevertheless impact the quality and safety of the care given.¹³

Where a legal cause of action does exist—such as following a medical error resulting from negligent practice—communication between the primary physician involved and the patient can become an ethical and legal dilemma.¹⁴ A number of barriers may be present that prevent clinicians from engaging in the disclosure of an unanticipated outcome, regardless of if errors were present or not (since an aggrieved patient may not differentiate in the aftermath of a serious incident). As Truog et al. observe, “Barriers to disclosure are deeply rooted in the human psyche as well as in conditioned fears about onerous legal consequence that might befall a physician who chooses to be

¹⁰ O Rabinovich-Einy, ‘Escaping the Shadow of Malpractice Law’ (2011) 74 *Law and Contemporary Problems* 241, 263; R Brinkert, ‘A Literature Review of Conflict Communication Causes, Costs, Benefits and Interventions in Nursing’ (2010) 18 *Journal of Nursing Management* 145.

¹¹ A Matlow et al., ‘Disclosure of Medical Error to Parents and Paediatric Patients: Assessment of Parents’ Attitudes and Influencing Factors’ (2010) 95 *Archives of Disease in Childhood* 286.

¹² O Rabinovich-Einy, ‘Escaping the Shadow of Malpractice Law’ (2011) 74 *Law and Contemporary Problems* 241, 263.

¹³ *ibid* 248.

¹⁴ See further: Chapter 11.2 ‘The Obligation to Disclose: An Ethical and Legal Duty.’

honest.”¹⁵ In addition to the practical consequences of the process; disciplinary procedures, adverse publicity, and a lack of uniformity in disclosure and apology laws have prolonged the reluctance to engage in these conversations with patients.¹⁶ In contrast to communication that is open and collaborative; defensive communication can appear closed, lacking in empathy, confrontational, or distant. Such communication may be driven by the traditionally paternalistic nature of the doctor-patient relationship, the desire to obscure medical decisions, organisational culture, previous medical education and training, or as a means of protecting one’s self from liability.¹⁷ Contrary to such intentions, defensive communication can lead to an increase in both the likelihood of medical error and liability.¹⁸ In this regard, Rabinovich-Einy rightly asserts, “... defensive communication serves as a barrier to the informal resolution of individual disputes, to the adoption of ADR processes in the healthcare setting, and to the inculcation of more flexible communication skills in clinicians.”¹⁹ Owing to the potential gravity of patient safety incidents, it is now necessary to examine the consequences—beyond liability—that can occur and create barriers in communication.

¹⁵ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 121. See further: Chapter 11.3 ‘Barriers to Disclosure.’

¹⁶ A Howe and P Walsh, ‘The Impact on Patients and Healthcare Professionals’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 45.

¹⁷ O Rabinovich-Einy, ‘Escaping the Shadow of Malpractice Law’ (2011) 74 *Law and Contemporary Problems* 241, 243; R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 41-42; citing: F Baylis, ‘Errors in Medicine: Nurturing Truthfulness’ (1997) 8 *Journal of Clinical Ethics* 336-340; T Mizrahi, ‘Managing Medical Mistakes: Ideology, Insularity and Internists-In-Training’ (1984) 19 *Social Science Medicine* 135-146; C Bosk, *Forgive and Remember: Managing Medical Failure* (Chicago: University of Chicago Press, 2003)

¹⁸ O Rabinovich-Einy, ‘Escaping the Shadow of Malpractice Law’ (2011) 74 *Law and Contemporary Problems* 241, 243; citing: D Hetzler et al., ‘Curing Conflict: A Prescription for ADR in Healthcare’ (2004) *Dispute Resolution Magazine* 5, 6; B Taylor et al., ‘Do Medical Inpatients Who Report Poor Service Quality Experience More Adverse Events and Medical Errors?’ 46 (2008) *Medical Care* 224, 226.

¹⁹ *ibid* 243.

10.3 The Psychological Consequences of Medical Error and Disclosure

The period immediately following an unanticipated outcome can be extremely overwhelming for patients and their families who may experience feelings of isolation, abandonment, grief, or anger.²⁰ Patients may also worry about being stigmatised, or that an inquiry or complaint will result in care being withheld. In addition, a patient harmed in the course of their care may be left to deal with the physical consequences, as well as the loss of career or financial opportunities.²¹ Early and comprehensive communication can aid in rebuilding the trust and confidence of the patient in their healthcare team and proposed care plan, improve compliance with the recommended course of action, and reduce the likelihood of the incident being viewed as being the result of incompetence.²² However, as Truog et al. argue, the issue of competing ethics may occur simultaneously, specifically:

“... the need for the patient and family to have a timely, plausible, and coherent explanation for what has happened as soon as possible versus the importance of clinicians avoiding speculation, steering clear of premature explanations, and carefully establishing ‘the facts’ of what happened.”²³

²⁰ D Waluube, *Medical Errors and Adverse Events: Managing the Aftermath* (US: Xlibris, 2011) 115-117.

²¹ A Howe and P Walsh, ‘The Impact on Patients and Healthcare Professionals’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 41; D Waluube, *Medical Errors and Adverse Events: Managing the Aftermath* (US: Xlibris, 2011) 115-117.

²² R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 32, 34-35; citing: D Hilfiker, ‘Facing Our Mistakes’ (1984) 310 NEJM 118-122; A Gawked, *Complications: A Surgeon’s Notes on an Imperfect Science* (New York: Metropolitan Books, 2002); W Levinson and P Dunn, ‘A Piece of My Mind: Coping with Fallibility’ (1989) 261 JAMA 2252. See generally: T Gallagher et al., ‘Patients’ and Physicians’ Attitudes Regarding the Disclosure of Medical Errors’ (2003) 289(8) JAMA 1001-1007; K Mazor et al., ‘Communicating with Patients About Medical Errors: A Review of the Literature.’ (2004) 164 Archives of Internal Medicine 1690-1697; M Beyer et al., ‘Communication and Patient Safety’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 16.

²³ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 72.

For many patients, the desire for information surrounding their care outweighs their desire for monetary remedies. As Wu argued, when an adverse outcome has occurred, “Patients want an explanation, acknowledgment of responsibility, expression of regret and apology and a commitment to preventing recurrences.”²⁴ Appropriate and timely communication increases patient satisfaction and trust, fosters a successful therapeutic relationship between the patient and physician, and reduces the likelihood that the patient will seek legal remedies as a means to gain information.²⁵ In this regard, effective communication is fundamental to both mitigation and ultimately, learning.

For healthcare professionals, unanticipated incidents can also cause distress and negative psychological consequences; including feelings of inadequacy and depression, to grief and remorse.²⁶ On a practical level, physicians may fear impending liability or damage to their careers and reputations.²⁷ This is well borne out by an analysis of the literature. For example, in a study by Waterman et al., physician

²⁴ A Wu et al., ‘Disclosure of Adverse Events in the United States and Canada: An Update, and a Proposed Framework for Improvement’ (2013) 2(3) *Journal of Public Health Research* 186, 187-188. See also: T Gallagher et al., ‘Patients’ and Physicians’ Attitudes Regarding the Disclosure of Medical Errors’ (2003) 289(8) *JAMA* 1001; K Mazor et al., ‘Health Plan Members’ Views About Disclosure of Medical Errors.’ (2004) 140 *Annals of Internal Medicine* 409; O Rabinovich-Einy, ‘Escaping the Shadow of Malpractice Law’ (2011) 74 *Law and Contemporary Problems* 241, 252; W Cox, ‘The Five A’s: What do Patients Want After an Adverse Event?’ 25(3) *Journal of Healthcare Risk Management* 25. According to Cox, the five A’s patients require are an apology, all the facts, assurance and appropriate compensation.

²⁵ J Moskop et al. ‘Emergency Physicians and Disclosure of Medical Errors.’ (2006) 48(5) *Annals of Emergency Medicine* 523, 524; American Medical Association Council on Ethical and Judicial Affairs, *Code of Medical Ethics: Current Opinions with Annotations 2014-2015* (Chicago: American Medical Association Press, 2014) [8.121]; M Waite, ‘To Tell the Truth: The Ethical and Legal Implications of Disclosure of Medical Error’ (2005) 13 *Health Law Journal* 1, 21; citing: K Mazor et al., ‘Health Plan Members’ Views About Disclosure of Medical Errors.’ (2004) 140 *Annals of Internal Medicine* 409.

²⁶ D Waluube, *Medical Errors and Adverse Events: Managing the Aftermath* (US: Xlibris, 2011) 92-99, discussing mechanisms used by Physicians to cope with the aftermath of medical error.

²⁷ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 43; citing: D Hilfiker, ‘Facing Our Mistakes’ (1984) 310 *NEJM* 118-122; M Smith and H Forster, ‘Morally Managing Medical Mistakes’ (2000) 9 *Cambridge Quarterly of Healthcare Ethics* 38-53; A Gawande, *Complications: A Surgeon’s Notes on an Imperfect Science* (New York: Metropolitan Books, 2002); A White et al., ‘Supporting Healthcare Workers After Medical Errors: Considerations for Health Care Leaders’ (2008) 15 *Journal of Clinical Outcomes Management* 240-247.

participants reported that following an adverse event: job satisfaction, confidence in their professional capabilities, and their ability to sleep were all affected.²⁸ Wu has similarly argued that in such situations, clinicians can become the “second victim” of medical error.²⁹ Nurses reported the same emotional outcomes in addition to feelings of tension when placed in a position to act as a buffer between the physicians, healthcare organisations, and patients.³⁰ These emotions may be elevated where the physician or nurse is encouraged to withhold information from the patient.³¹ Notably, the psychological repercussions may be greater where organisational support is not available. In a study examining, *inter alia*, the emotional response to error of physicians and nurses in the United States and United Kingdom, Harrison et al. found that the emotional response and coping strategies did not differ based on jurisdiction, but rather were strongly connected to their profession and the organisational support services available. With respects to jurisdiction, this finding is significant because it delinks the fear of litigation (believed to be more common as a result of the so-called ‘litigation crisis’ within the United States) from the emotional response to error.³² As it pertains to occupation, the authors found that nurses scored stronger feelings of intensity in relation to negative emotions, such as distress or worry. In response, the authors suggest this may be related to nurses being closer to the sharp end, and having higher levels of patient interaction. The authors further argue their findings suggest a ‘one size fits all’ approach may not be the most effective, and suggest the use of

²⁸ A Waterman et al., ‘The Emotional Impact of Medical Errors on Practicing Physician in the United States and Canada.’ (2007) 33 *Joint Commission Journal on Quality and Patient Safety* 467-476.

²⁹ A Wu, ‘Medical Error: The Second Victim. The Doctor Who Makes the Mistake Needs Help Too.’ (2000) 320 *BMJ* 726, 727. See further: Chapter 4.2 ‘Healthcare and the Culture of Blame.’

³⁰ O Rabinovich-Einy, ‘Escaping the Shadow of Malpractice Law’ (2011) 74 *Law and Contemporary Problems* 241, 259.

³¹ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 43; citing: D Hilfiker, ‘Facing our mistakes’ (1984) 310 *NEJM* 118-122; A Gawked, *Complications: A Surgeon’s Notes on an Imperfect Science* (New York: Metropolitan Books, 2002) See generally: S Shannon et al., ‘Disclosing Errors to Patients: Perspectives of Registered Nurses’ (2009) 35 *Joint Commission Journal on Quality and Patient Safety* 5-12.

³² H Reema et al., ‘Emotion and Coping in the Aftermath of Medical Error: A Cross-Country Exploration’ (2015) 11(1) *Journal of Patient Safety* 28, 32.

disclosure and communication training, as well as emotional skills training to aid in supporting healthcare professionals after a medical error, and for future prevention efforts.³³

Preventing defensive and limited communication, as well as the psychological consequences for both patients and healthcare professionals is crucial to safety and quality improvement. For this reason, it is now necessary to examine the components of constructive communication in the context of the physician-patient relationship.

10.4 Constructive Communication

Improving the emotional well-being of healthcare professionals and patients following a patient safety incident requires a multifaceted approach. As analysed previously, a just culture refrains from blaming behaviour and using fear as deterrent, instead prioritising safe accountable care through learning, prevention, and mitigation.³⁴ As Claridge and Sandars assert:

“Cultural change is concerned with how people feel and think about issues. Opportunities have to be created for people to freely state their opinions, and this openness then needs to be transferred to systems that allow all individuals to report and discuss patient safety incidents. A ‘no blame’ culture gives individuals an opportunity to disclose and discuss without fear of punishment, but it does not absolve individuals from being accountable for their actions.”³⁵

³³ *ibid* 33.

³⁴ R Tevlin et al., ‘Improving Disclosure and Management of Medical Error - An Opportunity to Transform the Surgeons of Tomorrow’ (2013) 11(6) *The Surgeon* 338. See further: Chapter 4 ‘Healthcare Culture and Accountability’ and Chapter 9 ‘Incident Reporting and Analysis.’

³⁵ T Claridge and J Sandars, ‘Patient Safety Culture’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 21-22.

This is an important point for at least two reasons. First, to restore trust in the physician-patient relationship, patients need to know that those responsible will be held accountable. Indeed, a misconception that flows from organisational silence is the belief that there is a ‘coverup’ or lack of accountability. As examined in chapter 2 of this thesis, litigation is only one of the many mechanisms available to ensure individuals and organisations are held accountable for their actions (or inactions.) Second, patients often want to know that such an incident will “never happen again.” A just culture that encourages open, honest, and transparent communication allows issues to be addressed thoroughly, thereby improving safety and quality practices within the organisation. This, ideally, contributes to prevention.

From a clinical perspective, constructive communication with the patient—in the course of general care or following a patient safety incident—can improve the accuracy of a diagnosis and care plan, as well as increase patient comprehension and compliance.³⁶ Where an incident has occurred, disclosure has been shown to mitigate potentially divisive relationships with patients, facilitate peer support, and aid in reducing the negative psychological emotions connected with error, including: guilt, remorse, the desire to explain or show empathy.³⁷ It is necessary, prior to the disclosure conversation, that the emotional and psychological needs of the physician be assessed as the response of the patient is difficult to predict and may be further detrimental.³⁸ Although the patient may embrace a physician’s vulnerability and openness, it may

³⁶ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 82.

³⁷ S Eastaugh, ‘Reducing Litigation Costs Through Better Patient Communication’ (2004) 30(3) *Physician Executive* 36, 37; citing: D Safran, ‘Defining the Future of Care: What Can We Learn From Patients?’ (2003) 138(3) 248-255; S Eastaugh, ‘CQI and Planning’ (1999) 70(6) *Academic Medicine* 465-470. See also: R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 37.

³⁸ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 58.

not be met with the reciprocal action of forgiveness.³⁹ As Truog et al. observe, “Often, however, patients and their families will not be prepared to forgive at the time of the initial conversation, and sometimes they will not be inclined to forgive at any point in time. This can create the potential for the clinician to feel even worse, having shown vulnerability through the act of apologizing without receiving the reassurance that comes from the reciprocal act of forgiveness.”⁴⁰ The concern and anxiety related to the unpredictability of the patient’s reaction can cause further defensive communication, defensive practice, and withholding of information: all of which may contribute to a patient’s decision to initiate litigation.⁴¹ In this regard, the need for (and use of) ‘Second Victim’ support services becomes intrinsically connected to enabling effective disclosure conversations.⁴²

Participation in communication and disclosure training, as well as consultation with disclosure coaches and counsellors, can be beneficial in reducing physician anxiety following the incident.⁴³ An interdisciplinary approach is preferable as research has shown that different specialities may have contrasting views of the disclosure

³⁹ N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005) 112.

⁴⁰ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 89-90.

⁴¹ O Rabinovich-Einy, ‘Escaping the Shadow of Malpractice Law’ (2011) 74 *Law and Contemporary Problems* 241, 268.

⁴² In relation to the ‘Section Victim’ and available support services, see further: Chapter 4.2 ‘Healthcare and the Culture of Blame.’

⁴³ See further: Chapter 11.6 ‘Communication and Disclosure Programs.’

process.⁴⁴ In an interesting study using survey responses from physicians in the United States and Canada, Bell et al. sought to determine the attitudes of physician's towards transparency and the disclosure of medical errors.⁴⁵ The authors found that support for transparent communication was most common based on, *inter alia*: sex (female physicians were more likely than their male colleagues); location (American physicians were more likely than Canadians); number of years practicing (younger physicians were more likely, as were surgeons and those with previous disclosure experience and education); the belief that disclosure decreased the likelihood of litigation; as well as the belief that error reporting could lead to systemic improvement. Perhaps unsurprisingly, physicians who believed that disclosure would decrease patient trust were less likely to support disclosure policies. In response to their findings, Bell et al. strongly advocate for increased disclosure training opportunities, and the adoption of disclosure as part of an organisational policy approach—both of which are consistent with the recommendations made throughout this thesis.⁴⁶ Incorporating ethics education—both before and in the aftermath of a patient safety incident—may be further beneficial.⁴⁷ In this regard, Berlinger recommends ethics education opportunities be used within healthcare institutions:

⁴⁴ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 124; citing: T Gallagher et al., 'Choosing Your Words Carefully: How Physicians Would Disclose Harmful Medical Errors to Patients' (2006) 166 *Archives of Internal Medicine* 1585-1593; D Chan et al., 'How Surgeons Disclose Medical Errors to Patients: A Study Using Standardized Patients' (2005) 138 *Surgery* 851-858; D Loren et al., 'Medical Error Disclosure Among Pediatricians: Choosing What We Might Say to Patients' (2008) 162 *Archives of Pediatrics & Adolescent Medicine* 922-927; S Shannon et al., 'Disclosing Errors to Patients: Perspectives of Registered Nurses' (2009) 35 *Joint Commission Journal on Quality and Patient Safety* 5-12.

⁴⁵ S Bell et al., 'Transparency When Things Go Wrong: Physician Attitudes About Reporting Medical Errors to Patients, Peers, and Institutions' (24 February 2015) *Journal of Patient Safety* [epub ahead of print].

⁴⁶ *ibid.*

⁴⁷ A Cole et al., 'On Higher Ground: Ethical Reasoning and Its Relationship with Error Disclosure' (2013) 22 *BMJ Quality & Safety* 580.

“... to help clinicians, other healthcare professionals, and students to develop their capacity to understand medical harm from the patient’s perspective; learn how to frame forgiveness after harm as detachment predicated on justice while recognizing non-Western paradigms of reconciliation or resolution after harm, and identifying and challenging any aspects of institutional culture that deny the fallibility, and therefore the humanity, of healthcare providers, or that work against the interests of those injured...”⁴⁸

Finally, support tools such as the Second Victim Experience and Support Tool (SVEST) are useful in addressing a wide range of concerns in regards the emotional wellbeing of the clinical staff. These tools assist in the implementation and tracking of support services available throughout the organisation and can be particularly useful following an adverse incident.⁴⁹

With the increasing influence of the patient safety movement, as well as an emphasis on patient engagement and patient-centred care, many healthcare organisations have slowly begun to amend their approach to disclosure from a focus on legal risk, to one that emphasises informed consent through open and honest communication. As Truog et al. have argued, “... in an era in which improving and enhancing ‘patient-centred care’ has become a virtual litmus for any proposed changes in our healthcare systems, it is hard to imagine any reform that has the potential to integrate patients more powerfully into their own care than a commitment to sharing knowledge with them

⁴⁸ N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005) 112.

⁴⁹ J Burlison et al., ‘The Second Victim Experience and Support Tool: Validation of an Organizational Resource for Assessing Second Victim Effects and the Quality of Support Resources.’ (26 August 2014) *Journal of Patient Safety* [epub ahead of print]; A Wu, ‘Medical Error: The Second Victim. The Doctor Who Makes the Mistake Needs Help Too.’ (2000) 320 *BMJ* 726.

about adverse events and errors.”⁵⁰ Truog’s comment reinforces three of the primary patient safety objectives: patient-centred care, accountability, and mitigation following harm. Research in the area of disclosure has shown that in their decision to pursue legal remedies, patients place a greater emphasis on the level of communication received from their physician and the organisation, than the characteristics and severity of the incident.⁵¹ The next section will examine general recommendations and examples for improving communication during the disclosure process. It is not intended to represent the legality of such disclosures (which will be examined in greater detail in the following chapter) but rather present a general overview of best practices in the context of physician-patient communication.

10.5 Communication Programs

Increasingly, healthcare organisations have begun to incorporate communication programs into professional development requirements for the purposes of reducing the adversarial culture, engaging patients and families, and furthering quality and safety. According to Denham et al., there are five core concepts that should be included in a communication training program. These include: human performance factors, authority gradient factors (i.e. “hierarchical relationships and status differentials”), caregiver-to-caregiver communication factors, health literacy issues, and active listening principles.⁵² Additionally, it is important to incorporate information about the healthcare organisation’s policies and procedures, as well as information specific to

⁵⁰ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 37.

⁵¹ O Rabinovich-Einy, ‘Escaping the Shadow of Malpractice Law’ (2011) 74 *Law and Contemporary Problems* 241, 251-252; citing: D Hetzler et al., ‘Curing Conflict: A Prescription for ADR in Healthcare’ (Fall 2004) *Dispute Resolution Magazine* 7; G Wood Geckeler, ‘The Clinton–Obama Approach to Medical Malpractice Reform: Reviving the Most Meaningful Features of Alternative Dispute Resolution’ (2007) 8 *Pepperdine Dispute Resolution Law Journal* 171, 177–78; B Virshup et al., ‘Strategic Risk Management: Reducing Malpractice Claims Through More Effective Patient–Doctor Communication’ (1999) 14 *American Journal of Medical Quality* 153.

⁵² C Denham et al., ‘Are You Listening... Are You Really Listening?’ (2008) 4(3) *Journal of Patient Safety* 148, 149.

disclosure (both as they relate to communication and the law).⁵³ Many of these concepts are examined throughout this thesis in relation to patient safety and disclosure training. Enabling healthcare professionals with these fundamental communication skills, in contrast to teaching disclosure as a defense mechanism, is advantageous in that it not only mitigates the incident after the fact, but can also prevent the incident from reoccurring by allowing transparency surrounding the events. As Hetzler insightfully points out:

“Because good communication before and after care is the essence of good healthcare, it will be important for healthcare enterprises to anticipate that communication skills and conflict skills will become primary predictors of the organization's ability to progress in both quality improvement and patient safety, and will therefore equip its caregivers and administrators with these skills. For those who do adopt this approach, they can expect lower turn-over, less burnout, increased patient loyalty and lower rates of medical errors.”⁵⁴

It is essential, in this regard, that the content of a communication program reflect the reality of clinical interactions and best practice. To accomplish this, programs should further include topics such as the value of expressing empathy, emotional connection and engagement; an understanding of the impact and consequences of medical error; recognising situations in which the healthcare professional should be removed from the situation, and the importance of collaboration and peer support.⁵⁵ As it applies to improving direct communication with patients, a communication program should also

⁵³ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 58.

⁵⁴ D Hetzler et al., ‘Conflict Management in Hospital Systems: Not Just For Leadership’ (2011) 5 *American Journal of Mediation* 65.

⁵⁵ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 58.

emphasise the use of eye contact, affirming patients in their own words, the use of open-ended questions and the importance of not interrupting the patient in the first minute of conversation. On the latter point, a study observing physician-patient consultations found that on average, physicians interrupt their patients after only eighteen seconds.⁵⁶ Programs that teach healthcare professionals how to educate, engage, and enlist the patient in their care may improve this. As Eastaugh notes, “Typical physicians who think they provided six minutes of patient education actually only provided 40 seconds when we play back the videotapes. Most of the 40 seconds is jargon. The majority of patients have zero understanding of messages.”⁵⁷ Given the traditionally paternalistic nature of medicine, involving patients can influence profound change both in general care and following an incident. The obvious counter-argument that could be made is that physicians simply do not have the time to devote to lengthy patient conversations. However, shown in this chapter and distinct to my analysis, is that improving communication between patients and their caregivers is not solely concerned with quantity—but rather quality. Referring back to my earlier analysis within this chapter, the benefits of effective communication extend beyond safety improvement, they also include a reduction in the time and costs associated with adverse incidents and conflict.

Although communication training programs have yet to be universally embraced, some healthcare organisations have begun delivering them on a voluntary basis. For example, Evelina London Children’s Hospital in England offers a voluntary in-hospital program to all of its staff members. Unique to the program is the focus on training staff to “recognise the triggers for conflict and ways to start rebuilding trust when a

⁵⁶ S Eastaugh, ‘Reducing Litigation Costs Through Better Patient Communication’ (2004) 30(3) *Physician Executive* 36; citing: S Eastaugh, *Health care Finance and Economics* (Sudbury, Mass: Jones and Bartlett, 2003).

⁵⁷ *ibid.*

situation has already deteriorated.”⁵⁸ The program also incorporates ADR based skills, such as those used in the process of facilitative mediation.⁵⁹ The development of programs such as this is encouraging. As the benefits of improving communication skills become more widely acknowledged, ideally, programs such as the one offered at Evelina London Children’s Hospital will become standard. Future research should be directed towards their development and implementation.

10.6 Internal Dispute Resolution

Although the analysis within this thesis is primarily concerned with an examination of legal mechanisms that can be used to prevent and mitigate *litigable* disputes, it is now useful to briefly examine some of the mechanisms available to promote accountability and mitigate disputes at the first instance of conflict. The process of Internal Dispute Resolution (IDR) concerns those disputes not yet meriting legal intervention. Within a healthcare organisation, IDR mechanisms may be appropriate for the early and confidential resolution of internal conflicts, for example: disputes concerning treatment decisions, adjudicating internal conflict, or patient complaints. Primary IDR mechanisms include the use of complaint management systems, Hospital Ombudsmen, Hospital Ethics Committees, a hospital-based panel of neutrals, and patient advocates.⁶⁰

⁵⁸ L Tickle, ‘Why Mediation Training Should be Offered in Hospitals.’ *The Guardian Professional* (London, 10 December 2014) <<http://www.theguardian.com/healthcare-network/2013/dec/10/mediation-training-offered-hospitals>>.

⁵⁹ O Rabinovich-Einy, ‘Escaping the Shadow of Malpractice Law’ (2011) 74 *Law and Contemporary Problems* 241, 264. See further: Chapter 12.3 ‘Healthcare Mediation.’

⁶⁰ T Pope, ‘Multi-Institutional Healthcare Ethics Committees: The Procedurally Fair Internal Dispute Resolution Mechanism’ (2009) 31 *Campbell Law Review* 257. Pope recommends the adjudicatory authority of Healthcare Ethics Committees be relocated to multi-institutional Healthcare Ethics Committees in an effort to increase resources, create greater diversity of perspectives and increase the neutrality and independence required by due process; R Orr, ‘Methods of Conflict Resolution at the Bedside’ (2001) 1(4) *The American Journal of Bioethics* 45.

In an effort to efficiently address and resolve patient complaints, healthcare organisations such as England's NHS have introduced sophisticated complaint management systems. These systems have the benefit of addressing patient concerns, highlighting lapses in accountability and safety, alerting the organisation to blunt and latent defects early in the dispute process, as well as preventing future incidents by recommending improvements through the clinical governance process.⁶¹ Although the NHS introduced the complaints system in 1996 in an effort to reduce potential claims, the growing number of medical negligence claims against the NHS has led some commentators to question its effectiveness in this regard.⁶² However, legal fee structures (such as the "no win, no fee" agreement) may equally have contributed to this trend.⁶³ The NHS complaints process allows patients to informally make an oral, electronic, or written complaint. The patient (or relative/representative) can then decide whether to have the complaint directed towards the physician and hospital in question or to the local Clinical Commissioning Group. If the patient is satisfied with the response, the process is complete and no further action is taken.⁶⁴ If the patient is unsatisfied, the complaint is then referred to the Parliamentary and Health Service Ombudsman.⁶⁵ In response to a complaint, a 'fit for purpose' response must be given and include (depending on applicability): a summary of the complaint; explanation of

⁶¹ V Harpwood, *Medicine, Malpractice and Misapprehensions* (Oxon: Routledge-Cavendish, 2007) 169.

⁶² D Boffey, 'NHS Litigation Claims Double Under Coalition' *The Guardian* (London, 13 December 2014) <<http://www.theguardian.com/society/2014/dec/13/nhs-litigation-claims-double-under-coalition>>; citing NHS Litigation Authority, *NHS Litigation Authority: Reports and Accounts 2013/2014* (London: NHS Litigation Authority, 2014) <<http://www.nhsla.com/aboutus/Documents/NHS%20LA%20Annual%20Report%20and%20Accounts%202013-14.pdf>> accessed: 08 June 2015.

⁶³ Owing to the popularity of "no win, no fee" agreements and their potential impact on the rise of litigation within the UK, the English parliament effectively reformed the practice, reducing the potential costs payable by litigants should their claim be successful. See further: Part 2 of the Legal Aid, Sentencing and Punishment of Offenders Act 2012 (UK).

⁶⁴ The legislation governing the NHS complaints procedure is contained within the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009. See also: A Clwyd and T Hart, *A Review of the NHS Hospitals Complaints System: Putting Patients Back in the Picture* (London: Department of Health, 2013) 13.

⁶⁵ Legislation setting out the current remit of the Health Service Ombudsmen is contained with the Health Service Commissioners Act 1993 (as amended).

the steps taken to investigate; an account of what did or should have happened; an apology; feedback as to the lessons learned and action taken; as well as financial compensation for direct or indirect loss (where appropriate).⁶⁶ The involvement of a Health Service (or Hospital) Ombudsman is an additional mechanism for resolving complaints at an early stage, and ideally, a means to prevent litigation. However, as Rabinovich-Einy observes, where the role of the Ombudsman becomes overly legalistic and addresses claims based solely on their legal merit, the process can become predominantly formal and adjudicatory, thereby reducing its benefit.⁶⁷

Although the extent to which the complaint and ombudsman process has reduced the rates of medical negligence claims within England is debatable, it remains a useful tool for improving the organisation's ability to manage non-litigable disputes before they require the intervention of legal counsel.⁶⁸ This is dependent, however, on the organisation's willingness to embrace the information received and be accountable for addressing it. As Boylan has argued, "The effectiveness of the hospital complaints procedure depends very largely on the ethos or culture operating within the particular hospital. Furthermore the effectiveness of the complaints procedure is largely dependent upon the willingness of the medical staff attached to the hospital to cooperate with the hospital administrators in dealing within the patient's complaint."⁶⁹ Similar to the reporting of patient safety incidents,⁷⁰ it is necessary to not only

⁶⁶ NHS England, *Guide to Good Handling of Complaints for CCGs* (13 May 2013) 13 <<http://www.england.nhs.uk/wp-content/uploads/2012/03/20130513-Good-complaints-handling-for-CCGs-FINAL-version-for-publication.pdf>> accessed: 13 March 2015.

⁶⁷ O Rabinovich-Einy, 'Escaping the Shadow of Malpractice Law' (2011) 74 *Law and Contemporary Problems* 241, 262, 273.

⁶⁸ *ibid* 266; citing: S Szmania et al., 'Alternative Dispute Resolution in Medical Malpractice: A Survey of Emerging Trends and Practices' (2008) 26 *Conflict Resolution Quarterly* 71, 73. In discussing nonlitigable disputes, Rabinovich-Einy notes, 'Nonlitigable disputes often stem from the cultural differences between the professional and organizational cultures of healthcare professionals at hospitals and the expectations of patients.'

⁶⁹ M Boylan, 'Medical Negligence Litigation: Challenges for the Plaintiff's Lawyers' in C Craven and W Binchy (eds), *Medical Negligence Litigation: Emerging Issues* (Dublin: First Law, 2008) 140.

⁷⁰ See further: Chapter 9 'Incident Reporting and Analysis.'

encourage engagement by healthcare professionals, but also provide feedback that can benefit systemic improvement. For this reason, the NHS complaint system publishes detailed quarterly complaints reports that include, *inter alia*, an analysis of the complaints received, commentary about patterns or concerns, and what measures will be taken towards improvement.⁷¹

Lastly, initiatives such as the use of clinical ethics consultation, a hospital-based panel of neutrals, and patient advocates have also shown promise in resolving disputes at an early stage, thereby potentially reducing the escalation of a medical malpractice claims. This is primarily due their ability to narrow the relevant issues, focus on patient-centred care and recommend improvements for future practices.⁷²

10.7 Conclusion

This chapter has argued that improving communication between patients and healthcare professionals, particularly in response to medical error, is fundamental for advancing healthcare quality and safety. However, quality and safety initiatives to improve healthcare communication have been challenging to implement, primarily due to the threat of litigation and the culture of blame within healthcare. This is not to suggest the litigation process is without value. Indeed, litigation may be an appropriate last resort where alternative forms of dispute resolution have failed. As

⁷¹ NHS England, *Guide to Good Handling of Complaints for CCGs* (13 May 2013) 15-16 <<http://www.england.nhs.uk/wp-content/uploads/2012/03/20130513-Good-complaints-handling-for-CCGs-FINAL-version-for-publication.pdf>> accessed: 13 March 2015.

⁷² D Sine and V Sharpe, 'Ethics, Risk, and Patient-Centered Care: How Collaboration Between Clinical Ethicists and Risk Management Leads to Respectful Patient Care' (2011) 31(1) *Journal of Healthcare Risk Management* 32. The authors suggest clinical ethics consultation may reduce the escalation of potentially litigious situations; R Sullivan et al., 'Building Confidence into Communication of Bad News: The Role of the Patient Advocate' (2010) 29(4) *Journal of Healthcare Risk Management* 33. Sullivan notes that the incorporation of patient advocates in the initial disclosure may aid in more productive disclosure conversations; T Pope, 'Multi-Institutional Healthcare Ethics Committees: The Procedurally Fair Internal Dispute Resolution Mechanism' (2009) 31 *Campbell Law Review* 257. Pope recommends the adjudicatory authority of Healthcare Ethics Committees be relocated to multi-institutional Healthcare Ethics Committees in an effort to increase resources, create greater diversity of perspectives and increase the neutrality and independence required by due process; R Orr, 'Methods of Conflict Resolution at the Bedside' (2001) 1(4) *The American Journal of Bioethics* 45.

well, the litigation process offers both the plaintiff and defendant(s) an opportunity to publicly contest claims made against them. The problem, however, is that litigating a dispute can also be disadvantageous for a plaintiff and defendant for at least two reasons explored earlier in chapter 2 of this thesis. First, an adversarial environment inherently creates barriers in the communication process, thereby reducing the opportunity to address the root cause of the dispute. Second, an overly litigious culture does not reduce the rate of adverse incidents and medical error but rather contributes to defensive communication, defensive practice, low rates of reporting, and limited opportunity to learn and improve—all of which substantially undermine quality and safety initiatives.

In light of these challenges, this chapter sought to examine the role of communication in response to medical error, and demonstrated that by identifying and addressing the early needs of patients and healthcare professionals, preventing poor communication, and deconstructing communication barriers through communication programs and support services: the need to initiate legal proceedings can be reduced and patient safety efforts strengthened. In-hospital communication programs designed to improve the interpersonal communication skills of healthcare professionals can be of enormous benefit in this regard.⁷³ While the majority of communication programs are centred around disclosure and apology, increasingly healthcare organisations are also including interpersonal communication training. In reemphasising the value of communication programs, Truog et al. have argued that communication programs teach clinicians how to “discern and balance the perspectives of patient and family members, the care team involved and the organizational culture; which includes: existing disclosure policies, administrative priorities in relation to transparency, risk management issues, and the overall tone and atmosphere of the organization vis-à-vis

⁷³ L Tickle, ‘Why Mediation Training Should be Offered in Hospitals.’ *The Guardian Professional* (London, 10 December 2014) <<http://www.theguardian.com/healthcare-network/2013/dec/10/mediation-training-offered-hospitals>>.

adverse events and medical errors.”⁷⁴ The latter half of this chapter provided the foundation for the next two chapters of this thesis by illustrating the consequences of poor communication, and the benefits of (and opportunities for) constructive healthcare communication. The following chapter will examine in greater depth the legal and ethical duty of the physician to disclose patient safety incidents to the patient. Barriers to disclosure, as well as best practice in the disclosure of incidents and medical error will also be considered and analysed.

⁷⁴ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 72.

- Chapter 11 -

Communication: Disclosure and Apology

11.1 Introduction

The disclosure of medical error has traditionally been a contentious process. Despite evidence that patients desire information following a patient safety incident; the disclosure of such incidents has been fraught with concern—both by the physician and healthcare organisation—over legal liability. Dissonance between the immediate needs of patient and the potential consequences faced by the physician and healthcare organisation have prevented the effective communication of incidents and medical errors. As Rabinovich-Einy argues, “The shadow of legal doctrine provides distorted incentives which yield suboptimal results: high conflict rates, difficulties in communication, limited avenues for addressing disputes, and increased risk of litigation. Most important, this state of affairs has affected not only the manner in which members of medical staffs communicate, but also the quality of services they provide.”¹ In an effort to deconstruct the “shadow of legal doctrine” identified by Rabinovich-Einy, the first section of this chapter will critically analyse the legal and ethical duty placed on physicians and healthcare organisations in the United States, Canada and England to disclose an adverse incident, including medical error. Despite both legal and ethical obligations, barriers continue to restrict physicians and healthcare organisations from early and thorough disclosure. For this reason, the second section will examine the legal and psychological barriers preventing the effective disclosure of medical error. In the third section, best practices for disclosure as identified by the literature will be considered. This approach has been taken as jurisdictional limitations may vary. The fourth section of this chapter will critically analyse apologies given in the course of disclosure. Apologies for preventable incidents

¹ O Rabinovich-Einy, ‘Escaping the Shadow of Malpractice Law’ (2011) 74 *Law and Contemporary Problems* 241, 243.

continue to be considerably more legally contentious, despite the desire by patients for their inclusion. This section will examine the law in the United States, Canada, and England as it applies to apologies given in the course of disclosing preventable incidents. Finally, this chapter will conclude in the fifth section with specific examples of disclosure and communication programs that have had a demonstrable benefit in educating and enabling physicians to provide effective disclosure of patient safety incidents and medical error to patients.

11.2 The Obligation to Disclose: An Ethical and Legal Duty

The duty of a physician to disclose a patient safety incident—particularly where harm to the patient has occurred—can be said to arise from both an ethical duty and a legal duty.

The ethical duty to disclose derives from the fiduciary nature of the physician-patient relationship and the ethical obligation to respect patient autonomy.² Fiduciary obligations are imposed by the common law to ensure, “a person occupying a societal role with a high potential for the manipulation of vulnerable persons exercises utmost good faith.”³ The fiduciary nature of the physician–patient relationship was described by McLachlin J. (as she was then) in the Canadian case of *Norberg v Wynrib*:

² A Hannawa, ‘Principles of Medical Ethics: Implications for the Disclosure of Medical Errors’ (2012) 2 *Medicolegal and Bioethics* 1, 3–4. Hannawa makes the argument that requiring only the disclosure of serious harmful events compromises the moral right of patient autonomy. See further: A Wu et al., ‘To Tell the Truth—Ethical and Practical Issues in Disclosing Medical Mistakes to Patients’ (1997) 12 *Journal of General Internal Medicine* 770, 772; J Karla and M Entwistle, ‘Medical Error Disclosure and Professionalism: The Right Thing to Do’ (2014) 2(2) *Annals of Clinical Pathology* 1023, 1024. The authors argue that the disclosure of error is not only ethically necessary, but an inherent component of professionalism: “Physicians are professionals, and owe their ultimate allegiance to their patients. The physician duty to disclose is an inherent part of their role of (sic) professionals that further derives from an underlying moral basis of the practice of medicine.”

³ T Faunce and S Bolsin, ‘Fiduciary Disclosure of Medical Mistakes: The Duty to Promptly Notify Patients of Adverse Health Care Events’ (2005) 12 *Journal of Law and Medicine* 478; M Waite, ‘To Tell the Truth: The Ethical and Legal Implications of Disclosure of Medical Error’ (2005) 13 *Health Law Journal* 1, 17.

“The relationship of physician and patient can be conceptualized in a variety of ways. It can be viewed as a creature of contract, with the physician’s failure to fulfill his or her obligations giving rise to an action for breach of contract. It undoubtedly gives rise to a duty of care, the breach of which constitutes the tort of negligence. ... But perhaps the most fundamental characteristic of the doctor–patient relationship is its fiduciary nature. All the authorities agree that the relationship of physician to patient also falls into that special category of relationships which the law calls fiduciary.”⁴

The fiduciary duty is established at law when the physician agrees to treat a patient who, by express or implied consent, has sought or requires their services. This duty remains throughout the course of the patient’s care.⁵ Where a serious incident occurs during care, the fiduciary duty owed to the patient includes the duty to disclose information related to the incident and harm that has occurred. In addition, it could be argued that such a duty becomes increasingly significant for the patient who, following an incident, may be left vulnerable and seeking information.⁶

In addition to an ethical duty, physicians also owe a legal duty to the patient to inform them when an incident effecting their care has occurred, as will be examined in greater detail below. The legal duty arises from the doctrine of informed consent, as well as the

⁴ *Norberg v Wynrib* [1992] 2 SCR 226, 270–271, per McLachlin J.

⁵ E Picard and G Robertson, *Legal Liability of Doctors and Hospitals in Canada*. (4th edn, Toronto: Carswell, 2007) 7–8.

⁶ T Faunce and S Bolsin, ‘Fiduciary Disclosure of Medical Mistakes: The Duty to Promptly Notify Patients of Adverse Health Care Events’ (2005) 12 *Journal of Law and Medicine* 478, 481. In this regard the authors make the argument, “Where patients have suffered an adverse event, surely their vulnerability has been heightened. The equitable case for attaching a fiduciary duty to relevant aspects of the doctor-patient relationship is also undoubtedly increased in such circumstances.”

obligation to respect the patient's autonomy.⁷ In such instances, insuring the patient's consent is informed requires that not only the facts surrounding the incident be disclosed, but that material risks and benefits associated with subsequent necessary treatment also be disclosed.⁸ By establishing a legal duty to disclose, Hafemeister and Spinos note that such a duty, "sends a clear message that physicians must not succumb to the fears that may breed silence among some physicians. A legal duty to disclose gives physicians a tangible, concrete requirement that undercuts any rationalizing of a need for concealment."⁹ As will be analysed below, an ethical and legal duty has been recognised in many jurisdictions. The United States, Canada, and England will now be specifically analysed.

United States

From 2001, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) required hospitals with Joint Commission Accreditation to disclose all unanticipated outcomes to patients and their families.¹⁰ This includes an obligation on the physician and the healthcare organisation, failure of which can jeopardise accreditation approval. Shortly after, the National Quality Forum also published Safe Practice guidelines for the disclosure of medical error. The most recent edition of the

⁷ J Moskop et al. 'Emergency Physicians and Disclosure of Medical Errors.' (2006) 48(5) *Annals of Emergency Medicine* 523, 524; T Gallagher et al., 'Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors' (2003) 289(8) *JAMA* 1001.

⁸ For example, in the Canadian case of *Gerula v Flores* [1995] 126 DLR (4th) 506, the court held the defendant-physician had breached his fiduciary duty to the patient by failing to disclose an error during the initial surgery; the consequence of which lead to successive surgeries without the plaintiff-patient's informed consent. The court awarded the plaintiff special and general damages, as well as future care and loss of income. See further: T Hafemeister and S Spinos, 'Lean on Me: A Physician's Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient' (2009) 86(5) *Washington University Law Review* 1167, 1185, 1205-1206; citing the American case of *Canterbury v Spence* [1972] D.C. Cir. 464 F.2d 772.

⁹ T Hafemeister and S Spinos, 'Lean on Me: A Physician's Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient' (2009) 86(5) *Washington University Law Review* 1167, 1182.

¹⁰ Joint Commission on Accreditation of Healthcare Organizations, *Revisions to Joint Commission Standards in Support of Patient Safety and Medical Health Care Error Reduction*. (Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations, 2001). See Chapter 4.4.2 'Organisational and Professional Regulation.'

guidelines states that physicians and organisations should provide empathic and timely communication of the factual information regarding serious unanticipated outcomes, as well as express regret and offer an apology where the investigation reveals the incident was clearly caused by unambiguous errors or system failures.¹¹

As it applies to individual physicians, the American Medical Association's (AMA) *Code of Medical Ethics* expressly recognise the ethical duty owed to patient, stating:

“It is a fundamental ethical requirement that a physician should at all times deal honestly and openly with patients. Patients have a right to know their past and present medical status and to be free of any mistaken beliefs concerning their conditions. Situations occasionally occur in which a patient suffers significant medical complications that may have resulted from the physician's mistake or judgment. In these situations, the physician is ethically required to inform the patient of all the facts necessary to ensure understanding of what has occurred. Only through full disclosure is a patient able to make informed decisions regarding future medical care.

Ethical responsibility includes informing patients of changes in their diagnoses resulting from retrospective review of test results or any other information. This obligation holds even though the patient's medical treatment or therapeutic options may not be altered by the new information.”¹²

In contrast, the Canadian Medical Association (CMA) *Code of Ethics* simply states that physicians should, “Take all reasonable steps to prevent harm to patients; should harm

¹¹ National Quality Forum, *Safe Practices for Better Healthcare-2009 Update: A Consensus Report* (Washington: National Quality Forum, 2009) 117-119.

¹² American Medical Association Council on Ethical and Judicial Affairs, *Code of Medical Ethics: Current Opinions with Annotations 2014-2015* (Chicago: American Medical Association Press, 2014) [8.121].

occur, disclose it to the patient.”¹³ Although the duty set out by the CMA is beneficial insofar as it establishes a duty to disclose harm to the patient, the explicit statement by the AMA is preferable for a number of reasons. First, it clearly defines the duty to disclose as a fundamental ethical requirement. Second, the AMA make clear the duty to disclose is intrinsic to the patient’s informed consent. Finally, by comparison, the AMA’s statement on the duty to disclose is instructive, including the obligation of disclosure notwithstanding harm.

England

In England, the professional Duty of Candour has been recognised by the General Medical Council who state, “Every healthcare professional must be open and honest with patients when something goes wrong with their treatment or care which causes, or has the potential to cause, harm or distress.”¹⁴ This duty extends to telling the patient when something has gone wrong, apologising, offering an appropriate remedy or support, and explaining the short and long term effects of what has occurred.¹⁵ Likewise, the Royal College of Surgeons further recognise a professional duty, stating: “... candour means the quality of being open and honest. Patients should be well-informed about all elements of their care and treatment and all caring staff have a responsibility to be open and honest to those in their care. It follows then that care

¹³ Canadian Medical Association, *Code of Ethics* (Ottawa: Canadian Medical Association, 2004) [14]; as taken from: M Waite, ‘To Tell the Truth: The Ethical and Legal Implications of Disclosure of Medical Error’ (2005) 13 Health Law Journal 1, 9. For an examination of disclosure policies specific to the Canadian healthcare system, see further: J Kalra, *Medical Errors and Patient Safety: Strategies to Reduce and Disclose Medical Errors and Improve Patient Safety* (Berlin, New York: De Gruyter, 2011) 77-86; J Kalra, ‘Medical Error, Disclosure and Patient Safety: A Global View of Quality Care’ (2013) 46(13-14) *Clinical Biochemistry* 1161.

¹⁴ General Medical Council, *Good Medical Practice* (Manchester: General Medical Council, 2013) [55]; General Medical Council, ‘Joint Statement from the Chief Executives of Statutory Regulators of Healthcare Professionals’ (13 October 2014) <http://www.gmc-uk.org/Joint_statement_on_the_professional_duty_of_candour_FINAL.pdf_58140142.pdf> accessed: 17 November 2014.

¹⁵ *ibid.* See also: V Harpwood, *Medicine, Malpractice and Misapprehensions* (Oxon: Routledge-Cavendish, 2007) 197; K Dalton, ‘Physician Licensing and Disciplining in England and Europe’ in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 690.

organisations should have and sustain a culture which supports staff to be candid.”¹⁶ The ethical duty set out exemplifies the necessity of communication following an incident.

In 2003, a statutory duty of candour was proposed (although not acted upon until a decade later—albeit to a lesser extent) in the seminal UK report *Making Amends* which included, *inter alia*, “a duty of candour requiring clinicians and health service managers to inform patients about actions which have resulted in harm.”¹⁷

The Report of the Mid-Staffordshire NHS Foundation Trust Public Inquiry, also known as the “Francis Report,” expanded on the statutory duty proposed in *Making Amends*, placing the obligation, *inter alia*, “On healthcare providers who believe or suspect that treatment or care provided by it to a patient has caused death or serious injury to a patient to inform that patient or other duly authorised person as soon as is practicable of that fact and thereafter to provide such information and explanation as the patient reasonably may request.” The report also proposed extending the statutory duty on

¹⁶ D Dalton and N Williams, *Building a Culture of Candour: A Review of the Threshold for the Duty of Candour and of the Incentives for Care Organisations to be Candid* (London: Royal College of Surgeons, 2014) 2. <<https://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf>> accessed: 12 November 2014.

¹⁷ L Donaldson, *Making Amends: A Consultation Paper Setting Out Proposals for Reforming the Approach to Clinical Negligence in the NHS* (London: Department of Health, 2003) 18.

healthcare organisations to inform the patient where harm has occurred.¹⁸ The report defined “candour” as: “The volunteering of all relevant information to persons who have or may have been harmed by the provision of services, whether or not the information has been requested and whether or not a complaint or a report about that provision has been made.”¹⁹

In 2013, the duty of candour was incorporated into standard NHS contracts within England and Wales as a contractual term for healthcare professionals.²⁰ That same year, the Care Quality Commission (CQC)—an executive non-departmental public body of the Department of Health established to regulate health and social care in England—identified the duty of candour as a “fundamental standard” that requires the health service body to act in an open and transparent way with the relevant person in relation

¹⁸ R Francis, *Report of the Mid-Staffordshire NHS Foundation Trust Public Inquiry: Volume 3* (London: The Stationery Office, 2013) 1495. The statutory obligation proposed in Recommendation 181 of the *Francis Report* states:

“A statutory obligation should be imposed to observe a duty of candour:

- On healthcare providers who believe or suspect that treatment or care provided by it to a patient has caused death or serious injury to a patient to inform that patient or other duly authorised person as soon as is practicable of that fact and thereafter to provide such information and explanation as the patient reasonably may request;
- On registered medical practitioners and registered nurses and other registered professionals who believe or suspect that treatment or care provided to a patient by or on behalf of any healthcare provider by which they are employed has caused death or serious injury to the patient to report their belief or suspicion to their employer as soon as is reasonably practicable.

The provision of information in compliance with this requirement should not of itself be evidence or an admission of any civil or criminal liability, but non-compliance with the statutory duty should entitle the patient to a remedy.”

¹⁹ *ibid* 1442.

²⁰ M Devlin, ‘Why the New Duty of Candour Could be Detrimental to the NHS’ *The Guardian Professional* (London, 8 April 2014) <<http://www.theguardian.com/healthcare-network/2014/apr/08/duty-of-candour-nhs>>. Noting: “The contractual duty of candour was introduced into standard NHS contracts in England in 2013 and applies to organisations, rather than individuals. It requires that patients or their relatives be told about moderate or severe harm, or incidents that result in death, and recognises it is almost always doctors who do this.”

to the treatment provided, including the disclosure of a “notifiable safety incident.”²¹ The statutory duty of candour applies to all NHS Bodies (including trusts, foundation trusts and special health authorities) as of 01 October 2014, and will apply to all other care providers registered with the CQC as of the 01 April 2015.²² However, it should be noted that while some of the recommendations made in the *Francis Report* as to the duty of candour were adopted, the new CQC did not include a statutory duty on healthcare professionals, only the Health Service Body.²³ This was strongly recommended by the National Advisory Group on the Safety of Patients in England who argued, “We do not support the creation of a statutory duty for healthcare workers to report beliefs or suspicions about serious incidents to their employer, as this duty is adequately addressed in relevant professional codes of conduct and guidance.”²⁴ Physician accountability for disclosure, however, continues to be enforced via ethical, licensing, and legislative (e.g. the duty of care) requirements.

²¹ Care Quality Commission, *Guidance for Providers on Meeting the Fundamental Standards and on CQC’s Enforcement Powers* (Consultation Paper, July 2014) 104-105. <http://www.cqc.org.uk/sites/default/files/20140725_fundamental_standards_and_enforcement_consultation_final.pdf> accessed: 12 November 2014. See further: Health and Social Care Act 2008 (which sets out the functions of the Care Quality Commission); section 20, Health and Social Care Act 2008, as amended by section 81, Care Act 2014 (regarding the duty of candour on NHS Bodies where an incident of a specified description affects a person’s safety.)

²² Care Quality Commission, *Guidance for NHS Bodies on the Fit and Proper Person Requirement for Directors and the Duty of Candour* (Consultation Paper, July 2014) 2. <http://www.cqc.org.uk/sites/default/files/20140725_nhs_fppr_and_doc_consultation_final.pdf> accessed: 18 November 2014.

²³ *ibid* 9. CQC Regulation 20 sets out the requirements for the Duty of Candour:

“The aim of the regulation is to ensure that providers are open and honest with patients when things go wrong with their care and treatment. To meet the requirements of the regulation, a provider has to:

- Make sure it has an open and honest culture across and at all levels within its organisation
- Tell patients in a timely manner when particular incidents have occurred. Consultation: Guidance on the fit and proper person requirement for directors and the duty of candour 10
- Provide in writing a truthful account of the incident and an explanation about the enquiries and investigations that they will carry out
- Offer an apology in writing
- Provide reasonable support to the person after the incident.”

²⁴ D Berwick, *A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England* (London: Department of Health, 2013) 34; see further: Chapter 4.4.2 ‘Organisational and Professional Regulation.’

Failure to Adhere to the Standard of Care

In principle, the standard of care will be satisfied when the physician can establish he/she has fulfilled their ethical and legal duty to the patient. Consequently, failure to adhere to the standard of care may leave few defences available to the physician.²⁵ The exception being therapeutic privilege, which arises when—in the best interests of the patient—nondisclosure is appropriate based on the condition of the patient.²⁶

However, as the American Medical Association state, “On balance, this privilege should be interpreted narrowly; invoking it too

broadly can undermine the entire concept of informed consent.”²⁷ In such instances, the benefits of nondisclosure must outweigh the duty to inform the patient.²⁸

Where the ethical and legal duty to disclose has been breached, the patient may be entitled to equitable relief in terms of restitution, or an award of monetary compensation by way of special and general damages.²⁹ Moreover, aggravated or punitive damages may be awarded in situations where there has been a flagrant breach of the duty to disclose or where the court determines the physician’s conduct merits

²⁵ T Hafemeister and S Spinos, ‘Lean on Me: A Physician’s Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient’ (2009) 86(5) *Washington University Law Review* 1167, 1182.

²⁶ J Moskop et al. ‘Emergency Physicians and Disclosure of Medical Errors.’ (2006) 48(5) *Annals of Emergency Medicine* 523, 525. The authors note, “In rare circumstances, it may be appropriate for emergency physicians to limit disclosure of information to their patients on the basis of ‘therapeutic privilege.’ Like the reasonable person standard of information disclosure, the doctrine of therapeutic privilege has its origins in the law of informed consent.”

²⁷ American College of Physicians, *American College of Physicians Ethics Manual*. 3rd edn. (1992) 117 *Annals of Internal Medicine* 947–960; as taken from: A Wu et al., ‘To Tell the Truth—Ethical and Practical Issues in Disclosing Medical Mistakes to Patients’ (1997) 12 *Journal of General Internal Medicine* 770, 771.

²⁸ J Moskop et al. ‘Emergency Physicians and Disclosure of Medical Errors.’ (2006) 48(5) *Annals of Emergency Medicine* 523, 525; citing: M Smith and H Forster, ‘Morally Managing Medical Mistakes’ (2000) 9 *Cambridge Quarterly of Healthcare Ethics* 38–53. See further: S Abigail, ‘The Obstacle of Therapeutic Privilege in Healthcare Mediation’ (2011) *American Journal of Mediation* 1.

²⁹ T Hafemeister and S Spinos, ‘Lean on Me: A Physician’s Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient’ (2009) 86(5) *Washington University Law Review* 1167, 1198; citing: M Mehlman, ‘Dishonest Medical Mistakes’ (2006) 59 *Vanderbilt Law Review* 1137, 1153. See further: M Waite, ‘To Tell the Truth: The Ethical and Legal Implications of Disclosure of Medical Error’ (2005) 13 *Health Law Journal* 1, 15–16.

sanction.³⁰ Despite the gravity of sanctions, the American Medical Association's *Code of Ethics* expressly states, "Concern regarding legal liability which might result following truthful disclosure should not affect the physician's honesty with a patient."³¹

Having examined the legal and ethical duties to disclosure, it is now useful to consider the many barriers that can prevent effective disclosure.

11.3 Barriers to Disclosure

Despite the ethical and legal duty to disclose the occurrence of an incident, it is evident from an analysis of the literature that a "Disclosure Gap" continues to exist between the stated ideals of disclosure and current practice. As Truog et al. argue, the persistence of such a gap:

"... likely reflects the mixed messages that organizations continue to send regarding disclosure. These messages mirror the deep ambivalence that individual clinicians themselves experience related to this issue. For individual clinicians, the positive effects of transparency are often outweighed by a lack of confidence in their capacity to communicate effectively in these situations and by fears about negative consequences that may ensue."³²

For example, in a study surveying American and Canadian physicians, Gallagher et al. found that 98% of physicians surveyed said they would disclose a serious error, and

³⁰ M Waite, 'To Tell the Truth: The Ethical and Legal Implications of Disclosure of Medical Error' (2005) 13 Health Law Journal 1, 21.

³¹ American Medical Association Council on Ethical and Judicial Affairs, *Code of Medical Ethics: Current Opinions with Annotations 2014-2015* (Chicago: American Medical Association Press, 2014) [8.121].

³² R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 121; H Woodward et al., 'What Have We Learned About Interventions to Reduce Medical Errors?' (2010) 31 Annual Review of Public Health 479, 486.

74% supported disclosing minor errors.³³ However, actual rates of disclosure may not be meeting this stated ideal. This was demonstrated in a study by Kaldjian et al., in which the authors found that while a high rate of the physician and resident respondents felt errors should be disclosed, there was a discrepancy in the actual rates of disclosure. Although 97% said they would disclose a minor error, only 41% had previously. Likewise, 93% said major errors should be disclosed, yet the authors found that only 5% of the respondents had disclosed a major error in practice.³⁴ Similarly, in a 2007 study of more than 3600 physicians across the United States, Campbell et al. found that 93% of physicians agreed with the statement “Physicians should report all significant medical errors they observe to hospital, clinic, or other relevant authorities;” yet only 85% of physicians agreed with the statement “Physicians should disclose all significant medical errors to affected patients and/or guardians.”³⁵

The reason behind this may be more closely connected to the varying levels of disclosure and information contained therein. This was demonstrated in a study Fein et al. who found that while the majority of physicians surveyed would disclose an error, the level of disclosure ranged from full disclosure, which contained an explicit link between the error and the effect; to only partial disclosure which contained components of a full disclosure but was deficient in one of three ways. As the authors observed, this may include failing to provide a link “between the error and the effect (Connect-the-dots), an obfuscation of whether the error constituted a mistake or was a

³³ T Gallagher et al., ‘US and Canadian Physicians’ Attitudes and Experiences Regarding Disclosing Errors to Patients’ (2006) 166 (15) *Archives of Internal Medicine* 1605-1611.

³⁴ L Kaldjian et al., ‘Disclosing Medical Errors to Patients: Attitudes and Practices of Physicians and Trainees’ (2007) 22(7) *Journal of General Internal Medicine* 988. The authors also found that “Experience with malpractice litigation was not associated with less actual or hypothetical error disclosure. Faculty were more likely than residents and students to disclose a hypothetical error and less concerned about possible negative consequences of disclosure.”

³⁵ E Campbell et al., ‘Professionalism in Medicine: Results of a National Survey of Physicians’ (2007) 147(11) *Annals of Internal Medicine* 795, 797.

natural part of the disease process or care (Mislead), or a deferral of interpretation of events without intent to reach closure (Defer).”³⁶

Legal Barriers

An analysis of the literature strongly suggests that the fear of liability is a leading barrier to the disclosure of medical error.³⁷ Lachman has argued that the present system of tort liability discourages the level of honesty and openness required for the effective disclosure of error.³⁸ In addition to the threat of an action in negligence and breach of fiduciary duty; the potential for emotional and legal costs, possible suspension or revocation of one’s medical license, as well as jurisdictional issues are all factors that—from a pragmatic perspective—can outweigh the presumed benefits of disclosing medical error.³⁹ Specifically in relational to the latter point, a useful example

³⁶ S Fein et al., ‘The Many Faces of Error Disclosure: A Common Set of Elements and Definition’ (2007) 22(6) *Journal of General Internal Medicine* 755, 757-759.

³⁷ J Moskop et al. ‘Emergency Physicians and Disclosure of Medical Errors.’ (2006) 48(5) *Annals of Emergency Medicine* 523, 526; citing: C Hobgood et al., ‘Medical Errors: What and When Do Patients Want to Know?’ (2002) 9 *Academic Emergency Medicine* 1156-1161; R Blendon et al., ‘Views of Practicing Physicians and the Public on Medical Errors.’ (2002) 347 *NEJM* 1933-1940; T Brennan and M Mello, ‘Patient Safety and Medical Malpractice: A Case Study.’ (2003) 139 *Annals of Internal Medicine* 267-273. See also: T Gallagher and W Levinson, ‘Disclosing Harmful Medical Errors to Patients: A Time for Professional Action.’ (2005) 165 *Archives of Internal Medicine* 1819-1823; B Liang, ‘A System of Medical Error Disclosure.’ (2002) 11 *BMJ Quality & Safety* 64-68; S Wolk et al., ‘Institutional Disclosure: Promise and Problems’ (2014) 33(3) *Journal of Healthcare Risk Management* 24. Wolk notes that “Although fear of legal action is frequently put forward as the reason that disclosure programs have been slow to be adopted by the medical community, social and nonjurisprudential explanations also pose challenges.”

³⁸ V Lachman, ‘Patient Safety: The Ethical Imperative’ (2008) 20(2) *Journal of the Dermatology Nursing Association* 134, 135. Further arguing, “Viewed from the perspective of utility (‘greatest good for the greatest number’), the tort process is ineffective.”

³⁹ T Hafemeister and S Spinos, ‘Lean on Me: A Physician’s Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient’ (2009) 86(5) *Washington University Law Review* 1167, 1178; citing: T Gallagher and W Levinson, ‘Disclosing Harmful Medical Errors to Patients: A Time for Professional Action’ (2005) 165(16) *Archives of Internal Medicine* 1819, 1819. See further: A Wu et al., ‘To Tell the Truth—Ethical and Practical Issues in Disclosing Medical Mistakes to Patients’ (1997) 12 *Journal of General Internal Medicine* 770, 774. Wu notes, “From a pragmatic point of view, physicians are often most concerned about the potentially harmful personal consequences of disclosing a mistake. In blunt terms, physicians may question whether any possible benefits to the patient are worth the possible risks of a lawsuit to their career or livelihood. This clash between ethical ideals and pragmatic reality is a difficult one.”

of a jurisdiction specific barrier is that of the National Practitioner Data Bank (NPDB). In the event of a settlement, Healthcare Practitioners and Insurance Companies in the United States are required to report details of the value of the settlement to the NPDB—regardless of the value of the settlement—in accordance with the Health Care Quality Improvement Act 1986. While the details of a NPDB report remain confidential from the public, healthcare organisations are required to query the NPDB when initially credentialing physicians and every two years following their employment.⁴⁰ Although the requirement on healthcare organisations to investigate previous malpractice cases against a new or current employee certainly has merit, and in itself could be considered a safety barrier, it is equally understandable that owing to this, physicians are hesitant about agreeing to settlement offers. In his 2014 publication, Wu argued that for disclosure programs to be effective, they must be separated from regulatory scrutiny:

“Disclosure and offer programs cannot be successful if they trigger increased regulatory scrutiny. Because liability compensation may flow from disclosure, linked processes are needed such that adopters are not penalized. Current processes that were not designed to incentivize open disclosure may need to be modified to reduce barriers to open disclosure. One solution might be to separate cases in which providers or institutions are found culpable via litigation from cases in which a disclosure and offer program is in place. It might also help if participation in disclosure and offer programs was recognized by regulators as a mitigating factor, although it

⁴⁰ H Morreim, ‘Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank’ (2012) 27(1) *Ohio State Journal on Dispute Resolution* 109; A Block, ‘Disclosure of Adverse Outcomes and Apologizing to the Injured Patient’ in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 287; J Gic, ‘Nursing and the Law’ in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 495.

would be undesirable to create the impression that apology is a replacement for accountability.”⁴¹

Two important points can be taken from Wu’s proposed solutions to regulatory scrutiny as a barrier to disclosure. The first is the recommendation that a finding of liability awarded in the course of litigation would be distinguished from an award of compensation in the course of a disclosure program or ADR. Although certainly reasonable insofar as it would incentivise the use of disclosure programs and reduce one of the barriers preventing their wide spread use; it also raises a potential conflict. In the following section, the example of the University of Michigan Health System’s Disclosure program will be examined in depth; however, it is useful to note at this stage that a key component of the program is the offer of disclosure, apology and early-compensation where care is found to be inappropriate. Where, following investigation, the care provided is found to be appropriate, the claim is aggressively defended by the University.⁴² Indeed, the argument could be made that a finding of liability will only occur when the defendant has been negligent, and therefore, a separate standard should apply to them. However, owing to the potential uncertainty of the standard of care, a hospital investigation may determine the care was appropriate, only to be found subsequently liable. In essence, a criticism of Wu’s proposal—from a legal perspective—is that a separate standard may prejudice a defendant who chooses to rebut a claim against them based on current best practice standards and the evidence against them.

⁴¹ A Wu et al., ‘Disclosing Adverse Events to Patients: International Norms and Trends’ (08 April 2014) *Journal of Patient Safety* 1, 4 [epub ahead of print]; citing: Sorry Works!, ‘Book 2.0.’ <<http://sorryworkssite.bondwaresite.com/what-is-the-problem-cms-44>>.

⁴² R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 47; R Boothman et al., ‘A Better Approach to Medical Malpractice Claims? The University of Michigan Experience’ (2009) 2 *Journal of Health & Life Sciences Law* 125.

The second observation that can be taken from Wu's analysis relates to the proposal that disclosure and offer programs be recognised by regulators as a mitigating factor. This seems a reasonable and feasible suggestion, not least because it is line with judicial practices when determining liability and compensation. However, Wu's observation that "it would be undesirable to create the impression that apology is a replacement for accountability" is certainly legitimate and not unique to the aforementioned proposal. Despite often wanting an apology, patients are more inclined to pursue litigation and reject early offers of compensation where they perceive the apology or offer as merely an attempt to avoid litigation (and therefore, accountability.)⁴³ In this respect, it is essential that patients are active participants throughout all applicable accountability processes—not just the legal process. This can include participation in disciplinary procedures, incident investigation and analysis, policy recommendations, and governance boards. When the care provided has fallen below the appropriate standard, the process of holding the individual accountable must be transparent and just for all parties involved. Patients need to see that those responsible cannot be absolved of accountability by merely admitting to it. Notwithstanding the above, the actual relationship between disclosure and liability is somewhat dubious. As Wu observed in his 2013 publication, "It is certain that absence of disclosure may drive litigation in an effort to find out what happened, and studies suggest that when disclosure is made, awards might be lower. However, there are also cases in which litigation occurs subsequent to the revelation of an unsuspected error."⁴⁴ Indeed a greater risk than disclosing an error may be in not disclosing it. Where a physician fails to disclose a serious error and a subsequent action in negligence is brought by the patient, the physician may be liable for the harm caused, and the failure

⁴³ L Murtagh et al., 'Disclosure-And-Resolution Programs That Include Generous Compensation Offers May Prompt A Complex Patient Response' (2012) 31(12) Health Affairs 2681.

⁴⁴ A Wu et al., 'Disclosure of Adverse Events in the United States and Canada: An Update, and a Proposed Framework for Improvement' (2013) 2(3) Journal of Public Health Research 186, 188; citing: P Popp, 'How Will Disclosure Affect Future Litigation?' (2003) 23 Journal of Healthcare Risk Management 5; D Studdert et al., 'Medical Malpractice' (2004) 350 NEJM 283.

to disclose it.⁴⁵ As it applies to minor errors, Moskop suggests that while a physician may not be legally or ethically obliged to disclose error of marginal or no impact, benefit can be gained from disclosure. On this point, he notes, "... minor mistakes, which are much more common than more serious errors, may provide a fertile training ground for acquiring the communication skills and comfort level necessary to admit error."⁴⁶

Despite conventional beliefs, numerous empirical and academic studies strongly suggest that disclosure is closely associated a decreased risk of liability and compensation awards.⁴⁷ An interesting example examining in detail disclosure and

⁴⁵ J Moskop et al. 'Emergency Physicians and Disclosure of Medical Errors.' (2006) 48(5) *Annals of Emergency Medicine* 523, 527; citing: J Cohen, 'Advising Clients to Apologize.' (1999) 72 *Southern California Law Review* 1009-1069; E Dauer, 'A Therapeutic Jurisprudence Perspective on Legal Responses to Medical Error.' (2003) 24 *Journal of Legal Medicine* 37-50; C Hobgood et al., 'Parental Preferences for Error Disclosure, Reporting, and Legal Action After Medical Error in the Care of their Children.' (2005) 116 *Journal of Pediatrics* 1276-1286; C Liebman and C Hyman, 'A Mediation Skills Model to Manage Disclosure of Errors and Adverse Events to Patients.' (2004) 23 *Health Affairs* 22-32; A Wu, 'Handling Hospital Errors: Is Disclosure the Best Defense?' (1999) 131 *Annals of Internal Medicine* 970-972. See also: A Wu et al., 'To Tell the Truth—Ethical and Practical Issues in Disclosing Medical Mistakes to Patients' (1997) 12 *Journal of General Internal Medicine* 770, 772; citing: T Gutheil et al., 'Malpractice Prevention Through the Sharing of Uncertainty. Informed Consent and the Therapeutic Alliance.' (1984) 311 *NEJM* 49-51; W Levinson, 'Patient-Physician Communication. A Key to Malpractice Prevention.' (1994) 272 *JAMA* 1619-1620.

⁴⁶ J Moskop et al. 'Emergency Physicians and Disclosure of Medical Errors.' (2006) 48(5) *Annals of Emergency Medicine* 523, 528; citing: J Banja, *Medical Errors and Medical Narcissism* (Massachusetts: Jones and Bartlett, 2005).

⁴⁷ A Wu et al., 'To Tell the Truth—Ethical and Practical Issues in Disclosing Medical Mistakes to Patients' (1997) 12 *Journal of General Internal Medicine* 770, 772; citing: T Gutheil et al., 'Malpractice Prevention Through the Sharing of Uncertainty. Informed Consent and the Therapeutic Alliance.' (1984) 311 *NEJM* 49-51; W Levinson, 'Patient-Physician Communication. A Key to Malpractice Prevention.' (1994) 272 *JAMA* 1619-1620. See also: J Moskop et al. 'Emergency Physicians and Disclosure of Medical Errors.' (2006) 48(5) *Annals of Emergency Medicine* 523, 527; citing: J Cohen, 'Advising Clients to Apologize.' (1999) 72 *Southern California Law Review* 1009-1069; E Dauer, 'A Therapeutic Jurisprudence Perspective on Legal Responses to Medical Error.' (2003) 24 *Journal of Legal Medicine* 37-50; C Hobgood et al., 'Parental Preferences for Error Disclosure, Reporting, and Legal Action After Medical Error in the Care of their Children.' (2005) 116 *Journal of Pediatrics* 1276-1286; S Kraman and G Hamm, 'Risk Management: Extreme Honesty May Be The Best Policy.' (1999) 131 *Annals of Internal Medicine* 963-967; C Liebman and C Hyman, 'A Mediation Skills Model to Manage Disclosure of Errors and Adverse Events to Patients.' (2004) 23 *Health Affairs* 22-32; A Wu, 'Handling Hospital Errors: Is Disclosure the Best Defense?' (1999) 131 *Annals of Internal Medicine* 970-972. In opposition of the argument that disclosure will reduce risk of liability, see: D Studdert et al., 'Disclosure of Medical Injury to Patients: An Improbable Risk Management Strategy' (2007) 25 *Health Affairs* Health 215.

liability risk can be seen in a study by Painter et al., in which the authors sought to determine if legislation in the state of Pennsylvania requiring the written and verbal disclosure of serious events was associated with an increase in malpractice claims or compensation costs. Perhaps surprisingly, while the authors found that written mandatory disclosure of serious events did not increase malpractice risk nor litigation rates; the awards of compensation increased for claims that had been disclosed, compared with those that had not. In commenting on the findings, the authors suggest that, "The circumstances of the disclosed situations were clear enough for the incidents to be labeled as serious events, thus giving the claimants the upper hand in negotiating settlements. Undisclosed situations were not so clear cut and thus more amenable to being contested which lowers settlement values."⁴⁸ In contrast, both the Veterans Affairs Hospital and the University of Michigan Health System Disclosure Programs (examined below) noticed a demonstrable reduction in the value of claims following disclosure.⁴⁹ However, the distinction may lie in the seriousness of the injury disclosed. As Painter identified above, it would be difficult to contest liability where a patient has been seriously harmed in the course of care and the organisation has disclosed all of the relevant facts necessary for a malpractice claim.

Where a patient decides to take legal action as a result of a complete lack of disclosure or the lack of timely disclosure, and the organisation wishes to contest it, a number of defenses are available. According to Hafemeister and Spinos, the physician in their defense can argue that, on the balance of probabilities:

⁴⁸ L Painter et al., 'Do Written Disclosures of Serious Events Increase Risk of Malpractice Claims? One Health Care System's Experience' (31 March 2015) *Journal of Patient Safety* 1, 6 [epub ahead of print].

⁴⁹ A Kachalia et al., 'Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program' (2010) 153(4) *Annals of Internal Medicine* 213, 217; G Balcerzak and K Leonhardt, 'Alternative Dispute Resolution in Healthcare: A Prescription for Increasing Disclosure and Improving Patient Safety' *Patient Safety & Quality Healthcare* (July–Aug. 2008) <<http://psqh.com/julaug08/resolution.html>> accessed: 31 October 2014. See further: Chapter 11.6 'Communication and Disclosure Programs.'

“(1) the physician did not owe a fiduciary duty to the patient (e.g., a physician-patient relationship did not exist at the time of discovery or the discovery was not made in a reasonable period of time after the relationship ended), (2) the physician did not have actual knowledge of an [emergent medical risk], (3) what the physician discovered was not a material risk, (4) a reasonable patient who received disclosure would not have pursued a course of action significantly different from that followed by this patient, or (5) the patient was not harmed by the physician’s failure to provide timely disclosure.”⁵⁰

Additionally, where a physician has disclosed an error and the patient has suffered adverse consequences, the disclosure itself puts the patient on notice of their current medical condition and subsequently has an obligation to mitigate the harm caused.⁵¹

Psychological Barriers

Beyond satisfying the legal and ethical duty, disclosure of information to a patient may have psychological benefits for both the patient and the physician.⁵² Notwithstanding, for physicians, significant barriers may impede the desire to disclose information. For example, a reluctance to disclose error may be the result of the physician’s character itself. As Moskop contends:

⁵⁰ T Hafemeister and S Spinos, ‘Lean on Me: A Physician’s Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient’ (2009) 86(5) Washington University Law Review 1167, 1189; citing: M Mehlman, ‘Dishonest Medical Mistakes’ (2006) 59 Vanderbilt Law Review 1137, 1147.

⁵¹ *ibid* 1208; noting, “After disclosure, the patient generally has an obligation to minimize any harm that has been incurred, and to seek treatment or take other steps to redress the [emergent medical risk]; a failure to act may offset any legal damages available to the patient.”

⁵² N Meruelo, ‘Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.’ (2008) 29 Journal of Legal Medicine 285, 290. See further: T Hafemeister and S Spinos, ‘Lean on Me: A Physician’s Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient’ (2009) 86(5) Washington University Law Review 1167, 1207-1208.

“Physicians with anxiety, depression, lack of self-confidence, or lack of confidence in due process may also be reluctant to disclose errors. Character defects such as arrogance or narcissism can make some physicians believe that duties of disclosure and honesty do not apply to them, because such physicians may view the interests of others as subordinate to their individual concerns. Other (hopefully rare) physicians who are slothful or avaricious or who abuse drugs or alcohol may also be unwilling to disclose medical errors.”⁵³

However, for the majority of physicians, the reluctance to disclose error may be the consequence of a culture that strives for perfectionism.⁵⁴ As Berlinger notes, “Some physicians may not be able to admit that they are capable of making errors, and so tell themselves and others that there was a ‘complication’ or that the patient was ‘noncompliant.’ Or they do not investigate the possibility of error and take refuge in ‘not knowing’ what happened—and thus have nothing to disclose.”⁵⁵ Additionally, physicians may have feelings of guilt, shame, incompetence, or fear that communicating the circumstances of an error will negatively impact their reputation and career⁵⁶ or may “... result in an irremediable erosion of patient trust both in them as individuals and in the medical profession as a whole.”⁵⁷

⁵³ J Moskop et al. ‘Emergency Physicians and Disclosure of Medical Errors.’ (2006) 48(5) *Annals of Emergency Medicine* 523, 526; citing: J Banja, *Medical Errors and Medical Narcissism* (Massachusetts: Jones and Bartlett, 2005).

⁵⁴ See further: Chapter 4.2 ‘Healthcare and the Culture of Blame.’

⁵⁵ N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005) 41.

⁵⁶ T Hafemeister and S Spinos, ‘Lean on Me: A Physician’s Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient’ (2009) 86(5) *Washington University Law Review* 1167, 1180; J Banja, *Medical Errors and Medical Narcissism* (Massachusetts: Jones and Bartlett, 2005) 19-46; A Wu et al., ‘To Tell the Truth—Ethical and Practical Issues in Disclosing Medical Mistakes to Patients’ (1997) 12 *Journal of General Internal Medicine* 770, 774; J Moskop et al. ‘Emergency Physicians and Disclosure of Medical Errors.’ (2006) 48(5) *Annals of Emergency Medicine* 523, 526.

⁵⁷ J Moskop et al. ‘Emergency Physicians and Disclosure of Medical Errors.’ (2006) 48(5) *Annals of Emergency Medicine* 523, 526.

Aside from subjective factors relating to the physician, the patient's circumstances themselves may pose a barrier to disclosure of error. As Moskop explains, "Even if an error is quickly identified, the patient may already be dead or may be unable to receive the information because he or she is unconscious, demented, intoxicated, or otherwise mentally impaired. As immigration and travel increase, language and cultural differences between patients and physicians are becoming more common barriers to engaging in sensitive, nuanced discussion of medical errors."⁵⁸ Likewise, system factors may also contribute to the reluctance to disclose error. Barriers can be created where there is a perceived lack of institutional support,⁵⁹ where the healthcare organisation places little value on non-punitive reporting of error, or as a result of time constraints inherent to the practice of medicine.⁶⁰ Moreover, a lack of emphasis on the identification of local barriers or communication skills training can also contribute to a reluctance to disclose error.⁶¹ As a means of addressing the latter issue, the Accreditation Council for Graduate Medical Education in the United States have made interpersonal and communication skills training a core competency for all

⁵⁸ *ibid*; A Wu et al., 'Disclosure of Adverse Events in the United States and Canada: An Update, and a Proposed Framework for Improvement' (2013) 2(3) *Journal of Public Health Research* 186, 188.

⁵⁹ M Mello et al., 'Communication-And-Resolution Programs: The Challenges And Lessons Learned From Six Early Adopters' (2014) 33(1) *Health Affairs* 20; A Hannawa, 'Principles of Medical Ethics: Implications for the Disclosure of Medical Errors' (2012) 2 *Medicolegal and Bioethics* 1, 2; citing: T Gallagher et al., 'Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors' (2003) 289(8) *JAMA* 1001; J Waring, 'Beyond Blame: Cultural Barriers to Medical Incident Reporting.' (2005) 60 *Social Science & Medicine* 1927; L Kaldjian et al., 'An Empirically Derived Taxonomy of Factors Affecting Physicians' Willingness to Disclose Medical Errors.' (2006) 21 *Journal of General Internal Medicine* 942.

⁶⁰ T Hafemeister and S Spinos, 'Lean on Me: A Physician's Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient' (2009) 86(5) *Washington University Law Review* 1167, 1178. The authors further note that in some jurisdictions, physicians may not be reimbursed for costs relating to redressing medical errors.

⁶¹ A Wu et al., 'Disclosure of Adverse Events in the United States and Canada: An Update, and a Proposed Framework for Improvement' (2014) 2(32) *Journal of Public Health Research* 186; A Wu et al., 'To Tell the Truth—Ethical and Practical Issues in Disclosing Medical Mistakes to Patients' (1997) 12 *Journal of General Internal Medicine* 770, 772-774.

residency programs.⁶² Ideally, however, patient safety education and communication training should be comprehensively included within healthcare related university programs, and subsequently in continuing professional development.⁶³

11.4 Procedure⁶⁴

Perhaps unsurprisingly, when a patient safety incident occurs—particularly where the patient has been harmed in the process—patients desire information. This may include an explanation of the event, what will be done to prevent a future occurrence, and their options for future treatment. Patients may further desire accountability, compassion, empathy, and where appropriate, an apology.⁶⁵ Above all, the patient’s perception of the patient-physician interaction may be more important—both in terms of restoring the therapeutic relationship and in the decision to pursue a legal claim—than the actual words used during the conversation.⁶⁶ As Meruelo has argued, “... disclosure

⁶² J Moskop et al. ‘Emergency Physicians and Disclosure of Medical Errors.’ (2006) 48(5) *Annals of Emergency Medicine* 523, 526; citing: Accreditation Council for Graduate Medical Education, *Outcomes Project. General Competencies: Minimum Program Requirements Language* (Chicago: ACGME, 1999).

⁶³ M Communal et al., ‘An Assessment of Basic Patient Safety Skills in Residents Entering the First Year of Clinical Training’ (12 June 2015) *Journal of Patient Safety* [epub ahead of print]. In this regard, the authors suggest, “... there is a need for additional training and perhaps new methods of training and reinforcement in medical school and beyond, to hardwire these basic patient safety skills.”; WHO World Alliance for Patient Safety, *Patient Safety Workshop: Learning from Error* (Geneva: WHO, 2008) WHO/IER/PSP/2008.09. p10. The WHO have noted, “Topics such as task management, multidisciplinary team working, risk perception and prediction, decision making and recognition of personal and technological limitations all contribute to a deeper understanding of error and have been shown to prevent error. Nevertheless, these concepts are still not taught with the same rigour as more traditional educational topics.”

⁶⁴ This section is intended as an overview of best clinical practice as it relates to the disclosure of patient safety incidents. However, it should be noted that legislation specific to the jurisdiction may apply as to the admissibility of statements made during the course of the disclosure.

⁶⁵ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 32; citing: N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005). See further: T Gallagher et al., ‘Patients’ and Physicians’ Attitudes Regarding the Disclosure of Medical Errors’ (2003) 289(8) *JAMA* 100; K Mazor et al., ‘Health Plan Members’ Views about Disclosure of Medical Errors.’ (2004) 140 *Annals of Internal Medicine* 409.

⁶⁶ A Wu et al., ‘Disclosing Medical Errors to Patients: It’s Not What You Say, It’s What They Hear.’ (2009) 24 *Journal of General Internal Medicine* 1012.

may ultimately strengthen a physician-patient relationship because of all the ancillary psychological effects such behavior has on patients.”⁶⁷ Patients, however, may define error more broadly than healthcare professions, including patient safety incidents where error is not present. For example, Wu suggests that a patient’s definition of error may include communication problems; a feeling of disrespect, or lack of compassion; as well as non-preventable incidents.⁶⁸ As such, a challenge arises for physicians in knowing when and what to disclose to a patient, as well as adequately communicating information about non-preventable incidents. Owing to the gravity of these elements, the next section will address best practices as they apply to the disclosure of a patient safety incident.

The Timeliness of Disclosure

A number of factors are relevant in determining the most appropriate time for disclosing information. As Truog et al. note, at the first indication of an incident all relevant persons, including key members of the care team, hospital administration, and risk management should be notified, and the facts surrounding the incident should be collected. Where medical equipment may be involved, it should be sequestered until an investigation can take place. Although the initial investigation will likely contain a number of questions that cannot be answered immediately, it is essential in making a determination as to whether the event meets the threshold for disclosure.⁶⁹ Key considerations will include severity, amount of information known at the time,

⁶⁷ N Meruelo, ‘Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.’ (2008) 29 *Journal of Legal Medicine* 285, 290; citing: Letter to the Editor, ‘When Doctors Hide Medical Errors’ *New York Times* (New York, 9 September 2006) ”

⁶⁸ A Wu et al., ‘Disclosure of Adverse Events in the United States and Canada: An Update, and a Proposed Framework for Improvement’ (2013) 2(3) *Journal of Public Health Research* 186; citing: T Burroughs et al., ‘Patient Concerns About Medical Errors During Hospitalization’ (2007) 33(1) *Joint Commission Journal on Quality and Patient Safety* 5; K Mazor et al., ‘Towards Patient-Centered Cancer Care: Patient Perceptions of Problematic Events, Impact, and Response.’ (2012) 30 *Journal of Clinical Oncology* 1784.

⁶⁹ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 75-78.

subjective patient factors, and legal and ethical considerations. If it is found to merit disclosure, consideration must then be given as to whether it would be beneficial to the patient to disclose the information at that time. Although rare, therapeutic privilege may apply at this stage and be in the best interests of the patient.⁷⁰ It is further necessary at this time to remain fully committed and collaborative to the care of the patient, this may involve developing an up-to-date care plan or consulting medical or surgical specialists.⁷¹

From the perspective of the patient, the greater the acuity of the patient safety incident, the more medically and psychologically necessary timeliness becomes. As Truog et al. recommend, "... clinicians should be committed to disclosure as soon as the patient and family are capable of having the conversation. Decisions to the contrary must meet a very high threshold of justification; indeed, one hospital's disclosure policy explicitly requires consultation from an ethics committee before clinicians can choose not to disclose."⁷² Considering the perspective of the patient is necessary as patients and physicians may have differing views of the significance of an incident.⁷³ However, in contrast to conjecture, only the facts as they are known at the time of the meeting should be disclosed. Where the facts have yet to be known or clarified, this should be clearly communicated to the patient and assurance should be given that the facts will be disclosed as they are known.⁷⁴

⁷⁰ S Abigail, 'The Obstacle of Therapeutic Privilege in Healthcare Mediation' (2011) 5 American Journal of Mediation 1-8.

⁷¹ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 75.

⁷² *ibid* 86.

⁷³ *ibid* 78.

⁷⁴ M Waite, 'To Tell the Truth: The Ethical and Legal Implications of Disclosure of Medical Error' (2005) 13 Health Law Journal 1, 29. In this regard, the author notes, "Health providers who will be having these discussions need to be trained to deal with these questions in a positive and effective manner without implicating the care provided."

It is at this time that the thorough reporting, audit, and analysis of the incident is fundamental. In an effort to provide additional information to the patient and family, as well as further quality and safety initiatives, some organisations perform an accelerated root cause analysis where possible.⁷⁵ By accelerating the process and providing early information surrounding the incident, physicians and healthcare organisations can more accurately determine culpability, and where appropriate, offer compensation. As well, accelerated root cause analysis allows the organisation to put in place reforms to prevent similar future incidents and communicate this back to the patient at an early date, thereby reducing the need to litigate where the terms of the agreement meet the patient's expectations.⁷⁶ From a legal perspective, it is important to note that not all of the information in a root cause analysis will be given to the patient as the report itself is protected by quality improvement privilege. However, the facts (not privileged) must be legally and ethically disclosed and may be used when determining early offers of compensation.

Disclosure Coaches

A fundamental component of for improving communication, reducing error, and increasing disclosure has been the implementation of disclosure coaches. Disclosure coaching is not done in isolation; the role is a fundamental component of a team that includes individuals from the clinical risk management department, patient safety and

⁷⁵ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 88; citing: T Gallagher, 'A 62-Year-Old-Woman with Skin Cancer Who Experienced Wrong-Site Surgery: Review of Medical Error.' (2009) 302 JAMA 669-677. See further: Chapter 9 'Incident Reporting and Analysis' for an examination of root cause analysis.

⁷⁶ See further: Chapter 9.3 'Incident Analysis.'

quality, and when necessary, insurance providers.⁷⁷ However, the role is independent insofar as the disclosure coach's primary responsibility is not to lower the likelihood of liability, but rather to support the clinician in the aftermath of an incident—be it through consulting in procedure, ethical dilemmas, or support. Given the potential gravity of patient safety incidents—particularly those of an acute nature—and the broad spectrum of areas of clinical practice in which they occur, a disclosure coach must be available at all times and represent a cross-section of professional disciplines.⁷⁸ It is recommended that the initial conversation with a patient should occur within the first twenty-four hours following an adverse event, as such, the availability of disclosure coaches is essential. In this regard, the National Quality Forum in the United States recommend a “just in time” model to facilitate early disclosure and support for the care team, as well as the patient.⁷⁹ However, it must be noted that the responsibilities of a disclosure coach are to support and facilitate the meeting, not to displace the physician who has the responsibility of leading the conversation with the patient.⁸⁰

The Disclosure Meeting

If they have not yet be contacted, disclosure coaches should be brought in in advance of the disclosure meeting so as to assist the care team and hospital administration in

⁷⁷ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 60. However, Truog makes the observation that “In some hospitals, professional risk managers (often with a background in nursing) already seem to be functioning extremely well with many of the skill sets that we have identified as essential for the coaching role. At other hospitals, however, risk managers are recognized more for their expertise in the analysis of adverse events and in making complex but technical recommendations regarding potential liability, reportability, and the like rather than for their ability to help clinicians have these difficult conversations.”

⁷⁸ *ibid* 76.

⁷⁹ National Quality Forum, *Safe Practices for Better Healthcare– 2010 Update: A Consensus Report* (Washington: National Quality Forum, 2010) 133-135.

⁸⁰ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 62.

conducting the meeting. Patient advocates, hospital chaplains,⁸¹ or more extensive independent therapeutic services may also be required by the patient.⁸² Designated risk managers may also be present, however, care must be taken of the message being sent to the patient. For example, the involvement of clinical risk managers or legal counsel acting on behalf of the hospital may appear from the patient's perspective as a "cover up" or a desire to legally protect the physician and healthcare organisation. Therefore, the decision of whom to involve will be based on both current hospital practices and ethos, as well as subjective factors surrounding the patient and the nature of the event.⁸³

Once the decision to disclose a patient safety incident has been made, a disclosure plan should be put in place. This includes setting an agenda for the meeting, deciding who should be present for the conversation and responsible for leading it, what core information will be given to the patient and how the patient's culture, health literacy, and current condition may impact the conversation.⁸⁴ As Truog et al. note,

"In general, an initial conversation should occur very early, within the first few hours if possible and nearly always within the first 24 hours. Responding in a timely manner conveys seriousness and a relational commitment to the patient and family and avoids giving the impression that the team is 'buying time' to cover up the event. One implication of

⁸¹ N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005) 108. Berlinger makes the observation that: "... hospital chaplains often go unrecognized as potential resources for health care institutions attempting to improve the care of persons affected by medical error has been absent from chaplains' own professional literature."

⁸² *ibid.* In this regard, Berlinger notes that to avoid the appearance of bias, it is appropriate for the patient to attend an independent counsellor not employed within the same healthcare organisation.

⁸³ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 79.

⁸⁴ *ibid* 81.

having a conversation early, however, is that there are likely to be fewer facts available.”⁸⁵

To compensate for an early lack of information, it is necessary to designate a key individual to be responsible for following up with the patient or family. Additionally, it may be reassuring and beneficial to offer to arrange a second opinion or recommend consultation with subspecialists. Depending on the circumstances, it may be necessary to transition care to another team of physicians. However, for the sake of continuity of care and any preexisting relationships, this decision must be in the best interests of, and in consultation with, the patient.⁸⁶

Contents of the Disclosure

In the absence of legislation or clear hospital policy, the decision on what information to include when disclosing an error is left to the physician, hospital administration, risk management and (where available) the disclosure coach. However, prior to the disclosure meeting with the patient and (where appropriate) the family, it is necessary for those involved to come to an agreement about the facts as they are known at the time. This is not to suggest collusion, rather consistency and assurance for the patient. Where information surrounding the event is merely conjecture, this must be clearly communicated to the patient.⁸⁷ According to Morath and Turnbull, a presumption of truth telling should guide all discussions, with the ultimate goal being “... to use a thoughtful, well-defined process that will re-establish confidence and maintain a therapeutic relationship.”⁸⁸ For Hafemeister and Spinos, the purpose of error disclosure is to, “... ensure that the patient receives information that is potentially vital

⁸⁵ *ibid.*

⁸⁶ *ibid* 81-87.

⁸⁷ *ibid* 85.

⁸⁸ J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 151.

to his or her medical well-being. In meeting this goal, the physician should be able to decide how to craft the disclosure. The best way of transmitting this information will vary somewhat from patient to patient. Doctors, exercising their medical expertise, can shape their disclosure accordingly.”⁸⁹ In shaping the conversation, Moskop suggests that, on the basis of the reasonable person standard, the physician should disclose, “... what a reasonable person in the patient’s position would want to know to make an intelligent and informed treatment decision.”⁹⁰ Again, it is necessary to only disclose the factual information known thus far, however, the objective standard suggested by Moskop would likely satisfy the legal and ethical duties required by the aforementioned jurisdictions, in particular the legal obligations dictated by the standard of care and doctrine of informed consent.

More specific guidance can be found in the American Medical Association’s *Code of Ethics*, which states that when an adverse event has occurred, “Physicians must offer professional and compassionate concern toward patients who have been harmed, regardless of whether the harm was caused by a healthcare error. An expression of concern need not be an admission of responsibility.”⁹¹ In addition, commentators have suggested that the minimal information that should be included by the physician includes an explicit statement that an error or adverse event has occurred, how such an event was different from the intended treatment, and an explanation of what the

⁸⁹ T Hafemeister and S Spinos, ‘Lean on Me: A Physician’s Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient’ (2009) 86(5) *Washington University Law Review* 1167, 1189.

⁹⁰ J Moskop et al. ‘Emergency Physicians and Disclosure of Medical Errors.’ (2006) 48(5) *Annals of Emergency Medicine* 523, 524; citing: D Brock, ‘Informed Consent’ in D Van DeVeer and T Regan (eds) *Health Care Ethics* (Philadelphia: Temple University Press, 1987) 98-116.

⁹¹ American Medical Association Council on Ethical and Judicial Affairs, *Code of Medical Ethics: Current Opinions with Annotations 2014-2015* (Chicago: American Medical Association Press, 2014) [8.121].

organisation is doing to prevent future occurrences.⁹² As a guiding principle, it is useful to disclose information contained within the patient's medical record, and the facts as they are known at present.⁹³ Where appropriate, an apology may also be given.⁹⁴ It is important at such an early stage to avoid discussion of causation or fault, particularly before a full analysis has taken place.⁹⁵ In particular, the duty to disclose extends only to information about the patient's medical condition and treatment.⁹⁶ As Moskop explains, "Physicians need not, for example, provide purely technical or insignificant information to their patients, because total disclosure is neither practical for physicians nor desired by (or advantageous for) patients."⁹⁷ Information about the identities of relevant staff members should also not be given. While this information may be revealed subsequently, the initial disclosure meeting should be limited to information relevant to the patient and their health status.⁹⁸

⁹² R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 74; citing: T Gallagher et al., 'Patients' and Physicians' Attitudes Regarding Disclosure of Medical Errors' (2003) 289(8) JAMA 1001. See also: American Medical Association Council on Ethical and Judicial Affairs, *Code of Medical Ethics: Current Opinions with Annotations 2014-2015* (Chicago: American Medical Association Press, 2014) [8.121]; T Gallagher and W Levinson, 'Disclosing Harmful Medical Errors to Patients: A Time for Professional Action.' (2005) 165 Archives of Internal Medicine 1819; The Full Disclosure Working Group, *When Things Go Wrong: Responding to Adverse Events. A Consensus Statement of the Harvard Hospitals* (Boston, MA: Massachusetts Coalition for the Prevention of Medical Errors, 2006); D Hetzler et al., 'Conflict Management in Hospital Systems: Not Just For Leadership' (2011) 5 American Journal of Mediation 65, 70.

⁹³ *ibid* 78-85. Truog notes that, as patients have access to their medical records, a failure to include such information may be interpreted as an attempt to conceal or minimise. Moreover, there is little risk in disclosing facts as they are known as such information will come out in the course of discovery should legal proceedings commence.

⁹⁴ See below: Chapter 11.5 'The Decision to Apologise.'

⁹⁵ D Hetzler et al., 'Conflict Management in Hospital Systems: Not Just For Leadership' (2011) 5 American Journal of Mediation 65, 70; J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 150.

⁹⁶ J Moskop et al. 'Emergency Physicians and Disclosure of Medical Errors.' (2006) 48(5) Annals of Emergency Medicine 523, 524; citing: G Gabbard and C Nadelson, 'Professional Boundaries in the Physician-Patient Relationship.' (1995) 273 JAMA 1445-1449.

⁹⁷ *ibid*; citing: D Brock, 'Informed Consent' in D Van DeVeer and T Regan (eds) *Health Care Ethics* (Philadelphia: Temple University Press, 1987) 98-116.

⁹⁸ J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 151.

A further issue that may arise within the initial disclosure meeting are questions concerning financial issues. In jurisdictions where healthcare is not socialized, such as the United States, patients may be concerned with the payment of medical related costs. As these enquiries do not concern the direct medical care of the patient, clinicians should acknowledge the validity of the concern and assure the patient or their family that such questions will be addressed as soon as possible by those persons with appropriate authority; most likely a designated individual from the Risk Management department.⁹⁹ This concern should not be minimised, however, as disagreement regarding future health expenses is a significant point of contention that can spur litigation.

The terminology used during the disclosure meeting is also important. In addition to assisting in comprehension, appropriate terminology may reduce the likelihood of patients requiring legal remedies in an effort to understand the nature of the incident. Appropriate terminology can also promote cultural reform. In this regard, Wu has suggested, "It is possible that changing terminology could help to shift the attitudes and expectations of both patients and providers toward a more sophisticated understanding of patient safety."¹⁰⁰ Canada offers an interesting example of this. In 2008, the Canadian Medical Protective Association, adopted the phrases 'patient safety incident' and 'harmful incident' in contrast to 'adverse event' and 'error' so as to minimize emotional connotations connected to the two words, and to encourage less adversarial dialogue.¹⁰¹ Another example, particularly important in the context of disclosure, is the term 'complication.' Although in a medical setting the term may include error, patients may interpret such a term as disingenuous and be less inclined

⁹⁹ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 88.

¹⁰⁰ A Wu et al., 'Disclosing Adverse Events to Patients: International Norms and Trends' (08 April 2014) *Journal of Patient Safety* [epub ahead of print].

¹⁰¹ *ibid*; citing: Canadian Medical Protective Association, *Communicating With Your Patient About Harm: Disclosure of Adverse Events*. (Ottawa: Canadian Medical Protective Association, 2008)

to accept the information.¹⁰² Likewise, Block points out that, “‘Mistake’ is terminology for ‘it wasn’t suppose to happen,’ and as such is commonly linked to implications of wrongdoing. Here, through the choice of terms such as ‘My choice of antibiotic’ and ‘mistake’, the apologizing physician is moving beyond regret and introducing an insinuation of responsibility for wrongdoing.”¹⁰³ On that point, it is important to avoid unnecessarily incriminating expressions that could be interpreted as admonishment of the other staff involved or appear to be shifting the blame to the patient.¹⁰⁴ Descriptive terms, which may be seen as reflecting the position of the physician, should also be avoided. Alternatively, the “... use of absolute numbers, combined with the presentation of both positive and negative outcomes...” may prove beneficial in aiding the patient’s comprehension and reception of the information disclosed.¹⁰⁵ Caution must also be taken to prevent the patient from feeling disrespected because the clinicians either overly use medical jargon or oversimplify the information. In general consultation or during a conversation disclosing a patient safety incident, patient comprehension is a necessary component for informed consent by enabling the patient to understand and participate in decision-making and improves the likelihood of compliance with the prescribed course of treatment.¹⁰⁶ In this regard, Wu et al. make the observation that, “Disclosure of a mistake also provides patients with information needed to make informed decisions. Patients may develop more realistic expectations about their doctors’ interventions. Acknowledgment of fallibility brings uncertainties into the open, reduces the possibility of misunderstandings, and encourages the

¹⁰² N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005) 104.

¹⁰³ A Block, ‘Disclosure of Adverse Outcomes and Apologizing to the Injured Patient’ in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 281-282.

¹⁰⁴ *ibid* 282.

¹⁰⁵ M Beyer et al., ‘Communication and Patient Safety’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 18.

¹⁰⁶ *ibid* 16.

patient to take greater responsibility for his or her own care.”¹⁰⁷ To avoid misinterpretation or limited comprehension, it is beneficial to be aware of the cognitive capabilities of the patient, and the language used to reflect such capabilities.¹⁰⁸

Physician Participation in the Disclosure Meeting

The decision of which healthcare professionals should be involved in the disclosure meeting is unique to both the organisation and the circumstances surrounding the incident. As it applies to the patient’s perception of the meeting, consideration should be given to the number of clinicians and administrative staff present, particularly those from the legal department and risk management. Depending on the circumstances, this may be necessary and indeed advisable, for example, where the incident is complex and merits explanation from different specialities and disciplines. However, it also has the potential to intimidate the patient or give the impression of concealment, particularly where defense counsel are present.¹⁰⁹

Where the physician is experiencing negative psychological effects as a result of the error or in relation to the disclosure conversation—a condition Wu describes as being the “second victim” of medical error—it may be inappropriate for him or her to attend the meeting.¹¹⁰ Organisations such as the Lexington Veterans Affairs Medical Center support the view that since error is the result of both human and system factors, the

¹⁰⁷ A Wu et al., ‘To Tell the Truth—Ethical and Practical Issues in Disclosing Medical Mistakes to Patients’ (1997) 12 *Journal of General Internal Medicine* 770, 771.

¹⁰⁸ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 82.

¹⁰⁹ *ibid* 79.

¹¹⁰ A Wu et al., ‘Disclosure of Adverse Events in the United States and Canada: An Update, and a Proposed Framework for Improvement’ (2013) 2(3) *Journal of Public Health Research* 186, 189. The authors note, “Some providers may find a disclosure discussion healing but others may suffer after a disclosure discussion and an error. The initial reaction is consistent with acute stress disorder, with shock, anxiety, depressive symptoms, social withdrawal and agitation, compounded by feelings of shame, guilt and self-doubt..” See also: A Wu, ‘Medical Error: The Second Victim. The Doctor Who Makes the Mistake Needs Help Too.’ (2000) 320 *BMJ* 726; Chapter 4.2 ‘Healthcare and the Culture of Blame.’

ethical obligation to disclose error is institutional.¹¹¹ Regardless, where a constructive prior relationship with the patient exists, having all physicians who were clinically involved, and in particular the most responsible physician, participate has the benefit of reassuring the patient and providing continuity of care, as well as being potentially therapeutic for the physician(s).¹¹²

Disclosure of Near-Misses and Errors of Another

The decision as to whether to disclose the occurrence of a near-miss, minor incident, or the error of another healthcare professional can be a difficult one. In this regard, Truog et al. have argued that, “On the one hand, disclosure of some near misses may provide no benefit and only serve to increase the patient’s fears and anxieties. On the other hand, particularly when a patient may have been aware that something happened that was not routine or was out of the ordinary, disclosure may be imperative in order to maintain trust and avoid creating the impression that a secret is being kept from that patient.”¹¹³ While concern may arise as to disclosing a near-miss to the patient despite no harm being suffered (a necessary component in an action for negligence), Waite has suggested that there is little legal downside as the likelihood of a successful claim is minimal given the nominal or nonexistent damages available to the patient.¹¹⁴ As with

¹¹¹ N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005) 106. However, Berlinger notes that a contributing factor to this policy may be that a large number of the physicians employed within the VA are medical and surgical residents.

¹¹² In this regard, the American Medical Association Council on Ethical and Judicial Affairs have stated: “(4) Physicians have a responsibility to provide for continuity of care to patients who may have been harmed during the course of their health care. If, because of the harm suffered under the care of a physician, a patient loses trust in that physician, the obligation may best be fulfilled by facilitating the transfer of the patient to the care of another physician.” See: American Medical Association Council on Ethical and Judicial Affairs, *Code of Medical Ethics: Current Opinions with Annotations 2014-2015* (Chicago: American Medical Association Press, 2014) [8.121]; D Hetzler et al., ‘Conflict Management in Hospital Systems: Not Just For Leadership’ (2011) 5 *American Journal of Mediation* 65, 70.

¹¹³ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 78.

¹¹⁴ M Waite, ‘To Tell the Truth: The Ethical and Legal Implications of Disclosure of Medical Error’ (2005) 13 *Health Law Journal* 1, 21.

incident reporting, the decision of what to disclose can be a complicated one. Guidance must be taken from the requisite ethical and legal obligations—particularly as they apply to informed consent. Should the law be more definitive in this area and legislate beyond the requirement to disclose serious (sentinel) incidents? My opinion is no, particularly taking into account the above arguments concerning therapeutic privilege and the inherently subjective nature of medicine and error. This is not to suggest that physicians practice paternalistically, or escape accountability. However, much like incident reporting, it would be neither feasible, nor in the best interest of the majority of patients to legislate for the disclosure of *all* incidents. While there is an inherent danger in relying on individual physicians or organisations to determine their own standard of disclosure for minor errors, it is not unlike many areas of medicine where the healthcare professional must make a decision based on the subjective best interests of the patient.

The decision of whether to disclose an error made by another physician is also difficult. In such situations, the physician has a number of options. These include waiting for or advising the other physician to disclose the error directly to the patient; arranging a joint meeting between the physicians involved, the patient, medical leadership and/or patient advocates; or telling the patient directly in a private consultation.¹¹⁵ Moskop has suggested irregardless of how the patient is told, the professional duty of truthfulness likely requires that the attending physician disclose such information to the patient so as to ensure their informed consent with future treatment decisions.¹¹⁶ However, consideration must be given to the negative consequences of such a disclosure. Disclosing the errors of another physician may incite legal action and strained professional relations, particularly where all the facts are yet to be known. For

¹¹⁵ A Wu et al., 'To Tell the Truth—Ethical and Practical Issues in Disclosing Medical Mistakes to Patients' (1997) 12 *Journal of General Internal Medicine* 770, 774.

¹¹⁶ J Moskop et al. 'Emergency Physicians and Disclosure of Medical Errors.' (2006) 48(5) *Annals of Emergency Medicine* 523, 529.

this reason, it may well be best to inform the patient in consultation with the aforementioned parties.

Following the Disclosure Meeting

Following the disclosure meeting, an opportunity for the members of the care team, risk managers, and disclosure coaches should be held to debrief. Documentation following the disclosure of a patient safety incident is fundamental, both legally and for continuity of care. However, documentation in the patient's record should be limited to only the patient's care plan and treatment, as well as the interactions with clinical staff. Any information relating to the coaching intervention should be documented separately.¹¹⁷

11.5 The Decision to Apologise

Much like the disclosure of medical error and patient safety incidents, the offering of an apology has been traditionally fraught with barriers and concern over liability. Welch describes this scenario, arguing that, "... practitioners and workers in healthcare have been effectively gagged by the culture of healthcare and kept from speaking these natural and healing words."¹¹⁸ The problem, however, is that where an ethical and legal duty may exist to disclose information, the extent of the legal protection for statements that express remorse or responsibility is far more illusive and dependent on

¹¹⁷ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 90-91.

¹¹⁸ S Welch, 'The Medical Apology: Who and How?' (2012) 28(3) *Frontiers of Health Services Management* 42. See generally: R Carroll, 'Beyond Compensation: Apology as a Private Law Remedy' in J Berryman (ed), *The Law of Remedies: New Directions in the Common Law* (Toronto: Irwin Law, 2010) 323-385 for a wider discussion of the use of apology to complement non-pecuniary damages in civil litigation.

the jurisdiction; this has had the result of limiting their therapeutic value and potential to reduce liability.¹¹⁹

Despite evidence that patients not only desire but expect an apology following a medical error,¹²⁰ the pitfalls and hazards of apologizing can fall disproportionately on the physician. As Block notes, this can include serious professional and psychological implications, the possibility of conflict with the insurance carrier, as well as the apology being admitted in evidence as an admission of fault.¹²¹ Despite these concerns, where the law permits, displaying empathy, compassion, and offering an apology in the course of disclosing a medical error can be emotionally beneficial for both the physician and patient by reestablishing a potentially broken trust-based patient-physician relationship.¹²² In this regard, Howley suggests that the effectiveness of an

¹¹⁹ W Choctaw, 'How to Say "I'm Sorry" Without Admitting Guilt' in *Avoiding Medical Malpractice: A Physician's Guide to the Law* (New York: Springer, 2008) 55-60; A Sheikh, 'Open Disclosure, Candour and the Patient' (2013) 19(1) *Medico-Legal Journal of Ireland* 58; M Alberstein and N Davidovitch, 'Apologies in the Healthcare System: From Clinical Medicine to Public Health' (2011) 74 *Law and Contemporary Problems* 151; R Dresser, 'The Limits of Apology Laws' (2009) 38(3) *The Hastings Center Report* 6; N Saitta and S Hodge Jr., 'Efficacy of a Physician's Words of Empathy: An Overview of State Apology Laws' (2012) 112(5) *Journal of the American Osteopathic Association* 302.

¹²⁰ C Hyman et al., 'Interest-Based Mediation of Medical Malpractice Lawsuits: A Route to Improved Patient Safety?' (2010) 35(5) *Journal of Health Politics, Policy and Law* 797, 822; citing: T Gallagher et al., 'Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors.' (2003) 289(8) *JAMA* 1001, 1005.

¹²¹ A Block, 'Disclosure of Adverse Outcomes and Apologizing to the Injured Patient' in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 279-280; E Zonana, 'Getting Healthier: A Proposal for Improving Medical Malpractice Mediation' (2001) 5 *American Journal of Mediation* 9, 23.

¹²² A Block, 'Disclosure of Adverse Outcomes and Apologizing to the Injured Patient' in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 280. Block notes, "Having an attending physician compassionately explain what happened, why and how it occurred, how it now can be handled, and what results can be anticipated can enormously comforting to a patient beset with both pain and uncertainties. Filling that breach with warm, sympathetic support can be a powerful act of understanding and caring in a moment of despair." See also: N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005) 96; E Zonana, 'Getting Healthier: A Proposal for Improving Medical Malpractice Mediation' (2001) 5 *American Journal of Mediation* 9, 22; citing: C Liebman and C Hyman, 'Medical Error Disclosure, Mediation and Malpractice Litigation: A Demonstration Project in Pennsylvania' (2009) 45 <http://www.pewtrusts.org/~media/legacy/uploadedfiles/wwwpewtrustsorg/reports/medical_liability/LiebmanReportpdf.pdf>.

apology depends on the degree of patient satisfaction, the presence and relative balance of the explanation and atonement given.¹²³ An effective apology may also mitigate the negative psychological effects of error in patients, which are often a determinant of whether or not to commence legal proceedings.¹²⁴ In addition, apologies can be “value creating,” particularly in the course of mediation, an apology may be necessary for the resolution process to move forward and a settlement to be reached.¹²⁵

At the onset, it is necessary to draw a distinction between an apology offered as an expression of empathy and compassion, and an apology that implies responsibility on behalf of the physician and organisation. In this regard, Truog et al. argue:

“Expressions of empathy and compassion for what the patient is experiencing are always appropriate (‘I am so sorry this happened to you’). However, expressions of personal or institutional responsibility for an adverse event should also be made when facts indicate that the event was an avoidable consequence of a medical error. While clinicians may feel somewhat psychologically cleansed by telling a patient that ‘this was our fault and we are so sorry,’ it is in fact unwarranted—and unethical—to

¹²³ M Howley Jr., ‘The Use of Apology in Health Care’ (2009) 9(4) *Journal of Medical Marketing* 1745.

¹²⁴ B Ho and E Liu, ‘Does Sorry Work? The Impact of Apology Laws on Medical Malpractice’ (2011) 43 *Journal of Risk and Uncertainty* 141; E Zonana, ‘Getting Healthier: A Proposal for Improving Medical Malpractice Mediation’ (2001) 5 *American Journal of Mediation* 9, 22; citing: J Todres, ‘Toward Healing and Restoration for All: Refraining Medical Malpractice Reform’ (2006) 39 *Connecticut Law Review* 667, 686.

¹²⁵ E Zonana, ‘Getting Healthier: A Proposal for Improving Medical Malpractice Mediation’ (2001) 5 *American Journal of Mediation* 9, 23; citing: J Cohen, ‘Advising Clients to Apologize’ (1999) 72 *Southern California Law Review* 1009, 1016; A Block, ‘Disclosure of Adverse Outcomes and Apologizing to the Injured Patient’ in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 279.

accept such responsibility on behalf of oneself and others when the facts have not yet shown it to be true.”¹²⁶

Moreover, there is a very legitimate risk of an apology that accepts responsibility on the part of the physician or healthcare organisation being admitted as evidence of liability. The extent of the legal protection afforded for an expression of apology is determined according to jurisdiction. This can range from protecting the apology itself, to protecting the apology and acknowledgment of fault. By way of example, the extent of protection for apologies offered in the course of disclosure will now be examined in relation to the United States, Canada, and England.

United States

In the United States, to date, thirty-six states have enacted ‘apology laws’ which prevent certain statements and expressions from being admitted as evidence in legal proceedings.¹²⁷ In general, language of sympathy and benevolence are permitted, but not the admission of fault.¹²⁸ In the absence of legislation or mutual agreement providing otherwise, apologies that admit fault are admissible as evidence establishing liability in civil proceedings. This may also include apologies made in the course of

¹²⁶ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 70-71, 82; citing: L Taft, ‘On Bended Knee (With Fingers Crossed)’ (2005) 55 DePaul Law Review 1; T Gallagher, ‘A 62-Year-Old Woman with Skin Cancer Who Experienced Wrong-Site Surgery: Review of Medical Error’ (2009) 302 JAMA 669; A Lazare, ‘Apology in Medical Practice: An Emerging Clinical Skill’ (2006) 296 JAMA 1401.

¹²⁷ States to have enacted apology legislation include: Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Iowa, Indiana, Louisiana, Maine, Maryland, Massachusetts, Michigan, Missouri, Montana, Nebraska, New Hampshire, New Jersey, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wyoming. See further: Sorry Works!, ‘Making Disclosure a Reality for Healthcare Organisations’ <<http://www.sorryworks.net/apology-laws-cms-143>> accessed: 02 June 2016.

¹²⁸ An example can be seen in California’s Evidence Code 1160 which states: “(a) The portion of statements, writing, or benevolent gestures expressing sympathy or a general sense of benevolence relating to pain, suffering, or death of a person involved in an accident and made to that person or to the family of that person shall be inadmissible as evidence of an admission of liability in a civil action. A statement of fault, however, which is part of, or in addition to, any of the above shall not be inadmissible pursuant to this section.”

settlement negotiations.¹²⁹ Alternatively, mediation may provide the best means by which to apologise without attracting liability. This is because communication during a mediation session is predominantly confidential and privileged, and apologies made during a mediation conference may be protected by federal legislation.¹³⁰ However, given the discrepancy in protection—both in jurisdictional differences and content—Mastroianni has suggested that the effectiveness of apology laws in the United States could be better achieved through improved statutory design, as well as more detailed communication of the new legal requirements and protection available to clinicians.¹³¹ The problem with this is two-fold. Legislators are reluctant to limit the liability connected to apologies because it could be perceived as limiting accountability—and therefore being weak in their protection of the public. Physicians, on the other hand, have been conditioned to perceive patients as potential adversaries. While an amendment of the legislation is a positive step forward, it is unlikely to result in wide-scale safety and quality improvement without significant cultural intervention and organisational support.

The judiciary in the United States have, in general, taken a pragmatic approach when admitting evidence of an apology. For example, in the Vermont cases of *Phony v Vinson* (1992) and *Senesac v Associates in Obstetrics & Gynecology* (1982), the courts held that an apology alone was not sufficient to determine legal culpability; a breach of the

¹²⁹ A Block, 'Disclosure of Adverse Outcomes and Apologizing to the Injured Patient' in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 281-282; citing: Federal Rules of Evidence 408 which provides for the exceptions to admissibility in settlement negotiations. Block notes that exceptions to the admissibility of apologies in settlement negotiations are limited to apologies preceded by exclusionary words, apologies framed in the hypothetical or where the apology can be shown to be an integral part of the settlement negotiations.

¹³⁰ See further: Chapter 12.3 'Healthcare Mediation' for an analysis of confidentiality in the mediation process.

¹³¹ A Mastroianni et al., 'The Flaws in State 'Apology' and 'Disclosure' Laws Dilute Their Impact on Malpractice Suits' (2010) 29(9) *Health Affairs* 1611.

standard of care and causation are also necessary.¹³² On this point Block notes, “Mistake, error and a bad result are predominantly *medical* concepts, requiring *medical* judgments, whereas fault, negligence, and culpability are *legal* concepts, defined by legal standards. There is case law to support the contention that occasionally even poor judgment, mistake, and error can fall within the purview of ‘usual, acceptable care’ as defined by the standard of care.”¹³³ Owing to this, the courts have thankfully taken a more liberal view of apologies—patients, however, may be less understanding or objective. Again, strong legislation to protect apologies in the United States would be beneficial but it will equality require cultural change amongst healthcare professionals and patients alike.

Canada

In Canada, apology legislation is substantially less restrictive than in the United States.¹³⁴ To date, eight of the ten provinces and one of the three territories have enacted legislation which provides that an apology—regardless of an express or implied admission of fault—does not constitute a legal admission of fault or liability, nor can it be taken into consideration or admitted as evidence when determining fault

¹³² *Phony v Vinson* [1992] 158 Vt. 646, 605 A.2d 849; *Senesac v Associates in Obstetrics & Gynecology* [1982] 141 Vt. 310, 449 A. 2d 900 141 Vt. 310, 449 A.2d 900 (1982); N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005) 54.

¹³³ A Block, ‘Disclosure of Adverse Outcomes and Apologizing to the Injured Patient’ in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 282; citing: *Phony v Vinson* [1992] 158 Vt. 646, 605 A.2d 849; *Sutton v Calhoun* [1979] CA10 Okla. 593 F. D2d 127; *Senesac v Associates in Obstetrics & Gynecology* [1982] 141 Vt. 310, 449 A. 2d 900; *Greenwood v Harris* [1961] Okla. 362 P. 2d 85.

¹³⁴ See generally: W Levinson and T Gallagher, ‘Disclosing Medical Errors to Patients: A Status Report in 2007’ (2007) 177(3) Canadian Medical Association Journal 265; J Kalra, *Medical Errors and Patient Safety: Strategies to Reduce and Disclose Medical Errors and Improve Patient Safety* (Berlin, New York: De Gruyter, 2011) 81-84.

or liability.¹³⁵ This is a significant and progressive departure from traditional legislation, as well as the approaches taken in the United States and England.

England

In England, section 17 of the Compensation Act 2006 states that “An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty.”¹³⁶ However, while the act protects an apology, it does not expressly define what constitutes an apology for the sake of the act.¹³⁷ In contrast, the Care Quality Commission, in accordance with the Regulations on the duty of candour, define apology as “an expression of sorrow or regret in respect of a notifiable safety incident.” Regulation 20 requires the health service body to provide a written apology following a notifiable safety event; failure of which can result in prosecution without

¹³⁵ The provinces and territories to have enacted apology legislation include: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Nova Scotia, Prince Edward Island, Newfoundland and Labrador and Nunavut. See: Canadian Medical Protective Association, *Apology Legislation in Canada: What it Means for Physicians* (April 2013) <<https://oplfrpd5.cmpa-acpm.ca/-/apology-legislation-in-canada-what-it-means-for-physicians>> accessed: 05 June 2016. An example can be seen in section 2 of British Columbia’s Apology Act 2006, which states:

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

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

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

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

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

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

¹³⁶ Compensation Act 2006 (UK), section 17.

¹³⁷ P Vines, ‘Apologies and Civil Liability in England, Wales and Scotland: The View from Elsewhere’ (2007) 61 University of New South Wales Faculty of Law Research Series 6. <<http://ssrn.com/abstract=1366505>> accessed: 18 November 2014.

first being given a warning notice.¹³⁸ While the Regulation places the duty on the Health Service Body, the decision as to who is most appropriate to provide the apology is left at the discretion of the Health Service Body. Consideration is given to seniority, relationship to the patient as well as the experience and expertise in the type of notifiable incident that has occurred.¹³⁹ Given the scope of the Duty of Candour as set out by the CQC and the legislative protection contained within the Compensation Act 2006, it is probable that an apology made by a physician would be protected from liability attaching to the apology, provided the Health Service Body is aware of the “notifiable safety event” and reporting requirements have been met.

This section has considered apologies given in the course of disclosure. Owing to ambiguity within the various jurisdictions, it is perhaps no surprise that physicians continue to be wary of apologies—particularly where little guidance is available. For this reason, it is necessary to further explore and analyse the benefits of communication and disclosure training programs offered throughout the United States that can assist in this important quality and safety initiative, and reduce the barriers created by ambiguous legislation.

11.6 Communication and Disclosure Programs

As examined previously, hospitals in various jurisdictions have begun offering skill training programs designed to preemptively teach healthcare professionals how to effectively communicate and disclose the occurrence of an incident. Despite variance in the contents of the communication and disclosure programs described below, all are premised on improving communication and support for healthcare professionals. In most jurisdictions, programs are tailored subjectively to the healthcare organisation.

¹³⁸ Care Quality Commission, *G Guidance for NHS Bodies on the Fit and Proper Person Requirement for Directors and the Duty of Candour* (Consultation Paper, July 2014) 25. <http://www.cqc.org.uk/sites/default/files/20140725_nhs_fppr_and_doc_consultation_final.pdf> accessed: 18 November 2014.

¹³⁹ Care Quality Commission, *G Guidance for NHS Bodies on the Fit and Proper Person Requirement for Directors and the Duty of Candour* (Consultation Paper, July 2014) 27. <http://www.cqc.org.uk/sites/default/files/20140725_nhs_fppr_and_doc_consultation_final.pdf> accessed: 18 November 2014.

Insurance companies have also had input on the content and necessity of disclosure programs; either by making it a condition of the insurance contract or providing a reduction in premiums.¹⁴⁰ In addition to improving communication between healthcare professionals and patients, such programs promote transparency, support, and potentially a reduction in liability for the clinician and healthcare organisation.¹⁴¹ It is now instructive to consider a selection of case studies so as to illustrate the development and benefits of disclosure programs currently used throughout the United States.

Kaiser Permanente

Kaiser Permanente,¹⁴² one of the largest healthcare organisations in America, provides a useful example of a multi-faceted disclosure program. Kaiser developed detailed policy statements regarding disclosure, 'situation management teams' for use immediately following serious incidents, and created the role of healthcare ombudsman. The healthcare ombudsmen is a certified mediator whose primary role is to act as an intermediary between the care team, and the patient and family.¹⁴³ Further support mechanisms for physicians include developing a peer support program and offering communication training.¹⁴⁴ The communication training program includes

¹⁴⁰ M Beyer et al., 'Communication and Patient Safety' in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 19; citing: National Patient Safety Agency (UK) <<http://www.npsa.nhs.uk/>> accessed: 21 October 2014.

¹⁴¹ See generally: S Bell et al., 'Disclosure, Apology and Offer Programs: Stakeholders' Views of Barriers to and Strategies for Broad Implementation' (2012) 90(4) *The Milbank Quarterly* 682; W Levinson, 'Disclosing Medical Errors to Patients: A Challenge for Health Care Professionals and Institutions' (2009) 76 *Patient Education and Counseling* 296.

¹⁴² Kaiser Permanente, 'History of Kaiser Permanente' <<http://share.kaiserpermanente.org/article/history-of-kaiser-permanente/>> accessed: 18 October 2014. Kaiser Permanente is comprised of not-for-profit hospitals and managed care medical groups.

¹⁴³ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 54.

¹⁴⁴ Kaiser Permanente, 'Patient Safety' <<https://healthy.kaiserpermanente.org/health/care/consumer/center/>> accessed: 18 October 2014.

medical interpreters, multilingual education materials, and assistive technology to accommodate individual patient care needs.¹⁴⁵

Brigham and Women's Hospital, Boston, Massachusetts

The Centre for Professionalism and Peer Support at Brigham and Women's Hospital in Boston established a comprehensive support program for physicians and healthcare staff. The program is comprised of four initiatives: an educational program focusing on professionalism; disclosure coaching; peer-support services; and the "Defendant Support Program." The latter two are available to physicians following a patient safety incident, and provide a mechanism when more intensive support or services may be required.¹⁴⁶

The University of Michigan Health System (UMHS)

In 2001, the University of Michigan Health System began an early disclosure and compensation program. The program identified patient injuries through reports made by clinical staff, patients or their lawyers. Where medical error was determined by an internal investigation to be the cause of the adverse event, the UMHS would offer the patient information from the investigation, an offer of compensation, and (where appropriate) an apology.¹⁴⁷ However, care found to be appropriate would be aggressively defended.¹⁴⁸ Data collection from 1995 to 2007 showed that the median time from claim reporting to resolution decreased from 1.36 to 0.95 years and the

¹⁴⁵ *ibid.*

¹⁴⁶ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 55.

¹⁴⁷ H Morreim, 'Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank' (2012) 27(1) *Ohio State Journal on Dispute Resolution* 109, 122-123; R Boothman et al., 'A Better Approach to Medical Malpractice Claims? The University of Michigan Experience' (2009) 2 *Journal of Health & Life Sciences Law* 125; R Boothman, 'Apologies and a Strong Defense at the University of Michigan Health System' (2006) 32(2) *Physician Executive* 6.

¹⁴⁸ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 47; R Boothman et al., 'A Better Approach to Medical Malpractice Claims? The University of Michigan Experience' (2009) 2 *Journal of Health & Life Sciences Law* 125.

average cost per lawsuit decreased from \$405,921 to \$228,308.¹⁴⁹ In addition, the average monthly costs for total liability, patient compensation, and non-compensation related legal costs also decreased.¹⁵⁰ The program emphasises honesty and transparency, links the investigation process with peer review, as well as quality and safety initiatives throughout the organisation.¹⁵¹

The Veterans Affairs Hospital in Lexington, Kentucky

As one of the first disclosure programs in the United States, the Veterans Affairs Medical Center in Lexington, Kentucky provides an interesting structural example for the early disclosure of adverse events. Originally developed in 1987, the program has since been instituted through all of the VA Medical Centers in the United States. The program is based on proactive early and complete disclosure of the circumstances surrounding the event, as well as a potential offer of compensation and an apology. The approach is unique insofar as it features categories of disclosure. 'Clinical disclosure' is the least formal and consists of sharing clinical information with the patient and assuring them of a forthcoming investigation. The second category, termed 'institutional disclosure,' takes place where there is the potential for liability, and serious harm or death has occurred as a result of medical error. In such instances, a more formal process is used and both an apology and early offer of compensation may be offered.¹⁵² Interestingly, designated medical center staff members negotiate decisions of compensation with the patient or family. As the hospitals are specifically designed to treat United States Veterans, compensation typically involves corrective

¹⁴⁹ A Kachalia et al., 'Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program' (2010) 153(4) *Annals of Internal Medicine* 213, 217.

¹⁵⁰ *ibid* 213.

¹⁵¹ H Morreim, 'Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank' (2012) 27(1) *Ohio State Journal on Dispute Resolution* 109, 122; citing: A Kachalia et al., 'Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program' (2010) 153(4) *Annals of Internal Medicine* 213, 213–214.

¹⁵² R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 51-52; citing: Veterans Health Administration, *Disclosure of Adverse Events to Patients* (VHA Directive 2008-002, 18 January 2008).

medical or surgical procedures, increased disability ratings, or monetary restitution. Since its implementation, the number of claims has risen with the VA Medical Centers, however, the value of the claims has significantly decreased.¹⁵³

Critics of communication skill training programs have argued that such programs merely protect the physician against litigation and frivolous claims, as well as adding a further burden (albeit duty) to the already burdensome role of the physician.¹⁵⁴

However, patients frequently judge the quality of the care they have received by their interaction with the care team and the information provided may reduce or eliminate the need to file a claim.¹⁵⁵ As Rabinovich-Einy notes, “While working under extreme conditions, doctors and other staff members trying to do their job well and to avoid mistakes adopt an abrupt and authoritative mode of communication, but it is often precisely such an environment that breeds mistakes.”¹⁵⁶

While improving communication skills may decrease litigation, improving quality, safety, and patient care are the main objectives of communication and disclosure training.¹⁵⁷

¹⁵³ G Balcerzak and K Leonhardt, ‘Alternative Dispute Resolution in Healthcare: A Prescription for Increasing Disclosure and Improving Patient Safety’ *Patient Safety & Quality Healthcare* (July–August 2008) <<http://psqh.com/julaug08/resolution.html>> accessed: 31 October 2014.

¹⁵⁴ O Rabinovich-Einy, ‘Escaping the Shadow of Malpractice Law’ (2011) 74 *Law and Contemporary Problems* 241, 270.

¹⁵⁵ D Golann, ‘Dropped Medical Malpractice Claims: Their Surprising Frequency, Apparent Causes, and Potential Remedies’ (2011) 30(7) *Health Affairs* 1343. The author found that the most common reason plaintiffs drop a medical negligence claim is the acquisition of information, not because the claim itself was frivolous.

¹⁵⁶ O Rabinovich-Einy, ‘Escaping the Shadow of Malpractice Law’ (2011) 74 *Law and Contemporary Problems* 241, 270.

¹⁵⁷ M Beyer et al., ‘Communication and Patient Safety’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 19; citing: National Patient Safety Agency (UK) <<http://www.npsa.nhs.uk/>> accessed: 21 October 2014.

11.7 Conclusion

This chapter has put forth the argument that communication and disclosure following an adverse incident is fundamental to meeting the immediate needs of the patient, and for quality and safety improvement. It has also specifically addressed one of the main barriers to healthcare communication—the elusiveness surrounding disclosure policies, procedures, and laws. Although governmental and organisational support for disclosure and apology has been widely promoted internationally,¹⁵⁸ in addition to the aforementioned jurisdictions, legislation to support such an initiative has been far more ambiguous. Despite the adoption of legislation in many jurisdictions requiring the disclosure of *serious* incidents, legal barriers still persist. As the American Society For Risk Management have advised:

“Depending upon the jurisdiction in which the healthcare organization operates, there could be legal restrictions on how much you are allowed to tell the patient about outcomes of investigation without jeopardizing the protection of healthcare workers to speak candidly during the investigative process. This can have a chilling effect on the willingness of staff to help solve problems and remediate latent unsafe situations. There may also be rules about reporting practitioners involved in medical errors to

¹⁵⁸ For example, both Ireland and Australia have published extensive reports citing the need for cultural reform, including the use of disclosure and apology. In an Irish context, see further: Department of Health and Children (Ireland), *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance* (Dublin: Department of Health, 2008); D Madden, ‘Saying Sorry for Medical Mistakes’ *Irish Examiner* (Cork, 03 February 2014) <<http://www.irishexaminer.com/ireland/saying-sorry-for-medical-mistakes-257419.html>. In the context of Australia, see further: Australian Council for Safety and Quality in Health Care, *National Patient Safety Education Framework* (Australia: Australian Council for Safety and Quality in Health Care, 2005); Australian Commission on Safety and Quality in Health Care, *Saying Sorry: A Guide to Apologising and Expressing Regret During Open Disclosure* (Sydney: Australian Commission on Safety and Quality in Health Care, 2013). It should be noted that on the 31 December 2005, the activities of the Australian Council for Safety and Quality in Health Care ceased and were assumed by the now, Australian Commission for Safety and Quality in Health Care.

professional licensure boards which can instil fear about participating in a disclosure discussion.”¹⁵⁹

The National Medical Error Disclosure and Compensation Bill of 2005 in the United States, introduced by then Senators Hillary Clinton and Barack Obama, sought to address some of the aforementioned barriers. The bill legally required, *inter alia*, that physicians report medical errors and adverse events to both a patient safety officer and the patient, as well as a legal obligation to offer to negotiate compensation and provide an apology to the patient. It is regrettable that the Bill failed to be enacted, however, it could be argued that such a strong legislative endorsement of disclosure, early compensation and apologies is likely to have benefited and contributed to the just culture movements set out throughout this thesis, which is a necessary prerequisite for safety and quality improvement.¹⁶⁰

In England—notwithstanding the contractual duty of candour incorporated into NHS contracts, and the recommendations of the Care Quality Commission and Royal College of Surgeons—proposals have been made to legislate the legal duty to disclose error according to the level of harm suffered.¹⁶¹ Critics of such varying thresholds question the need for additional legalisation. In this regard, Devlin has argued:

¹⁵⁹ American Society for Healthcare Risk Management, *Disclosure of Unanticipated Events in 2013* (Chicago: ASHRM, 2013) Prologue.

¹⁶⁰ National Medical Error Disclosure and Compensation (MEDiC) Act 2005, S 1784, 109th Cong, 1st Sess.; H Clinton and B Obama, ‘Making Patient Safety the Centerpiece of Medical Liability Reform’ (2006) 354(21) NEJM 2205. See further: H Woodward et al., ‘What Have We Learned About Interventions to Reduce Medical Errors?’ (2010) 31 Annual Review of Public Health 479, 486.

¹⁶¹ D Dalton and N Williams, *Building a Culture of Candour: A Review of the Threshold for the Duty of Candour and of the Incentives for Care Organisations to be Candid* (London: Royal College of Surgeons, 2014)

<<https://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf>> accessed: 12 November 2014. The authors argue that such a statutory duty be set at the level of “death and serious injury, or death, serious duty, and moderate harm.”

“This adds up to one longstanding, ethical duty and two different legal duties. Will this really benefit patients? Patients might be surprised to learn that whether there is a legal duty to tell them might depend on an NHS manager grappling with definitions as to what fits into the contractual or statutory duty (or both). Doctors, however, know they need to tell patients when something has gone wrong.”¹⁶²

For disclosure policies to be effective, collaboration must exist between the healthcare culture and the legal climate in which it operates. To this point, Sage has argued that legislators must recognise and attempt to diminish the litigation, economic, and reputational concerns of physicians, as well as facilitate patient participation in the resolution process.¹⁶³ Complexities of disclosure at the individual level can not be understated. As one physician wrote, “The emotional resistance to admitting error, the shame and guilt, are powerful barriers to owning up to error. These emotions cannot be legislated away.”¹⁶⁴ For this reason, organisational support for a just culture—which prioritises transparency—is fundamental. Likewise investment in the development and marketing of disclosure and communication programs, as well as support services, is also necessary.¹⁶⁵ As Wu notes, “While critical, national policies are unlikely to be sufficient. Local policies, based in part on these guidelines, need to reiterate the importance of disclosure, and customize guidance and expectations to the specific

¹⁶² M Devlin, ‘Why the New Duty of Candour Could be Detrimental to the NHS’ *The Guardian Professional* (London, 8 April 2014) <<http://www.theguardian.com/healthcare-network/2014/apr/08/duty-of-candour-nhs>>.

¹⁶³ W Sage et al., ‘How Policy Makers Can Smooth The Way For Communication-And-Resolution Programs’ (2014) 33(1) *Health Affairs* 11.

¹⁶⁴ D Ofri, ‘The Emotional Resistance to Admitting Error Cannot be Legislated Away’ (KevinMD, 13 September 2010) <<http://www.kevinmd.com/blog/2010/09/emotional-resistance-admitting-error-legislated.html>> accessed: 18 December 2014.

¹⁶⁵ M Mello et al., ‘Communication-And-Resolution Programs: The Challenges And Lessons Learned From Six Early Adopters’ (2014) 33(1) *Health Affairs* 20; M Mello et al., ‘Implementing Hospital-Based Communication-And-Resolution Programs: Lessons Learned in New York City’ (2014) 33(1) *Health Affairs* 30.

institutional context. These policies in turn provide the foundation for educational and training efforts.”¹⁶⁶

This chapter began by first analysing the legal and ethical duty placed on physicians and healthcare organisations in the United States, Canada, and England to disclose serious incidents, including medical error. Second, the legal and psychological barriers preventing the effective disclosure of medical error were examined. In the third section, best practices for the effective disclosure of patient safety incidents were considered from the perspective of improving patient-physician communication, and ultimately: safety and quality. The fourth section of this chapter critically analysed apologies given in the course of disclosure in the United States, Canada, and England. Lastly, the fifth section concluded with specific examples of disclosure and communication programs that have had a demonstrable benefit in educating and enabling physicians to provide effective disclosure of patient safety incidents to patients.

Enabling healthcare professionals and organisations with the skills and legal support to disclose a preventable incident and error, as well as overcoming the barriers, is essential. However, in many instances, disclosing an incident—particularly where harm has occurred or subsequent care is required—may only be the first step in the resolution process. Where the standard of care provided is in question, or compensation is sought, a patient may choose to instigate a medical malpractice claim. In an effort to reduce the rates of litigation, many healthcare organisations have begun embracing alternative dispute resolution as a means of resolving healthcare disputes in a time efficient, cost effective, and patient-centred manner. For this reason, the following chapter will examine alternative dispute resolution within healthcare and

¹⁶⁶ A Wu et al., ‘Disclosure of Adverse Events in the United States and Canada: An Update, and a Proposed Framework for Improvement’ (2013) 2(3) *Journal of Public Health Research* 186, 190.

specifically advocate for the use of mediation as a means of improving communication, quality and safety.

- Chapter 12 -

Alternative Dispute Resolution in Healthcare

12.1 Introduction

Alternative dispute resolution (ADR) can be defined as “any means of settling disputes outside of the courtroom”¹ and has gained favour as an alternative to litigation due to the significant reduction in cost and time that can be achieved, as well as offering participants a means by which to receive nonmonetary remedies unachievable through traditional mechanisms.² As Balcerzak and Leonhardt point out, “The public’s increased awareness of patient safety and demand for transparency of medical errors, along with the significant cost, complexity, and volume of malpractice cases, has opened the door for utilizing different methods for conflict resolution.”³ As examined in the previous chapter, poor communication is a significant barrier to effective conflict resolution.⁴ ADR offers the parties a forum by which to facilitate communication, potentially avoid the emotional trauma that may result from prolonged litigation, and offers the ability for both complex and minor disputes to be heard.⁵

¹ G Balcerzak and K Leonhardt, ‘Alternative Dispute Resolution in Healthcare: A Prescription for Increasing Disclosure and Improving Patient Safety’ *Patient Safety & Quality Healthcare* (July–Aug. 2008) <<http://psqh.com/julaug08/resolution.html>> accessed: 31 October 2014.

² H Morreim, ‘Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank’ (2012) 27(1) *Ohio State Journal on Dispute Resolution* 109, 121; citing: C Liebman and C Hyman, ‘A Mediation Skills Model to Manage Disclosure of Errors and Adverse Events to Patients’ (2004) 23 *Health Affairs* 22, 24. See also: K Benesch, ‘Why ADR and Not Litigation for Healthcare Disputes’ (2011) 66(3) *Dispute Resolution Journal* 52, 55-57; C Liebman, ‘Medical Malpractice Mediation: Benefits Gained Opportunities Lost’ (2011) 74 (135) *Law and Contemporary Problems* 135, 148.

³ G Balcerzak and K Leonhardt, ‘Alternative Dispute Resolution in Healthcare: A Prescription for Increasing Disclosure and Improving Patient Safety’ *Patient Safety & Quality Healthcare* (July–Aug. 2008) <<http://psqh.com/julaug08/resolution.html>> accessed: 31 October 2014.

⁴ See generally: Chapter 11.3 ‘Barriers to Disclosure.’

⁵ S Sanbar, ‘Alternative Dispute Resolution’ in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 308; S Szmania et al., ‘Alternative Dispute Resolution in Medical Malpractice: A Survey of Emerging Trends and Practices’ (2008) 26 *Conflict Resolution Quarterly* 71, 74-75.

This chapter will analyse the use of alternative dispute resolution (ADR) in the context of healthcare disputes. By way of introduction, the first section will identify and critically explore the primary forms of alternative dispute resolution engaged to resolve clinical disputes. This includes the traditional forms of dispute resolution, namely: mediation, arbitration, and negotiation. In addition, contemporary forms of ADR will be examined, including: 'mediation-arbitration,' early neutral evaluation, and healthcare screening panels. In the second section, the mediation process and its applicability to healthcare disputes will be analysed in greater detail. The argument will be put forth that the mediation process is ideally suited to resolve healthcare disputes, primarily due to the facilitative nature of the process and its ability to promote communication, early disclosure, and apology between the parties.⁶ Moreover, mediation provides the means by which to effect cultural change through information sharing and the use of mutually agreed nonmonetary remedies, both of which strongly support the objectives of the patient safety movement. Key aspects of the mediation process will be considered within the second section, beginning first with an analysis of the facilitative and evaluative methods of mediation. As distinct from evaluative mediation in which the mediator evaluates and gives an opinion on the parties claims; facilitative mediation is based on the premise that the mediator facilitates communication and enables the parties to reach a mutually acceptable agreement. Second, the strengths and weaknesses of the facilitative mediation process will be evaluated as an alternative to litigation. This analysis is particularly relevant to deconstructing the barriers preventing the wide scale implementation and use of healthcare mediation. The last section will address the primary barrier to mediation's wide spread use: the voluntary nature of the process and the prioritization of compensation. Specifically, this section will argue for the legislative requirement for mediation at the first instance of a dispute. The disclosure of root cause analysis reports, the use of compensation caps, and changes to regulatory disclosure policies

⁶ See generally: Chapter 11.3 - 11.5 analysing disclosure and apology following a patient safety incident.

will also be examined as a means of increasing the use and successful operation of mandated mediation programs.

12.2 Analysis of Alternative Dispute Resolution in Healthcare

By way of introduction, this section will outline the primary forms of alternative dispute resolution used to resolve clinical disputes. This will include the traditional forms of dispute resolution, namely: mediation, arbitration and negotiation. As well, contemporary forms of ADR will be examined, including: 'mediation-arbitration,' early neutral evaluation and healthcare screening panels.⁷

Mediation

Mediation is a nonbinding, voluntary, and confidential conflict resolution mechanism involving the use of a neutral third party to facilitate communication between parties in a dispute. Mediation may take on a facilitative or evaluative form, based on organisational policy, the nature of the conflict or by predetermination of the parties. In addition, the use of co-mediators⁸ or neutral evaluators⁹ may be used to further aid in the mediation process. Mediation is also beneficial where communication has broken down between the parties or where nonmonetary remedies are sought by the

⁷ In the medical context, the most common forms of alternative dispute resolution used are mediation and arbitration. See further: K Benesch, 'Why ADR and Not Litigation for Healthcare Disputes' (2011) 66(3) *Dispute Resolution Journal* 52.

⁸ The co-mediation model involves the use of two mediators, each of which are practicing medical malpractice lawyers. See further: S Sanbar, 'Alternative Dispute Resolution' in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 305.

⁹ A Neutral Evaluator may be preselected and involved in a mediation session as either a co-mediator or to advise the mediator and parties in an expert capacity. See further: R Glenn and C Allen, 'Neutral Experts, Standing Neutrals' (2006) 13 *Dispute Resolution Magazine* 29; R Webb, 'The Hospital/ Medical Staff Standing Neutral—An Idea Whose Time Has Come' (2011) 37(5) *Physician Executive Journal* 50.

plaintiff.¹⁰ In the context of healthcare, an analysis of the research suggests that in addition to compensation, patients desire and place equal significance on nonmonetary remedies, including: an explanation, apology, empathy, sympathy or forgiveness—all of which are strongly in line with the objectives of the patient safety movement.¹¹ For this reason, the second section of this chapter will examine in greater detail the mediation process, its suitability to healthcare dispute resolution, and advocate for its legislated mandatory introduction. For the purposes of comparison, it is now useful to further identify and critically examine alternative forms of dispute resolution used within a healthcare context.

Arbitration

Arbitration is one form of dispute resolution in which the parties to the dispute take their claim before a single or predetermined number of arbitrators who, after hearing the evidence presented, impose a decision. As distinct from other forms of dispute resolution, the arbitration process most closely resembles litigation proceedings insofar as it is adversarial by nature, requires evidence be presented by the parties, and an opinion on both law and fact is delivered by the arbitrator.¹²

¹⁰ C Gorton, 'Using Mediation to Resolve Disputes in Health Care' (2005) 31(4) *Physician Executive* 34, 37; N Meruelo, 'Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.' (2008) 29 *Journal of Legal Medicine* 285, 296; R Apple, 'Mediation Offers Less Costly Way to Resolve Disputes' (2013) 39(6) *Physician Executive Journal* 60

¹¹ See generally: C Hyman and C Schechter, 'Mediating Medical Malpractice Lawsuits Against Hospitals: New York City's Pilot Project' (2006) 25 *Health Affairs* 1394; A Merry and A McCall-Smith, *Errors, Medicine and the Law* (Cambridge: Cambridge University Press, 2001) 221; H Morreim, 'Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank' (2012) 27(1) *Ohio State Journal on Dispute Resolution* 109, 153; C Hyman et al., 'Interest-Based Mediation of Medical Malpractice Lawsuits: A Route to Improved Patient Safety?' (2010) 35(5) *Journal of Health Politics, Policy and Law* 797, 826; S Meller and S Barclay, 'Mediation: An Approach to Intractable Disputes Between Parents and Paediatricians' (2011) 96(7) *Archives of Disease in Childhood* 619, 620; D Mellman and M Adelman, 'Mediation in Health Care: An External Solution to Internal Problems' (2010) 36(6) *Physician Executive* 58; T Bogdanoski, 'Medical Negligence Dispute Resolution: A Role for Facilitative Mediation and Principled Negotiation?' (2009) 20(2) *Australian Dispute Resolution Journal* 77, 80.

¹² N Meruelo, 'Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.' (2008) 29 *Journal of Legal Medicine* 285, 296-297.

The arbitration decision may be binding or non-binding on the parties. Where a decision is binding, the liability and damage determination are final. Nonbinding arbitration allows either party to subsequently litigate the dispute or judicially review the decision should they be unhappy with the process, provided the arbitration was entered into voluntarily. Mandatory arbitration may be dictated by statute or pre-existing contractual terms; for example, in a contract of employment or for healthcare services.¹³ Where arbitration has been entered into voluntarily, the parties retain their right to a jury trial.¹⁴ Due to the gravity of the potential outcome, organisations such as the American Bar Association have given their endorsement to arbitration which has been "... entered into on a voluntary basis after a dispute has arisen and only if the disputant has full knowledge of the consequences of entering into such an agreement."¹⁵

Advantages of arbitration include the ability of the parties to select an arbitrator according to expertise and specialisation. Unlike a court or jury who may have difficulty assessing the applicable standard of care, an expert arbitrator will already be familiar with the applicable standard. On this point, Shieh has argued that, "Because departures from the standard of care are more likely to result in liability for the parties under an arbitration regime, the parties have greater incentive to exercise the proper standard of care than they would have under a litigation regime."¹⁶ Subject to any contractual terms previously agreed by the parties, arbitrators have the authority to

¹³ For a discussion of arbitration in the context of employment-related healthcare disputes, see generally: A Lash, 'Arbitration's Key Role in Resolving Employment-Related Health Care Disputes' (2014) 69(3) *Dispute Resolution Journal* 11.

¹⁴ S Sanbar, 'Alternative Dispute Resolution' in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 306.

¹⁵ N Meruelo, 'Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.' (2008) 29 *Journal of Legal Medicine* 285, 297; citing: P Gaul, 'ABA Endorses Voluntary Mediation in Medical Malpractice; Opposes Current Health Courts Proposals' (American Bar Association News Release, 23 June 2006).

¹⁶ D Shieh, 'Unintended Side Effects: Arbitration and the Deterrence of Medical Error' (2014) 89(5) *New York University Law Review* 1806, 1817; citing: S Shavell, 'Alternative Dispute Resolution: An Economic Analysis' (1995) 24 *The Journal of Legal Studies* 1, 6.

impose similar remedies to those used in formal litigation, such as monetary damages and equitable relief. The parties may also have an input on the procedural rules that will apply. In contrast to litigation, the arbitration process is time efficient and cost effective, primarily due to the limited discovery required, as well as the informal and expedient nature of the process.¹⁷ Where issues of enforcement occur, a party can have the arbitration award judicially confirmed, after which, failure to abide by the decision constitutes contempt of court.¹⁸

In contrast to other forms of dispute resolution, arbitration may be disadvantageous as the parties may ultimately be unsatisfied with the outcome and left feeling like they have not “had their day in court.”¹⁹ Moreover, in contrast to mediation, arbitration does not look to the parties future relationship, is susceptible to arbitrator bias, and primarily concerned with monetary remedies.²⁰ For this reason, arbitration does not have the same potential to improve healthcare culture or reduce communication barriers as does mediation because the decision is not one of mutual agreement and conciliation, but rather adjudicatory and similar to that of litigation.

¹⁷ K Benesch, ‘How To Save Time and Cost in Healthcare Arbitration: Can It Really Be Less Expensive than Litigation?’ (2014) 69(3) *Dispute Resolution Journal* 1; D Shieh, ‘Unintended Side Effects: Arbitration and the Deterrence of Medical Error’ (2014) 89(5) *New York University Law Review* 1806, 1821; citing: K DeVille, ‘The Jury Is Out: Pre-Dispute Binding Arbitration Agreements for Medical Malpractice Claims: Law, Ethics, and Prudence’ (2007) 28 *Journal of Legal Medicine* 333, 370-371.

¹⁸ K Benesch, ‘Why ADR and Not Litigation for Healthcare Disputes’ (2011) 66(3) *Dispute Resolution Journal* 52, 55-57; D Shieh, ‘Unintended Side Effects: Arbitration and the Deterrence of Medical Error’ (2014) 89(5) *New York University Law Review* 1806, 1818; citing: S Shavell, ‘Alternative Dispute Resolution: An Economic Analysis’ (1995) 24 *The Journal of Legal Studies* 1, 5, 21.

¹⁹ N Meruelo, ‘Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.’ (2008) 29 *Journal of Legal Medicine* 285, 296-297.

²⁰ S Sanbar, ‘Alternative Dispute Resolution’ in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 310; D Shieh, ‘Unintended Side Effects: Arbitration and the Deterrence of Medical Error’ (2014) 89(5) *New York University Law Review* 1806, 1825.

Mediation-Arbitration

'Mediation-Arbitration' is a form of alternative dispute resolution that enables the parties to begin the resolution process through mediation and progress to arbitration should a mutual resolution not be reached. In such instances, the mediator effectively takes on the role of the arbitrator and has the authority to render a decision on the matter. Conversely, 'Arbitration-Mediation' begins as arbitration, whereby the parties present their evidence and the arbitrator arrives at a decision. The parties are then given the opportunity to mediate. Should the mediation session fail, the decision by the arbitrator will be made known.²¹ This process is advantageous in that it provides a conciliatory environment for the parties to communicate while ensuring the dispute will ultimately be settled.²² However, Antona notes that a question may arise over the neutrality of the mediator who is required at a separate point to arbitrate the dispute.²³ Likewise, Dubler and Liebman make the critical observation that the process can be controversial as the parties may be influenced during the mediation process by the knowledge that the arbitrator will ultimately be making a determination.²⁴ While both criticisms certainly should be taken into account by the parties when selecting the most appropriate form of ADR, mediation-arbitration is beneficial insofar as it allows the parties to communicate and also ensures a relatively expedited resolution (as distinct to litigation).

²¹ N Dubler and C Liebman, *Bioethics Mediation: A Guide to Shaping Shared Solutions* (New York: United Hospital Fund of New York, 2004) 13; J Nolan-Haley, 'Mediation: The "New Arbitration"' (2012) 17(61) *Harvard Negotiation Law Review* 61, 86; S Sanbar, 'Alternative Dispute Resolution' in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 307.

²² S Sanbar, 'Alternative Dispute Resolution' in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 307.

²³ D Antona, 'Med-Arb: A Choice Between Scylla and Charybdis' (2014) 69(3) *Dispute Resolution Journal* 101, 109-110.

²⁴ N Dubler and C Liebman, *Bioethics Mediation: A Guide to Shaping Shared Solutions* (New York: United Hospital Fund of New York, 2004) 13.

Negotiation

In contrast to mediation or arbitration in which the third party remains neutral during the procedure, negotiation involves the use of a partisan negotiator who has been invited into the process in an effort to advocate and advance the position of the party whom they represent with the intention of settling the dispute in that party's favour.²⁵ For a patient who may be ill-equipped or uncomfortable in a relatively adversarial setting, employing a negotiator to act on their behalf has the distinct advantage of 'leveling the playing field.'²⁶ However, for many patients who want the opportunity to be heard or would like some form of verbal reparation from the defendant, mediation is arguably preferable.

Early Neutral Evaluation

Early neutral evaluation is a process whereby the parties to a dispute obtain an early, neutral and non-binding evaluation of the strengths and weakness of their case.²⁷ As Meruelo notes, "... the main goal of this process is to get parties to give up elements of their complaints that will not win and to suggest the best pretrial tactics for each

²⁵ R Orr, 'Methods of Conflict Resolution at the Bedside' (2001) 1(4) *The American Journal of Bioethics* 45; T Bogdanoski, 'Medical Negligence Dispute Resolution: A Role for Facilitative Mediation and Principled Negotiation?' (2009) 20(2) *Australian Dispute Resolution Journal* 77, 79-84. See generally: L Marcus et al., *Renegotiating Health Care: Resolving Conflict to Build Collaboration* (2nd edn, San Francisco: Jossey-Bass, 2011).

²⁶ N Dubler and C Liebman, *Bioethics Mediation: A Guide to Shaping Shared Solutions* (New York: United Hospital Fund of New York, 2004) 11. As Dubler and Liebman note, "Frequently, in the context of modern medical facilities, the patient's voice is muted, if not lost, and the patient's ability to vindicate his or her interests is overpowered. The power imbalance in a hospital setting comes from many sources: the difference in level of knowledge and expertise between most patients and the treatment team, the highly technical and unfamiliar physical setting, and the imperfectly aligned interests of the patient and the treatment team members."

²⁷ S Sanbar, 'Alternative Dispute Resolution' in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 308; N Meruelo, 'Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.' (2008) 29 *Journal of Legal Medicine* 285, 299; citing: R Lowery Gitchell and A Plattner, 'Mediation: A Viable Alternative to Litigation for Medical Malpractice Cases' (1999) 2 *DePaul Journal of Health Care Law* 421, 457-58.

party.”²⁸ Unless the plaintiff is found to have a meritless claim, the adversarial process will continue notwithstanding the early neutral evaluation. A disadvantage of this process is that where the plaintiff’s claim is found to be meritless or too financially risky to continue, the plaintiff may be left without achieving any or all of the objectives that lead to the claim in the first place; such as receiving information surrounding the event. However, early neutral evaluation can also be beneficial, particularly for the defendant(s), in reducing the time and costs associated with the litigation process or prolonged ADR.

Healthcare Screening Panels

Somewhat akin to early neutral evaluation, healthcare screening panels are specifically tailored to the clinical setting. Procedure, timing and composition of the screening panel is dictated by the law in the applicable jurisdiction. The screening panel may offer a non-binding opinion on the extent of liability of the defendant or potential compensation.²⁹ While healthcare screening panels may reduce litigation insofar as a plaintiff may be discouraged from proceeding with a claim where the claim has been deemed to lack merit, screening panels may fail to recognise the diverse reasons for which patients initiate litigation in the first place.³⁰ In this respect, Meruelo has argued, “Screening panels have been hailed as a way to prevent cases without merit from going to court; however, the same benefit may be realized by the use of mediation.”³¹ Ideally, healthcare screening panels could be used in conjunction with

²⁸ N Meruelo, ‘Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.’ (2008) 29 *Journal of Legal Medicine* 285, 299.

²⁹ *ibid* 297-298. For example, Meruelo notes that a judge, lawyer, healthcare practitioner, and healthcare provider selected from a court-approved list chair the screening panel in Maine, unless the parties agree otherwise. By contrast, screening panels in Massachusetts require a judge of the Superior Court, physician and lawyer to hear all medical malpractice complaints prior to litigation.

³⁰ *ibid* 297-298; S Sanbar, ‘Alternative Dispute Resolution’ in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 308.

³¹ N Meruelo, ‘Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.’ (2008) 29 *Journal of Legal Medicine* 285, 298; citing: W Kridelbaugh and D Palmisano, ‘A 20-Year Experience with Malpractice Screening Panels’ (1997) 82 *Bulletin of the American College of Surgeons* 21.

mediation, so as to narrow issues of liability, while allowing the emotional issues of the claim to be addressed (i.e. information or an apology.)

Unlike the forms of dispute resolution examined above, healthcare mediation provides the parties with an impartial and informal process to facilitate communication and allows for a greater understanding of the issues that lead to the dispute. It also places the greatest emphasis on nonmonetary remedies; a practice strongly endorsed by the patient safety movement as a means of improving quality and safety. For this reason, the next section will analyse in greater detail the process and benefits of healthcare mediation.

12.3 Healthcare Mediation

As stated above, mediation is a nonbinding, voluntary process in which a neutral third party (the Mediator) assists the parties to productively communicate by exchanging information, exploring options regarding the dispute, and negotiating a mutually acceptable resolution.³²

Mediation as a mechanism for conflict resolution originated during the 1960s and 1970s in an effort to reform what was believed to be an “overwhelmed, inefficient court system.” Simultaneously, a “grassroots” movement was underway that sought to address social conflict.³³ The objectives of both movements contributed to what are

³² See generally: L DeAngelo, ‘Mediation in Health Care Settings: Some Theoretical and Practical Concepts’ (2000) 7(2) *Journal of Clinical Psychology in Medical Settings* 133; N Meruelo, ‘Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.’ (2008) 29 *Journal of Legal Medicine* 285, 292; C Hyman et al., ‘Interest-Based Mediation of Medical Malpractice Lawsuits: A Route to Improved Patient Safety?’ (2010) 35(5) *Journal of Health Politics, Policy and Law* 797, 798; R Apple, ‘Mediation Offers Less Costly Way to Resolve Disputes’ (2013) 39(6) *Physician Executive Journal* 60, 61; D Mellman and M Adelman, ‘Mediation in Health Care: An External Solution to Internal Problems’ (2010) 36(6) *Physician Executive* 58.

³³ C Gorton, ‘Using Mediation to Resolve Disputes in Health Care’ (2005) 31(4) *Physician Executive* 34, 35; citing: C Picard, *Mediating Interpersonal and Small Group Conflict* (Ottawa: Golden Dog Press, 2002) 7-8. See further: E Zonana, ‘Getting Healthier: A Proposal for Improving Medical Malpractice Mediation’ (2001) 5 *American Journal of Mediation* 9, 12.

currently the hallmarks of the mediation process. These include: a commitment to confidentiality unless mutually agreed by the parties; an informal environment to carry out the mediation; self-determination of the parties; and the option to litigate should either party be unsatisfied with the process or outcome.³⁴ In regards to confidentiality, virtually all jurisdictions, by way of the common law and legislation, recognize information disclosed during mediation as privileged and confidential. The purpose of this is grounded in public policy. There is a legitimate public interest in encouraging participation in the mediation process, and this is only possible where the parties do not fear that their statements will be later used against them.³⁵ Likewise, mediators cannot later be subpoenaed to testify on the contents of the session unless expressly agreed upon by the parties or when mandated by law (e.g. a statutory requirement to report abuse effecting a minor).³⁶ Additionally, at the beginning of the mediation process, it is common practice to agree upon and sign a mediation contract which clearly sets out that the proceedings are privilege and confidential, and any potential exceptions specific to the circumstances.

As the mediation process has continued to evolve, so to have the models which are used. The next section will critically contrast the use of facilitative and evaluative voluntary mediation in a clinical setting.

³⁴ C Gorton, 'Using Mediation to Resolve Disputes in Health Care' (2005) 31(4) *Physician Executive* 34, 35; J Nolan-Haley, 'Mediation: The "New Arbitration"' (2012) 17(61) *Harvard Negotiation Law Review* 61, 69; C Liebman, 'Medical Malpractice Mediation: Benefits Gained Opportunities Lost' (2011) 74 (135) *Law and Contemporary Problems* 135, 149.

³⁵ For example: in the United States, State and Federal law provide for confidentiality in the mediation process. Federally, the law providing for privileged communications during a mediation settlement can be found in US Federal Rules of Evidence Rule 501, Rule 408, and the common law rules. Rule 501 provides for the sole rule on evidentiary privilege; while Rule 408 includes provisions for privilege in settlement negotiations. However, depending on the circumstances, privilege may be restricted where a court determines it is in the interests of justice or where the evidence is offered for another purpose, such as to establish bias. See further: C Ehrhardt, 'Federal Courts (Confidentiality in Mediation)' (1998) 5(2) *Dispute Resolution Magazine* 17; H Morreim, 'Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank' (2012) 27(1) *Ohio State Journal on Dispute Resolution* 109, 151-152.

³⁶ C Gorton, 'Using Mediation to Resolve Disputes in Health Care' (2005) 31(4) *Physician Executive* 34, 36.

12.3.1 Types of Mediation

Mediation can be divided into two main models, facilitative mediation and evaluative mediation. Facilitative mediation, as the name suggests, is based on the premise that the mediator facilitates communication between the parties; the objective being that a mutually acceptable agreement is reached. Within the facilitative model, two separate approaches can be taken by the mediator: an interest-based approach or rights-based approach. Interest-based mediation does not involve an evaluation of the legal strengths and weaknesses of each party's case but rather allows for a mutually acceptable agreement to be reached. The mediator remains neutral and merely assists the parties in reaching an agreement. Where emotions become a barrier to communication between the parties, 'shuttle diplomacy' allows the mediator to work individually with the parties in reaching an agreement.³⁷ Where a rights-based model is utilised, the mediator places a strong emphasis on the legal positions of the parties when facilitating communication between them.³⁸ The Massachusetts Voluntary Mediation Program is a useful example of facilitation mediation in practice. First developed in 1997 as a pilot project, the program gives participants the opportunity to voluntarily resolve the dispute in a facilitative, confidential setting with the assistance of a neutral third-party.³⁹ For the physician, the program provides the opportunity to offer information and an apology where appropriate. If the dispute was successfully mediated, the claim is removed from the physician's public record. For the patient, the mediation program offers the opportunity for an explanation of the event that

³⁷ C Gorton, 'Using Mediation to Resolve Disputes in Health Care' (2005) 31(4) *Physician Executive* 34, 35; K Knickle et al., 'Beyond Winning: Mediation, Conflict Resolution, and Non-Rational Sources of Conflict in the ICU' (2012) 16(3) *Critical Care* 308, 309.

³⁸ S Sanbar, 'Alternative Dispute Resolution' in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 305. The author makes the observation that because rights-based mediation places a greater emphasis on the legal rights of the parties, the process is more akin to an evaluative process.

³⁹ E Dauer and L Marcus, 'Adapting Mediation to Link Resolution of Medical Malpractice Disputes with Health Care Quality Improvement' (1997) 60 *Law and Contemporary Problems* 185. The program was developed as a pilot project by the Massachusetts Board of Registration in Medicine in conjunction with the Program for Health Care Negotiation and Conflict Resolution at Harvard University.

occurred, compensation and an apology.⁴⁰ According to Dauer and Marcus, out of the first ten patients to participate in the program, nine settled. Of the nine, only four resulted in the payment of monetary compensation; the other five settled with an apology, explanation of circumstances or in one case, the defendant physician agreeing to attend a continuing medication education course.⁴¹

Evaluative mediation, as distinct from facilitative mediation, requires the mediator to evaluate the merits of each party's position and give opinions based on the likely outcome in accordance with the laws pertaining to that jurisdiction.⁴² Somewhat akin to the rights-based mediation model is bioethics mediation. The main difference being that the bioethics mediator places a stronger emphasis on the parties' ethical and legal rights.⁴³ By way of example, the Rush University Medical Centre Model in Chicago ("The Rush Model") was created in 1995 following concern over the rapid growth in litigation, legal costs and judicial awards. The process is non-binding, evaluative and offered to all patients and physicians voluntarily. Costs of the program are shared by the parties. The defining feature of the Rush Model is the use of co-mediators. At each mediation session, a medical malpractice defense lawyer and a medical malpractice plaintiff lawyer, chosen by the patient, are present and assist the parties as expert-neutral third parties. The primary focus of the mediation is on the legal merits and monetary value of the case rather than the party's interests. In general, only the patient and their counsel, the defendant's counsel and the mediators attend—the physician

⁴⁰ *ibid* 206.

⁴¹ *ibid* 207.

⁴² E Zonana, 'Getting Healthier: A Proposal for Improving Medical Malpractice Mediation' (2001) 5 *American Journal of Mediation* 9, 24-25; D Spencer and M Brogan, *Mediation Law and Practice* (Cambridge: Cambridge University Press, 2007) 105-106.

⁴³ N Dubler and C Liebman, *Bioethics Mediation: A Guide to Shaping Shared Solutions* (New York: United Hospital Fund of New York, 2004) 14. The authors raise the question of whether bioethics mediation is truly mediation, as the position of the mediator—in emphasizing the ethical and legal rights of the parties—may not be a truly neutral third party, as is a defining feature of traditional mediation. See also: H Morreim, 'Conflict Resolution in the Clinical Setting: A Story Beyond Bioethics Mediation' (2015) 43(4) *Journal of Law, Medicine & Ethics* 843-856.

does not. In the first five years of the program, eighty percent of the cases that proceeded to mediation were resolved within one year. Despite monetary settlements being slightly lower than those awarded by a jury, patients were generally satisfied with the settlements as they were able to receive them significantly faster than a court settlement.⁴⁴ Zonana makes the observation that “Rush University considers their program to be a great success and, when viewing it through a prism of avoiding litigation time and monetary expenditures, it is.”⁴⁵

Critical Comparison of the Mediation and Litigation Process

The mediation process may not be appropriate for all healthcare disputes, particularly where the consequences of the injury cannot yet be adequately assessed, where there is fundamental disagreement about the cause of the event or the standard of care having been met. Alternatively, when the breakdown of communication has contributed to the plaintiff’s decision to litigate, mediation may be useful in reestablishing communication and clarifying the issues.⁴⁶ As Hyman observes, “Even if a lawsuit does not settle at the mediation table, the momentum created by the negotiations started in mediation may result in narrowing the issues in dispute or lead to settlement

⁴⁴ A Block, ‘Disclosure of Adverse Outcomes and Apologizing to the Injured Patient’ in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 297-298; N Meruelo, ‘Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.’ (2008) 29 *Journal of Legal Medicine* 285, 304; S Sanbar, ‘Alternative Dispute Resolution’ in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 306; G Balcerzak and K Leonhardt, ‘Alternative Dispute Resolution in Healthcare: A Prescription for Increasing Disclosure and Improving Patient Safety’ *Patient Safety & Quality Healthcare* (July–Aug. 2008) <<http://psqh.com/julaug08/resolution.html>> accessed: 31 October 2014.

⁴⁵ E Zonana, ‘Getting Healthier: A Proposal for Improving Medical Malpractice Mediation’ (2001) 5 *American Journal of Mediation* 9, 25; citing: M Brown, ‘Rush Hospital v Medical Malpractice Mediation Program: An ADR Success Story’ (1998) 86(8) *Illinois Bar Journal* 432, 434.

⁴⁶ C Hyman et al., ‘Interest-Based Mediation of Medical Malpractice Lawsuits: A Route to Improved Patient Safety?’ (2010) 35(5) *Journal of Health Politics, Policy and Law* 797, 813.

after the mediation.”⁴⁷ In the event the mediation is unsuccessful, the parties may proceed to arbitration or undertake litigation.⁴⁸

In contrast to litigation, mediation also has the advantage of being flexible, cost effective and can be entered into at any stage of the dispute process.⁴⁹ Even when mediation is legislatively mandated, the process does not require extensive discovery, and can therefore begin soon after an incident has occurred. Although it remains necessary for clinical risk managers and each party’s legal counsel to carry out an investigation, the amount of information necessary to proceed with mediation is not as great as preparing for the discovery process.⁵⁰ Research by Hyman found that on average, lawyers spent between three and ten hours preparing for mediation, while the average number of hours spent preparing for litigation ranged between fifty and one-hundred.⁵¹ Consequently, a mediation settlement can reduce the potential costs associated with litigation, such as discovery and court fees; while the fair value of the case can remain relatively the same.⁵² Moreover, facilitative mediation can reduce many of the obstacles that typically lengthen the litigation process. In this regard, Boothman et al. make the observation:

⁴⁷ *ibid* 812.

⁴⁸ L DeAngelo, ‘Mediation in Health Care Settings: Some Theoretical and Practical Concepts’ (2000) 7(2) *Journal of Clinical Psychology in Medical Settings* 133, 135.

⁴⁹ H Morreim, ‘Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank’ (2012) 27(1) *Ohio State Journal on Dispute Resolution* 109, 125; C Hyman et al., ‘Interest-Based Mediation of Medical Malpractice Lawsuits: A Route to Improved Patient Safety?’ (2010) 35(5) *Journal of Health Politics, Policy and Law* 797, 812. See further: Chapter 2: ‘The Role of Medical Malpractice Law and Litigation in the Reduction of Medical Error’ for an analysis of the disadvantages of litigating a clinical dispute.

⁵⁰ C Hyman et al., ‘Interest-Based Mediation of Medical Malpractice Lawsuits: A Route to Improved Patient Safety?’ (2010) 35(5) *Journal of Health Politics, Policy and Law* 797, 813.

⁵¹ *ibid* 809.

⁵² R Apple, ‘Mediation Offers Less Costly Way to Resolve Disputes’ (2013) 39(6) *Physician Executive* 60; C Hyman et al., ‘Interest-Based Mediation of Medical Malpractice Lawsuits: A Route to Improved Patient Safety?’ (2010) 35(5) *Journal of Health Politics, Policy and Law* 797, 811; S Seabury, ‘Defensive Costs of Medical Malpractice Claims’ (2012) 366(14) *NEJM* 1354.

'By interrupting the march to the courthouse, the animosity intrinsic to suing someone is lessened and often avoided, which allows for discussions not impassioned by name-calling, threats of professional ruin, reinforced victimhood, exaggerated claims, and dismissive defenses. If it appears that compensation is owed, the discussion shifts from the typical approach, in which both sides take equally unreasonable financial positions and work towards a middle ground, evidence-based discussions about what is truly owed because of the medical error. With this approach, it is not uncommon for a settlement amount to be very close to the original offer and for both sides to agree on the substantive basis for the settlement.'⁵³

Contrary to the judicial process where damages may not be awarded for a significant period of time following the event, a monetary settlement in mediation can be received relatively soon after the harm occurred, the terms of which are enforced under the law of contract.⁵⁴ Where the parties have the opportunity to come together and discuss the relevant issues—as opposed to their lawyers—there is a move away from a strictly monetary focus to more facilitative and creative remedies.⁵⁵

⁵³ R Boothman et al., 'A Better Approach to Medical Malpractice Claims? The University of Michigan Experience' (2009) 2 *Journal of Health & Life Sciences Law* 125, 142; as taken from: H Morreim, 'Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank' (2012) 27(1) *Ohio State Journal on Dispute Resolution* 109, 125.

⁵⁴ C Hyman et al., 'Interest-Based Mediation of Medical Malpractice Lawsuits: A Route to Improved Patient Safety?' (2010) 35(5) *Journal of Health Politics, Policy and Law* 797, 813; S Sanbar, 'Alternative Dispute Resolution' in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 305.

⁵⁵ C Hyman et al., 'Interest-Based Mediation of Medical Malpractice Lawsuits: A Route to Improved Patient Safety?' (2010) 35(5) *Journal of Health Politics, Policy and Law* 797, 826; citing: C Liebman and C Hyman, 'Medical Error Disclosure, Mediation Skills, and Malpractice Litigation: A Demonstration Project in Pennsylvania.' (2005) 61-65. <www.pewtrusts.org/our_work_report_detail.aspx?id=24398>; A London, 'Med-Mal Mediation Offers Promise, but Systemic Obstacles Remain' (2006) 61(3) *Dispute Resolution Journal* 27, 30.

Mediation and Patient Safety

Facilitative mediation embodies many of the objectives of the Patient Safety movement, including increased communication, a commitment to learning from error and reporting, as well as focus on the root cause of the incident. As Hyman argues,

“The patient safety case for malpractice mediation rests on a conceptual tripod: (1) communication with patients and their families after an adverse event or medical error, (2) apology when appropriate, and (3) commitment to learn from errors and bad outcomes. Each leg requires the open participation of plaintiffs as well as directness, authenticity, and empathy on the part of defendants and their lawyers.”⁵⁶

Where human or system factors have contributed to the dispute and must be addressed, the information shared within a mediation session can be useful in reforming current processes.⁵⁷ This is facilitated by attaching two types of privilege—that derived by the mediation process, and that gathered for quality improvement purposes. By committing to open dialogue and action, based on the information acquired, Hyman’s conceptual tripod can best be directly and indirectly achieved.⁵⁸ For this to be possible, however, the active participation of the physician, the healthcare organisation, and the patient is required.

An interesting program that directly embodies the objectives of the patient safety movement and exemplifies the components of Hyman’s conceptual tripod is the practice of pre-mediation. Although a precursor to the mediation programs described throughout this chapter, the pre-mediation program encompasses the philosophies of

⁵⁶ *ibid* 814. See also: C Hyman, ‘Mediation and Medical Malpractice: Why Plaintiffs, Hospitals and Physicians Should Be at the Table’ (2011) 66(3) *Dispute Resolution Journal* 32-37.

⁵⁷ *ibid* 813.

⁵⁸ *ibid* 817.

patient and family-centred care, learning, transparent communication, accountability, and expedited dispute resolution.

In their 2011 article entitled 'Conflict Management in Hospital Systems: Not Just For Leadership',⁵⁹ Hetzler et al. describe the operation of their hospital-based pre-mediation program which seeks to establish communication with the patient, family and their lawyer immediately following a patient safety incident. The use of such a program is promising, as Hetzler explains: "By making contact immediately and offering the chance to meet and hear from the patient or family directly, you set the stage for a collaborative approach to solving the problem presented."⁶⁰ The procedure set out by the authors will now be examined.⁶¹

Following an incident, an initial meeting between the hospital administration and patient is organised. The purpose of the meeting is solely for listening to the patient's narrative, after which the patient is informed an investigation will take place and a second meeting date is set. In the interim, a thorough investigation of the events, including interviews with all relevant persons are conducted. At the second meeting, the information collected during the investigation is shared with the patient or family. This includes relevant sections of the medical record, a summary of the employee interviews and all non-privileged information. Following the disclosure, the administration expressly inquire if there is anything else they can do for the patient. Hetzler notes that at this point, some patients are satisfied with the information provided and choose not to pursue the matter further. However, for some patients, a

⁵⁹ D Hetzler et al., 'Conflict Management in Hospital Systems: Not Just For Leadership' (2011) 5 American Journal of Mediation 65.

⁶⁰ *ibid* 80-86.

⁶¹ *ibid* 83-84.

form of redress is necessary. In this instance, the administration ask the patient “what a resolution might look like?”⁶²

An emphasis is placed on the importance of carefully listening to the response of the patient. Such redress may include compensation, a change in policy or an apology. In regards the latter, Hetzler states:

“We offer an apology in the context of understanding that the patient trusted us with his or her well-being and that we have failed the patient’s expectation of being cared for. It is sincere, and it is offered in the hope that the patient will trust us in the future. ... When a policy is in question, we offer to send the patient a copy of any changes we make when the policy is changed. The offer includes some information on how our policies are developed, and not a promise that we can change as the patient wants, but that we will look at the opportunity to be sure we have the industry standard, and that we will address all of the concerns the patient has identified in the process.”⁶³

Should the patient not require compensation, the matter will be concluded.

Where compensation is sought, a third meeting is held following consultation with the appropriate claims committee. If the amount is acceptable to the patient, the matter again could conclude at this stage. In instances where it is not sufficient, the administration encourage the patient to pursue a method of dispute resolution. This may include facilitative mediation or litigation. Where litigation is preferable to the patient and their lawyer, the administration attempt to expedite discovery in an effort to resolve the matter as quickly as possible.⁶⁴ On average, where mediation or litigation

⁶² *ibid* 83-84.

⁶³ *ibid* 84.

⁶⁴ *ibid* 85-86.

are not sought, the process occurs over a sixty-day period. During which—where the patient accepts—the hospital remains committed to the care and treatment of the patient.⁶⁵

The aforementioned mediation programs each have defining features. The pre-mediation program endorsed by Hetzler et al., provides for an early opportunity to intervene, disclose information and offer unique remedies to the patient; in addition to the opportunity to negotiate compensation, if necessary. The program also encourages early investigation and analysis of the incident, as well as a means of addressing quality and safety issues. Both practices strongly endorsed by the patient safety movement. Likewise, the Massachusetts program offers a means by which to address the plaintiff's claim in a cost and time effective manner. For physician's, the program is particularly enticing because it removes the disincentive of having a settled claim on their public record. The Rush Model is also unique insofar as the use of co-mediators ensures the parties' legal interests are protected. However, as has been examined previously in regards evaluative mediation, the Rush Model focuses primarily on monetary remedies. Where the plaintiff seeks remedies that extend beyond monetary compensation—such as an apology or information from the physician involved in their care—the Rush Model may be less appealing as compared to the programs advocated by Hetzler or used within Massachusetts.

Arguably, Hetzler's program would in practice be relatively easy to implement on a local level because it is intrinsically connected with existing disclosure and quality improvement processes. However, as with all voluntary dispute resolution programs, compliance relies heavily on both parties conceding. Where a higher level of compensation can be awarded via litigation, the benefits of such a program will likely be dismissed. This obstacle will be examined further below with respects to the introduction of mandatory mediation programs.

⁶⁵ *ibid* 85-86.

The Role of the Mediator and Legal Counsel in Mediation

As examined above, attendance at a mediation session is dictated by the type of mediation being conducted. In general, those in attendance may include: the plaintiff (patient and family); the defendant (physician or healthcare staff involved); lawyers for both parties; an insurance claims representative (where appropriate) and the mediator.⁶⁶

In a facilitative setting, the participation of the patient and physician/healthcare professional is customary as the goal is to facilitate communication and mutual agreement between the parties.⁶⁷ In contrast, in an evaluative setting, the primary focus is monetary and concerned with legal requisites.⁶⁸ As a result, the attendance of the defendant physician/healthcare professional directly involved may have less value attached or may even be discouraged. While a compromise on the monetary value of the case is beneficial in that it reduces the chance of progressing to litigation, opportunities for creative resolutions are reduced; including, for example: an apology, disclosure and exchange of information, changes to institution policy, or improvements to patient safety.⁶⁹ The absence of the parties may also have the effect of blurring the

⁶⁶ E Zonana, 'Getting Healthier: A Proposal for Improving Medical Malpractice Mediation' (2001) 5 *American Journal of Mediation* 9, 32; citing: J Cohen, 'Advising Clients to Apologize' (1999) 72 *Southern California Law Review* 1009, 1016; D Levi, 'The Role of Apology in Mediation' (1997) 72 *New York University Law Review* 1165, 1176; T Relis, 'Consequences of Power' (2007) 12 *Harvard Negotiation Law Review* 445, 457; T Metzloff et al., 'Empirical Perspectives on Mediation and Malpractice' (1997) 60(1) *Law and Contemporary Problems* 107, 151.

⁶⁷ *ibid* 28.

⁶⁸ *ibid* 25-26.

⁶⁹ C Hyman et al., 'Interest-Based Mediation of Medical Malpractice Lawsuits: A Route to Improved Patient Safety?' (2010) 35(5) *Journal of Health Politics, Policy and Law* 797, 817; citing: C Liebman and C Hyman, 'Medical Error Disclosure, Mediation Skills, and Malpractice Litigation: A Demonstration Project in Pennsylvania.' (2005) 61, 62. <www.pewtrusts.org/our_work_report_detail.aspx?id=24398>; E Galton, 'Mediation of Medical Negligence Claims' (2000) 28 *Capital University Law Reform* 321, 325. See generally: Chapter 11 'Communication: Disclosure and Apology.'

line between mediation as a collaborative event, and arbitration where less value is placed on conciliation.⁷⁰

The role of the mediator is unique to any of the alternative dispute resolution mechanisms. Unlike an arbitrator who typically has expertise in the subject matter of the dispute or is responsible for evaluating and determining a resolution in the dispute; the role of the mediator requires impartiality, ethical awareness, analytical skills, empathy, and an ability to facilitate communication.⁷¹ As Orr suggests, “The mediator is a nonpartisan catalyst who is to facilitate discussion so that the two parties can reach their own resolution. He or she can pose questions, clarify answers, reframe issues, express empathy or look for creative options for resolution, but assiduously avoids taking sides.”⁷² Similarly, Meruelo makes the observation that, “... because mediators tend to be trained in a variety of different styles, they are able to take on a therapeutic and facilitative style a judge never could. This allows mediators to pay close attention to the underlying needs of the parties, as well as clarify the issues that must be resolved, without being restrained by the need to focus on legal norms.”⁷³

⁷⁰ J Nolan-Haley, ‘Mediation: The “New Arbitration”’ (2012) 17(61) *Harvard Negotiation Law Review* 61, 63. The author refers to a phenomenon called ‘legal mediation’ in which the boundaries between mediation and arbitration are blurred by the presence of the parties lawyers actively advocating during the mediation.

⁷¹ K Knickle et al., ‘Beyond Winning: Mediation, Conflict Resolution, and Non-Rational Sources of Conflict in the ICU’ (2012) 16(3) *Critical Care* 308, 309; citing: R Benjamin, ‘Managing the Natural Energy of Conflict’ in D Bowling and D Hoffman (eds) *Bringing Peace into the Room: How the Personal Qualities of the Mediator Impact the Process of Conflict Resolution*. (San Francisco, CA: Jossey-Bass, 2003) 92,109,111,112. See also: S Sanbar, ‘Alternative Dispute Resolution’ in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 305; L DeAngelo, ‘Mediation in Health Care Settings: Some Theoretical and Practical Concepts’ (2000) 7(2) *Journal of Clinical Psychology in Medical Settings* 133, 135; N Meruelo, ‘Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.’ (2008) 29 *Journal of Legal Medicine* 285, 295.

⁷² R Orr, ‘Methods of Conflict Resolution at the Bedside’ (2001) 1(4) *The American Journal of Bioethics* 45. See further: K Knickle et al., ‘Beyond Winning: Mediation, Conflict Resolution, and Non-Rational Sources of Conflict in the ICU’ (2012) 16(3) *Critical Care* 308, 309.

⁷³ N Meruelo, ‘Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.’ (2008) 29 *Journal of Legal Medicine* 285, 293.

Both Orr and Meruelo's comments emphasise an important distinction in the mediation process: the mediator's role is facilitative, not adjudicatory. In this regard, the mediation process can be tailored to the subjective needs of the parties, as distinct to a focus solely on the legal merits of the claim. However, an alternative argument can be made for employing a mediator with medical expertise. Zonana suggests that while medical expertise may have the effect of influencing the neutrality of the mediator or increasing the likelihood that the mediator will provide expert-evaluations, it can be advantageous insofar as the mediator is better able to follow the discussion, as well as raise issues that may not be apparent to either party.⁷⁴ This is particularly relevant in regards complex claims. In advance of the first mediation session, a predetermined agreement will determine the extent of the mediator's responsibility, expertise, and involvement following a resolution.⁷⁵

A potential barrier to successful mediation and the facilitative role of the mediator is a situation in which the parties' lawyers take an adversarial approach at the expense of facilitative communication between the parties. Lawyers have the ability to act as "gatekeepers" to a mediation; influencing the level of participation of their client, as well as the client's decision to settle.⁷⁶ In this regard, Liebman notes that lawyers may discourage their clients from participating in mediation because they may be attempting to protect their client from an emotionally burdensome experience; may lack the experience or knowledge to be aware of the full range of benefits mediation can offer, particularly the noneconomic benefits; a previous poor experience; concern over future liability should the mediation not be successful; or concern that mediation

⁷⁴ E Zonana, 'Getting Healthier: A Proposal for Improving Medical Malpractice Mediation' (2001) 5 American Journal of Mediation 9, 30-31. Where the mediator does not possess previous expertise, reviewing the relevant law and best practice prior to the mediation session can be equally beneficial. As Zonana notes, in medical malpractice litigation, no less is expected of a judge presiding over the case or jury, where applicable.

⁷⁵ L DeAngelo, 'Mediation in Health Care Settings: Some Theoretical and Practical Concepts' (2000) 7(2) Journal of Clinical Psychology in Medical Settings 133, 135.

⁷⁶ C Hyman et al., 'Interest-Based Mediation of Medical Malpractice Lawsuits: A Route to Improved Patient Safety?' (2010) 35(5) Journal of Health Politics, Policy and Law 797, 813.

is not as financially advantageous as litigation.⁷⁷ While it is not suggested that the parties' counsel be absent from the mediation process, the potential benefits of mediation may not be realised where a greater emphasis is placed on advocacy than on interest-based communication and resolution.⁷⁸ On this point, Guthrie argues that "Lawyers operate according to a standard philosophical map that predisposes them to practice law and mediation in an evaluative rather than a facilitative way."⁷⁹ Indeed, legal education and training certainly contribute to such practices.⁸⁰ This raises an important point: just as physicians and healthcare organisations must embrace a facilitative role in the interests of early resolution, so to must lawyers who agree to represent clients involved in the healthcare mediation process. As Peeples has argued: the greater the involvement of lawyers, the less therapeutically beneficial mediation becomes.⁸¹ Such a departure from traditional advocacy is inevitably bound to be met with resistance. As Liebman acknowledged above, plaintiff lawyers may be concerned that that mediation is not financially advantageous for their client, or themselves, as compared to litigation. However, it is worth noting that the mediation process may result in a higher rate of turnover of cases, thereby compensating for any loss in legal

⁷⁷ C Liebman, 'Medical Malpractice Mediation: Benefits Gained Opportunities Lost' (2011) 74 (135) *Law and Contemporary Problems* 135, 148.

⁷⁸ J Nolan-Haley, 'Mediation: The "New Arbitration"' (2012) 17(61) *Harvard Negotiation Law Review* 61, 84; citing: K Kovach and L Love, 'Mapping Mediation: The Risks of Riskin's Grid' (1998) 3 *Harvard Negotiation Law Journal* 71, 92-93.

⁷⁹ C Guthrie, 'The Lawyer's Philosophical Map and the Disputants Perceptual Map: Impediments to Facilitative Mediation and Lawyering' (2001) 6 *Harvard Negotiation Law Review* 145, 180; as taken from: J Nolan-Haley, 'Mediation: The "New Arbitration"' (2012) 17(61) *Harvard Negotiation Law Review* 61, 83.

⁸⁰ J Nolan-Haley, 'Mediation: The "New Arbitration"' (2012) 17(61) *Harvard Negotiation Law Review* 61, 76 (footnote 88); citing: M Heumann and J Hyman, 'Negotiation Methods and Litigation Settlement Methods in New Jersey: 'You Can't Always Get What You Want'' (1997) 12 *Ohio State Journal on Dispute Resolution*. 253; J Lande and J Sternlight, 'The Potential Contribution of ADR to an Integrated Curriculum: Preparing Law Students for Real World Lawyering' (2010) 25 *Ohio State Journal on Dispute Resolution*. 247, 263-64.

⁸¹ R Peeples et al., 'Following the Script: An Empirical Analysis of Court-Ordered Mediation of Medical Malpractice Cases' (2007) 1 *Journal of Dispute Resolution* 101, 117-118.

fees.⁸² The widespread challenge of acceptance and compliance will be addressed further below.

While the above analysis strongly advocates for the use of mediation, this is not to suggest mediation will be appropriate for all clinical disputes. For this reason, it is now necessary to evaluate in greater detail the strengths and weaknesses of the mediation process in the context of healthcare disputes.

12.3.2 Evaluation of the Mediation Process

Strengths of the Mediation Process

In contrast to litigation which is public, adversarial, and expensive; mediation offers the parties a mechanism by which to resolve disputes confidentially in a harmonious and cost effective manner.⁸³ Mediation facilitates communication between the parties; provides the means to identify and disclose common interests, and shifts the focus of the dispute from the past to the future.⁸⁴ In a study by Meller and Barclay, the authors found that mediation allowed the parties to better address the original causes of the dispute, as well as reduce the possibility of alienation and damage within the patient-

⁸² N Meruelo, 'Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.' (2008) 29 *Journal of Legal Medicine* 285, 306; citing: L Morton, 'A New Approach to Health Care ADR: Training Law Students to Be Problem Solvers in the Health Care Context' (2005) 21 *Georgia State University Law Review* 965, 970. See also: A London, 'Med-Mal Mediation Offers Promise, but Systemic Obstacles Remain' (2006) 61 (3) *Dispute Resolution Journal* 26, 31. On this point, London makes the critical observation that when paid on a contingency fee basis, the interests of the lawyer and the plaintiff may not be the same.

⁸³ S Szmania et al., 'Alternative Dispute Resolution in Medical Malpractice: A Survey of Emerging Trends and Practices' (2008) 26 *Conflict Resolution Quarterly* 71, 74; L DeAngelo, 'Mediation in Health Care Settings: Some Theoretical and Practical Concepts' (2000) 7(2) *Journal of Clinical Psychology in Medical Settings* 133; citing: M Hiltrop and J Rubin, 'Effects of Intervention Mode and Conflict of Interest on Dispute Resolution.' (1982) 42 *Journal of Personality and Social Psychology* 665-672.

⁸⁴ S Sanbar, 'Alternative Dispute Resolution' in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 305; E Zonana, 'Getting Healthier: A Proposal for Improving Medical Malpractice Mediation' (2001) 5 *American Journal of Mediation* 9, 12; citing: N Welsh, 'The Thinning Vision of Self-Determination in Court-Connected Mediation: The Inevitable Price of Institutionalization?' (2001) 6 *Harvard Negotiation Law Review* 1, 15-16.

physician relationship.⁸⁵ Where the process is voluntary and consensual, a mediated agreement can provide the opportunity to meet the economic, emotional and psychological needs of the parties resulting in a higher rate of compliance.⁸⁶

Conflict within a healthcare setting can occur for many reasons. In addition to the consequences of a patient safety incident, patient's may be experiencing severe illness and stress. Poor communication, misperceptions, high levels of emotion, issues not directly related to the situation, or a disagreement about the events or future care plan can all contribute to conflict.⁸⁷ Mediation is well-suited to the healthcare domain because of the emphasis placed on facilitating communication; namely problem-solving, compromise, and the promotion of healing. As Meruelo explains, "... unlike litigation, mediation shares many of the same goals as medicine, including the promotion of healing. As a result, mediation is an excellent fit for the unique dynamic that exists between patients and healthcare providers and the societal importance we attach to cementing and preserving the qualities of trust and caregiving that are particular to this relationship."⁸⁸

⁸⁵ S Meller and S Barclay, 'Mediation: An Approach to Intractable Disputes Between Parents and Paediatricians' (2011) 96(7) *Archives of Disease in Childhood* 619, 620; citing: L Mulcahy, *Mediating Medical Negligence Claims: An Option for the Future?* (Norwich: The Stationary Office, 2006)

⁸⁶ *ibid* 619. The authors argue that if delivered in a truly independent manner by an expert mediator, mediation can provide a better solution than the externally imposed judgment of the court.; N Meruelo, 'Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.' (2008) 29 *Journal of Legal Medicine* 285, 295; L DeAngelo, 'Mediation in Health Care Settings: Some Theoretical and Practical Concepts' (2000) 7(2) *Journal of Clinical Psychology in Medical Settings* 133, 138.

⁸⁷ K Knickle et al., 'Beyond Winning: Mediation, Conflict Resolution, and Non-Rational Sources of Conflict in the ICU' (2012) 16(3) *Critical Care* 308, 309; citing: W Felstiner et al., 'The Emergence and Transformation of Disputes: Naming, Blaming and Claiming' in J Macfarlane (ed) *Dispute Resolution: Readings and Case Studies*. (2nd edn, Toronto, ON: Emond Montgomery Publications, 2003) 2-3; L DeAngelo, 'Mediation in Health Care Settings: Some Theoretical and Practical Concepts' (2000) 7(2) *Journal of Clinical Psychology in Medical Settings* 133, 138; C Gorton, 'Using Mediation to Resolve Disputes in Health Care' (2005) 31(4) *Physician Executive* 34.

⁸⁸ N Meruelo, 'Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.' (2008) 29 *Journal of Legal Medicine* 285, 293; citing: E Galton, 'Mediation of Medical Negligence Claims' (2000) 28 *Capital University Law Reform* 321.

The facilitative model of mediation can level the playing field,⁸⁹ giving both sides a voice early on in the process and allowing each to address the issues they believe most relevant.⁹⁰ Facilitative mediation can also deal effectively with the apportionment of liability; something Bogdanoski identifies as often being a barrier to the settlement of clinical negligence disputes.⁹¹ Where trust within the relationship has been breached, facilitative mediation can restore that trust by providing information that may otherwise be minimised by a strict focus on the legal merits of the dispute. In contrast, the evaluative model places a greater emphasis on the legal merits of the dispute and the possible financial outcome. Hyman suggests that lawyers—being emphatically familiar with the evaluative approach—may be overly focused on the financial outcome while minimising the potential of mediation to meet the emotional needs of the parties.⁹² In addition, the mediators practicing the evaluative model may focus exclusively on the legal issues while trivialising non-legal issues, including the parties interests and noneconomic needs.⁹³ In this regard, Zonana argues in favour of the facilitative approach; stating the “facilitative approach will give doctors and patients the potential to experience moral growth, greater strength and greater compassion⁹⁴ as

⁸⁹ N Dubler and C Liebman, *Bioethics Mediation: A Guide to Shaping Shared Solutions* (New York: United Hospital Fund of New York, 2004) 11.

⁹⁰ N Meruelo, ‘Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.’ (2008) 29 *Journal of Legal Medicine* 285, 292; citing: R Lowery Gitchell and A Plattner, ‘Mediation: A Viable Alternative to Litigation for Medical Malpractice Cases’ (1999) 2 *DePaul Journal of Health Care Law* 421, 424. Meruelo notes, ‘Mediation enables the parties to deal with the issues they believe to be important, as opposed to giving attorneys cart blanche to argue the legal merits or what they perceive as the most important issues; rather mediation provides the parties with a sense of being heard.’

⁹¹ T Bogdanoski, ‘Medical Negligence Dispute Resolution: A Role for Facilitative Mediation and Principled Negotiation?’ (2009) 20(2) *Australian Dispute Resolution Journal* 77, 83; citing: R Charlton, *Dispute Resolution Guidebook* (Sydney: LBC Information Services, 2000) 171.

⁹² C Hyman et al., ‘Interest-Based Mediation of Medical Malpractice Lawsuits: A Route to Improved Patient Safety?’ (2010) 35(5) *Journal of Health Politics, Policy and Law* 797, 817.

⁹³ E Zonana, ‘Getting Healthier: A Proposal for Improving Medical Malpractice Mediation’ (2001) 5 *American Journal of Mediation* 9, 24-25; citing: E Galton, ‘Mediation of Medical Negligence Claims’ (2000) 28 *Capital University Law Reform* 321, 324.

⁹⁴ *ibid* 28-29.

they give expression to the deeper underlying interests that may be of far greater significance to them than the monetary and liability issues that rise up on the face of their disputes.”⁹⁵ A facilitative approach also enhances the autonomy of the parties and can “make clear and strengthen the agreed-upon principles of healthcare provision.”⁹⁶ Notwithstanding the benefits of the facilitative model, the evaluative model remains the dominate model used in malpractice claims, particularly when the mediation is court-ordered.⁹⁷

Weaknesses of the Mediation Process

A number of observations can be made as to the appropriateness of mediation in the context of healthcare disputes. First, a defendant may be disinclined from engaging in mediation in situations where the cause of the incident—and therefore the liability of the defendant—may be in doubt. Where a physician or healthcare organisation anticipates a judgement by the court in their favour, the defendant is more likely to proceed through the formal adjudication process in an effort to avoid paying costs and compensation.⁹⁸ This is further complicated where the defendants are indemnified against the costs of a potential jury or judge verdict.⁹⁹ Similarly, a barrier to the mediation process can occur when there are objections by the defendant’s insurance provider and a refusal to agree to a compensation offer on technical grounds requiring judicial determination (i.e. whether the standard of care was breached or if causation

⁹⁵ *ibid* 28-29.

⁹⁶ N Dubler and C Liebman, *Bioethics Mediation: A Guide to Shaping Shared Solutions* (New York: United Hospital Fund of New York, 2004) 10.

⁹⁷ E Zonana, ‘Getting Healthier: A Proposal for Improving Medical Malpractice Mediation’ (2001) 5 *American Journal of Mediation* 9, 24-25; citing: L Riskin and N Welsh, ‘Is That All There Is? “The Problem” In Court-Oriented Mediation’ (2008) 15 *George Mason Law Review* 863, 864.

⁹⁸ S Sanbar, ‘Alternative Dispute Resolution’ in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 308. As Sanbar notes, “... any voluntary process requires participation by all parties and their attorneys. However, the parties may believe that a trial by jury will increase their chance of success.”

⁹⁹ N Meruelo, ‘Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.’ (2008) 29 *Journal of Legal Medicine* 285, 305.

can not be adequately established.) However, the increasing insistence by the courts, as well as contractual requirements (such as terms of an employment or insurance contract) to attempt mediation in advance of the parties initiating litigation may decrease this behaviour in the future.¹⁰⁰ Moreover, legislatively mandated mediation has become increasingly popular as a means of encouraging the parties to settle their dispute before litigation becomes necessary. The advantages and disadvantages of mandatory mediation will be critically analysed below.

The second observation exists by default within the mediation process. As Gorton sets out, "Mediation is great for improving relationships but it does not address the problem behaviour of a single individual.... Mediation cannot resolve issues that fall beyond the parties' scope of authority. Because it is confidential and private, mediation is not a good mechanism for resolving issues that will likely set precedent for other uninvolved parties."¹⁰¹ For this reason, it is necessary that in addition healthcare organisations are held accountable for putting in place corrective actions and defining expected standards of practice, all of which falls under the realm of quality and safety improvement. While the information shared within the mediation session is privileged, the facts of the incident are not, and it is those facts which can form the basis of a subsequent quality investigation. Indeed the primary advantage of the mediation process—from a patient safety perspective—is in its ability to (albeit confidentially) allow the issues to be examined, in contrast to the 'deny and defend' mentality inherent in the litigation process.

Referring back to my earlier analysis, I argued that the facilitative model of mediation is preferable to the evaluative model for the promotion of safety and quality

¹⁰⁰ J Dingle, 'Mediation in Clinical Negligence Disputes' in M Powers, N Harris and A Barton (eds), *Clinical Negligence* (4th edn, Haywards Heath: Tottel, 2008) 40. For a discussion of the English Courts encouragement of mediation, see further: J Nolan- Haley, 'Mediation Exceptionality' (2009) 78 *Fordham Law Review* 1247.

¹⁰¹ C Gorton, 'Using Mediation to Resolve Disputes in Health Care' (2005) 31(4) *Physician Executive* 34, 36-37.

improvement. This is largely due to the facilitative nature of the process in allowing the parties to deconstruct their positions and establish creative remedies based on the merits of the claim they believe most relevant. On this point, Zonana makes the observation that, “The evaluative model is mostly concerned with a doctor’s legal ‘duty of care’ to a patient and whether a doctor has negligently breached that duty; however, the evaluative model can miss what a patient may view as a doctor’s other duties, which the law may not recognize....”¹⁰² The evaluative process, alternatively, may limit the nonmonetary benefit to parties such as an explanation, an apology, or compromise—all key features of the facilitate model and essential to organisational learning, quality and safety improvement. Undoubtedly, the same arguments can be said of the litigation process.

The final weakness of the mediation process is the enforceability of mediated agreements. While mutual agreement inherently results in higher rates of compliance, mediation agreements—particularly when the mediation has been court ordered—are increasingly being litigated.¹⁰³ Likewise, where mediation is used by either party as a “fishing expedition” or the confidentiality inherent to mediation has been breached in advance of anticipated litigation, the benefits of mediation cannot be realised.¹⁰⁴ The consequence is that participants and their lawyers place less trust in the mediation process, in particular when the cost savings achieved through mediation are overtaken

¹⁰² E Zonana, ‘Getting Healthier: A Proposal for Improving Medical Malpractice Mediation’ (2001) 5 *American Journal of Mediation* 9, 25-26.

¹⁰³ J Nolan-Haley, ‘Mediation: The “New Arbitration”’ (2012) 17(61) *Harvard Negotiation Law Review* 61, 87; citing: J Coben and P Thompson, ‘Disputing Irony: A Systematic Look at Litigation About Mediation’ (2006) 11 *Harvard Negotiation Law Review* 43. The author makes the observation that as mediation increasingly becomes court mandated, parties have become increasingly likely to challenge the enforceability of mediated agreements.

¹⁰⁴ *ibid* 82; citing: J Macfarlane, ‘Culture Change? A Tale of Two Cities and Mandatory Court-Connected Mediation’ (2002) *Journal of Dispute Resolution* 241, 267; J Coben and P Thompson, ‘Disputing Irony: A Systematic Look at Litigation About Mediation’ (2006) 11 *Harvard Negotiation Law Review* 43.

by litigation costs or where binding arbitration is preferred by the parties in an effort to finalise a resolution.

The aforementioned mediation programs each have defining features. The pre-mediation program endorsed by Hetzler et al., provides an early opportunity to intervene, disclose information, offer unique remedies, and negotiate compensation (if necessary). The program also encourages early investigation and analysis of incidents, as well as provides a mechanism for addressing quality and safety issues—both practices strongly endorsed by the patient safety movement. Likewise, the Massachusetts program offers a mechanism by which to address the plaintiff's claim in a cost and time effective manner. For physician's, the program is particularly enticing because it removes the disincentive of having a settled claim on their public record. The Rush Model is also unique insofar as the use of co-mediators ensures the parties' legal interests are protected. However, as has been examined previously in regards evaluative mediation, the Rush Model focuses primarily on monetary remedies. Where the plaintiff seeks remedies that extend beyond monetary compensation—such as an apology or information from the physician involved in their care—the Rush Model may be less appealing.

At an individual level, mediation can potentially reduce the length of time, cost, and emotional burden of a dispute on the parties. At an organisational level, hospital-based programs can provide a mechanism by which quality of care and safety issues can be identified, and organisational policies can be tailored and implemented to address them. The problem, however, is an immensely practical one: if litigation can result in a higher award of damages, the likelihood of a mediated settlement will be greatly reduced, notwithstanding the benefits. To address this significant barrier, the next section will argue for the legislative implementation of mandatory mediation.

12.3.3 Mandatory Mediation

Despite all of the evidence cited above that suggests mediation meets the multiple therapeutic needs of the patient and family, improves healthcare communication, and can be used to reduce delay in compensation—if litigation can result in a higher award of damages, the plaintiff’s counsel will likely advise against it, owing arguably to their perception of the ethical obligation to advise in their client’s best interests. Using the law to address this is not simple. Certainly the plaintiff’s counsel should always do what is in the best interests of their client, however, my argument is that the plaintiff-patient’s best interests are not solely quantifiable in monetary terms. Notwithstanding, when litigation can deliver a higher award, the reality is that there is very little incentive to accept a lower (mediated) settlement. Therefore, the question is: how can a plaintiff be incentivised to engage in a mediation conference and accept an early offer of compensation, when litigation would result in a larger award of compensation? The answer to this is a pragmatic one—they must be compelled via legislation. Legislating for the adoption of mandatory mediation in combination with compensation caps, is arguably the most effective method of compelling and incentivising both parties to engage in mediation and early settlement, and therefore furthering the patient safety objective of mitigation after the event. Before analysing further the advantages and disadvantages of mandatory mediation, it is important to first distinguish mandatory mediation from mandatory binding arbitration, and explain why my analysis favours mandatory (non-binding) mediation.

Mandatory Arbitration

Both mandatory mediation and binding arbitration have predominantly been introduced as a result of local level initiatives between healthcare organisations and their insurance companies, and incorporated via contractual agreement with the patient. The motive for this has been to reduce the extraordinary and unpredictable awards that result when a claim is litigated. For example, Kaiser Permanente established their mandatory binding arbitration system in 1999 throughout the State of

California. Following the case of *Engalla v Permanente Medical Group*,¹⁰⁵ Kaiser's arbitration system is now managed by the Office of the Independent Administrator—a company completely separate to Kaiser. Accountability for ensuring the process is fair, impartial, and timely is overseen by the Arbitration Oversight Board. For the purposes of this analysis, there are two important factors which allow this mandatory arbitration to be feasible. First, arbitration clauses are a contractual term when the patient becomes a member of the Kaiser Foundation Health Plan. As with most health insurance companies in the United States, membership requires the patient to attend only Kaiser Permanente hospitals or affiliates to receive medical coverage. Second, all medical staff are employed by Kaiser (in contrast to being independent contractors) and are not required to purchase outside insurance, but must contractually agree to the arbitration clause. As all employees are covered by Kaiser's insurance, the organisation is the sole defendant for all claims and retains the exclusive right to pay a claim, notwithstanding any adverse consequences the employee may endure, or their objection to settlement.¹⁰⁶ The characteristics of this program are unique and may not be possible in other jurisdictions. For example, in Canada, healthcare is socialised and therefore does not require insurance; as well, physicians are independently contracted to their health region. This makes the Kaiser initiative arguably difficult to implement on a wider scale both in the United States and abroad.

In an effort to make the arbitration process fair, time efficient and cost effective, Kaiser has attempted to address some of the traditional disadvantages of the arbitration and litigation process. For example, the Office of the Independent Administrator (OIA) ensures the filing fee is less than the cost of the court filing fee. As well, where the

¹⁰⁵ *Engalla v Permanente Medical Group* (1997) 64 Cal. Rpt 843, 938 P.2d 903, 15 Cal 4th 951. The court was critical of Kaiser's excessive delay in holding the arbitration hearings, the appointment of neutral arbitrators, and their lack of independent oversight. See further: A Morrison, 'Can Mandatory Arbitration of Medical Malpractice Claims be Fair? The Kaiser Permanente System' (2015) 70(3) *Dispute Resolution Journal* 35, 36.

¹⁰⁶ A Morrison, 'Can Mandatory Arbitration of Medical Malpractice Claims be Fair? The Kaiser Permanente System' (2015) 70(3) *Dispute Resolution Journal* 35, 39-40.

plaintiff forgoes the option for a three person panel and agrees not to argue procedural unfairness, Kaiser agrees to pay the cost of the filing fee and the fee for the single arbitrator.¹⁰⁷ Furthermore, the OIA require that all decisions be decided within 18 months, and the arbitrator provides written findings of fact and law.¹⁰⁸

In contrast to binding arbitration, retaining the option of litigation is preferable for a number of reasons. First, litigating a dispute allows it to be heard in public, by an anonymous judge or jury of one's peers (depending on the jurisdiction). This, of course, is a founding and central principle within the legal system—something mandatory binding arbitration challenges. Second, opponents of mandatory arbitration argue that as arbitration does not produce precedents, does not allow for appeal, and the hearings are closed to the public: the process reduces transparency and jeopardises the accountability process.¹⁰⁹ Third, while theoretically economical compared to litigation, the discovery process, medical testimony and arbitration fees can all significantly increase the cost of arbitration making it in some instances comparable to litigation. Fourth, owing to the gravity of having to report compensation claims, where there is a genuine dispute about the merits of a claim, litigation may be in the best interests of both parties.¹¹⁰ Lastly, introducing mandatory non-binding mediation, versus mandatory binding arbitration, removes a large barrier for the legislature: the possibility of a constitutional challenge based on one's right to have their dispute heard in public, as well as patient and practitioner group opposition.

In addition to the above criticisms, there are several disadvantages to the arbitration process that, in my opinion, make mandatory mediation (with the option of litigation) a preferable initiative. For example, as noted in the previous section, arbitration does

¹⁰⁷ *ibid* 46-47.

¹⁰⁸ *ibid* 48-52.

¹⁰⁹ *ibid* 42.

¹¹⁰ *ibid* 41.

not look to the parties' future relationship, is susceptible to arbitrator bias, and is primarily concerned with monetary remedies.¹¹¹ Furthermore, binding arbitration is not open to the public and has a limited right of appeal, both of which may leave the parties unsatisfied with the outcome—an issue mediation attempts to remedy.¹¹² If communication and apology are to be thought of as remedies in themselves, arbitration does not provide the circumstances that allow for their inclusion; a criticism also made of the litigation process.

The advantages and disadvantages of the mediation process have been extensively analysed above. However, it is now useful to examine in greater detail the process of mandatory mediation. To do this, the example of the Florida Patient Safety and Presuit Mediation Program will now be analysed.

Mandatory Mediation

In 2008, the University of Florida Health System, which encompasses six university hospitals, introduced the Florida Patient Safety and Presuit Mediation Program (FLPSMP). As with Kaiser's arbitration agreement, University of Florida patients sign an agreement to mediate when being admitted for care. The mediation agreement requires presuit mediation, but allows the patient to retain the right to litigate should the process not be successful. All disclosures made during the mediation process remain strictly confidential and privileged. All costs are paid by the FLPSMP, including the cost of a neutral mediator, investigation and expert witness fees, and counsel costs

¹¹¹ S Sanbar, 'Alternative Dispute Resolution' in S Sanbar, *American College of Legal Medicine* (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 310; D Shieh, 'Unintended Side Effects: Arbitration and the Deterrence of Medical Error' (2014) 89(5) *New York University Law Review* 1806, 1825.

¹¹² A Morrison, 'Can Mandatory Arbitration of Medical Malpractice Claims be Fair? The Kaiser Permanente System' (2015) 70(3) *Dispute Resolution Journal* 35.

for both of the parties.¹¹³ The results of the program are impressive. In the first five years after implementation (2008-2013), Jenkins et al., found that claims were resolved 81% faster than through traditional litigation, legal liability costs for the hospitals were reduced by 90%, and the plaintiffs retained 34% more of the settlement paid per claim. The average length of time per claim was reduced from 27.5 months to 6.2 months.¹¹⁴ Jenkins notes that the program has positively affected patient safety by:

“... giving providers the opportunity to learn from each claim and implement improvements years earlier than would be the case if the claim were resolved through extended litigation. Smaller claims that would not ordinarily be litigated receive the same attention under this program, again promoting early recognition of patient care issues and allowing preventative measures and patient care improvements to be enacted earlier.”¹¹⁵

A common criticism of mandatory mediation is that, as mediation is already available voluntarily under current legal frameworks, it is not necessary to mandate it—either through legislation or organisational policy. Jenkins addresses this criticism by noting that voluntary mediation often occurs following years of costly discovery, as well, defendants may be less inclined to participate for fear it appears a sign of weakness. The FLPSMP is designed to reduce the necessity of extended discovery by offering early disclosure of information, including an extended analysis of medical records and

¹¹³ R Jenkins et al., ‘Mandatory Presuit Mediation: 5-Year Results of a Medical Malpractice Resolution Program’ (2014) 33(4) *Journal of Healthcare Risk Management* 15, 16-17. For an earlier account of the program, see further: R Jenkins et al., *Mandatory Pre-Suit Mediation: Local Malpractice Reform Benefiting Patients and Healthcare Providers* (2010) 30(2) *American Society for Healthcare Risk Management* 27-35.

¹¹⁴ *ibid* 18; citing: T Cohen and A Hughes, *Medical Malpractice Insurance Claims in Seven State, 2000-2004* (Washington: US Department of Justice, 2007).

¹¹⁵ *ibid* 20.

independent quality reviews.¹¹⁶ Because all work-product disclosed in the course of mediation is privileged, the information can not be later used in the course of civil proceedings.

As a direct result of the program's success, in 2012, the State of Vermont legislature introduced the mandatory presuit mediation program on a State-wide basis. In combination with section 24(a), which requires a certificate of merit be filed at the onset of a claim, section 24(c) requires the parties attempt non-binding mediation as a prerequisite before a claim can be litigated. The Act clearly sets out the purpose for requiring mediation at the first instance:

“The purpose of mediation prior to filing a medical malpractice case is to identify and resolve meritorious claims and reduce areas of dispute prior to litigation, which will reduce the litigation costs, reduce the time necessary to resolve claims, provide fair compensation for meritorious claims, and reduce malpractice-related costs throughout the system.”¹¹⁷

Although this passage focuses primarily on mediation's monetary value, it also highlights mediation's therapeutic value in terms of reducing areas of dispute and enabling timely access to fair compensation.

However, the question still remains: when mediation is mandatory but not binding, how can a plaintiff be incentivised to fully engage in the mediation process and accept early compensation offers when litigation would result in a larger award of compensation? As well, how can the defendant be incentivised to engage in a

¹¹⁶ *ibid* 21.

¹¹⁷ Act 171 of 2012, An Act Relating to Health Care Reform Implementation, Vermont (US); R Lunge and A Martin, *Report on Impact of Vermont Malpractice Reform Act 171 of 2012, Section 24e* (State of Vermont Agency of Administration, 29 August 2014.) <<http://www.leg.state.vt.us/reports/2014ExternalReports/302733.pdf>> accessed: 16 April 2016.

mediation conference and offer early compensation when there is a genuine dispute regarding liability, or the consequence of an offer is increased regulatory scrutiny or censure? (i.e. mandatory reporting of settlements to the National Practitioners Data Bank , or equivalent.) To answer these questions, it is necessary to consider three key amendments that would require legislative consideration for mandatory mediation to be most effective: a legislative requirement for the disclosure of material facts, compensation caps, and changes to the way in which mediated settlements are reported to professional regulators.

Early Disclosure of Material Facts

Referring back to chapter 11 of this thesis, which set out in detail the ethical and legal requirements for disclosure of information following an adverse incident, the obligation of disclosure is not limited to only those facts that do not prejudice the defendant. For this reason, a presuit mediation program must include a legislative requirement that all material facts be disclosed to the plaintiff—prior to the commencement of the mediation process—for them to make an informed decision as to resolution. This logic is consistent with all of the mediation programs cited above, but differs from arbitration in which discovery and expert testimony are procedural and adversarial.

In practice, defendants may be concerned about the extent of disclosure required, arguing that it can provide the plaintiff with additional information that can be used against them or that additional information gathered may be subject to quality improvement privilege.¹¹⁸ However, a number of arguments can be made against this: first, while analysis conducted in the course of quality improvement is generally deemed to be privileged, the material facts are not privileged and any information disclosed within a mediation session would equally be subject to (litigation) privilege

¹¹⁸ A Alexander, 'Complaints, Grievances, and Claims Against Physicians: Does Tort Reform Make a Difference?' (2010) 30(1) *Journal of Healthcare Risk Management* 32, 37.

and confidentiality requirements. Second, notwithstanding early disclosure, the defendant would be required to disclose this information during discovery proceedings regardless. Furthermore, if the matter does proceed to litigation, delayed disclosure inevitably will result in increased time and counsel costs. Unlike the traditional ‘deny and defend’ mentality, if the care provided met the standard of care, early disclosure of material facts aids in resolving the claim quickly by providing the plaintiff the information they need to allow them to adequately judge the merits of their case, and receive the information required to move forward with future care.¹¹⁹

Compensation Caps

As examined briefly in chapter 2, compensation caps are often proposed and enacted as a means of reducing litigation, either by way of a statutory limitation on damages or a predetermined maximum award dependent on the injury and level of harm caused.¹²⁰ The advantages and disadvantages of compensation caps will be examined further below. First, however, it is useful to briefly distinguish an award of compensation from an offer of compensation. An award of compensation is characteristic of the adversarial process and is unilaterally decided in the course of arbitration or litigation. Alternatively, an offer of compensation by the defendant to the plaintiff can be seen as an attempt to resolve the dispute and may only be accepted by mutual agreement of the parties. In this regard, Berlinger expresses the opinion that:

“Compensation after medical harm is a form of reparation in at least two senses. Fair compensation, offered as part of a health care system’s formal

¹¹⁹ R Jenkins et al., ‘Mandatory Presuit Mediation: 5-Year Results of a Medical Malpractice Resolution Program’ (2014) 33(4) *Journal of Healthcare Risk Management* 15, 21; D Hetzler et al., ‘Conflict Management in Hospital Systems: Not Just For Leadership’ (2011) 5 *American Journal of Mediation* 65.

¹²⁰ W Sage et al., ‘How Policy Makers can Smooth the Way for Communication-and-Resolution Programs’ (2014) 33(1) *Health Affairs* 11, 12-13; A Alexander, ‘Complaints, Grievances, and Claims Against Physicians: Does Tort Reform Make a Difference?’ (2010) 30(1) *Journal of Healthcare Risk Management* 32-42; M Mello et al., ‘The Medical Liability Climate and Prospects for Reform’ (2014) 312(20) *JAMA* 2146, 2148-2149.

disclosure process rather than through the tort system, symbolizes a willingness to repair the damaged relationship between injured patients and providers. It also represents a willingness to acknowledge and repair the actual damage done to the body and life of an injured patient as the result of a medical mistake.”¹²¹

Berlinger’s comment illustrates the reparatory potential of compensation as distinct from punitive. Central to my analysis throughout this thesis: the ultimate objective of the patient safety movement is to learn, prevent, and mitigate following a preventable patient safety incident. As such, an early compensation offer as a legal remedy provides one possible means by which to mitigate the harm caused. Indeed the argument can be made that monetary damages cannot repair the actual damage done, regardless of whether the amount is capped or not. However, this argument is not unique to healthcare harm. As it may be impossible to return a plaintiff to their original position, monetary compensation is the primary (and possibly only) remedy available through the tort process. Unlike the disclosure of information, early offers of compensation are not judicially or statutory mandated. Nonetheless, they have become increasingly prevalent in the context of clinical disputes due largely to their success in expediting claims and reducing the associated costs of litigation. For example, the United States Veterans Affairs Hospitals have incorporated the offer of “fair compensation” into their disclosure policies, owing to the organisation’s ethos that injured patients deserve both information and compensation.¹²² However, early offers of compensation contain their own caveat: despite patients desire for compensation, increasing the amount offered did not necessary improve the outcome. In this regard, Murtagh et al. have found that, “Full-compensation offers did not decrease the likelihood of seeking legal advice and increased the likelihood that people perceived

¹²¹ N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005) 66-67.

¹²² N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005) 70. See further Chapter 11.6 ‘Communication and Disclosure Programs.’

the disclosure and apology as motivated by providers' desire to avoid litigation."¹²³ Despite these concerns, early and fair compensation offers have gained favour within the patient safety community as a practice that promotes early resolution and mitigation following a preventable incident, particularly in the course of disclosure and mediation. As Leape has argued, "Unless we have a fair compensation scheme—which we should because it's the right thing to do—people will still have an incentive to sue."¹²⁴

The question then becomes, even with a fair compensation scheme that includes an early offer of compensation, can legislated compensation caps incentivise engagement with the mediation process? As well, will a cap on compensation reduce the likelihood that a plaintiff will seek legal advice and interpret the offer as an attempt to avoid litigation, as pointed out above by Murtagh? From an insurance perspective, on behalf of the defendant physician and healthcare organisation, a limit on damages is clearly desirable. As examined above, if the principle argument against the patient engaging in mediation is that their settlement would likely be lower than if they went to trial, it would certainly stand to reason that compensation caps would make mediation a more attractive option.

But for the patient, compensation caps may be disadvantageous because they may not adequately reflect the long term compensation that may be required. Although compensation caps are intended to represent a more accurate reflection of the compensation necessary, patient injuries and healthcare harm are inherently subjective and a compensation cap—while appropriate for some—may be entirely inadequate for others. This can be a particularly contentious issue in jurisdictions which do not have single-tiered healthcare; compensation takes on added importance because damages

¹²³ L Murtagh et al., 'Disclosure-And-Resolution Programs That Include Generous Compensation Offers May Prompt a Complex Patient Response' (2012) 31(12) Health Affairs 2681.

¹²⁴ As taken from: N Berlinger, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005) 61. Original citation not given.

may be required to cover future medical expenses. Although the cap would equally apply to a litigated award, this can be another significant hurdle to a mediated settlement because the costs of future care requirements can be a *de facto* ground for the plaintiff and defendant to contest. In other words, while compensation caps can provide guidance for early compensation offers, a legitimate criticism is that they do not accurately reflect the needs of the individual patient.¹²⁵ Notwithstanding this concern, where compensation caps are legislatively mandated, ADR may be more advantageous to the plaintiff insofar as a jury award would equally be impacted. For example, since 1978, California has capped damages for pain and suffering to \$250,000. Because arbitrators are aware of this cap, they are more likely to award higher damages for other elements of the claim in an effort to offset the cap. In contrast, juries are not informed of the cap and therefore, the damages awarded by a jury will later be reduced by the court with no ability to offset. In this respect, knowledge of the cap may also be a selling feature for defendants in mandatory mediation settlements because the ability to offset is not available in litigation proceedings.¹²⁶

In light of the arguments for and against compensation caps, the question arises: is it better to incentivise mandatory mediation settlements through the use of compensation caps, or mandate mediation without caps, and therefore leave the option of litigating for a high settlement? Again, compensation caps in this regard are primarily beneficial to the defendant because they encourage acceptance of mediated offers. Mediation, however, is beneficial to both parties (as explained in significant depth above). Specifically, mediation can significantly reduce the cost and time of a claim, provide opportunities to learn from the incident, and engage the patient in a far more therapeutic manner than litigation. Certainly these are benefits to the plaintiff as well, but their counsel would likely prioritise a higher award of compensation. While

¹²⁵ W Sage et al., 'How Policy Makers can Smooth the Way for Communication-and-Resolution Programs' (2014) 33(1) Health Affairs 11, 12.

¹²⁶ A Morrison, 'Can Mandatory Arbitration of Medical Malpractice Claims be Fair? The Kaiser Permanente System' (2015) 70(3) Dispute Resolution Journal 35, 56.

the interests of individual plaintiffs must be a priority, particularly in the context of enacting legislation consistent with healthcare's goal of patient and family-centred care, the common good must also be a priority. Mediation reduces healthcare spending and time, both of which can be streamed back into the system. It also provides a level of transparency and patient engagement not present throughout the litigation process.

For this reason, mandatory mediation inclusive of compensation caps with the option of litigating is, in my opinion, preferable. Some injuries merit the censure and liability that the litigation process delivers. This is why, in New Zealand for example, patients have the option of filing for punitive damages.¹²⁷ Although compensation caps would also apply to any litigated settlement, depending on the offer made by the defendant or where the plaintiff seeks the publicity of trial, litigation may be in their interests. For the vast majority, however, mediation should be encouraged at the first instance and this is only achievable by legislatively mandating it.

Limiting Reporting on Mediated Settlements

Lastly, legislation can also incentivise defendant physicians into settling a claim by exempting mediated settlements from regulatory scrutiny to, for example in the United States, the National Practitioners Data Bank. To date, mediated settlements must still be reported to the NPDB. The decision for this was recently restated by the US Department of Health and Human Services, whose primary concern was that by avoiding reporting requirements, patients would not be protected from negligent physicians.¹²⁸ While there is a legitimate argument for keeping track of the claims against physicians, when the NPDB records impact licensure and credentialing (and therefore a physician's livelihood), the chances of a physician agreeing to a quick resolution when the case is anything but clear-cut are greatly reduced. This is

¹²⁷ See further: Chapter 4.4.3 'Necessity of Civil Litigation in the Accountability Process.'

¹²⁸ K Sebelius, *Memorandum Decisions* (22 May 2014) < <http://www.citizen.org/documents/2211%20Enclosure.pdf> > accessed: 14 April 2016.

particularly problematic when the cause of an incident (as set out at length throughout previous chapters) is likely the result of a multitude of systemic and human factors. If mediation is to be effective for all of the reasons cited above, then modifications must be made. In response, Sage has insightfully suggested that settlement offers continue to be mandatorily reported, but remain confidential from regulatory scrutiny until a pattern emerges (for example, more than three negligence claims.) This would address patterns of negligence, while also being an effective tool for incentivising defendants to embrace the mediation process.¹²⁹ Additionally, Sage has suggested that having physicians employed by the organisation may reduce the fear connected to reporting requirements, as could having claims settled by the organisation.¹³⁰

Accountability

A concern that often arises with respects to mandatory arbitration and mediation is whether the defendant will still be held accountable despite the liability process being confidential, or in the case of Kaiser, the sole defendant being the healthcare organisation. This concern is also often raised in relation to New Zealand's no-fault compensation system. In practice, accountability is intrinsic to both the quality improvement process and the legal process. Healthcare organisations are ethically and legally required to ensure the clinicians working within the organisation are licensed and fit to practice. Where an incident has occurred and a question arises as to whether the clinician is fit to practice, the organisation's risk management department is responsible for ensuring the safety of their patients and evaluation of risk; based on the circumstances, this may likely mean that they are required to conduct a disciplinary investigation and report the clinician to the appropriate licensing body if necessary. Furthermore, in some jurisdictions, the legal obligation flows from the settlement itself; such as in California, who requires claims of over \$30,000 USD be reported to the

¹²⁹ W Sage et al., 'How Policy Makers can Smooth the Way for Communication-and-Resolution Programs' (2014) 33(1) Health Affairs 11, 16.

¹³⁰ *ibid* 15-16.

appropriate licensing body.¹³¹ Although a settlement may resolve the legal aspects of a claim, that does not exempt it from disciplinary and quality improvement scrutiny. While patient safety and quality work product may be privileged—and indeed a firewall should exist between quality and safety improvement processes and risk management—that does not negate the requirements on risk management to report clinicians they suspect are not fit to practice. Similarly, if a claim has been settled by alternative dispute resolution or litigation, it does not in any way bypass the accountability mechanisms put in place to insure safe quality healthcare is being provided by the clinicians or healthcare organisation (i.e. disciplinary proceedings, legislation, or a review of accreditation credentials.)

In conclusion, for mediation to be effective in a litigious culture, healthcare professionals and patients must at the very minimum be compelled to attempt it. Certainly one could argue that where the option of litigation remains, any attempts to mediate will be futile where litigation can result in a higher settlement. In practice, it is understandable to conclude that compensation is the only appropriate remedy for the plaintiff, since one cannot be returned to their original position. However, this position fails to take account of the additional benefits mediation can provide such information sharing and patient engagement, apology, and timely dispute resolution—all of which should not be thought of as distinct and ancillary, but rather remedies in their own right that deserve equal consideration.

The examples of hospital-based mediation programs listed above are evidence that when available, even voluntarily, both plaintiffs and defendants are willing to engage in mediation, often leading to a successful resolution. Again, for a variety of reasons, litigation may be preferable and as argued above, that should remain an option. However, requiring the parties attempt to mediate healthcare disputes at the first

¹³¹ A Morrison, 'Can Mandatory Arbitration of Medical Malpractice Claims be Fair? The Kaiser Permanente System' (2015) 70(3) *Dispute Resolution Journal* 35, 58; citing: California Business & Professions Code, ss 801.1.

instance must be a legislative priority, as the benefit lies in the majority of cases that would be quickly resolved by providing necessary information, perhaps an apology, or simply a fair and equitable offer of compensation. Including in the legislation a requirement for early disclosure of all material facts, compensation caps, and amendments to reporting requirements can all greatly increase the ultimate success of mandated mediation programs.

12.4 Conclusion

This chapter has analysed the mediation process in the context of healthcare disputes; arguing that mediation is the most suitable mechanism by which to address conflict and further the objectives of the patient safety movement and reduce barriers in communication. In the first section, the primary forms of alternative dispute resolution used within healthcare were identified and critically compared. This was necessary for the purpose of establishing alternatives to healthcare litigation and to provide a foundation by which to contrast the latter half of this chapter in which the argument was put forth that mediation is ideally suited to resolve healthcare disputes. The second section examined the mediation process in greater detail; beginning first by contrasting the facilitative and evaluative processes. This was followed by an analysis of the strengths and weaknesses of healthcare mediation. The last section addressed the primary barrier to mediation's wide spread use: the voluntary nature of the process and the prioritization of compensation. Specifically, this section argued for the legislative requirement for mediation at the first instance of a dispute, a legislative requirement for the early disclosure of material facts, the use of compensation caps, and changes to regulatory disclosure policies were also examined as a means of increasing the use and successful operation of mandated mediation programs.

In terms of clinical dispute resolution, mediation offers the parties a confidential and collaborative means by which to mitigate the consequences of harm. It could be argued that arbitration is equally advantageous in respect of being time and cost efficient, as

well as in its potential to reduce litigation. However, mediation is unique in that it also provides the parties the opportunity to collaboratively approach monetary and non-monetary remedies, as well as increased compliance, and being therapeutically beneficial.¹³²

Availing of mediation's full potential will at a minimum require cultural change amongst patients, healthcare professionals, and the organisation as a whole.¹³³ As argued above, promoting this type of collaboration will not be easy, particularly when it remains voluntary. For this reason, implementing legislation that both compels and incentivises is fundamental.

While legislating for mandatory mediation will certainly begin the process of cultural change, it is likely not enough. As noted in chapter 11, despite the legal requirements for disclosure, there remains hesitation on the part of the medical community. For this reason, healthcare organisations and governments must also implement programs that educate on the benefits of improving communication, both before the incident and at the resolution stage. In furthering this objective, hospital-based conflict management training can provide a means by which to normalise the objectives of ADR in routine clinical care. For example, in England, the program offered at the Evelina Children's Hospital¹³⁴ offers both voluntary mediation to participants at the first instance of conflict, but also offers combined communication training and conflict management training to all staff members in an effort to preemptively recognise and remedy the

¹³² J Nolan-Haley, 'Mediation: The "New Arbitration"' (2012) 17(61) *Harvard Negotiation Law Review* 61, 69-70.

¹³³ C Hyman, 'Mediation and Malpractice: Why Plaintiffs, Hospitals and Physicians Should be at the Table' (2011) 66(3) *Dispute Resolution Journal* 33.

¹³⁴ The program was previously examined in relation to Communication programs. See further: Chapter 10.5 'Communication Programs' at page 281-282.

triggers of conflict.¹³⁵ From a patient safety perspective, conflict management training is an extremely useful technique in improving communication, reducing the circumstances that lead to error and prompt litigation, as well as promoting cultural change. Future research should focus closely on the benefits of hospital-based communication and conflict management training for healthcare professionals, in addition to the benefits of mandatory mediation.

¹³⁵ L Tickle, 'Why Mediation Training Should be Offered in Hospitals' *The Guardian Professional* (London: 10 December 2013) <<<http://www.theguardian.com/healthcare-network/2013/dec/10/mediation-training-offered-hospitals>>; Medical Mediation Foundation, 'Evelina Resolution Project' <<http://www.medicalmediation.org.uk/evelina-resolution-project/>> accessed: 19 December 2014.

- Chapter 13 -

Conclusion

13.1 Summary of the Chapters

This thesis is based on the research question '*An assessment of strategies which, operating in tandem with medical malpractice actions, will improve patient safety (and based on comparative analysis of how these strategies have worked in different jurisdictions)*' and has sought to examine two intrinsically connected themes: an assessment of strategies for reducing medical error based on patient safety methodology, and second, the role of medical malpractice law and litigation in the reduction and mitigation of medical error. Additionally, my analysis sought to demonstrate that the adoption of strategies that improve healthcare communication by way of legislative and organisational reform are the most effective mechanism by which to reduce medical error because they are uniquely capable of bridging the dichotomy between the collaborative ideals of the patient safety movement and the inherently adversarial nature of the legal system. Before concluding, it is useful to revisit the contents of this thesis.

Chapter 2: 'The Role of Medical Malpractice Law and Litigation in the Reduction of Medical Error'

Chapter 2 provided the comparative basis for the legal component of this thesis, specifically the role of medical malpractice law and litigation in the reduction of medical error, which was later contrasted throughout the chapters with quality improvement strategies originating from the patient safety movement. Furthermore, it sought to examine the dichotomy between the legal system's and medical system's approach to quality and safety improvement. The first section of this chapter briefly outlined the requirements for an action in negligence, and examined the policy objectives of medical negligence law. The second section analysed the advantages and disadvantages of medical malpractice litigation as it relates to patients, healthcare professionals, and healthcare culture. In particular, it examined the diverse reasons

patients initiate a medical malpractice claim and the adverse consequences of such a decision for patients, healthcare professionals, and healthcare culture in general. The third section of this chapter considered in further detail the role of malpractice litigation and addressed the question of what role the law currently has, and ideally should have, in the reduction of medical error. The use of compensation caps, the doctrine of informed consent, vicarious liability, and role of privileged communications were all examined. Lastly, the fourth section examined the role of the criminal law in the case of medical error.

Chapter 3: 'The Origins of the Patient Safety Movement'

This chapter examined the seminal publications that influenced the development of the Patient Safety Movement within the United States, England, Canada, Ireland, and the World Health Organization; and provided the foundation for the remainder of this thesis in which the key elements of the patient safety movement were extensively analysed for their ability to improve patient safety, both in their own right and working in tandem with medical malpractice actions.

Chapter 4: 'Healthcare Culture and Accountability'

Chapter 4 analysed the role of healthcare culture and accountability in the prevention of medical error. The patient safety movement sought to dispel the role of blame, instead moving towards a culture that recognises human error as inevitable and concentrates on prevention, accountability, transparency, learning, and mitigation. The first and second sections of this chapter examined the role of blame within healthcare organisations, contrasting it with a 'just culture.' The third section examined in greater depth the role of, and requirements for, accountability in a just culture. Beginning first with an analysis of the contribution of clinical governance, risk management, and audit in the promotion and maintenance of safe accountable care. Second, the equally fundamental contribution of organisational and professional regulation was examined. Lastly, New Zealand's unique no-fault compensation system was analysed as a means

of examining whether monetary liability and blame are inescapable prerequisites for ensuring accountability.

Chapter 5: 'Human Factors vs The System'

This chapter critically compared the role of human factors and system factors in the causation of patient safety incidents. Implementing a systems-centred approach is fundamental to the development of a just culture, and begins with the presumption that error is inevitable and as such, the goal is to engineer an error-tolerant system. In contrast, the person-centred approach focuses on the role of human factors and the way in which individuals interact within their working environment.¹ This chapter begun by examining the role of human factors and systems theory. In the second section, the significant contribution of Reason's "Swiss Cheese" Model (SCM) was analysed to demonstrate the causal relationship between human factors and system-design, in addition to criticisms of the SCM model, and the adapted Healthcare Error Proliferation model.

Chapter 6: 'The Nature of Medical Error'

Building on the role of human and system factors that operate at the blunt end and active end of the healthcare spectrum; chapter 6 extended that analysis by examining in detail the role that human and system failure have in the causation of medical error. The first section identified the many diverse causes of active failure that occur at the sharp end. In an effort to contextualise latent and active failure, the second section examined the role of work environment, individual, social, and organisational factors that contribute to the causation of medical error. This chapter was essential to understanding the multifactorial nature of error, and the necessity to ensure accountability is appropriately directed, and interventions strategies effectively designed and implemented.

¹ P Fortune et al. (eds), *Human Factors in the Healthcare Setting: A Pocket Guide for Clinical Instructors* (UK: Wiley-Blackwell, 2013) 6.

Chapter 7: 'Safety Interventions: Preventing Patient Safety Incidents and Medical Error'

Having examined the role of culture, system redesign, incident reporting, and the multifactorial nature of medical error; chapter 7 built on that analysis by considering specific intervention strategies for the purpose of medical error reduction, and ultimately, safety and quality improvement. In the first section, interventions at the level of the patient, caregiver, workplace and system-level were analysed for the purpose of illustrating the various levels in which intervention strategies can be applied. For this purpose, the first section also examined specific examples of workplace and system interventions strategies that can be implemented so as to improve quality and safety. By way of example, the second section examined the prevention of adverse drug events. This section was particularly useful in understanding how a specific patient safety incident can be targeted within the organisation, at both the blunt and sharp end, and be prevented.

Chapter 8: 'Case Study: Resident Duty Hours'

Chapter 8 critically explored the challenges of cultural change by way of a case study contrasting the regulation of resident duty hours in the United States, Canada, and the European Union. This chapter begun with an examination of how the tragic 1984 death of Libby Zion in New York State resulted in State legislation and brought to a national and international stage the consequences of resident fatigue. The challenges of implementing the 2003 and 2011 Accreditation Council for Graduate Medical Education *Common Duty Hour Standards*, which limited the number of hours residents within the United States could be continuously scheduled for duty, were also examined.² In the second section, the use of collective bargaining agreements in Canada as a means of reducing resident duty hours was critically considered. In particular, the arbitration case of *McGill University Health Centre v Association des*

² I Philibert et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME, 2011).

Résidents de McGill.³ This case set precedent within the province of Québec by acknowledging the dangers of excessive duty hours for both residents and patients. The third section considered legislative and judicial developments within Europe. Specifically, the European Working Time Directive and the 2015 Irish case of *European Commission v Ireland*⁴ which excluded ‘training hours’ from the definition of working time set out within the Directive. The final section considered the impact of the resident duty hour restrictions and the practical challenges of implementing cultural change within an organisation. This chapter was relevant in the context of safety and quality improvement because it clearly illustrates the extraordinary challenges of cultural change and safety intervention when legislative intervention is absent, and governments and regulatory organisations are reluctant to reform the status quo and acknowledge systemic error.

Chapter 9: ‘Incident Reporting and Analysis’

This chapter critically analysed the role of incident reporting and incident analysis in the response to, and prevention of, medical error; as well as illustrated the necessity and challenges of data collection, analysis and trending. Specifically, the first section considered the role and purpose of incident reporting in healthcare, mandatory and voluntary reporting systems, and the necessity of confidentiality. By way of example, incident reporting systems from the United States, England, and Canada were analysed. The second section argued that for incident reporting to be effective, detailed analysis of incident reports and feedback to those reporting is fundamental. In examining incident analysis and feedback, the example of root-cause analysis was used to demonstrate the practical mechanisms for identifying the causation of patient safety incidents and specifically, the latent and active failures that contribute to their occurrence. Lastly, the third section identified and critically explored the primary

³ *McGill University Health Centre v Association des Résidents de McGill* (Arbitration Board, Québec, Canada. 07 June 2011. Grievance No. 4-CUSM-0809-01) [1].

⁴ Case C-87/14 *European Commission v Ireland* [2015] ECLI:EU:C:2015:449.

barriers to incident reporting, including: organisational culture, time pressures, the administrative burden of reporting, and lack of adequate response and feedback from the organisation. This chapter sought to provide the foundation for understanding how intervention strategies are identified and developed following a patient safety incident.

Chapter 10: 'Communication: Bridging the Patient-Physician Relationship'

Chapter 10 began by examining the challenges of communication in the wake of medical error. The second section considered the psychological consequences of medical error and the impact of such on patients and physicians, particularly as it relates to communication between the parties. The third section considered the benefits and barriers to constructive communication. Lastly, the fourth and fifth sections examined the use of in-hospital communication programs and internal dispute mechanisms designed to enable physician-patient communication. The chapter sought to examine the role and benefits of healthcare communication in reducing medical error and the need to initiate a medical malpractice claim. In this respect, it considered both the response to medical error, and strategies for improving patient safety.

Chapter 11: 'Communication: Disclosure and Apology'

In chapter 11, the argument was put forth that incident disclosure and apologies promote the early resolution of disputes, improve physician-patient communication and enhance patient-centred care. This chapter began by analysing the legal and ethical duty placed on physicians and healthcare organisations in the United States, Canada, and England to disclose serious incidents, including medical error. Second, the legal and psychological barriers preventing the effective disclosure of medical error were examined. In the third section, best practices for the effective disclosure of patient safety incidents were considered from the perspective of improving patient-physician communication, and ultimately: improving safety and quality. The fourth section of this chapter critically analysed apology legislation in the United States, Canada, and

England. The last section then concluded with specific examples of disclosure and communication programs that have had a demonstrable benefit in educating and enabling physicians to provide effective disclosure of patient safety incidents and medical error to patients. This chapter sought to address one of the main barriers to healthcare communication: elusiveness surrounding disclosure policies, procedures, and laws.

Chapter 12: 'Alternative Dispute Resolution in Healthcare'

Lastly, chapter 12 analysed the mediation process in the context of clinical disputes; arguing that mediation is the most suitable mechanism by which to address conflict, further the objectives of the patient safety movement, and reduce barriers in communication. In the first section, the primary forms of alternative dispute resolution used within healthcare were identified and compared. The second section examined the mediation process in greater detail; beginning first by contrasting the facilitative and evaluative processes. This was followed by an evaluation of the strengths and weaknesses of the mediation process. The last section addressed the primary barrier to mediation's wide spread use: the voluntary nature of the process and the prioritisation of compensation. Specifically, this section argued for a legislative requirement for mediation at the first instance of a litigable healthcare dispute, and sought to answer two questions: how can a plaintiff be incentivised to engage in a mediation conference and accept early compensation offers when litigation would result in a larger award of compensation? Second, how can the defendant be incentivised to engage in a mediation conference and offer early compensation when there is a genuine dispute regarding liability, or the consequence of an offer is increased regulatory scrutiny or censure? In answering this, a legislative requirement for the early disclosure of material facts, the use of compensation caps, and changes to regulatory disclosure policies were also examined as a means of increasing the use and successful operation of mandated mediation programs.

13.2 Dissonance Between Patient Safety and Medical Malpractice Litigation

The World Health Organization have instructed that the safety of patients can be enhanced by way of three complementary actions: the prevention of adverse events, acknowledging and understanding their occurrence, and mitigating their effects.⁵ This thesis has sought to extensively expand on these three actions by first, consolidating and critically analysing the growing body of patient safety literature so as to provide a foundation for safety and quality practices within healthcare. In this respect, it has examined methods for preventing, learning from, and understanding the complex factors that result in patient harm. Second, it has contrasted patient safety methodology with the traditional litigious approach to causation which was based on the philosophies of deterrence, retribution, and individual responsibility. Third, it has demonstrated that the adoption of strategies that improve healthcare communication by way of legislative and organisational reform are the most effective mechanism by which to reduce medical error because they are uniquely capable of bridging the dichotomy between the collaborative ideals of the patient safety movement and the inherently adversarial nature of the legal system.

In deconstructing how patient safety methodology can be combined with statutory intervention to improve safety and reduce medical error, it is necessary to again distinguish between the preventative approach (patient safety), and the deterrent approach (civil/criminal liability) traditionally taken to healthcare harm. A useful illustration of this can be seen in common patient safety rhetoric that echoes traditional legal ideology. For some advocates of the patient safety movement, the maxim 'chasing zero' or 'zero harm' has been used to denote patient safety efforts towards learning, prevention, and deterrence.⁶ While campaigns to promote patient safety principles to a

⁵ World Health Organization (Report by the Secretariat), *Quality of Care: Patient Safety* (23 March 2002) A55/13. [12].

⁶ For example: *Discovery Channel, Chasing Zero: Winning the War on Healthcare Harm* (USA: Discovery Channel, 2010) <<http://www.safetyleaders.org/pages/chasingZeroDocumentary.jsp>> accessed: 13 March 2015.

wider audience—particularly to patients—are undeniably beneficial, implying that zero errors is an achievable goal contradicts the premise on which the patient safety movement is based: that error is inevitable because ‘To Err is Human.’ This argument has similarly been put forth by Berwick, who notes,

“While ‘Zero Harm’ is a bold and worthy aspiration, the scientifically correct goal is ‘continual reduction’. All in the NHS should understand that safety is a continually emerging property, and that the battle for safety is never ‘won’; rather, it is always in progress.”⁷

The recognition of the inevitability of error in human performance is central to the distinction between the preventative and deterrent approaches to safety and quality improvement.

The impact of the perceived threat of malpractice litigation to deter behaviour and its role in providing compensation have been examined numerous times throughout this thesis. Owing to their significance, it is useful now to synthesise the various arguments. In regards the first, the deterrence function of tort law seeks to deter negligent and reckless behaviour through the legislative and judicial regulation of skill and quality—essentially holding healthcare professionals accountable to the requisite standard of care and penalising them when they fall below it.⁸ This imposition of direct and vicarious liability presumes that behaviour can be altered or deterred by virtue of the potential legal consequences, and seeks to ensure individuals and organisations meet predetermined standards of safety and practice. The problem with this, however, is that seeking to deter behaviour implies a level of intention or indifference, and

⁷ D Berwick, *A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England* (London: Department of Health, 2013) 14.

⁸ T James, ‘Fault and Blame in the NHS: Review and Replacement of the Clinical Negligence System in the UK’ in J Tingle et al. (eds), *Regulating Healthcare Quality: Legal and Professional Issues* (Edinburgh; New York: Butterworth-Heinemann, 2004) 55.

control over one's circumstances. If the threat of liability were an effective deterrent, one would then expect to see a very low rate of medical malpractice claims because very few incidents involving harm would occur, but this is not the case. For example, in a study by Seabury et al., the authors found that on average, physicians practicing within the United States spend nearly 11% of an assumed forty year career engaged in unresolved malpractice claims.⁹ Whether the physicians practiced negligently or not in the litigated claims against them, this study would suggest that the prospect of liability and litigation is not solving the underlying problem, namely that harmful incidents continue to occur.

In contrast, the patient safety approach to behaviour which presumes that 'To Err is Human' and therefore concentrates on implementing system barriers and procedural modification to prevent error that could ultimately—under the law of negligence—result in a finding of liability. In this regard, accountability falls to both the blunt and sharp end to ensure that training and system barriers prevent future incidents. As Donaldson and Raik contend, "Where errors occur, individuals must be held responsible for their actions. Nonetheless, accountability is not the same as making systems safer. Redesigning care processes reduces errors more effectively than blaming individuals."¹⁰ This comment concisely sums up the distinction between the deterrent approach and the preventative: that holding individuals liable, and misplacing accountability, will not correct the systemic factors that contribute to the causation of an incident and therefore, will not prevent reoccurrence. A similar argument can be made with respects to tort reform and malpractice litigation, as Greenberg et al. have noted, "Arguments about the merits of statutory tort intervention will surely continue in the future, but to the extent that improved safety performance can be shown to have a demonstrable impact on malpractice claims, that offers another focal point for

⁹ S Seabury et al., 'On Average, Physicians Spend Nearly 11 Percent Of Their 40-Year Careers With An Open, Unresolved Malpractice Claim' (2013) 32(1) *Health Affairs* 32.

¹⁰ M Donaldson and B Raik, 'Preventing Errors' in E Siegler, S Mirafzali and J Foust (eds), *An Introduction to Hospitals and Inpatient Care* (NY: Springer, 2003) 297.

policymakers in seeking to address the malpractice crisis.”¹¹ This again emphasises the need to correct underlying systemic defects rather than remedy and mitigate the consequences.

It is important, however, to reiterate that although the patient safety movement and human factors theory recognises the inevitability of error, this is not to suggest that individuals or healthcare organisations should not be held accountable. Referring back to the principle of reciprocal accountability inherent in a just culture, reciprocal accountability is a departure from the traditional mechanisms of accountability and requires that healthcare organisations are equally accountable for ensuring safe, quality care.¹² For example, in England, legislation has been influential in ensuring this by placing a statutory duty on healthcare organisations to have in place effective governance structures, including the ability to assess, monitor and drive improvement, conduct audit processes, seek feedback, and mitigate risk.¹³ The need for statutory intervention at the blunt end has also been recognised in jurisdictions such as Ireland who in 2008 advocated for the introduction of a legal duty on the part of the Board of Management and Chief Executives to “put and keep in place arrangements for the purpose of monitoring and improving the safety and quality of healthcare.”¹⁴ Following the publication of *To Err is Human*, there was an express recognition that human error is inevitable and blame is counter-productive. While progressive and

¹¹ M Greenberg et al., RAND Institute for Civil Justice, *Is Better Patient Safety Associated with Less Malpractice Activity? Evidence from California* (CA: RAND Corporation, 2010) 19.

¹² J Morath and J Turnbull, *To Do No Harm: Ensuring Patient Safety in Health Care Organizations* (San Francisco: Jossey-Bass, 2005) 158; A Halligan, ‘Clinical Governance’ in M Powers, N Harris and A Barton (eds), *Clinical Negligence* (4th edn, Haywards Heath: Tottel, 2008) 38.

¹³ Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, Regulation 17.

¹⁴ Department of Health (Ireland), *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance* (Dublin: Department of Health, 2008) 98. “As part of the licensing framework, a clear legal duty should be imposed on the Board of Management of each facility or group of facilities to put and keep in place arrangements for the purpose of monitoring and improving the safety and quality of healthcare. A similar statutory duty should be placed on the Chief Executive and Board of the HSE to ensure that all the Boards under its remit are complying with these requirements.”

insightful, implementing practices that sought to remove blame also proved untenable because they failed to recognise that blame and accountability are arguably a theoretical distinction, and accountability is fundamental for enforcing safe practices and standards.

In this regard, chapter 4 set out in depth the avenues of accountability that are necessary for ensuring safe quality care, and work in tandem with medical malpractice actions. For the purposes of this conclusion, it is useful to summarise. First and foremost, where the organisation is aware of the incident, they have a legal and ethical obligation to their patients to investigate, learn from, and (when appropriate) put in place mechanisms to prevent reoccurrence. This is primarily ensured by way of mandatory or voluntary accreditation or licensing requirements specific to the jurisdiction, as well as civil and criminal legislation and jurisprudence. In this respect, the accountability process is both proactive and retrospective.

Second, organisations have an obligation to ensure the healthcare professionals they employ or independently contract are practicing at a standard consistent with the standard of care. This is intrinsically connected with the obligations of professional bodies, and can be enforced by way of a statutory, tortious, or contractual duty. Similarly, healthcare professionals have an obligation to ensure they are following best practices and in the event of a serious incident, that they report it to the appropriate body. This obligation was extensively examined throughout chapter 2 and 9. While this does not discount the very real and pragmatic barriers that prevent reporting, reciprocal accountability in a just culture includes the obligation to contribute to systemic improvement.

Lastly, referring back to chapter 11 regarding disclosure, healthcare organisations and healthcare professionals have a legal and ethical obligation to their patients following harm. In some instances this may include the offer of compensation or an apology, at a

minimum it requires that the patient be informed of the relevant facts surrounding their care, and efforts be made to mitigate the situation (i.e. through the use of collaborative mediation as opposed to a 'deny and defend' mentality.)

The aforementioned approaches to accountability, however, illustrate the dichotomy between the preventative (patient safety) approach and the deterrent (litigious) approach. Where patient safety theory advocates accountability through a commitment to proactive and retrospective improvement, the legal process requires that individuals be held personally liable for the care they provide—as distinct to the organisation's failure to correct systemic factors that contributed to it. This is true even when the organisation is held vicariously liable because a malpractice claim still requires a respondent be named who allegedly committed the tort. Even where the organisation has themselves been negligent of underlying systemic flaws, it can be extremely challenging for a plaintiff to succeed in a claim against the organisation. For example, speaking specifically about England and the NHS, Jones and Cook have argued that:

“It would be difficult for a judge to condemn as negligent a practice widely adopted in the NHS, even if this is recognized as increasing the risk of harm to patients, because to address it would require major financial and political investment. Under these circumstances judges find it easier to conclude that the individual practitioner at the end of the chain of responsibility was negligent, and then hold the organization vicariously liable for that individual's negligent mistake.”¹⁵

In this respect, the negligent practice referred to by the authors—under patient safety theory—would itself be a latent factor possibly resulting from, for example, the use of heuristics or the normalisation of deviance. Without the requisite financial and political

¹⁵ M Jones and G Cook, 'Patient Safety and the Law' in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 36.

investment the authors refer to, primarily by way of system redesign, the practice may continue, notwithstanding a judgment against the individual defendants. However, this is not to entirely dismiss the deterrence principle of tort law with respect to a particular practice or behaviour. Arguably, without the potential for civil liability, particularly in monetary terms, organisations may be less incentivised to mitigate the consequences of harm and reform ingrained practices, especially where reform requires financial and political investment. As examined in chapters 2 and 4, both vicarious liability, regulatory requirements, and the above cited statutory duties on organisations can play a key role in holding organisations accountable and addressing blatant organisational disregard for safety. Although criminal sanctions have not been addressed to any great degree within this thesis, it is worth noting again that the National Advisory Group on the Safety of Patients in England (lead by Prof. Donald Berwick) strongly advocated for the criminal offense of ill-treatment or wilful neglect of patients and service users, later enacted in section 20-25 of the Criminal Justice and Courts Act 2015:¹⁶

“We believe that legal sanctions in the very rare cases where individuals or organisations are unequivocally guilty of wilful or reckless neglect or mistreatment of patients would provide deterrence whilst not impeding a vital open, transparent learning culture.... Ultimately, by far the greatest benefit to patient safety will be achieved by increasing the skills and the knowledge of the many rather than penalising the very few. We do not support the punishment of organisational leaders, Boards and chief executives, or others for poor performance that occurs for reasons beyond their control. We do recommend penalties for leaders who have acted wilfully, recklessly, or with a “couldn’t care less” attitude and whose

¹⁶ Criminal Justice and Courts Act 2015, sections 20-25.

behaviour causes avoidable death or serious harm, or who deliberately withhold information or provide misleading information.”¹⁷

Despite the negative consequences that the threat of criminal and civil liability may present within healthcare, they each have a legitimate role to play in reducing medical error and improving quality and safety. It is worth reiterating the premise on which this thesis is based: that all efforts must be put towards prevention, but where harm has occurred, all efforts must then be made to mitigate the consequences and learn from it. In this respect, compensation, mitigation, and deterrence are not mutually exclusive. Indeed, without the threat of liability for negligence and large compensation awards, the argument could certainly be made that healthcare professionals and organisations may be more prone to paternalistic or ‘risky’ behaviour and less likely to address it. However, this argument is somewhat negated by virtue of the fact that the requirement for healthcare professionals and organisations to have liability insurance may undermine the deterrent function of the law.¹⁸ The larger issue is the consequence of relying on deterrence mechanisms such as fear to achieve safety improvement. As set out extensively in chapter 2 and chapter 4, this reliance creates a culture of fear and destroys the psychologically safe environment necessary for individuals to come forward and report known problems—in a sense, to be accountable for them. This is perhaps the clearest example of the difference between accountability and blame: accountability can be both a proactive and retrospective process, blame alternatively is retrospective and emotion driven. While again, I would argue they are often theoretical in practice (largely because the consequence of a failed accountability structure is blame), cultural attributes such as blame are the result of a collective attitude connected to the organisation’s understanding and enforcement of

¹⁷ D Berwick, *A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England* (London: Department of Health, 2013) 33.

¹⁸ N Meruelo, ‘Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.’ (2008) 29 *Journal of Legal Medicine* 285, 305.

accountability and their accountability structures.¹⁹ Misdirected accountability diverts organisational resources away from initiating safety and quality initiatives because of a misplaced reliance on deterrence, and reduces any sense of urgency from the legislature to implement legislation that legally protects quality improvement initiatives. This is important because the relationship between safety improvement mechanisms and negligence claims can not be understated. For example, in a study concerning the relationship between malpractice claiming and the occurrence of adverse incidents, Greenberg et al., found a direct link between the two, noting—perhaps unsurprisingly—that where the law does not legally protect safety initiatives (such as root cause analysis) a perverse effect can be seen on the rate of adverse incidents, and consequently: the rate of malpractice claiming.²⁰ Specifically, their research concluded that on average, a decrease in 10 adverse events per year, correlated with a decrease in 3.7 malpractice claims. Drawing on their findings, the authors make the recommendation that, “... these kinds of relationships and concerns represent an entirely different set of levers for policymakers to consider in regard to malpractice, quite apart from more conventional statutory tort interventions like caps on damages in tort claims.”²¹ As this thesis is predominantly concerned with the interaction between patient safety methodology and the civil law, and accordingly, focuses on legislative and organisational reform intended to reduce the secrecy and fear associated with healthcare culture, it is now useful to reexamine for the purposes of concluding legislative strategies for furthering safety in the context of a just culture.

¹⁹ M Paul, ‘Moving from Blame to Accountability’ (2016) < <https://thesystemsthinker.com/moving-from-blame-to-accountability/> > accessed: 07 July 2017.

²⁰ M Greenberg et al., RAND Institute for Civil Justice, *Is Better Patient Safety Associated with Less Malpractice Activity? Evidence from California* (CA: RAND Corporation, 2010) 15-16.

²¹ Ibid. In relation to their findings, the authors note, “Our results showed a highly significant correlation between the frequency of adverse events and malpractice claims: On average, a county that shows a decrease of 10 adverse events in a given year would also see a decrease of 3.7 malpractice claims. Likewise, a county that shows an increase of 10 adverse events in a given year would also see, on average, an increase of 3.7 malpractice claims. According to the statistical analysis, nearly three-fourths of the within-county variation in annual malpractice claims could be accounted for by the changes in patient safety outcomes.”

13.3 The Law in a Just Culture

An important component to the reduction of medical error has been reforming the culture in which care is delivered. While idealistic, blame cannot in any practical manner be separated from the process of accountability, or safety and quality improvement. This is because the distinction between blame and accountability is largely theoretical. Certainly there are steps that can be taken to move the culture of a healthcare organisation away from using blame solely as a tool for accountability, and this thesis has critically considered a number of legislative interventions that can be used to further that purpose. Ultimately, however, when an incident occurs, there must be a root cause. Determining who is accountable for its occurrence and prevention, and whether there should be censure attached to that determination is one of the primary objectives of a just culture. The challenge is in finding a balance between accountability and learning, while attempting to reduce the negative attributes of blame. As Hetzler has noted, “Providing a collaborative process of solving problems and addressing conflict that is also appropriate for the situation will create a more harmonious, productive work environment that provides a consistent, higher quality service of care.”²² It is now useful to briefly summarise my main arguments, as set out throughout this thesis, with respects to how the law can influence cultural change, and ultimately, reduce medical error.

First, a move towards a more just culture that encourages what I believe to be the main objectives of the patient safety movement (learning, prevention, and mitigation) can be aided by legally requiring serious incidents (i.e. those involving serious disability or death) are reported, and by ensuring all work product related to quality and safety improvement is privileged.²³ As demonstrated throughout the previous chapters,

²² D Hetzler et al., ‘Conflict Management in Hospital Systems: Not Just For Leadership’ (2011) 5 American Journal of Mediation 65, 89.

²³ See further: Chapter 3.2 ‘The United States,’ Chapter 9.2 ‘Key Elements of Incident Reporting Systems,’ and specifically section 7 of Patient Safety and Quality Improvement Act 2005, S 544, HR 3205, Public Law 109-41.

individuals are less likely to report or disclosure incidents when they are fearful and unaware of the potential consequences. Removing the fear of liability and regulatory scrutiny from the work of quality improvement allows the organisation to learn from the event, and ideally, prevent its reoccurrence. There is one caveat to this: privilege must not be interpreted by the organisation as a right to secrecy. Indeed, healthcare organisations and professionals have an ethical and legal duty to information surrounding their care. In this regard, the second suggestion is to limit liability surrounding healthcare communication, examined extensively throughout chapters 9 to 12. While this duty does not in itself reduce the fear of blame, it does contribute to the development of a just culture by requiring transparency and patient engagement—both of which are necessary for moving beyond an adversarial culture and towards collaboration and mitigation.

Third, the law can aid in cultural change by holding individuals and organisations accountable for the quality of their choices, not solely the severity of outcome.²⁴ This concept clearly differs from the traditional approach which, by default, relies on severity to establish causation and the value of monetary liability. As Griffith notes in relation to a just (versus blame) culture:

“Rather than just assume that a bad outcome has a bad person associated with it, we focus on the differences between human error, at-risk behavior, and reckless behavior—and administer justice based on the quality of the person’s choice. To effectively manage human behavior, a Just Culture understands the “severity bias” that emerges when the level of actual harm determines whether someone is disciplined. This can often lead organizations toward a dangerous “no harm, no foul” view of accountability. However, a Just Culture recognizes that human error is

²⁴ P Boysen, ‘Just Culture: A Foundation for Balanced Accountability and Patient Safety’ (2013) 13 Ochsner Journal 400; citing: D Marx, *Patient Safety and the Just Culture: A Primer for Health Care Executives*. (New York, NY: Trustees of Columbia University, 2001);.

inadvertent, while at-risk behavior and reckless acts are conscious choices, regardless of whether harm was intended.”²⁵

Although, admittedly, the civil law does already in many respects prioritise the quality of choice versus severity; for example, by placing emphasis on generally approved practices and the standard of care. Another way in which this can be encouraged, as examined thorough this thesis, is by accelerated epidemiological analysis and early attempts at mitigation and conflict resolution. As suggested above, protecting incident analysis allows for consideration of systemic factors that have contributed to the quality of the choice. As well, it allows accountability to be appropriately assigned based on causation and not result or severity. Where the incident is subject to liability, early resolution by way of mandatory mediation provides the ideal setting to refocus the issue away from severity and towards multi-factorial causation.

Lastly, as mentioned in greater detail above, the law can assist in cultural change by legislating a requirement for non-linear, multi-disciplinary accountability structures. The UK’s Health and Social Care Acts are an excellent of this. Unlike the United States who rely on voluntary accreditation,²⁶ NHS hospitals and private healthcare providers are legally accountable for meeting the appropriate standards of quality and safety.²⁷ Regulation 20 is particularly relevant in this regard, giving the Care Quality Commission the authority to issue a warning, prosecute, or revoke accreditation of an NHS healthcare organisation for failure to act in an open and transparent manner.²⁸

²⁵ K Griffith, ‘The Growth of a Just Culture’ (2009) 9(12) Joint Commission Perspectives on Patient Safety 8, 9.

²⁶ For the most recent version of the JCAHO Accreditation Standards, see further: Joint Commission on Accreditation of Healthcare Organizations, *2016 Hospital Accreditation Standards*. (Oakbrook Terrace, IL: Joint Commission Resources, 2015).

²⁷ See further: Chapter 4.4.2 ‘Organisational and Professional Regulation’ and the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

²⁸ Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, Regulation 20.

13.4 Reducing the Barriers to Healthcare Communication

Lastly, this thesis has argued that the adoption of strategies that improve healthcare communication by way of legislative and organisational reform are the most effective mechanism by which to reduce medical error because they are uniquely capable of bridging the dichotomy between the collaborative ideals of the patient safety movement and the inherently adversarial nature of the legal system. Disputes within healthcare are unique, not least because in many instances, they require concurrent management of the patient's present and future health concerns.²⁹ For this reason, previous chapters of this thesis have analysed in-depth the significance of communication before and after a preventable medical error. Specifically, the disclosure of such incidents and the appropriateness of the mediation process in resolving healthcare disputes. However, transforming the culture of a healthcare organisation dominated by a fear of blame, liability, and professional regulatory censure to a culture that recognises the inevitability of error and embraces transparent communication is not a small task. It is important to reemphasise that it is the values and beliefs held by members of the organisation that are most effected by contemporary legal processes.³⁰ Arguably, nowhere is this more obvious than in the fear of incident reporting and error disclosure. Despite both legal and ethical obligations to disclose incidents, the level in which physicians and healthcare organisations comply remains questionable. For example, in a study examining the self-reported perceptions of patients following a harmful event in the United States from 2012-2013, Lyu et al. found that of the 236 patients, only 9.3% of healthcare organisations and 7.6% of physicians had voluntarily disclosed the incident. Moreover, 37.7% and 46.3% of the respondents stated that the healthcare organisation and physician denied responsibility, respectively. Of those in

²⁹ S Sanbar, 'Alternative Dispute Resolution' in S Sanbar, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007) 309. In this regard, Sanbar has noted, "... the provider's reputation, the health of a party, and the emotional concerns intimately related to illness, disease, and treatment make disputes in the health care arena unique. Some circumstances, such as end-of-life situations, simply are not well suited to ADR or formal adjudication."

³⁰ S Singer et al., 'Relationship of Safety Climate and Safety Performance in Hospitals' (2009) 44 *Health Services Research* 399, 400.

which the incident was disclosed, only 11.4% of the responding patients or their families reported that they received an apology from the healthcare organisation or the physician.³¹ Although significant process has been made in encouraging disclosure and apology, this study suggests there is still considerable work to be done.

For similar reasons to those regarding disclosure, there has also been resistance within the medical community to embrace alternative dispute resolution. This is primarily due to cultural barriers and “tension between the values underlying ADR processes and those underlying organizational culture and professional training in medicine.”³² This is unfortunate, owing to the numerous benefits of engaging in the mediation process. As demonstrated throughout chapter 12.3 of this thesis, mediation—in contrast to litigation—is conciliatory in nature and provides an informal setting in which the parties can address the legal and medical issues involved.³³ Hyman has further emphasised this, noting that mediation has a strong therapeutic and settlement-oriented approach, while also avoiding the uncertainty of a judge or jury’s decision.³⁴ However, merely facilitating mediation services or instructing healthcare

³¹ H Lyu et al., ‘Medical Harm: Patient Perceptions and Follow-up Actions’ (13 November 2014) *Journal of Patient Safety* [epub ahead of print] 1-3; A Wu et al., ‘Disclosing Adverse Events to Patients: International Norms and Trends’ (08 April 2014) *Journal of Patient Safety* 5 [epub ahead of print]. In examining current disclosure trends, Wu notes, “Important progress has been made toward creating a health care culture in which patients can expect to be informed openly, promptly, and compassionately when they are injured by their health care. However, the journey toward actually informing patients after these events is still in its early stages.”

³² O Rabinovich-Einy, ‘Escaping the Shadow of Malpractice Law’ (2011) 74 *Law and Contemporary Problems* 241, 254-255; citing: S Szmania et al., ‘Alternative Dispute Resolution in Medical Malpractice: A Survey of Emerging Trends and Practices’ (2008) 26 *Conflict Resolution Quarterly* 71, 73.

³³ See further: Chapter 12.3 ‘Healthcare Mediation.’

³⁴ C Hyman et al., ‘Interest-Based Mediation of Medical Malpractice Lawsuits: A Route to Improved Patient Safety?’ (2010) 35(5) *Journal of Health Politics, Policy and Law* 797, 812.

professionals to disclose an incident will not ensure such mechanisms are universally embraced.³⁵ As explained by Truog et al.:

“On the organizational level, formal policies supporting disclosure are also frequently trumped by fears, such as harm to institutional reputation or damage to trust within the population of patients served. On a unit or departmental level, even when organizational leaders are voicing strong support for disclosure, residents may see their attending physician pursuing a path of limited disclosure and conclude that this approach is the cultural norm within their specialty.”³⁶

Truog’s comments are instructive because they highlight the importance of holistically addressing organisational culture in quality and safety improvement—as distinct from merely implementing policy or legislation.³⁷ This is equally relevant with respects to a proposed legislative requirement for mediation at the first instance of a litigable dispute, examined extensively in chapter 12.3.3. An unfortunate but interesting example of the challenges of compliance and enforcement can be seen in the implementation of disclosure policy within the NHS. Although the NHS formally adopted a national policy and guidelines for disclosure in 2005, a study conducted over the subsequent two year period found that only 36% of physicians were in favour

³⁵ D Dalton and N Williams, *Building a Culture of Candour: A Review of the Threshold for the Duty of Candour and of the Incentives for Care Organisations to be Candid* (London: Royal College of Surgeons, 2014) 2. <<https://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf>> accessed: 12 November 2014. As the authors note, “Candour cannot be an ‘add on’ or a matter of compliance; candour will only be effective as part of a wider commitment to safety, learning and improvement. This will require a considerable commitment to supporting staff through induction, training, and processes of review and implies inculcating a ‘just culture’ focused on learning and improvement and avoiding the temptations of defensiveness and blame.”

³⁶ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 121.

³⁷ See generally: R Campbell, ‘Creating a Winning Organizational Culture’ (2009) 28 *Health Care Manager* 328; E Arnold, ‘Improving Organizational Climate for Excellence in Patient Care’ (2013) 23(3) *Health Care Manager* 280; M Chassin, ‘Improving The Quality of Health Care: What’s Taking So Long?’ (2013) 32(10) *Health Affairs* 1761.

of its use.³⁸ Perhaps unsurprisingly, Wu argues that early disclosure remains fragmented within the NHS—notwithstanding the contractual obligation implemented by the UK government in 2010—due largely to organisational barriers such as time pressures and a fear of censure.³⁹ It is worth noting, however, an encouraging study from England using survey responses to examine healthcare professionals’ attitudes toward patient involvement. The study by Davis et al. found that both nurses and physicians were supportive of patient involvement in safety-related behaviour, which included: asking challenging questions, confirming medications and reporting adverse incidents. Although the study did not investigate attitudes towards communication related processes (such as mediation or disclosure), the results suggest that the culture within healthcare is becoming increasingly supportive of patient engagement and safety-centred initiatives, which may then lead to improved rates of compliance with more progressive safety and quality legislation.⁴⁰

Reforming a healthcare organisation's culture requires those at the blunt end to embrace and promote unconventional and multidisciplinary tools, encourage a holistic approach to risk,⁴¹ proactively include patients,⁴² provide formal training to all

³⁸ A Wu et al., ‘Disclosing Adverse Events to Patients: International Norms and Trends’ (08 April 2014) *Journal of Patient Safety* [epub ahead of print]; citing: National Patient Safety Agency (UK). *Safer Practice Notice: Being Open When Patients are Harmed* (2005) < <http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=59991>.>

³⁹ *ibid* 2.

⁴⁰ R Davis et al., ‘Patient Involvement in Patient Safety: The Health-Care Professional’s Perspective’ (2012) 8(4) *Journal of Patient Safety* 182. It is noteworthy, however, that a limitation of this study was the sample size. As well, the participants were self-selected and the level of harm was not contrasted with medical records. Therefore, the authors note that a selection bias may have yielded exaggerated findings.

⁴¹ D Sale, *Understanding Clinical Governance and Quality Assurance: Making It Happen* (Hampshire: Palgrave Macmillan, 2005) 41.

⁴² S Winokur and K Beauregard, ‘Patient Safety: Mindful, Meaningful, and Fulfilling’ (2005) 22(1) *Frontiers of Health Services Management* 17, 25.

relevant medical and legal professionals involved,⁴³ and place safety and quality as a top organisational priority.⁴⁴ While the safety and quality benefits of cultural change are well-established and persuasive, it may be that the most compelling reason for healthcare organisations to adopt a just culture, reform healthcare communication, and improve safety and quality are the economic benefits. As Heasell has insightfully argued,

“Decisions which imply the using up of scarce resources of any kind can be expected to reflect perceptions of beneficial and costly consequences, more systematically if the decision making period is an extended one. Anything which appears to affect differences in cost, between adverse events and taking precautions to prevent them, generates a cost incentive which has potential to influence decisions.”⁴⁵

Although quality and safety should always be the priority (hence the ethical maxim ‘do no harm’), implementing legal mechanisms that can additionally reduce healthcare expenditure will be equally beneficial for advancing patient safety efforts. As Harpwood pragmatically argues,

“The inescapable logic is that because claims have increased, less funding is available for patient care. This results in greater expenditure on risk

⁴³ A Wu et al., ‘Disclosing Adverse Events to Patients: International Norms and Trends’ (08 April 2014) *Journal of Patient Safety* [epub ahead of print]; D Hetzler et al., ‘Conflict Management in Hospital Systems: Not Just For Leadership’ (2011) 5 *American Journal of Mediation* 65, 78. Specific to ADR training, Hetzler recommends that every member of the claims committee (which may include the chief nursing officer, chief medical officer, chief financial officer, chief legal officer, risk management representatives) as well as outside counsel who may be involved in handling general or hospital liability cases, should be trained in collaborative communication and mediation techniques.

⁴⁴ T Claridge and J Sandars, ‘Patient Safety Culture’ in J Sandars and G Cook (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007) 21.

⁴⁵ S Heasell, ‘Economic Aspects of Patient Safety’ in J Tingle and P Bark (eds) *Patient Safety, Law Policy and Practice* (Oxon: Routledge, 2011) 152 .

management, more cost-cutting on staff training and safety equipment, creeping privatisation by the contracting out of essential services such as cleaning and laundry, and therefore more mistakes.”⁴⁶

Moreover, the cost of conflict extends beyond that of litigation. Direct costs of conflict (and initially poor communication) can also include a loss of productivity, turnover costs, and disability stress claims. Similarly, the indirect costs of conflict can include diminished team morale, decreased patient satisfaction, loss of the reputation, and emotional costs.⁴⁷ All of these are latent factors in their own right, and all detrimental to healthcare culture, communication, and ultimately safety and quality improvement.

Regardless of whether an organisation implements policy reform on the basis of economic benefits or quality and safety, the result is the same: by learning from, preventing, and mitigating conflict and harm—safety and quality can be improved. Arguably the most efficient means by which to prevent, learn, and mitigate is by redirecting those resources otherwise used to resolve conflict, back into system redesign and safety training. This, however, requires healthcare organisations and governments to endorse a systemic approach to safety initiatives. As Heasell has commented, “A systemic approach to patient safety invites systematic analysis of policy and practice. It also involves, therefore, developing awareness of interdependent decisions by various individuals and in various organisations, framed by various social institutions, including law.”⁴⁸ For healthcare organisations and regulators, this includes embracing legislative changes to disclosure, apology, and

⁴⁶ V Harpwood, *Medicine, Malpractice and Misapprehensions* (Oxon: Routledge-Cavendish, 2007) 75; citing: A Pollock, *NHS plc: The Privatisation of our Healthcare* (Verso: London, 2004).

⁴⁷ A Simpao, ‘Conflict Management in the Health Care Workplace’ (2013) 39(6) *Physician Executive Journal* 54, 58; citing: D Gerardi, ‘Using Mediation Techniques to Manage Conflict and Create Healthy Work Environments’ (2004) 15(2) *American Association of Critical-Care Nurses Clinical Issues* 182-195.

⁴⁸ S Heasell, ‘Economic Aspects of Patient Safety’ in J Tingle and P Bark (eds) *Patient Safety, Law Policy and Practice* (Oxon: Routledge, 2011) 152 .

early compensation offers; incorporating ADR processes and communication training; collaboration between the legal and medical community; and reforming the organisation's ethos to reduce cultural barriers.⁴⁹ This too can be a barrier to the mediation process can occur when there are objections by the defendant's insurance provider and a refusal to agree to a compensation offer on technical grounds requiring judicial determination (i.e. whether the standard of care was breached or if causation can not be adequately established.) In the prioritisation of safety, the legal community and insurance providers must be compelled to participate. In this regard, Hetzler pragmatically points out, "Even when a hospital adopts an approach to engage in early evaluation and attempt early resolution, often it is met with an opinion from outside insurance counsel that formal discovery and case evaluation by the firm is necessary before any case can be considered for resolution."⁵⁰ This is not to suggest that the merits of a potential claim should not be evaluated, indeed it may be professionally negligent for the defence's counsel not to do so. However, such a situation presumes a dichotomy exists between a quality and safety approach to healthcare dispute resolution, and a legal, costs-based approach. While legal, cost-based evaluation may be appropriate for individual cases; a more objective analysis arguably recognises that by improving quality and safety, claims (and therefore costs) will inevitably decrease and can be used towards further prevention efforts.⁵¹ This position was similarly taken by Berwick who noted in relation to the healthcare budget within the NHS,

⁴⁹ R Pettignano et al., 'A Case for Including Lawyers on the Care Team' (2011) 37(2) Physician Executive 34. Discussing the positive impact to quality and safety improvements through the use of Health Law Partnerships.

⁵⁰ D Hetzler et al., 'Conflict Management in Hospital Systems: Not Just For Leadership' (2011) 5 American Journal of Mediation 65, 77.

⁵¹ R Truog et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011) 38. In this regard, the authors note, "In addition to these patient-centred benefits, improving safety and effectiveness is expected to reduce the cost of healthcare. Thus, those individuals and organizations who are deeply concerned about the cost of health care in the United States, and its implications for access to care, provide further support for the transparency that is so critical to improving care, as do public and private insurers who are no longer willing to pay for care characterized as 'never events.'"

“Resource constraints will undoubtedly continue in the NHS. There are two ways to deal with this reality. One is by simply cutting budgets and thereby placing the burden on staff of caring with fewer resources. The other, better, way is through improvement – introducing new models of care and new partnerships among clinicians, patients and carers that can produce better care at lower cost. Only a culture of learning and improvement can follow that better way.”⁵²

This thesis has sought to explore and analyse many of the elements necessary to support (as Berwick suggests) a “culture of learning and improvement” through ‘An assessment of strategies which, operating in tandem with medical malpractice actions, will improve patient safety (and based on comparative analysis of how these strategies have worked in different jurisdictions.)’ Additionally, my analysis sought to demonstrate that the adoption of strategies that improve healthcare communication by way of legislative and organisational reform are the most effective mechanism by which to reduce medical error because they are uniquely capable of bridging the dichotomy between the collaborative ideals of the patient safety movement and the inherently adversarial nature of the legal system. Strategies to achieve a just culture are still in their infancy, and the law’s role in that regard continues to raise interesting questions with complex answers. In light of all of the research and extraordinary work in the field of patient safety that has been accomplished to date, it remains clear that meeting the complex challenge of harm and error reduction will require more than censuring a few ‘bad apples,’ it will require multidisciplinary cooperation, adaptability, and commitment. It is hoped that this thesis will contribute to that momentum.

⁵² D Berwick, *A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England* (London: Department of Health, 2013) 14.

Bibliography

Cases

Canada

Bazley v Currie (1999) 2 SCR 534

Gerula v. Flores [1995] 126 DLR (4th) 506

McGill University Health Centre v Association des Résidents de McGill (Arbitration Board, Québec, Canada. 07 June 2011. Grievance No. 4-CUSM-0809-01)

Norberg v Wynrib [1992] 2 SCR 226

Reibl v Hughes (1980) 2 SCR 880

Stewart v Petite [1995] 1 SCR 131

European Union

Case C-87/14 *European Commission v Ireland* [2015] ECLI:EU:C:2015:192, Opinion of the Advocate General

Case C-87/14 *European Commission v Ireland* [2015] ECLI:EU:C:2015:449

United Kingdom

Blyth v Birmingham Waterworks Co [1856] 11 Ex Ch 781

Bolam v Friern Hospital Management Committee [1957] 2 ALL ER 635

Roe v Minister for Health [1954] 2 QB 66

Cassidy v Minister for Health [1951] 2 KB 343

United States

Canterbury v Spence [1972] D.C. Cir. 464 F.2d 772

Engalla v Permanente Medical Group (1997) 64 Cal. Rpt 843, 938 P.2d 903, 15 Cal 4th 951

Greenwood v Harris [1961] Okla. 362 P. 2d 85

Hospital Association of New York State v Axelrod [1989] N.Y. Sup. Ct. 546 N.Y.S.2d 531,
[1990] N.Y. App. Div. 565 N.Y.S.2d 243

King v Burwell [2015] 135 S. Ct. 475

National Federation of Independent Business v Sebelius [2012] 132 S. Ct. 2566

Phony v Vinson [1992] 158 Vt. 646, 605 A.2d 849

Report of the Fourth Grand Jury for the April/ May Term of 1986 Concerning the Care
and Treatment of a Patient and the Supervision of Interns and Junior Residents at
a Hospital in New York County 2.

Senesac v Associates in Obstetrics & Gynecology [1982] 141 Vt. 310, 449 A. 2d 900 141 Vt.
310, 449 A.2d 900

Sutton v Calhoun [1979] CA10 Okla. 593 F. D2d 127

Zion v New York Hospital [1992] N.Y. App. Div. 590 N.Y.S.2d 188

Legislation

Canada

Apology Act 2006 (British Columbia, CA)

European Union

European Council Directive 2000/34/EC of 22 June 2000 amending European Council
Directive 93/104/EC concerning certain aspects of the organization of working
time to cover sectors and activities excluded from that Directive. [2000] OJ
L195/41 (EU)

European Council Directive 2003/88/EC of the European Parliament and of the Council of 4 November 2003 concerning certain aspects of the organisation of working time. [2003] OJ L 2003/299 (EU)

European Council Recommendation on Patient Safety, Including the Prevention and Control of Healthcare Associated Infections [2009] (2009/C 151/01) (EU)

European Council Regulation 691/2010 of 29 July 2010 laying down a performance scheme for air navigation services and network functions and amending Regulation (EC) No 2096/2005 laying down common requirements for the provision of air navigation services. [2010] L 201/1 (EU)

European Council Regulation 996/2010 of the European Parliament and of the the Council of 20 October 2010 on the investigation and prevention of accidents and incidents in civil aviation and repealing Directive 94/56/EC. [2010] L 295/35 (EU)

European Council Regulation 390/2013 of 3 May 2013 laying down a performance scheme for air navigation services and network functions Text with EEA relevance. [2013] OJ L 128 (EU)

European Council Regulation 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007. [2014] OJ L 122 (EU)

Ireland

European Communities (Organisation of Working Time) (Activities of Doctors in Training) Regulations 2004, S.I. No. 494/2004, as amended by the 2010 Regulation, S.I. No. 533/2010. (Ireland)

New Zealand

Accident Compensation Act 2010 (as amended) (New Zealand)

United Kingdom

Care Quality Commission (Registration) Regulations 2009 (UK)

Criminal Justice and Courts Act 2015 (UK)

Fitness to Practise Rules 2004 (UK)

Health and Safety at Work Act 1974 (UK)

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (UK)

Health and Social Care Act 2012 (UK)

Health Service Commissioners Act 1993 (as amended) (UK)

Legal Aid, Sentencing and Punishment of Offenders Act 2012 (UK).

Local Authority Social Services and National Health Service Complaints (England)
Regulations 2009 (UK)

Medical Act 1983 (UK)

United States

Act 171 of 2012, An Act Relating to Health Care Reform Implementation, Vermont
(Vermont, US)

Evidence Code 1160 (California, US)

Medical Injury Compensation Reform Act 1975 (California, US)

National Medical Error Disclosure and Compensation (MEDiC) Act 2005, S 1784, 109th Cong, 1st Sess. (New York, US)

New York Codes, Rules and Regulations tit. 10, § 405.4 (US)

Patient and Physician Safety and Protection Act 2002, S. 2614, 107th Cong. (US)

Patient and Physician Safety and Protection Act 2005, Bill HR 1228, 109th Cong. (2005) (US)

Patient Protection and Affordable Care Act 2010, HR 3590 (111th), 42 US Code § 18001 (US)

Patient Safety and Quality Improvement Act 2005, S 544, HR 3205, Public Law 109-41 (United States)

Physician Safety and Protection Act 2001, HR 3236, 107th Cong. (US)

US Federal Rules of Evidence 408 (US)

Books

Ahmed A, *Review and Practice in Medical Care-Steps for Quality Assurance* (London: George McLaughlan, Nuffield Press, 1981)

Aronson E, *The Social Animal* (8th edn, New York: Worth Publishers, 1999)

Banja J, *Medical Errors and Medical Narcissism* (Massachusetts: Jones and Bartlett, 2005)

Berlinger N, *After Harm: Medical Error and the Ethics of Forgiveness* (Maryland: John Hopkins University Press, 2005)

Berryman J (ed), *The Law of Remedies: New Directions in the Common Law* (Toronto: Irwin Law, 2010)

Bogner M (ed), *Human Error in Medicine*. (Hillsdale, NJ: Lawrence Erlbaum Associates, 1994)

Bosk C, *Forgive and Remember: Managing Medical Failure* (Chicago: University of Chicago Press, 2003)

Bowling D and Hoffman D (eds) *Bringing Peace into the Room: How the Personal Qualities of the Mediator Impact the Process of Conflict Resolution*. (San Francisco, CA: Jossey-Bass, 2003)

Charlton R, *Dispute Resolution Guidebook* (Sydney: LBC Information Services, 2000)

Choctaw W, *Avoiding Medical Malpractice: A Physician's Guide to the Law* (New York: Springer, 2008)

Clarke A, *The Sociology of Healthcare* (2nd edn, Essex: Pearson, 2010)

Cohen M (ed), *Medication Errors* (Washington: American Pharmaceutical Association, 2007)

Craven C and Binchy W (eds), *Medical Negligence Litigation: Emerging Issues* (Dublin: First Law, 2008)

D Madden, *Medicine, Ethics and the Law* (2nd edn, Dublin: Bloomsbury Professional, 2011)

Dekker S, *The Field Guide to Human Error Investigations*. (Aldershot: Ashgate, 2002)

Dubler N and Liebman C, *Bioethics Mediation: A Guide to Shaping Shared Solutions* (New York: United Hospital Fund of New York, 2004)

Fielding S, *The Practice of Uncertainty: Voices of Physicians and Patients in Medical Malpractice Claims* (Connecticut: Auburn House, 1999)

Fortune P et al. (eds), *Human Factors in the Healthcare Setting: A Pocket Guide for Clinical Instructors* (UK: Wiley-Blackwell, 2013)

- Freshman B et al. (eds), *Collaboration Across the Disciplines in Health Care* (Sudbury, Mass: Jones and Bartlett Publishers, 2010)
- Gawande A, *Complications: A Surgeon's Notes on an Imperfect Science* (New York: Metropolitan Books, 2002)
- Gray A and Harrison S (eds), *Governing Medicine: Theory and Practice* (New York: Oxford University Press, 2004)
- Harpwood V, *Medicine, Malpractice and Misapprehensions* (Oxon: Routledge-Cavendish, 2007)
- Haynes K and Thomas M (eds), *Clinical Risk Management in Primary Care* (Oxon: Radcliffe, 2005)
- Health and Safety Commission, *Organizing for Safety: Third Report of the Human Factors Study Group of ACSNI* (Sudbury: HSE Books, 1993)
- Heinrich H, *Industrial Accident Prevention* (New York: McGraw-Hill, 1931)
- Henriksen K et al. (eds), *Advances in Patient Safety: From Research to Implementation. Volume 2: Concepts and Methodology* (Rockville: Agency for Healthcare Research and Quality, 2005)
- — *Advances in Patient Safety: From Research to Implementation. Volume 4: Programs, Tools, and Products* (Rockville: Agency for Healthcare Research and Quality, 2005)
- Herring J, *Medical Law and Ethics* (2nd edn, Oxford: Oxford University Press, 2008)
- Hughes R (ed), *Patient Safety and Quality: An Evidence-Based Handbook for Nurses: Volume 1* (Rockville: Agency for Healthcare Research and Quality, 2008)
- — *Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Volume 2* (Rockville: Agency for Healthcare Research and Quality, 2008)
- Hurwitz B and Sheikh A (eds), *Health Care Errors and Patient Safety* (UK: Wiley-Blackwell, 2009)

- Jackson E, *Medical Law: Text, Cases and Materials* (Oxford: Oxford University Press, 2006)
- Jastrow J (ed), *The Study of Human Error* (New York: D. Appleton-Century Company, 1936)
- Jenicek M, *Medical Error and Harm: Understanding, Prevention, and Control* (New York: Productivity Press, 2011)
- Joint Commission on Accreditation of Healthcare Organizations (eds), *Lexicon: Dictionary of Health Care Terms, Organizations, and Acronyms*. (2nd edn, Oakbrook Terrace: Joint Commission on Accreditation of Healthcare Organizations, 1998)
 — — *2016 Hospital Accreditation Standards*. (Oakbrook Terrace, IL: Joint Commission Resources, 2015)
- Kahneman D et al. (eds), *Judgment Under Uncertainty: Heuristics and Biases*. (Cambridge, UK: Cambridge University Press; 1982)
- Kalra J, *Medical Errors and Patient Safety: Strategies to Reduce and Disclose Medical Errors and Improve Patient Safety* (Berlin, New York: De Gruyter, 2011)
- Linden A and Feldthusen B, *Canadian Tort Law* (Toronto: LexisNexis Canada, 2015)
- Lunney M and Elephant K, *Tort Law: Text and Materials* (Oxford: Oxford University Press, 2010)
- Macfarlane J (ed) *Dispute Resolution: Readings and Case Studies*. (2nd edn, Toronto, ON: Emond Montgomery Publications, 2003)
- Marcus L et al., *Renegotiating Health Care: Resolving Conflict to Build Collaboration* (2nd edn, San Francisco: Jossey-Bass, 2011)
- Marx D, *Patient Safety and the Just Culture: A Primer for Health Care Executives. Report Prepared for MERS-TM* (New York: Columbia University, 2001)

- Maxfield D et al., *Silence Kills—The Seven Crucial Conversations for Healthcare* (Provo, UT: VitalSmarts, 2005)
- McHale J et al., *Health Care Law: Text and Materials* (2nd edn, London: Sweet & Maxwell, 2007)
- Merry A and McCall-Smith A, *Errors, Medicine and the Law* (Cambridge: Cambridge University Press, 2001)
- Mills S, *Clinical Practice and the Law* (Dublin: Butterworth (Ireland), 2002)
- Mulcahy L, *Mediating Medical Negligence Claims: An Option for the Future?* (Norwich: The Stationary Office, 2006)
- Peters G and Peters B, *Medical Error and Patient Safety: Human Factors in Medicine* (US: Taylor & Francais, 2008)
- Picard E and Robertson G, *Legal Liability of Doctors and Hospitals in Canada*. (4th edn, Toronto: Carswell, 2007)
- Powers M, Harris N and Barton A (eds), *Clinical Negligence* (4th edn, Haywards Heath: Tottel, 2008)
- R Wears R, *Oral Remarks at The SEIPS Short Course on Human Factors Engineering and Patient Safety—Part I* (Madison, WI: University of Wisconsin-Madison, 2004)
- Reason J, *Human Error* (Cambridge: Cambridge University, 1990)
— — *Managing the Risks of Organizational Accidents* (Aldershot: Ashgate 1997)
— — et al., *Revisiting the << Swiss Cheese >> Model of Accidents* (Bruxelles; France: Eurocontrol Experimental Center, 2006)
- Sale D, *Understanding Clinical Governance and Quality Assurance: Making It Happen* (Hampshire: Palgrave Macmillan, 2005)
- Sanbar S, American College of Legal Medicine (ed), *Legal Medicine* (7th edn, Philadelphia; London: Elsevier Mosby, 2007)

- Sandars J and Cook G (eds), *A B C of Patient Safety* (Oxford: Blackwell, 2007)
- Scrivens E, *Quality, Risk and Control in Health Care* (Oxford: Oxford University Press, 2005)
- Siegler E et al. (eds), *An Introduction to Hospitals and Inpatient Care* (NY: Springer, 2003)
- Spencer D and Brogan M, *Mediation Law and Practice* (Cambridge: Cambridge University Press, 2007)
- Stephens M (ed), *Hospital Pharmacy* (London: Pharmaceutical Press, 2003)
- Sutherland K and Leatherman S, *Regulation and Quality Improvement. A Review of the Evidence.* (London: The Health Foundation, 2006)
- Tingle J et al. (eds), *Regulating Healthcare Quality: Legal and Professional Issues* (Edinburgh; New York: Butterworth-Heinemann, 2004)
- Truog R et al., *Talking with Patients and Families about Medical Error: A Guide for Education and Practice* (Maryland: John Hopkins University Press, 2011)
- Van DeVeer D and Regan T (eds) *Health Care Ethics* (Philadelphia: Temple University Press, 1987)
- Vincent C, *Patient Safety* (2nd edn, UK: Wiley-Blackwell, 2010)
— — (ed), *Clinical Risk Management* (London: BMJ Books, 2001)
- Viscusi W (ed), *Regulation Through Litigation* (Washington: AEI-Brookings Joint Center for Regulatory Studies, 2002)
- Wachter R and Shojania K, *Internal Bleeding: The Truth Behind America's Terrifying Epidemic of Medical Mistakes.* (New York: Rugged Land, 2004)
- Waluube D, *Medical Errors and Adverse Events: Managing the Aftermath* (US: Xlibris, 2011)

Wilson J and Tingle J (eds), *Clinical Risk Modification: A Route to Clinical Governance* (Oxford: Butterworth-Heinemann, 1999)

Wilson L and Goldschmidt P, *Quality Management in Healthcare* (Sydney: McGraw-Hill, 1995)

Journal Articles

'A v. Bobtail' (2003) 2 New Zealand Law Review 721

Abigail S, 'The Obstacle of Therapeutic Privilege in Healthcare Mediation' (2011) 5 The American Journal of Mediation 1

Agrawal A, 'Medication Errors: Prevention Using Information Technology Systems' (2009) 76(6) British Journal of Clinical Pharmacology 681

Alam A et al., 'The Characteristics of Physicians Disciplined by Professional Colleges in Canada' (2011) 5(4) Open Medicine 166

Alberstein M and Davidovitch N, 'Apologies in the Healthcare System: From Clinical Medicine to Public Health' (2011) 74 Law and Contemporary Problems 151

Alexander A, 'Complaints, Grievances, and Claims Against Physicians: Does Tort Reform Make a Difference?' (2010) 30(1) Journal of Healthcare Risk Management 32

Alvarado K, 'Transfer of Accountability: Transforming Shift Handover to Enhance Patient Safety' [2006] 9(Supp) Healthcare Quarterly 75

American College of Physicians, *American College of Physicians Ethics Manual. 3rd edn.* (1992) 117 Annuals of Internal Medicine 947

Anderson J, 'A Systems Approach to Preventing Adverse Drug Events.' (2003) 92 Studies in Health Technology and Informatics 95

- Anderson R, 'Billions for Defense: The Pervasive Nature of Defensive Medicine' (1999) 159 Archives of Internal Medicine 2399
- Antona D, 'Med-Arb: A Choice Between Scylla and Charybdis' (2014) 69(3) Dispute Resolution Journal 101
- Apple R, 'Mediation Offers Less Costly Way to Resolve Disputes' (2013) 39(6) Physician Executive Journal 60
- Armor B and Bulkley C, 'English as a Second Language is a Risk for an Adverse Drug Event' (2014) 10(4) Journal of Patient Safety 231
- Arnold E, 'Improving Organizational Climate for Excellence in Patient Care' (2013) 23(3) Health Care Manager 280
- Aronson J, 'Medication Errors: Definitions and Classification' (2009) 67(6) British Journal of Clinical Pharmacology 599
- Arora V, 'Communication Failures in Patient Sign-Out and Suggestions for Improvement: A Critical Incident Analysis' [2005] 14(6) Quality and Safety in Health Care 401
- Artino Jr. A et al., 'Broadening Our Understanding of Clinical Quality: From Attribution Error to Situated Cognition' (2012) 91(2) Clinical Pharmacology and Therapeutics 167
- Asch D and Parker R, 'The Libby Zion Case: One Step Forward or Two Steps Backward?' (1988) 318 NEJM 771
- Ash J et al., 'Some Unintended Consequences of Information Technology in Health Care: The Nature of Patient Care Information System-Related Errors' (2004) 11 Journal of the American Informatics Association 104
- Baba-Akbar Sari A et al., 'Sensitivity of Routine System for Reporting Patient Safety Incidents in an NHS Hospital: Retrospective Case Note Review' (2007) 334 BMJ 79

- Baker G et al., 'The Canadian Adverse Events Study: the Incidence of Adverse Events Among Hospital Patients in Canada' (2004) 170 Canadian Medical Association Journal 1678
- Balcerzak G and Leonhardt K, 'Alternative Dispute Resolution in Healthcare: A Prescription for Increasing Disclosure and Improving Patient Safety' Patient Safety & Quality Healthcare (July–Aug. 2008)
- Banja K, 'The Normalization of Deviance in Healthcare Delivery' (2010) 53(2) Business Horizons 139
- Barach P and Small S, 'Reporting and Preventing Medical Mishaps: Lessons from Non-Medical Near Miss Reporting' (2000) 320 BMJ 759
- Barello S et al., 'Patient Engagement as an Emerging Challenge for Healthcare Services: Mapping the Literature' (2012) Nursing Research and Practice 1
- Barger L et al., 'Impact of Extended-Duration Shifts on Medical Errors, Adverse Events, and Attentional Failures.' (2006) 3(12) PLoS Medicine 487.
- Bartlett G et al., 'Impact of Patient Communication Problems on the Risk of Preventable Adverse Events in Acute Care Settings' (2008) 178(12) Canadian Medical Association Journal 1555
- Bates D, 'A 40-year-old Woman who Noticed a Medication Error' (2001) 285 JAMA 3134
- — et al., 'Incidence of Adverse Drug Events and Potential Adverse Drug Events: Implications for Prevention. ADE Prevention Study Group.' (1995) 274(1) JAMA 29
- — et al., 'Relationship Between Medication Errors and Adverse Drug Events.' (1995) 10(4) Journal of General Internal Medicine 199
- — et al., 'The Impact of Computerized Physician Order Entry on Medication Error Prevention,' (1999) 6(4) Journal of the American Medical Informatics Association 313

Baylis F, 'Errors in Medicine: Nurturing Truthfulness' (1997) 8 *Journal of Clinical Ethics* 336

Bell B, 'Reconsideration of the New York State Laws Rationalizing the Supervision and the Working Conditions of Residents' (2003) 20 *Einstein Journal of Biology and Medicine* 36

Bell S et al., 'Accountability for Medical Error: Moving Beyond Blame to Advocacy.' (2011) 140 *Chest* 519

— — 'Disclosure, Apology and Offer Programs: Stakeholders' Views of Barriers to and Strategies for Broad Implementation' (2012) 90(4) *The Milbank Quarterly* 682

— — et al., 'Transparency When Things Go Wrong: Physician Attitudes About Reporting Medical Errors to Patients, Peers, and Institutions' (24 February 2015) *Journal of Patient Safety* [epub ahead of print]

Benbasset J et al., 'Physicians' Attitudes Towards Litigation and Defensive Practice: Development of a Scale.' (2001) 27(2) *Behavioural Medicine* 52

Benesch K, 'Why ADR and Not Litigation for Healthcare Disputes' (2011) 66(3) *Dispute Resolution Journal* 52

— — 'How To Save Time and Cost in Healthcare Arbitration: Can It Really Be Less Expensive than Litigation?' (2014) 69(3) *Dispute Resolution Journal* 1

Berger Z et al., 'Promoting Engagement by Patients and Families to Reduce Adverse Events in Acute Care Setting: A Systematic Review' (2014) 23 *BMJ Quality & Safety* 548

Bernstein J, 'Not By Bread Alone: Shortcomings of the Pay-For-Performance Approach' (2014) 472 *Clinical Orthopaedics and Related Research* 405

Berwick D, 'Continuous Improvement as an Ideal in Health Care.' (1989) 320 *NEJM* 53

— — 'The Toxicity of Pay for Performance' (1995) 4(1) *Quality Management in Healthcare* 27

— — 'What "Patient-Centered" Should Mean: Confessions of an Extremist' (2009) 28(4) *Health Affairs* 555

— — ‘Era 3 for Medicine and Health Care’ JAMA (03 March 2016) [e-pub ahead of print]

Bhopal B, ‘Fallout From the Shipman Case. Death Registers in General Practice Would be a Means of Preventing Malpractice and Murder’ (2000) 320(7244) BMJ 1272

Bismark M et al., ‘Accountability Sought by Patients Following Adverse Events from Medical Care: The New Zealand Experience’ (2006) 175(8) Canadian Medical Association Journal 889

— — and Paterson R, ‘No-Fault Compensation in New Zealand: Harmonizing Injury Compensation, Provider Accountability, and Patient Safety’ (2006) 25(1) Health Affairs 278

Blendon R et al., ‘Views of Practicing Physicians and the Public on Medical Errors.’ (2002) 347 NEJM 1933

Blessner L et al., ‘Defining Pathways’ 2006 14(7) Journal of Nursing Management 553

Bliss L et al., ‘Thirty-Day Outcomes Support Implementation of a Surgical Safety Checklist.’ (2012) 215 Journal of the American College of Surgeons 766

Bloch A, ‘The Post-Bell Commission Residency: Sleep vs. Care’ [1989] 261 JAMA 3243

Blum J, ‘Beyond the Bylaws: Hospital–Physician Relationships, Economics and Conflicting Agendas’ (2005) 53 Buffalo Law Review 459

Bogdanoski T, ‘Medical Negligence Dispute Resolution: A Role for Facilitative Mediation and Principled Negotiation?’ (2009) 20(2) Australian Dispute Resolution Journal 77

Bogner M, ‘Stretching the Search for the “Why” of Error: The Systems Approach’ (2002) 27 Journal of Clinical Engineering 110

Bond C and Anderson E, ‘The Reluctance to Transmit Bad News: Private Discomfort of Public Display?’ (1987) 23 Journal of Experimental Social Psychology 176

- Boothman R, 'Apologies and a Strong Defense at the University of Michigan Health System' (2006) 32(2) Physician Executive 6
- — et al., 'A Better Approach to Medical Malpractice Claims? The University of Michigan Experience' (2009) 2 Journal of Health & Life Sciences Law 125
- Boyer E and Shannon M, 'The Serotonin Syndrome' (2005) 352(11) NEJM 1112
- Boysen P, 'Just Culture: A Foundation for Balanced Accountability and Patient Safety' (2013) 13 Ochsner Journal 400.
- Brady A and Fleming S, 'A Literature Review of the Individual and Systems Factors that Contribute to Medication Errors in Nursing Practice' (2009) 17 Journal of Nursing Management 679
- Brennan T et al., 'Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I' (1991) 324 NEJM 370
- — and Mello M, 'Patient Safety and Medical Malpractice: A Case Study.' (2003) 139 Annals of Internal Medicine 267
- Brenner L et al., 'Beyond the Standard of Care' (2012) 470 Clinical Orthopaedics and Related Research 1357
- Brinkert R, 'A Literature Review of Conflict Communication Causes, Costs, Benefits and Interventions in Nursing' (2010) 18 Journal of Nursing Management 145
- Brown M, 'Rush Hospital v Medical Malpractice Mediation Program: An ADR Success Story' (1998) 86(8) Illinois Bar Journal 432
- Burlison J et al., 'The Second Victim Experience and Support Tool: Validation of an Organizational Resource for Assessing Second Victim Effects and the Quality of Support Resources.' (26 August 2014) Journal of Patient Safety [epub ahead of print]

- Burroughs T et al., 'Patient Concerns About Medical Errors During Hospitalization' (2007) 33(1) Joint Commission Journal on Quality and Patient Safety 5
- Butt A, 'Medical Error in Canada: Issues Related to Reporting of Medical Error and Methods to Increase Reporting' (2010) 7(1) McMaster University Medical Journal 15
- Calikoglu S et al., 'Hospital Pay-For-Performance Programs in Maryland Produced Strong Results, Including Reduced Hospital-Acquired Conditions' (2012) 31(12) Health Affairs 2649
- Campbell E et al., 'Professionalism in Medicine: Results of a National Survey of Physicians' (2007) 147(11) Annals of Internal Medicine 795
- Campbell R, 'Creating a Winning Organizational Culture' (2009) 28 Health Care Manager 328
- Cardarelli R et al., 'Predicting Risk for Disciplinary Action by a State Medical Board.' (2004) 100 Texas Medicine Magazine 84
- — and Licciardone J, 'Factors Associated With High-Severity Disciplinary Action by a State Medical Board: A Texas Study of Medical License Revocation' (2006) 106(3) International Journal of Osteopathic Medicine 153
- Carman K et al., 'Patient and Family Engagement: A Framework for Understanding the Elements and Developing Interventions and Policies' (2013) 32(2) Health Affairs 223
- — 'Understanding An Informed Public's Views On The Role Of Evidence In Making Health Care Decisions' (2016) 35(4) Health Affairs 566
- Carrier E et al., 'High Physician Concern About Malpractice Risk Predicts More Aggressive Diagnostic Testing in Office-Based Practice' (2013) 32(8) Health Affairs 1383
- Chan D et al., 'How Surgeons Disclose Medical Errors to Patients: A Study Using Standardized Patients' (2005) 138 Surgery 851

- Chandraharan E and Arulkumaran S, 'Clinical Governance' (2007) 17(7) *Obstetrics, Gynecology and Reproductive Medicine* 222
- Chassin M, 'Improving The Quality of Health Care: What's Taking So Long?' (2013) 32(10) *Health Affairs* 1761
- — et al., 'The Ongoing Quality Improvement Journey: Next Stop, High Reliability' (2011) 30(4) *Health Affairs* 559
- Clay-Williams R, 'Military Rather than Civil Aviation Holds the Answers for Safer Healthcare' (2013) 347 *BMJ* f5570
- Clinton H and Obama B, 'Making Patient Safety the Centerpiece of Medical Liability Reform' (2006) 354(21) *NEJM* 2205–2208
- Cohen J, 'Advising Clients to Apologize' (1999) 72 *Southern California Law Review* 1009
- — and Thompson P, 'Disputing Irony: A Systematic Look at Litigation About Mediation' (2006) 11 *Harvard Negotiation Law Review* 43
- Cohen D and Rhydderch M, 'Support for Tomorrow's Doctors: Getting it Right, Meeting Their Needs' (2013) 63(1) *Occupational Medicine* 2
- Cole A et al., 'On Higher Ground: Ethical Reasoning and Its Relationship with Error Disclosure' (2013) 22 *BMJ Quality & Safety* 580
- Coleman J, 'Missed Medication Doses in Hospitalised Patients: A Descriptive Account of Quality Improvement Measures and Time Series Analysis' (2013) 25(5) *International Journal for Quality in Health Care* 564
- Communal M et al., 'An Assessment of Basic Patient Safety Skills in Residents Entering the First Year of Clinical Training' (12 June 2015) *Journal of Patient Safety* [epub ahead of print]
- Conner R et al. (eds), 'AORN Guidance Statement: Creating a Patient Safety Culture' (2012) 1 *Perioperative Standards and Recommended Practices* 657

- Connor M et al., 'Creating a Fair and Just Culture: One Institution's Path Towards Organizational Change.' (2007) 33(10) *Joint Commission Journal on Quality and Patient Safety* 617
- Cooke D et al., 'Using a Survey of Incident Reporting and Learning Practices to Improve Organizational Learning at a Cancer Care Center' (2007) 16 *Quality and Safety in Health Care* 342
- Cox W, 'The Five A's: What do Patients Want After an Adverse Event?' 25(3) *Journal of Healthcare Risk Management* 25
- Croskerry P, 'The Importance of Cognitive Errors in Diagnosis and Strategies to Minimize Them' (2003) 78(8) *Academic Medicine* 775
- Dabbs A et al., 'User-Centered Design and Interactive Health Technologies for Patients' (2010) 27(3) *Computers, Informatics, Nursing* 175
- Damberg C et al., 'Taking Stock of Pay-For-Performance: A Candid Assessment From The Front Lines' (2009) 28(2) *Health Affairs* 517
- Dauer E et al., 'Prometheus and the Litigators: A Mediation Odyssey' (2000) 21 *Journal of Legal Medicine* 159
- — 'A Therapeutic Jurisprudence Perspective on Legal Responses to Medical Error' (2003) 24 *Journal of Legal Medicine* 37
- — and Marcus L, 'Adapting Mediation to Link Resolution of Medical Malpractice Disputes with Health Care Quality Improvement' (1997) 60 *Law and Contemporary Problems* 185
- Davis P et al., 'Compensation for Medical Injury in New Zealand: Does "No-Fault" Increase the Level of Claims Making and Reduce Social and Clinical Selectivity?' (2002) 27(5) *Journal of Health Politics, Policy and Law* 833
- — 'Patient Involvement in Patient Safety: The Health-Care Professional's Perspective' (2012) 8(4) *Journal of Patient Safety* 182
- DeAngelo L, 'Mediation in Health Care Settings: Some Theoretical and Practical Concepts' (2000) 7(2) *Journal of Clinical Psychology in Medical Settings* 133

- Dekker S and Hugh T, 'A Just Culture After Mid-Staffordshire' (2014) 23 *BMJ Quality & Safety* 356
- Delbanco T and Bell S, 'Guilty, Afraid and Alone—Struggling with Medical Error' (2007) 357(17) *NEJM* 1682
- Denham C, 'SBAR for Patients' (2008) 4(1) *Journal of Patient Safety* 38
 — — et al., 'Are You Listening... Are You Really Listening?' (2008) 4(3) *Journal of Patient Safety* 148
- Deniz N et al., 'The Relationship between Employee Silence and Organizational Commitment in a Private Healthcare Company' (2013) 99 *Procedia Social and Behavioral Sciences* 691
- Derickson R et al., 'Psychological Safety and Error Reporting Within Veterans Health Administration Hospitals' (2015) 11(1) *Journal of Patient Safety* 60
- DeVille K, 'Act First and Look up the Law Afterward?: Medical Malpractice and the Ethics of Defensive Medicine' (1998) 19 *Theoretical Medicine and Bioethics* 569
 — — 'The Jury Is Out: Pre-Dispute Binding Arbitration Agreements for Medical Malpractice Claims: Law, Ethics, and Prudence' (2007) 28 *Journal of Legal Medicine* 333
- DiCuccio M, 'The Relationship Between Patient Safety Culture and Patient Outcomes: A Systematic Review' (27 February 2014) *Journal of Patient Safety* 1 [epub ahead of print]
- Dixon-Woods M et al., 'Culture and Behaviour in the English National Health Service: Overview of Lessons from a Large Multimethod Study' (2014) 23 *BMJ Quality & Safety* 106
- Donaldson L, 'Clinical Governance: a Statutory Duty for Quality Improvement' (1998) 52 *Journal of Epidemiology and Community Health* 73
 — — and Scally G, 'Clinical Governance and the Drive for Quality Improvement in the New NHS in England' (1998) 317 *BMJ* 61

- Doran T and Roland M, 'Lessons From Major Initiatives To Improve Primary Care In The United Kingdom' (2010) 29(5) Health Affairs 1023
- Dresser R, 'The Limits of Apology Laws' (2009) 38(3) The Hastings Center Report 6
- Driver T et al., 'Responding to Clinicians Who Fail to Follow Patient Safety Practices: Perceptions of Physicians, Nurses, Trainees, and Patients' (2014) 9 Journal of Hospital Medicine 99
- Dunn E et al., 'Medical Team Training: Applying Crew Resource Management in the Veterans Health Administration' (2007) 33(6) Joint Commission Journal on Quality and Patient Safety 317
- Eastaugh S, 'Reducing Litigation Costs Through Better Patient Communication' (2004) 30(3) Physician Executive 36
- Edmondson A, 'Learning from Mistakes Is Easier Said Than Done: Group and Organizational Influences on the Detection and Correction of Human Error' (1996) 32 Journal of Applied Behavioural Science 5
- — 'Psychological Safety and Learning Behavior in Work Teams.' (1999) 44 Administrative Science Quarterly 350
- — 'Learning from Failure in Health Care: Frequent Opportunities, Pervasive Barriers' (2004) 13(Suppl II) Quality and Safety in Health Care ii3
- Edwards A, "Recent Development: Medical Malpractice Non-Economics Damages Caps' (2006) 43 Harvard Journal on Legislation 213
- Edwards M, 'Minimizing Bias in Clinical Peer Review' (2011) 37(6) Physician Executive 50
- Ehrhardt C, 'Federal Courts (Confidentiality in Mediation)' (1998) 5(2) Dispute Resolution Magazine 17

- Elder N et al. 'Barriers and Motivators for Making Error Reports from Family Medicine Offices: A Report from the American Academy of Family Physicians National Research Network' (2007) 20 Journal of the American Board of Family Medicine 115
- Ennis M and Vincent C, 'The Effects of Medical Accident and Litigation on Doctors and Patients' (1994) 16(2) Law & Policy 97
- Epstein R and Street Jr. R, 'The Values and Value of Patient-Centered Care' (2011) 9(2) Annals of Family Medicine 100
- Etchegaray J et al., 'Structuring Patient and Family Involvement in Medical Error Event Disclosure and Analysis' (2014) 33(1) Health Affairs 46
- Farber H and White M, 'Medical Malpractice: An Empirical Examination of the Litigation Process' (1991) 22 Rand Journal of Economics 199
- Faunce T and Bolsin S, 'Fiduciary Disclosure of Medical Mistakes: The Duty to Promptly Notify Patients of Adverse Health Care Events' (2005) 12 Journal of Law and Medicine 478
- Federwisch M et al., 'The Sterile Cockpit: An Effective Approach to Reducing Medication Errors?' (2014) 114(2) American Journal of Nursing 47
- Fein S et al., 'The Many Faces of Error Disclosure: A Common Set of Elements and Definition' (2007) 22(6) Journal of General Internal Medicine 755
- Ferman J, 'Value-Based Purchasing Program Here to Stay: Payments will be Based on Performance.' (2011) 26 Health Executive 76
- Filkins J, "'With No Evil Intent": The Criminal Prosecution of Physicians for Medical Negligence' (2001) 22 Journal of Legal Medicine 467
- Fink L, 'Pay for Performance - A Clash of Cultures' (2006) 32(4) Physician Executive 34

- Flood C, 'New Zealand's No-Fault Accident Compensation Scheme: Paradise or Panacea?' (2000) 8(3) Health Law Review 3
- Fortescue E et al., 'Prioritizing Strategies for Preventing Medication Errors and Adverse Drug Events in Pediatric Inpatients.' (2003) 111 (4 Pt 1) Pediatrics 722
- Fraser J Jr., 'Technical Report: Alternative Dispute Resolution in Medical Malpractice' (2001) 107 Journal of Pediatrics 602
- Frazier S, 'Health Outcomes and Polypharmacy in Elderly Individuals: An Integrated Literature Review'' (2005) 31(9) Journal of Gerontological Nursing 4
- Freed G et al., 'Resident Work Hour Changes in Children's Hospitals: Impact on Staffing Patterns and Workforce Needs' (2012) 130(4) Pediatrics 700
- Friedman R et al., 'The Intern and Sleep Loss' (1971) 285(4) NEJM 201
- Gaba D et al., 'Production Pressure in the Work Environment. California Anesthesiologists' Attitudes and Experiences' (1994) 81 Anesthesiology 488
- Gabbard G and Nadelson C, 'Professional Boundaries in the Physician-Patient Relationship.' (1995) 273 JAMA 1445
- Gallagher T et al., 'Patients' and Physicians' Attitudes Regarding the Disclosure of Medical Errors' (2003) 289(8) JAMA 1001
- — and Levinson W, 'Disclosing Harmful Medical Errors to Patients: A Time for Professional Action.' (2005) 165 Archives of Internal Medicine 1819
- — et al., 'US and Canadian Physicians' Attitudes and Experiences Regarding Disclosing Errors to Patients' (2006) 166 (15) Archives of Internal Medicine 1605
- — et al., 'Disclosing Harmful Medical Errors to Patients: Current Concepts' (2007) 356 NEJM 2713
- — et al., 'Disclosing Unanticipated Outcomes to Patients: The Art and Practice' (2007) 3(3) Journal of Patient Safety 158
- Galton E, 'Mediation of Medical Negligence Claims' (2000) 28 Capital University Law Review 321

- Gaul P, 'ABA Endorses Voluntary Mediation in Medical Malpractice; Opposes Current Health Courts Proposals' (American Bar Association News Release, 23 June 2006)
- Gawron V et al., 'Medical Error and Human Factors Engineering' (2006) 21(1) American Journal of Medical Quality 57
- Gerardi D, 'Using Mediation Techniques to Manage Conflict and Create Healthy Work Environments' (2004) 15(2) American Association of Critical-Care Nurses Clinical Issues 182
- Giesen D, 'Medical Malpractice and the Judicial Function in Comparative Perspective' (1993) 1(3) Medical Law International 3
- Glenn R and Allen C, 'Neutral Experts, Standing Neutrals' (2006) 13 Dispute Resolution Magazine 29
- Golann D, 'Dropped Medical Malpractice Claims: Their Surprising Frequency, Apparent Causes, and Potential Remedies' (2011) 30(7) Health Affairs 1343.
- Gorton C, 'Using Mediation to Resolve Disputes in Health Care' (2005) 31(4) Physician Executive 34
- Griffith K, 'The Growth of a Just Culture' (2009) 9(12) Joint Commission Perspectives on Patient Safety 8
- Grissinger M, 'Too Many Abandon the "Second Victims" of Medical Errors' (2014) 39(9) Pharmacy and Therapeutics 591
- Groves P, 'The Relationship Between Safety Culture and Patient Outcomes: Results From Pilot Meta-Analyses' (2014) 36(1) Western Journal of Nursing Research 66
- Gulick P, 'E-health and the Future of Medicine: The Economic, Legal, Regulatory, Cultural and Organizational Obstacles Facing Telemedicine and Cybermedicine Programs' (2001-2002) 12 Albany Law Journal of Science and Technology 351

- Gutheil T et al., 'Malpractice Prevention Through the Sharing of Uncertainty. Informed Consent and the Therapeutic Alliance.' (1984) 311 NEJM 49
- Guthrie C, 'The Lawyer's Philosophical Map and the Disputants Perceptual Map: Impediments to Facilitative Mediation and Lawyering' (2001) 6 Harvard Negotiation Law Review 145
- Hafemeister T and Spinos S, 'Lean on Me: A Physician's Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient' (2009) 86(5) Washington University Law Review 1167
- Haig K et al., 'SBAR: A Shared Mental Model for Improving Communication Between Clinicians' (2006) 32 Joint Commission Journal on Quality and Safety 167
- Haller G et al., 'Effect of Crew Resource Management Training in a Multidisciplinary Obstetrical Setting' (2008) 20(4) International Journal for Quality in Health Care 254
- Hannawa A, 'Principles of Medical Ethics: Implications for the Disclosure of Medical Errors' (2012) 2 Medicolegal and Bioethics 1
- Hansen L et al., 'Perceptions of Hospital Safety Climate and Incidence of Readmission' (2011) 46(2) Health Services Research 596
- Hart E and Hazelgrove J, 'Understanding the Organizational Context for Adverse Events in the Health Services: The Role of Cultural Censorship' (2001) 10 Quality in Health Care 257
- Haynes A et al., 'A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population' (2009) 360 NEJM 491
- Hellinger F and Encinosa W, 'The Impact of State Laws Limiting Malpractice Damage Awards on Health Care Expenditures' (2006) 96(8) American Journal of Public Health 1375
- Helmreich R, 'On Error Management: Lessons From Aviation' (2000) 320 BMJ 781

- Henriksen K and Kaplan H, 'Hindsight Bias, Outcome Knowledge and Adaptive Learning' (2003) 12(Suppl II) *BMJ Quality & Safety* ii46
- — and Dayton E, 'Organizational Silence and Hidden Threats to Patient Safety' (2006) 41(4) *Health Services Research* 1539
- Hettinger A et al., 'An Evidence-Based Toolkit for the Development of Effective and Sustainable Root Cause Analysis System Safety Solutions' (2013) 33(2) *Journal of Healthcare Risk Management* 11
- Hetzler D et al., 'Curing Conflict: A Prescription for ADR in Healthcare' (2004) *Dispute Resolution Magazine* 5
- — et al., 'Conflict Management in Hospital Systems: Not Just For Leadership' (2011) 5 *American Journal of Mediation* 65
- Hibbard J et al., 'What the Evidence Shows about Patient Activation: Better Health Outcomes and Care Experiences; Fewer Data on Costs' (2013) 32(2) *Health Affairs* 207
- Hickson G et al., 'Factors That Prompted Families to File Medical Malpractice Claims Following Perinatal Injuries' (1992) 267(10) *JAMA* 1359
- — et al., 'Obstetricians' Prior Malpractice Experience and Patients' Satisfaction with Care' (1994) 272 *JAMA* 1583
- Hickson G et al., 'Patient Complaints and Malpractice Risk' (2009) 282(22) *JAMA* 2951
- Hilfiker D, 'Facing Our Mistakes' (1984) 310 *NEJM* 118
- Hilligoss B and Moffatt-Bruce S, 'The Limits of Checklists: Handoff and Narrative Thinking' (2014) 23 *BMJ Quality & Safety* 528
- Hiltrop M and Rubin J, 'Effects of Intervention Mode and Conflict of Interest on Dispute Resolution.' (1982) 42 *Journal of Personality and Social Psychology* 665
- Ho B and Liu E, 'Does Sorry Work? The Impact of Apology Laws on Medical Malpractice' (2011) 43 *Journal of Risk and Uncertainty* 141

- Hobgood C et al., 'Medical Errors: What and When Do Patients Want to Know?' (2002) 9 Academic Emergency Medicine 1156
- — et al., 'Parental Preferences for Error Disclosure, Reporting, and Legal Action After Medical Error in the Care of their Children.' (2005) 116 Journal of Pediatrics 1276
- Holbrook J, 'The Criminalization of Fatal Medical Mistakes.' (2003) 327 BMJ 1118
- Horowitz L et al., 'Development and Implementation of an Oral Sign-Out Skills Curriculum' [2007] 22(10) Journal of General Internal Medicine 1470
- Horstman M and Naik A, 'A "Just Culture" for Performance Measures' (2015) 24 BMJ Quality & Safety 486
- Howley Jr. M, 'The Use of Apology in Health Care' (2009) 9(4) Journal of Medical Marketing 1745
- Hubbeling D, 'Criminal Prosecution for Medical Manslaughter' (2010) 103 Journal of the Royal Society of Medicine 216
- Hughes R and Ortiz E, 'Medication Errors: Why They Happen, and How They Can Be Prevented.' (2005) 105(3) American Journal of Nursing 14
- Hyman C and Schechter C, 'Mediating Medical Malpractice Lawsuits Against Hospitals: New York City's Pilot Project' (2006) 25 Health Affairs 1394
- — et al., 'Interest-Based Mediation of Medical Malpractice Lawsuits: A Route to Improved Patient Safety?' (2010) 35(5) Journal of Health Politics, Policy and Law 797
- Jags R et al., 'Residents Report on Adverse Events and Their Causes' [2005] 165(22) Archives of Internal Medicine 2607
- Jenkins R et al., 'Mandatory Pre-Suit Mediation: Local Malpractice Reform Benefiting Patients and Healthcare Providers' (2010) 30(2) American Society for Healthcare Risk Management 27

- — ‘Mandatory Presuit Mediation: 5-Year Results of a Medical Malpractice Resolution Program’ (2014) 33(4) *Journal of Healthcare Risk Management* 15
- Joesten L et al., ‘Assessing the Perceived Level of Institutional Support for the Second Victim After a Patient Safety Event’ (2015) 11(2) *Journal of Patient Safety* 73
- Jones A and Kelly D, ‘Defensing Silence? Time to Reconsider Whether Organisations are Silent or Deaf When Things Go Wrong’ (2014) 23 *BMJ Quality & Safety* 709
- Jones J and Treiber L, ‘When Nurses Become the “Second Victim”’ (2012) 47(4) *Nursing Forum* 286
- Joosten T et al., ‘Application of Lean Thinking to Health Care: Issues and Observations’ (2009) 21(5) *International Journal for Quality in Health Care* 341
- Jylhä V et al., ‘Preventable Adverse Drug Events and Their Causes and Contributing Factors: The Analysis of Register Data.’ (2011) 23(2) *International Journal for Quality in Health Care* 187
- Kachalia A et al., ‘Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program’ (2010) 153(4) *Annals of Internal Medicine* 213
- Kaissi A, ‘“Learning” From Other Industries: Lessons and Challenges for Health Care Organizations’ (2012) 31(1) *Health Care Manager* 65
- Kaldjian L et al., ‘An Empirically Derived Taxonomy of Factors Affecting Physicians’ Willingness to Disclose Medical Errors.’ (2006) 21 *Journal of General Internal Medicine* 942
- — et al., ‘Disclosing Medical Errors to Patients: Attitudes and Practices of Physicians and Trainees’ (2007) 22(7) *Journal of General Internal Medicine* 988
- Kalra J, ‘Medical Error, Disclosure and Patient Safety: A Global View of Quality Care’ (2013) 46(13-14) *Clinical Biochemistry* 1161
- Kapp M, ‘Medical Error versus Malpractice.’ (1997) 1 *DePaul Journal of Health Care Law* 750

- Karla J and Entwistle M, 'Medical Error Disclosure and Professionalism: The Right Thing to Do' (2014) 2(2) *Annals of Clinical Pathology* 102
- Kavanagh K et al., 'The Relationship Between Tort Reform and Medical Utilization' (2014) 10(4) *Journal of Patient Safety* 222
- Kessler D and McClellan M, 'Do Doctors Practice Defensive Medicine?' (1996) 111(2) *The Quarterly Journal of Economics* 353
- — et al., 'Impact of Malpractice Reforms on the Supply of Physician Services' (2005) 293 (21) *JAMA* 2618
- Khatri K et al., 'From a Blame Culture to a Just Culture in Health Care' (2009) 34(4) *Health Care Management Review* 312
- Khodyakov D, 'Patient Engagement in the Process of Planning and Designing Outpatient Care Improvements at the Veterans Administration Health-care System: Findings from an Online Expert Panel' (23 February 2016) *Health Expectations* 2 [e-pub ahead of print]
- Kimsey D, 'Lean Methodology in Health Care' (2010) 92(1) *Association of Preoperative Nurses Journal* 53
- King A et al., 'Errors As Allies: Error Management Training in Health Professions Education' (2013) 22 *BMJ Quality & Safety* 516
- Kirch D and Boysen P, 'Changing the culture in medical education to teach patient safety.' (2010) 29(9) *Health Affairs* 1600
- Knickle K et al., 'Beyond Winning: Mediation, Conflict Resolution, and Non-Rational Sources of Conflict in the ICU' (2012) 16(3) *Critical Care* 308
- Koh H et al., 'A Proposed Health Literate Care Model Would Constitute A Systems Approach To Improving Patients' Engagement in Care' (2013) 32(2) *Health Affairs* 357

- Kollas C, 'Criminal Prosecutions of Physicians Providing Palliative or End-of-Life Care.' (2008) 11(2) Journal of Palliative Medicine 233
- Koning H et al., 'Lean Six Sigma in Healthcare' (2006) 28(2) Journal for Healthcare Quality 4
- Konrad T et al., 'It's About Time: Physicians' Perceptions of Time Constraints in Primary Care Medical Practice in Three National Healthcare Systems.' (2010) 48(2) Medical Care 95
- Kovach K and Love L, 'Mapping Mediation: The Risks of Riskin's Grid' (1998) 3 Harvard Negotiation Law Journal 71
- Kraman S and Hamm G, 'Risk Management: Extreme Honesty May Be The Best Policy.' (1999) 131 Annals of Internal Medicine 963
- Kridelbaugh W and Palmisano D, 'A 20-Year Experience with Malpractice Screening Panels' (1997) 82 Bulletin of the American College of Surgeons 21
- Krizek T 'Surgical Error: Ethical Issues of Adverse Events' (2000) 135 JAMA Surgery 1359
- Kurtzman E et al., 'Performance-Based Payment Incentives Increased Burden And Blame For Hospital Nurses' (2011) 30(2) Health Affairs 211
- Lachman V, 'Patient Safety: The Ethical Imperative' (2008) 20(2) Journal of the Dermatology Nursing Association 134
- Lafer G, 'Hospitals Speedups and the Fiction of a Nursing Shortage' (2005) 30(4) Labor Studies Journal 27
- Landrigan C et al., 'Effect of Reducing Interns' Work Hours on Serious Medical Errors in Intensive Care Units' (2004) 351(18) NEJM 1838

- Lang A, 'A New Approach to Tort Reform: An Argument for the Establishment of Specialized Medical Courts' (2004) 39 Georgia Law Review 293
- Lash A, 'Arbitration's Key Role in Resolving Employment-Related Health Care Disputes' (2014) 69(3) Dispute Resolution Journal 11
- Lavallee D et al., 'Incorporating Patient-Reported Outcomes Into Health Care To Engage Patients And Enhance Care' (2016) 35(4) Health Affairs 575
- Laverty A et al., 'High-Profile Investigations into Hospital Safety Problems in England Did Not Prompt Patients to Switch Providers.' (2012) 31 Health Affairs 593
- Lawal A et al., 'Lean Management in Health Care: Definition, Concepts, Methodology and Effects Reported' (2014) 3 Systematic Reviews 103
- Lawrence H, 'The Impact of Residents' Work Hour Restrictions' [2003] 3 Current Women's Health Reports 487
- Lazare A, 'Apology in Medical Practice: An Emerging Clinical Skill' (2006) 296 JAMA 1401
- Leape L, 'Error in Medicine' (1994) 272(23) JAMA 1851
- — 'Reporting of Medical Errors: Time for a Reality Check' (2001) 179 Western Journal of Medicine 156
- — et al., 'The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II' (1991) 324 NEJM 377
- — et al., 'Promoting Patient Safety by Preventing Medical Error' (1998) 280(16) JAMA 1444
- — et al. 'Adherence to Practice Guidelines: The Role of Specialty Society Guidelines' (2000) 145 American Heart Journal 19
- — and Berwick D, 'Five years after To Err is Human. What Have We Learned?' (2005) 293 JAMA 2384
- Lee A et al., 'Using Root Cause Analysis to Reduce Falls with Injury in Community Settings' (2012) 38(8) Joint Commission Journal on Quality and Patient Safety 366

- Lee C, 'Federal Regulation of Hospital Resident Work Hours: Enforcement With Real Teeth' (2006) 9(1) *Journal of Health Care Law & Policy* 162
- Légaré F, 'Shared Decision Making: Examining Key Elements and Barriers to Adoption into Routine Clinical Practice' (2013) 32(2) *Health Affairs* 276
- Lenzer J, 'Medical Courts Could Ease US Malpractice Crisis, Group Says' 2005 *BMJ* 330
- Leonard M et al., 'The Human Factor: The Critical Importance of Effective Teamwork and Communication in Providing Safe Care' (2004) 13 (Suppl 1) *BMJ Quality & Safety* i85
- — and Frankel A, 'The Path to Safe and Reliable Healthcare.' (2010) 80(3) *Patient Education Counseling* 288
- Levi D, 'The Role of Apology in Mediation' (1997) 72 *New York University Law Review* 1165
- Levinson W and Gallagher T, 'Disclosing Medical Errors to Patients: A Status Report in 2007' (2007) 177(3) *Canadian Medical Association Journal* 265
- Levinson W, 'Patient-Physician Communication. A Key to Malpractice Prevention.' (1994) 272 *JAMA* 1619
- — 'Disclosing Medical Errors to Patients: A Challenge for Health Care Professionals and Institutions' (2009) 76 *Patient Education and Counseling* 296
- Liang B, 'A System of Medical Error Disclosure.' (2002) 11 *BMJ Quality & Safety* 64
- Liebman C, 'Medical Malpractice Mediation: Benefits Gained Opportunities Lost' (2011) 74 (135) *Law and Contemporary Problems* 135
- — and Hyman C, 'A Mediation Skills Model to Manage Disclosure of Errors and Adverse Events to Patients' (2004) 23 *Health Affairs* 22
- Lockley S et al., 'Effects of Health Care Provider Work Hours and Sleep Deprivation on Safety and Performance' [2007] 33(11 Suppl) *Joint Commission Journal on Quality and Patient Safety* 7

- London A, 'Med-Mal Mediation Offers Promise, but Systemic Obstacles Remain' (2006) 61 (3) Dispute Resolution Journal 26
- Loren D et al., 'Medical Error Disclosure Among Pediatricians: Choosing What We Might Say to Patients' (2008) 162 Archives of Pediatrics & Adolescent Medicine 922
- Lowe C, 'Accidents Waiting to Happen: The Contribution of Latent Conditions to Patient Safety' (2006) 15(Supp 1) BMJ Quality & Safety i72
- Lowery Gitchell R and Plattner A, 'Mediation: A Viable Alternative to Litigation for Medical Malpractice Cases' (1999) 2 DePaul Journal of Health Care Law 421
- Luxhøj J and Kauffeld K, 'Evaluating the Effect of Technology Insertion into the National Airspace System' (2003) 5 The Rutgers Scholar 1
- Lyu H et al., 'Medical Harm: Patient Perceptions and Follow-up Actions' (13 November 2014) Journal of Patient Safety [epub ahead of print]
- Macfarlane J, 'Culture Change? A Tale of Two Cities and Mandatory Court-Connected Mediation' (2002) Journal of Dispute Resolution 241
- MacLeod L, "'Second Victim" Causalities and How Physician Leaders Can Help' (2014) 40(1) Physician Executive 8
- Macrae C, 'Early Warnings, Weak Signals and Learning from Healthcare Disasters' (2014) 23 BMJ Quality & Safety 440
- Mardon R et al., "Exploring Relationships Between Hospital Patient Safety Culture and Adverse Events' (2010) 6(4) Journal of Patient Safety 226
- Marewski J and Schooler L, 'Cognitive Niches: An Ecological Model of Strategy Selection' (2011) 118 Psychological Review 393
- — and Gigerenzer G, 'Heuristic Decision Making in Medicine' (2012) 14(1) Dialogues in Clinical Neuroscience 77

- Marshall M and Smith P, 'Rewarding Results: Using Financial Incentives to Improve Quality' (2003) 12 *BMJ Quality & Safety* 397
- Martin W, 'Quality Models: Selecting the Best Model to Deliver Results' (2007) 33(3) *Physician Executive* 24
- Massive D et al., 'Computerized Physician Order Entry in the Critical Care Environment: A Review of Current Literature' (2011) 26(3) *Journal of Intensive Care Medicine* 165
- M Masterson et al., 'Resident Duty Hours in Canada: A Survey and National Statement' (2014) 14(Suppl 1) *BMC Medical Education* S9.
- Mastroianni A et al., 'The Flaws in State 'Apology' and 'Disclosure' Laws Dilute Their Impact on Malpractice Suits' (2010) 29(9) *Health Affairs* 1611
- Matlow A et al., 'Disclosure of Medical Error to Parents and Paediatric Patients: Assessment of Parents' Attitudes and Influencing Factors' (2010) 95 *Archives of Disease in Childhood* 286
- Mazor K et al., 'Communicating with Patients About Medical Errors: A Review of the Literature.' (2004) 164 *Archives of Internal Medicine* 1690
- — et al., 'Health Plan Members' Views About Disclosure of Medical Errors.' (2004) 140 *Annals of Internal Medicine* 409
- — et al., 'Towards Patient-Centered Cancer Care: Patient Perceptions of Problematic Events, Impact, and Response.' (2012) 30 *Journal of Clinical Oncology* 1784
- McConaughy E, 'Crew Resource Management in Healthcare: The Evolution of Teamwork Training and MedTeams' (2008) 22(2) *The Journal of Perinatal & Neonatal Nursing* 96
- McDonald F, 'The Criminalisation of Medical Mistakes in Canada: a Review.' (2008) 16 *Health Law Journal* 1
- — 'Working to Death: The Regulation of Working Hours in Health Care' (2008) 30(1) *Law & Policy* 108

- McDonald K et al., 'The Patient Is In: Patient Involvement Strategies for Diagnostic Error Mitigation' (2013) 22(Supp 2) ii33
- McSherry R et al., 'Can Clinical Governance Act as a Cultural Barometer?' (2013) 109 (19) Nursing Times 12
- Mehlman M, 'Dishonest Medical Mistakes' (2006) 59 Vanderbilt Law Review 1137
- Meller S and Barclay S, 'Mediation: An Approach to Intractable Disputes Between Parents and Paediatricians' (2011) 96(7) Archives of Disease in Childhood 619
- Mellman D and Adelman M, 'Mediation in Health Care: An External Solution to Internal Problems' (2010) 36(6) Physician Executive 58
- Mello M et al., 'Fostering Rational Regulation of Patient Safety' (2005) 30(3) Journal of Health Politics, Policy and Law 375
- — et al., 'Communication-And-Resolution Programs: The Challenges And Lessons Learned From Six Early Adopters' (2014) 33(1) Health Affairs 20
- — et al., 'Implementing Hospital-Based Communication-And-Resolution Programs: Lessons Learned in New York City' (2014) 33(1) Health Affairs 30
- — et al., 'The Medical Liability Climate and Prospects for Reform' (2014) 312(20) JAMA 2146
- Meruelo N, 'Mediation and Medical Malpractice: The Need to Understand Why Patients Sue and a Proposal for a Specific Model of Mediation.' (2008) 29 Journal of Legal Medicine 285
- Metzloff T et al., 'Empirical Perspectives on Mediation and Malpractice' (1997) 60(1) Law and Contemporary Problems 107
- Mizrahi T, 'Managing Medical Mistakes: Ideology, Insularity and Internists-In-Training' (1984) 19 Social Science Medicine 135
- Mohr D et al., 'Does Employee Safety Matter for Patients Too? Employee Safety Climate and Patient Safety Culture in Health Care' (12 June 2015) Journal of Patient Safety [epub ahead of print]

- Monico E et al., 'The Criminal Prosecution of Medical Negligence' (2006) 5(1) Internet Journal of Law, Healthcare and Ethics 1
- Morreim H, 'Malpractice, Mediation, and Moral Hazard: The Virtues of Dodging the Data Bank' (2012) 27(1) Ohio State Journal on Dispute Resolution 109
- Morrison A, 'Can Mandatory Arbitration of Medical Malpractice Claims be Fair? The Kaiser Permanente System' (2015) 70(3) Dispute Resolution Journal 35
- Morton L, 'A New Approach to Health Care ADR: Training Law Students to Be Problem Solvers in the Health Care Context' (2005) 21 Georgia State University Law Review 965
- Moskop J et al. 'Emergency Physicians and Disclosure of Medical Errors.' (2006) 48(5) Annals of Emergency Medicine 523
- Murtagh L et al., 'Disclosure-And-Resolution Programs That Include Generous Compensation Offers May Prompt A Complex Patient Response' (2012) 31(12) Health Affairs 2681
- Nakhai B and Neves J, 'The Challenges of Six Sigma in Improving Service Quality' (2009) 26(7) International Journal of Quality & Reliability Management 663
- Nebreker J et al., 'High Rates of Adverse Drug Events in a Highly Computerized Hospital' (2005) 165(10) JAMA Internal Medicine 1111
- Neily J et al., 'Association Between Implementation of a Medical Team Training Program and Surgical Mortality' (2010) 304(15) JAMA 1683
- Nelson L et al., 'Damages Caps in Medical Malpractice Cases' (2007) 85(2) Milbank Quarterly 259
- Nelson W, 'Addressing the Second Victim in Medical Error' (2008) 28(2) Healthcare Executive 56

- Nemeth C et al., 'Between Choice and Chance: The Role of Human Factors in Acute Care Equipment Decisions' (2009) 5(2) Journal of Patient Safety 114
- Nieva V and Sorra J, 'Safety Culture Assessment: a Tool for Improving Patient Safety in Healthcare Organizations' (2003) 12(Suppl II) BMJ Quality & Safety ii17
- Nobel D and Pronovost P, 'Underreporting of Patient Safety Incidents Reduces Health Care's Ability to Quantify and Accurately Measure Harm Reduction' (2010) 6(4) Journal of Patient Safety 247
- Nolan-Haley J, 'Mediation: The "New Arbitration"' (2012) 17(61) Harvard Negotiation Law Review 61
- O'Hagan J and Persaud D, 'Creating a Culture of Accountability in Health Care' (2009) 29(2) Health Care Manager 124
- O'Leary K et al., 'Hospitalized Patients' Understanding of Their Plan of Care' (2010) 85(1) Mayo Clinic Proceedings 47
- Ong M et al., 'Automated Categorisation of Clinical Incident Reports Using Statistical Text Classification' (2010) 19 BMJ Quality & Safety e55
- Oriol M, 'Crew Resource Management: Applications in Healthcare Organizations' (2006) 36(9) Journal of Nursing Administration 402
- Orr R, 'Methods of Conflict Resolution at the Bedside' (2001) 1(4) The American Journal of Bioethics 45
- Painter L et al., 'Do Written Disclosures of Serious Events Increase Risk of Malpractice Claims? One Health Care System's Experience' (31 March 2015) Journal of Patient Safety [epub ahead of print].
- Palese A et al., "'I Am Administering Medication-Please Do Not Interrupt Me": Red Tabards Preventing Interruptions as Perceived by Surgical Patients' (12 June 2015) Journal of Patient Safety [epub ahead of print]

- Palmieri P et al., 'The Anatomy and Physiology of Error in Adverse Health Care Events' in T Grant et al., (eds) *Patient Safety and Health Care Management* (2008) 7 *Advances in Health Care Management* 33
- Paterick Z et al., 'The Challenges to Transparency in Reporting Medical Errors' (2009) 5(4) *Journal of Patient Safety* 205
- Patterson E et al., 'Compliance with Intended Use of Bar Code Medication Administration in Acute and Long-Term Care: An Observational Study' (2006) 48(1) *Human Factors* 15
- Peeples R et al., 'Following the Script: An Empirical Analysis of Court-Ordered Mediation of Medical Malpractice Cases' (2007) 1 *Journal of Dispute Resolution* 101
- Peters M, 'Perfectionism in Doctors' (2012) 344 *BMJ* 1674
- Pettignano R et al., 'A Case for Including Lawyers on the Care Team' (2011) 37(2) *Physician Executive* 34
- Pexton C, 'One Piece of the Patient Safety Puzzle: Advantages of the Six Sigma Approach' (Jan/Feb 2005) *Patient Safety & Quality Healthcare* 1
- Phansalkar S et al., 'A Review of Human Factors Principles for the Design and Implementation of Medication Safety Alerts in Clinical Information Systems.' (2010) 17(5) *Journal of the American Medical Informatics Association* 493
- Philibert I et al., 'New Requirements for Resident Duty Hours' [2002] 288(9) *JAMA* 1112
 — — 'Use of Strategies From High-reliability Organisations to the Patient Hand-off By Resident Physicians: Practical Implications' [2009] 18(4) *BMJ Quality & Safety* 261
- Pope T, 'Multi-Institutional Healthcare Ethics Committees: The Procedurally Fair Internal Dispute Resolution Mechanism' (2009) 31 *Campbell Law Review* 257

- Popp P, 'How Will Disclosure Affect Future Litigation?' (2003) 23 *Journal of Healthcare Risk Management* 5
- Posner R, 'The Concept of Corrective Justice in Recent Theories of Tort Law' (1981) 10 *Journal of Legal Studies* 187.
- Price M, 'When Doing Wrong Feels So Right: Normalization of Deviance' (07 March 2015) *Journal of Patient Safety* 1-2. [Epub ahead of print]
- Prochazka A et al., 'Patient Perceptions of Surgical Informed Consent: Is Repeat Back Helpful or Harmful?' (2014) 10(3) *Journal of Patient Safety* 140
- Pronovost P et al., 'Implementing and Validating a Comprehensive Unit-Based Safety Program' (2005) 1(1) *Journal of Patient Safety* 33
- Quick O, 'Patient Safety and the Problem and Potential of Law' (2012) 28(2) *Journal of Professional Negligence* 78
- Raban M and Westbrook J, 'Are Interventions to Reduce Interruptions and Errors During Medication Administration Effective?: A Systematic Review' (2014) 23 *BMJ Quality & Safety* 414
- Rabinovich-Einy O, 'Escaping the Shadow of Malpractice Law' (2011) 74 *Law and Contemporary Problems* 241
- Reason J, 'Human Error: Models and Management' (2000) 320(7237) *BMJ* 768
- Reema H et al., 'Emotion and Coping in the Aftermath of Medical Error: A Cross-Country Exploration' (2015) 11(1) *Journal of Patient Safety* 28
- Relis T, 'Consequences of Power' (2007) 12 *Harvard Negotiation Law Review* 445
- Rieskamp J and Otto P, 'SSL: A Theory of How People Learn to Select Strategies' (2006) 135 *Journal of Experimental Psychology* 207

- Riskin L and Welsh N, 'Is That All There Is? "The Problem" In Court-Oriented Mediation' (2008) 15 *George Mason Law Review* 863
- Roberts V and Perryman M, 'Creating a Culture for Health Care Quality and Safety' (2007) 26(2) *Health Care Manager* 155
- Roland M et al., 'Does Pay for Performance in Hospitals Save Lives?' (2014) 23(4) *BMJ Quality & Safety* 346
- Rule A et al., 'New Technology, New Errors: How To Prime an Upgrade of an Insulin Infusion Pump' (2007) 33(3) *Joint Commission Journal on Quality and Patient Safety* 155
- Runciman W et al., 'A Comparison of Iatrogenic Injury Studies in Australia and the USA II: Reviewer Behaviour and Quality of Care' (2000) 12(5) *International Journal for Quality in Health Care* 379
- Ryan A et al., 'Medicare's Flagship Test Of Pay-For-Performance Did Not Spur More Rapid Quality Improvement Among Low-Performing Hospitals' (2012) 31(4) *Health Affairs* 797
- Ryan S et al., 'Impact of a New Electronic Handover System in Surgery' (2011) 9(3) *International Journal of Surgery* 217
- Sage W et al., 'How Policy Makers Can Smooth The Way For Communication-And-Resolution Programs' (2014) 33(1) *Health Affairs* 11
- Saha K, 'Criminal Negligence: Another Unfortunate Incident of Intrathecal Vincristine Use' (2003) 327 *BMJ* 697
- Saitta N and Hodge Jr. S, 'Efficacy of a Physician's Words of Empathy: An Overview of State Apology Laws' (2012) 112(5) *Journal of the American Osteopathic Association* 302
- Salas E et al., 'What Crew Resource Management Training Will Not Do for Patient Safety: Unless...' (2007) 3(2) *Journal of Patient Safety* 62

- — et al., 'Does Team Training Work? Principles for Health Care' (2008) 15 *Academic Emergency Medicine* 1002
- Sammer C et al., 'What is Patient Safety Culture? A Review of the Literature' (2010) 42(2) *Journal of Nursing Scholarship* 156
- Scally G and Donaldson L, 'Clinical Governance and the Drive for Quality Improvement in the New NHS in England' (1998) 317 *BMJ* 61
- Scarpello J, 'After the Abolition of the National Patient Safety Agency' (2010) 341 *BMJ* 6076
- Schmutz J and Manser T, 'Do Team Processes Really Have an Effect on Clinical Performance? A Systematic Literature Review' (2013) 110(4) *British Journal of Anaesthesia* 529
- Scott S et al., 'The Natural History of Recovery for the Health Care Provider "Second Victim" After Adverse Patient Events.' (2009) 18(5) *BMJ Quality & Safety* 325
- Scott T et al., 'The Quantitative Measurement of Organizational Culture in Health Care: A Review of the Available Instruments' 38(3) *Health Services Research* 941
- Scott-Cawiezell J et al., 'Moving From a Culture of Blame to a Culture of Safety in a Nursing Home Setting' (2006) 41(3) *Nursing Forum* 133
- Seabury S, 'Defensive Costs of Medical Malpractice Claims' (2012) 366(14) *NEJM* 1354
- — et al., 'On Average, Physicians Spend Nearly 11 Percent Of Their 40-Year Careers With An Open, Unresolved Malpractice Claim' (2013) 32(1) *Health Affairs* 32
- Shanafelt T et al., 'Suicidal Ideation Among American Surgeons' (2011) 146 *JAMA Surgery* 54
- Shannon S et al., 'Disclosing Errors to Patients: Perspectives of Registered Nurses' (2009) 35 *Joint Commission Journal on Quality and Patient Safety* 5

- Sharkey C, 'Unintended Consequences of Medical Malpractice Damages Caps' (2005) 80(2) *New York University Law Review* 391
- Sharpe A, 'Promoting Patient Safety: An Ethical Basis for Policy Deliberation.' (2003) 33(5) *Hastings Center Report* S3
- Shavell S, 'Alternative Dispute Resolution: An Economic Analysis' (1995) 24 *The Journal of Legal Studies* 1
- Shea-Lewis A, 'Teamwork: Crew Resource Management in a Community Hospital' (2009) 31(5) *Journal for Healthcare Quality* 14
- Sheikh A, 'Open Disclosure, Candour and the Patient' (2013) 19(1) *Medico-Legal Journal of Ireland* 58
- Shieh D, 'Unintended Side Effects: Arbitration and the Deterrence of Medical Error' (2014) 89(5) *New York University Law Review* 1806
- Shojania K and Dixon-Woods M, "'Bad Apples": Time to Redefine as a Type of Systems Problem?' (2013) 22 *BMJ Quality & Safety* 528
- Shorrock S et al., 'Who Moved My (Swiss) Cheese?' (2005) (Jan/Feb) *Aircraft & Aerospace* 31
- Simpao A, 'Conflict Management in the Health Care Workplace' (2013) 39(6) *Physician Executive Journal* 54
- Sine D and Sharpe V, 'Ethics, Risk, and Patient-Centered Care: How Collaboration Between Clinical Ethicists and Risk Management Leads to Respectful Patient Care' (2011) 31(1) *Journal of Healthcare Risk Management* 32
- Singer J and Dean J, 'Emergency Physician Intershift Handovers: An Analysis of our Transitional Care' (2006) 22(10) *Pediatric Emergency Care* 751
- Singer S et al., 'Relationship of Safety Climate and Safety Performance in Hospitals' (2009) 44 *Health Services Research* 399

- — 'Identifying Organisational Cultures that Promote Patient Safety' (2009) 34(4) Health Care Manager Review 219
- Smith M and Forster H, 'Morally Managing Medical Mistakes' (2000) 9 Cambridge Quarterly of Healthcare Ethics 38
- Snyder L et al., 'Pay-for-Performance Principles that Promote Patient-Centered Care: An Ethics Manifesto' *Position Paper for the American College of Physicians Ethics, Professionalism and Human Rights Committee* (2007) 147 Annals of Internal Medicine 792
- Solet D et al., 'Lost in Translation: Challenges and Opportunities During Physician-to-Physician Communication During Patient Handoffs' (2005) 80(12) Academic Medicine 1094
- Solomon M, 'The Ethical Imperative And Moral Challenges Of Engaging Patients And The Public With Evidence' (2016) 35(4) Health Affairs 583
- Sorra J et al., 'Exploring Relationships Between Patient Safety Culture and Patient's Assessments of Hospital Care' (2012) 8(3) Journal of Patient Safety 131
- Staw B, 'Knee-Deep in the Big Muddy: A Study of Escalating Commitment to a Chosen Course of Action' (1976) 16 Organizational Behavior and Human Performance 27
- — , 'The Escalation of Commitment to a Course of Action' (1981) 6 Academy of Management Review 577
- Stein J et al., 'Reorganizing a Hospital Ward as an Accountable Care Unit' (2015) 10(1) Journal of Hospital Medicine 36
- Steurer J et al., 'Legal Concerns Trigger Prostate-Specific Antigen Testing' (2009) 15 Journal of Evaluation in Clinical Practice 390
- Studdert D et al., 'Medical Malpractice' (2004) 350 NEJM 283
- — et al., 'Claims, Errors, and Compensation Payments in Medical Malpractice Litigation' (2006) 354 NEJM 2024

— — et al., 'Disclosure of Medical Injury to Patients: An Improbable Risk Management Strategy' (2007) 25 *Health Affairs* Health 215

Sullivan P, 'Resident training: How many hours is too many?' (Canadian Medical Association, 8 May 2012)

Sullivan R et al., 'Building Confidence into Communication of Bad News: The Role of the Patient Advocate' (2010) 29(4) *Journal of Healthcare Risk Management* 33

Szmania S et al., 'Alternative Dispute Resolution in Medical Malpractice: A Survey of Emerging Trends and Practices' (2008) 26 *Conflict Resolution Quarterly* 71

Taft L, 'On Bended Knee (With Fingers Crossed)' (2005) 55 *DePaul Law Review* 1

Tai-Seale M et al., 'Enhancing Shared Decision Making Through Carefully Designed Interventions That Target Patient And Provider Behavior' (2016) 35(4) *Health Affairs* 605

Tan H, 'Minimizing Medical Litigation: A Review of Key Tort and Legal Reforms' (2009) 5(2) *International Journal of Law in Context* 179

Tang C et al., 'Interactive Systems for Patient-Centered Care to Enhance Patient Engagement' (2016) 23 *Journal of the American Medical Informatics Association* 2

Taylor B et al., 'Do Medical Inpatients Who Report Poor Service Quality Experience More Adverse Events and Medical Errors?' 46 (2008) *Medical Care* 224

Taylor-Adams S et al., 'Safety Skills for Clinicians: An Essential Component of Patient Safety' (2008) 4(3) *Journal of Patient Safety* 141

Tevlin T et al., 'Improving Disclosure and Management of Medical Error - An Opportunity to Transform the Surgeons of Tomorrow' (2013) 11(6) *The Surgeon* 338

Thomas E et al., 'Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado' (1999) 38(3) *Medical Care* 261

- — et al., 'A Comparison of Iatrogenic Injury Studies in Australia and the USA. I: Context, Methods, Casemix, Population, Patient and Hospital Characteristics.' (2000) 12(5) *International Journal for Quality in Health Care* 371
- Thomas J et al., 'Low Costs Of Defensive Medicine, Small Savings From Tort Reform' (2010) 29 *Health Affairs* 1578
- Thompson R, 'Is Pay for Performance Ethical?' (2005) 31(6) *Physician Executive* 60
- Thomson R et al., 'Towards an International Classification for Patient Safety: A Delphi Survey' (2009) 21(1) *International Journal for Quality in Health Care* 9
- Todres J, 'Toward Healing and Restoration for All: Refraining Medical Malpractice Reform' (2006) 39 *Connecticut Law Review* 667
- Tragin M et al., 'Physician Demographics and Risk of Medical Malpractice' (1992) 93 *American Journal of Medicine* 541
- Tucker A and Edmondson A, 'Why Hospitals Don't Learn from Failures: Organizational and Psychological Dynamics That Inhibit System Change' (2003) 45 *California Management Review* 55
- Urbach R et al., 'Introduction of Surgical Safety Checklists in Ontario, Canada' (2014) 370 *NEJM* 1029
- Uribe C et al., 'Perceived Barriers to Medical-Error Reporting: An Exploratory Investigation.' (2002) 47(4) *Journal of Healthcare Management* 263
- Veroff D et al., 'Enhanced Support for Shared Decision Making Reduced Costs of Care for Patients with Preference-Sensitive Conditions' (2013) 32(2) *Health Affairs* 285
- Vidarthi A et al., 'Managing Discontinuity in Academic Medical Centers: Strategies for a Safe and Effective Resident Sign-Out' (2006) 1(4) *Journal of Hospital Medicine* 257

- Vincent C et al., 'Why Do People Sue Doctors? A Study of Patients and Relatives Taking Legal Action' (1994) 343(8912) *Lancet* 1609
- — 'Incident Reporting and Patient Safety' (2007) 334 *BMJ* 51
- Vines P, 'Apologies and Civil Liability in England, Wales and Scotland: The View from Elsewhere' (2007) 61 *University of New South Wales Faculty of Law Research Series* 6
- Virshup B et al., 'Strategic Risk Management: Reducing Malpractice Claims Through More Effective Patient-Doctor Communication' (1999) 14 *American Journal of Medical Quality* 153
- Volpp K et al., 'Mortality Among Patients in VA hospitals in the First 2 Years Following ACGME Resident Duty Hour Reform' (2007) 298(9) *JAMA* 984
- Wachter R et al., 'Medicare's Decision to Withhold Payment for Hospital Errors: The Devil is in the Details' (2008) 34 *Joint Commission Journal on Quality and Patient Safety* 116
- — and Pronovost P, 'Balancing "No Blame" with Accountability in Patient Safety.' (2009) 361 *NEJM* 1401
- — 'Entering the Second Decade of the Patient Safety Movement: The Field Matures' (2009) 169(20) *JAMA Internal Medicine* 1894
- — 'Personal Accountability in Healthcare: Searching for the Right Balance' (2012) 22(2) *BMJ Quality & Safety* 176
- Waite M, 'To Tell the Truth: The Ethical and Legal Implications of Disclosure of Medical Error' (2005) 13 *Health Law Journal* 1
- Wakefield B et al., 'Organizational Culture, Continuous Quality Improvement, and Medication Administration Error Reporting.' (2001) 16(4) *American Journal of Medical Quality* 128
- Wallis K, 'New Zealand's 2005 "No-Fault" Compensation Reforms and Medical Professional Accountability for Harm' (2013) 126 (1371) *New Zealand Medical Journal* 33

- — and Dovey S, 'No-fault Compensation for Treatment Injury in New Zealand: Identifying Threats to Patient Safety in Primary Care' (2011) 20 *BMJ Quality & Safety* 587
- Walumbwa F and Schaubroeck J, 'Leader Personality Traits and Employee Voice Behavior: Mediating Roles of Ethical Leadership and Work Group Psychological Safety.' (2009) 5 *Journal of Applied Psychology* 1275
- Waring J, 'Beyond Blame: Cultural Barriers to Medical Incident Reporting' (2005) 60(9) *Social Science & Medicine* 1927
- Waterman A et al., 'The Emotional Impact of Medical Errors on Practicing Physician in the United States and Canada.' (2007) 33 *Joint Commission Journal on Quality and Patient Safety* 467
- Wears R and Leape L, 'Human Error in Emergency Medicine' (1999) 34 *Annals of Emergency Medicine* 370
- — et al., 'The Medicalization of Patient Safety' (2005) 1(1) *Journal of Patient Safety* 4
- Weaver S et al., 'Team-Training in Healthcare: A Narrative Synthesis of the Literature' (2014) 23 *BMJ Quality & Safety* 359
- Webb R, 'The Hospital/ Medical Staff Standing Neutral—An Idea Whose Time Has Come' (2011) 37(5) *Physician Executive Journal* 50
- Weingart S, 'What Can Hospitalized Patients Tell Us About Adverse Events? Learning from Patient-Reported Incidents' (2005) 20 *Journal of General Internal Medicine* 830
- Weissman J, 'Comparing Patient-Reported Hospital Adverse Events with Medical Record Review: Do Patients Know Something That Hospitals Do Not?' (2008) 149(2) *Annals of Internal Medicine* 100
- — et al., 'Error Reporting and Disclosure Systems: Views from Hospital Leaders' (2005) 293 *JAMA* 1359

- Welch S, 'The Medical Apology: Who and How?' (2012) 28(3) *Frontiers of Health Services Management* 42
- Welsh N, 'The Thinning Vision of Self-Determination in Court-Connected Mediation: The Inevitable Price of Institutionalization?' (2001) 6 *Harvard Negotiation Law Review* 1
- Werner R and Adams Dudley R, 'Making the "Pay" Matter in Pay-For-Performance: Implications For Payment Strategies' (2009) 28(5) *Health Affairs* 1498
- — et al., 'The Effect of Pay-For-Performance In Hospitals: Lessons For Quality Improvement' (2011) 30(4) *Health Affairs* 690
- West J, 'Criminalization of Medical Errors: When is a Mistake More Than Just a Mistake?' (2007) 27(1) *Journal of Healthcare Risk Management* 25
- Westbrook J et al., 'Effects of Two Commercial Electronic Prescribing Systems on Prescribing Error Rates in Hospital In-Patients: A Before and After Study.' (2012) 9(1) *PLoS Medicine* e1001164
- White A et al., 'Supporting Healthcare Workers After Medical Errors: Considerations for Health Care Leaders' (2008) 15 *Journal of Clinical Outcomes Management* 240
- Williams G, 'Aims of the Law of Tort' (1951) *Current Legal Problems* 137
- Wilson R et al., 'The Quality in Australian Health Care Study' (1995) 163 *Medical Journal of Australia* 458
- Winokur S and Beauregard K, 'Patient Safety: Mindful, Meaningful, and Fulfilling' (2005) 22(1) *Frontiers of Health Services Management* 17
- Wolk S et al., 'Institutional Disclosure: Promise and Problems' (2014) 33(3) *Journal of Healthcare Risk Management* 24
- Wood Geckeler G, 'The Clinton–Obama Approach to Medical Malpractice Reform: Reviving the Most Meaningful Features of Alternative Dispute Resolution' (2007) 8 *Pepperdine Dispute Resolution Law Journal* 171

- Woodward H et al., 'What Have We Learned About Interventions to Reduce Medical Errors?' (2010) 31 Annual Review of Public Health 479
- Woolf S et al., 'Authentic Engagement Of Patients And Communities Can Transform Research, Practice, And Policy' (2016) 35(4) Health Affairs 590
- Wright J and Shojania K, 'Measuring the Quality of Hospital Care' (2009) 338 BMJ 783
- Wu A, 'Handling Hospital Errors: Is Disclosure the Best Defense?' (1999) 131 Annals of Internal Medicine 970
- — 'Medical Error: The Second Victim. The Doctor Who Makes the Mistake Needs Help Too.' (2000) 320 BMJ 726
- — et al., 'To Tell the Truth: Ethical and Practical Issues in Disclosing Medical Mistakes to Patients.' (1997) 12 Journal of General Internal Medicine 770
- — et al., 'Disclosing Medical Errors to Patients: It's Not What You Say, It's What They Hear.' (2009) 24 Journal of General Internal Medicine 1012
- — et al., 'Disclosure of Adverse Events in the United States and Canada: An Update, and a Proposed Framework for Improvement' (2013) 2(3) Journal of Public Health Research 186
- — et al., 'Disclosing Adverse Events to Patients: International Norms and Trends' (08 April 2014) Journal of Patient Safety [epub ahead of print]
- Yeung K and Horder J, 'How Can The Criminal Law Support the Provision of Quality in Healthcare?' (2014) 23 BMJ Quality & Safety 519
- Young-Xu Y et al., 'Association Between Implementation of a Medical Team Training Program and Surgical Morbidity.' (2011) 146 JAMA Surgery 1368
- Zimmerman T and Amori G, 'Including Patients in Root Cause and System Failure Analysis: Legal and Psychological Implications' (2007) 27(2) Journal of Healthcare Risk Management 27
- Zinn C, '14,000 Preventable Deaths in Australia' (1995) 310 BMJ 1487
- Zonana E, 'Getting Healthier: A Proposal for Improving Medical Malpractice Mediation' (2001) 5 American Journal of Mediation 9

Official Publications

- Accreditation Council for Graduate Medical Education, *Outcomes Project. General Competencies: Minimum Program Requirements Language* (Chicago: ACGME, 1999)
— — *Report of the ACGME Work Group on Resident Duty Hours* (Chicago: ACGME, 2002)
- American Hospital Association et al., *Pathways for Medication Safety: Looking Collectively at Risk* (Chicago: Health Research and Educational Trust, 2002)
- American Medical Association Council on Ethical and Judicial Affairs, *Code of Medical Ethics: Current Opinions with Annotations 2014-2015* (Chicago: American Medical Association Press, 2014)
- American Medical Association, *State Medical Licensure Requirements and Statistics 2014* (United States: American Medical Association, 2013)
- American Society for Healthcare Risk Management, *Disclosure of Unanticipated Events in 2013* (Chicago: ASHRM, 2013)
- Australian Commission on Safety and Quality in Health Care, *The OSSIE Guide to Clinical Handover Improvement*. (Sydney: Australian Commission on Safety and Quality in Health Care, 2010)
— — *Saying Sorry: A Guide to Apologising and Expressing Regret During Open Disclosure* (Sydney: Australian Commission on Safety and Quality in Health Care, 2013)
- Australian Medical Association, *National Code of Practice—Hours of Work, Shiftwork and Rostering for Hospital Doctors* (Kingston ACT, Australia: Australian Medical Association Ltd, 2005)
- Berwick D, *A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England* (London: Department of Health, 2013)
- Better Regulation Task Force, *Better Routes to Redress* (London: Cabinet Office Publications, 2004)

Byrne S et al., *An Evaluation of the Inappropriate Prescribing in Older Residents in Long Term Care Facilities in the Greater Cork and Northern Ireland Regions Using the STOPP and Beers' Criteria*. (Ireland: Centre for Ageing Research and Development Ireland, 2011)

Canadian Association of Interns & Residents, 'Canadian Patient and Physician Safety and Wellbeing: Resident Duty Hours' Position Paper on Resident Duty Hours (Ottawa: April 2012)

Canadian Institute for Health Information, *Health Care in Canada in 2004* (Ottawa: Canadian Institute for Health Information, 2005)

Canadian Medical Association, *Code of Ethics* (Ottawa: Canadian Medical Association, 2004)

Canadian Medical Protective Association, *Communicating With Your Patient About Harm: Disclosure of Adverse Events*. (Ottawa: Canadian Medical Protective Association, 2008)

— — *Reporting and Responding to Adverse Events: A Medical Liability Perspective* (Ottawa: Canadian Medical Protective Association, 2009)

Care Quality Commission, *Guidance for NHS Bodies on the Fit and Proper Person Requirement for Directors and the Duty of Candour* (Consultation Paper, July 2014)

— — *Guidance for Providers on Meeting the Fundamental Standards and on CQC's Enforcement Powers* (Consultation Paper, July 2014)

Clwyd A and Hart T, *A Review of the NHS Hospitals Complaints System: Putting Patients Back in the Picture* (London: Department of Health, 2013)

Cohen T and Hughes A, *Medical Malpractice Insurance Claims in Seven State, 2000-2004* (Washington: US Department of Justice, 2007)

Dalton D and Williams N, *Building a Culture of Candour: A Review of the Threshold for the Duty of Candour and of the Incentives for Care Organisations to be Candid* (London: Royal College of Surgeons, 2014)

Department of Health (UK), 'Delivering Quality Standards' in *A First-Class Service: Quality in the New NHS* (London: Department of Health, 1998)

- — *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS* (London: Department of Health, 2000)
- — *Building a Safer NHS for Patients: Implementing an Organisation with a Memory* (London: Department of Health, 2001)
- — *Integrated Governance Handbook: A Handbook for Executives and Non-executives in Healthcare Organisations* (London: Department of Health, 2006)
- — Strategy and External Relation Directorate/ Quality Regulation, *New Criminal Offence of Ill-Treatment or Wilful Disregard* (London: Stationery Office, 2014)

Department of Health and Children (Ireland), *Primary Care: A New Direction*. (Dublin: Stationery Office, 2001)

- — *Quality and Fairness: A Health System for You* (Dublin: Stationery Office, 2001)
- — *Audit of Structures and Functions of the Health System* (carried out by Prospectus Consultants), (Dublin: Stationery Office, 2003).
- — *Health Service Reform Programme*. (Dublin: Stationery Office, 2003)
- — *Report of the Commission on Financial Management and Controls in the Health Service* (Dublin: Stationery Office, 2003).
- — *National Health Information Strategy* (Dublin: Stationery Office, 2004)
- — *Building a Culture of Patient Safety: Report of the Commission on Patient Safety and Quality Assurance* (Dublin: Stationery Office, 2008)

Donaldson L, *Making Amends: A Consultation Paper Setting Out Proposals for Reforming the Approach to Clinical Negligence in the NHS* (London: Department of Health, 2003)

European Commission Patient Safety and Quality of Care Working Group, *Key Findings and Recommendations on Reporting and Learning Systems for Patient Safety Incidents Across Europe* (Denmark: European Commission, May 2014)

Francis R, *Report of the Mid-Staffordshire NHS Foundation Trust Public Inquiry* (London: The Stationery Office, 2013)

General Medical Council, *Good Medical Practice* (Manchester: General Medical Council, 2013)

— — et al., *Effective Governance to Support Medical Revalidation: A Handbook for Boards and Governing Bodies* (London: General Medical Council, 2013)

Greenberg M et al., RAND Institute for Civil Justice, *Is Better Patient Safety Associated with Less Malpractice Activity? Evidence from California* (CA: RAND Corporation, 2010)

Health Information and Quality Authority, *A Guide to the National Standards for Safer Better Healthcare* (Dublin: HIQA, June 2012)

— — *Investigation into the Safety, Quality and Standards of Services provided by the Health Service Executive to Patients, Including Pregnant Women, At Risk of Clinical Deterioration, Including Those Provided in University Hospital Galway, and as Reflected in the Care and Treatment Provided to Savita Halappanavar* (Dublin: HIQA, 7 October 2013)

— — *'As Is' Analysis of Patient Safety Intelligence Systems and Structures in Ireland* (Dublin: Stationary Office, 2016)

— — *National Standards for Safer Better Maternity Services* (Dublin: HIQA, 2016)

Health Service Executive, Quality and Patient Safety Doctorate, *A Practical Guide to Clinical Audit* (Dublin: Stationary Office, 2013)

— — *Report of the Quality and Safety Clinical Governance Development Initiative – Sharing our Learning* (Dublin: Stationary Office, 2014)

Health Quality & Safety Commission. *Learning From Adverse Events: Adverse Events Reported to the Health Quality & Safety Commission 1 July 2014 to 30 June 2015* (Wellington: Health Quality & Safety Commission, 2015)

— — *From Knowledge to Action A Framework for Building Quality and Safety Capability in the New Zealand Health System* (Wellington: Health Quality & Safety Commission, October 2016).

Institute of Medicine, *Envisioning the National Health Care Quality Report*. (Washington: National Academies Press, 2001)

Institute of Medicine (Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety), *Resident Duty Hours:*

Enhancing Sleep, Supervision, and Safety. C Ulmer et al. (eds),
(Washington:Washington: National Academies Press, 2008)

Institute of Medicine (Committee on Quality of Health Care in America), *To Err Is Human: Building a Safer Health System.* L Kohn, J Corrigan and M Donaldson (eds),
(Washington: National Academy Press, 1999)

— — *Crossing the Quality Chasm : A New Health System for the 21st Century.* (Washington:
National Academy Press, 2001)

— — *Clinical Practice Guidelines We Can Trust* (Washington: Institute of Medicine,
March 2011)

Joint Commission on Accreditation of Healthcare Organizations, *Revisions to Joint
Commission Standards in Support of Patient Safety and Medical Health Care Error
Reduction.* (Oakbrook Terrace, IL: Joint Commission on Accreditation of
Healthcare Organizations, 2001)

Kennedy I, *Learning from Bristol: The Report of the Public Inquiry into Children's Heart
Surgery at the Bristol Royal Infirmary 1984–1995.* (London: The Stationery Office,
2001)

National Audit Office, *NHS Summary Accounts 1998/99.* (London: The Stationary Office,
2000)

National Clinical Effectiveness Committee, *Standards for Clinical Practice Guidance*
(Dublin: Stationary Office, November 2015)

National Institute for Clinical Excellence, *Principles for Best Practice in Clinical Audit*
(Oxon: Radcliffe Medical Press, 2002)

National Patient Safety Agency (UK), *Seven Steps to Patient Safety* (London: National
Patient Safety Agency, 2004)

— — *Building a Memory: Preventing Harm, Reducing Risks and Improving Patient Safety*
(London: National Patient Safety Agency, 2005)

— — *Act on Reporting: Five Actions to Improve Patient Safety Reporting* (London: NHS
Confederation, 2008)

- National Patient Safety Foundation, *Free from Harm: Accelerating Patient Safety Improvement Fifteen Years after To Err Is Human*. (Boston: National Patient Safety Foundation, 2015)
- National Quality Forum, *Safe Practices for Better Healthcare-2009 Update: A Consensus Report*. (Washington: National Quality Forum, 2009)
- — *Safe Practices for Better Healthcare– 2010 Update: A Consensus Report*. (Washington: National Quality Forum, 2010)
- National Steering Committee on Patient Safety (CA), *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care* (Ottawa: 2002)
- New York State Department of Health Ad Hoc Committee on Emergency Service, *Report on the New York State Ad Hoc Advisory Committee on Emergency Services: Supervision and Residents' Working Conditions* (New York: 1987)
- Philibert I et al. (eds), *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*, Accreditation Council for Graduate Medical Education (ACGME) Task Force on Quality Care and Professionalism (Chicago: ACGME, 2011)
- Postgraduate Medical Education and Training Board, *Patients' Role in Healthcare - The Future Relationship Between Patient and Doctor* (London: PMETB, 2008)
- Royal College of Obstetricians and Gynecologists, *Improving Patient Handover. Good Practice No 12* (London: Royal College of Obstetricians and Gynecologists, 2010)
- Shappell S and Wigeon D, *The Human Factors Analysis and Classification System*, Office of Aviation Medicine, Federal Aviation Administration (US Department of Transportation, 2000) DOT/FAA/AM-00/7
- Shojania K et al., (eds), *Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment* (No. 43. Rockville: US Agency for Healthcare Research and Quality, 2001)

- Smith J, *The Shipman Inquiry. Volume 1: Death Disguised* (Manchester: The Shipman Inquiry, 2002)
- — *The Shipman Inquiry. Volume 2: The Police Investigation of March 1998* (Manchester: The Shipman Inquiry, 2002)
- — *The Shipman Inquiry. Volume 3: Death Certification and Investigation of Deaths by Coroners* (Manchester: The Shipman Inquiry, 2002)
- United States Congress, Office of Technology Assessment, *Defensive Medicine and Medical Malpractice*, OTA-H-602 (Washington: US Government Printing Office, July 1994)
- United States Government Accountability Office, Report to Congressional Committees, *Hospital Value-Based Purchasing: Initial Results Show Modest Effects on Medicare Payments and No Apparent Change in Quality-of-Care Trends*. (GAO-16-9, Washington: US Government Printing Office, October 2015)
- United States General Accounting Office, *Medical Malpractice Insurance: Multiple Factors Have Contributed to Increased Premium Rates* (Washington: US General Accounting Office, June 2003)
- Veterans Health Administration, *Disclosure of Adverse Events to Patients* (VHA Directive 2008-002, 18 January 2008)
- WHO Regional Office for Europe, *The Tallinn Charter: Health Systems for Health and Wealth* (Denmark: World Health Organization, 27 June 2008)
- — *Patient Safety and Rights: Developing Tools to Support Consumer Health Literacy* (Denmark: World Health Organization, 2010)
- WHO World Alliance for Patient Safety, *World Alliance for Patient Safety Forward Programme* (Geneva: World Health Organization, 2004)
- — *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems: From Information to Action* (Geneva: World Health Organization, 2005) WHO/EIP/SPO/QPS/05.3
- — *Patient Safety Workshop: Learning from Error* (Geneva: World Health Organization, 2008) WHO/IER/PSP/2008.09

- World Health Organization (Report by the Secretariat), *Quality of Care: Patient Safety* (23 March 2002) A55/13
- — (Resolution of the Fifty-fifth World Health Assembly), *Quality of Care: Patient Safety* (18 May 2002) WHA55.18
- — *Patient Safety Workshop: Learning from Error* (Geneva: World Health Organization, 2008) WHO/IER/PSP/2008.09
- — *London Declaration by Patients for Patient Safety* (17 Jan 2006)
- — (Report by the Secretariat), *Progress Report* (23 November 2012) EB132/42

Thesis

M Buddecke, 'Defensive Medicine and Obstetrics' (LLM Thesis, University College Cork, 2009)

Internet Resources

- Accident Compensation Corporation, 'What Am I Entitled To?' (2005)
<www.acc.co.nz/claimscare/entitlements>
- Accreditation Council for Graduate Medical Education, 'Duty Hours: ACGME Standards' (ACGME, 1 July 2011) 17. <<http://www.acgme.org/acgmeweb/GraduateMedicalEducation/DutyHours.aspx>>
- — 'Resident Duty Hours in the Learning and Working Environment: Comparison of 2003 and 2011 Standards' <<http://www.acgme.org/acgmeweb/Portals/0/PDFs/dh-ComparisonTable2003v2011.pdf>>
- Agency for Healthcare Research and Quality, 'TeamSTEPPS: Strategies and Tools to Enhance Performance and Patient Safety' <<http://www.ahrq.gov/professionals/education/curriculum-tools/teamstepps/index.html>>
- American Medical Association, 'State Medical Boards' <<http://www.ama-assn.org/ama/pub/education-careers/becoming-physician/medical-licensure/state-medical-boards.page>>

Blanton D, 'Fox News Poll: Majorities Understand, Oppose ObamaCare' (Fox News, 27 March 2014) <<http://www.foxnews.com/politics/2014/03/27/fox-news-poll-majorities-understand-oppose-obamacare-1122817668/>>

Canadian Medical Protective Association, *Apology Legislation in Canada: What it Means for Physicians* (April 2013) <<https://oplfrpd5.cmpa-acpm.ca/-/apology-legislation-in-canada-what-it-means-for-physicians>>

Canadian Patient Safety Institute, 'Canadian Patient Safety Institute' <<http://www.patientsafetyinstitute.ca>>

Care Quality Commission, 'Notifications Required by the Health and Social Care Act 2008: Guidance for English NHS providers' (July 2013) <http://www.cqc.org.uk/sites/default/files/documents/statutory_notifications_for_nhs_bodies_-_provider_guidance_v6.pdf>

Department of Health (UK), *The "Never Events" List 2012/2013* (London: Department of Health, 2012) <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215206/dh_132352.pdf>

Department of Health and Children (Ireland), <'National Patient Safety Office' <<http://health.gov.ie/patient-safety/national-patient-safety-office/>>

Discovery Channel, *Chasing Zero: Winning the War on Healthcare Harm* (USA: Discovery Channel, 2010) <<http://www.safetyleaders.org/pages/chasingZeroDocumentary.jsp>>

EUROCONTROL, 'Just Culture' <<http://www.eurocontrol.int/articles/just-culture>>

Fédération des Médecins Résidents du Québec, *Collective Agreement* (2011-2015) <<http://www.fmrq.qc.ca/files/documents/e2/17/2013-03-19-fmrq-guide-interpretation-de-l-entente-2010-2015-va-finale-modifi-e.pdf>>

General Medical Council, 'Complaints and the Role of the GMC' <http://www.gmc-uk.org/concerns/complaints_and_role_of_the_gmc.asp>

— — 'Fitness to Practice Data' <<http://www.gmc-uk.org/concerns/24194.asp>>

- — ‘Fitness to Practice Panels’ (2014) <http://www.gmc-uk.org/concerns/hearings_and_decisions/fitness_to_practise_panels.asp>
- — ‘Good Medical Practice’ <<http://www.gmc-uk.org/guidance/index.asp>>
- — ‘Joint Statement from the Chief Executives of Statutory Regulators of Healthcare Professionals’ (13 October 2014) <http://www.gmc-uk.org/Joint_statement_on_the_professional_duty_of_candour_FINAL.pdf 58140142.pdf>
- — ‘The GMC’s Fitness to Practice Procedures’ <http://www.gmc-uk.org/DC4541_The_GMC_s_Fitness_to_Practise_procedures.pdf 25416512.pdf>

Health Canada, ‘Canada Vigilance Program’ <<http://www.hc-sc.gc.ca/dhp-mps/medeff/vigilance-eng.php>>

- — ‘Patient Safety’ <http://www.hc-sc.gc.ca/hcs-sss/qual/patient_securit/index-eng.php>

- — ‘SafeMedicationUse.ca’ <<http://www.safemedicationuse.ca>>

Health Service Executive, ‘Healthcare Audit’ <<http://www.hse.ie/eng/about/Who/qualityandpatientsafety/auditservices/>>

- — ‘Quality Improvement Division’ <<http://www.hse.ie/eng/about/Who/qualityandpatientsafety/>>

Heritage Foundation, ‘The Case Against Obama Care’ (2010) <<http://www.heritage.org/research/projects/the-case-against-obamacare>>

International Medication Safety Network, <www.intmedsafe.net/>

- — ‘Salamanca Declaration to Promote Safe Medication Practices Globally’ <http://www.intmedsafe.net/wp-content/uploads/2013/12/Salamanca_Declaration_INSMPC.pdf>

International Society for Quality in Health Care, ‘What is the International Accreditation Process (IAP)?’ <<http://www.isqua.org/accreditation-iap/what-is-the-iap>>

- — ‘Who we are?’ <<http://www.isqua.org/who-we-are/who-we-are>>

James J, ‘Health Policy Briefs: Patient Engagement’ (14 February 2013) <http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=86>

Joint Commission, 'Framework for Conducting a Root Cause Analysis and Action Plan' (22 March 2013) <[http://www.jointcommission.org/Framework for Conducting a Root Cause Analysis and Action Plan/](http://www.jointcommission.org/Framework%20for%20Conducting%20a%20Root%20Cause%20Analysis%20and%20Action%20Plan/)>

— — 'Benefits of Joint Commission Accreditation' (28 August 2015) <[http://www.jointcommission.org/benefits of joint commission accreditation/](http://www.jointcommission.org/benefits%20of%20joint%20commission%20accreditation/)>

— — 'Seminal Event Data: Root Causes by Event Type 2004-2Q 2014.' (The Joint Commission, 30 September 2014) <[http://www.jointcommission.org/assets/1/18/Root Causes by Event Type 2004-2Q 2014.pdf](http://www.jointcommission.org/assets/1/18/Root%20Causes%20by%20Event%20Type%202004-2Q%202014.pdf)>

— — 'Seminal Event Data' (2014) <[http://www.jointcommission.org/sentinel event.aspx](http://www.jointcommission.org/sentinel%20event.aspx)>

— — 'Sentinel Event Policy and Procedure' <[http://www.jointcommission.org/Sentinel Event Policy and Procedures/](http://www.jointcommission.org/Sentinel%20Event%20Policy%20and%20Procedures/)>

— — 'Transitions of Care: The Need For a More Effective Approach to Continuing Patient Care' (June 2012) <[http://www.jointcommission.org/assets/1/18/hot topics transitions of care.pdf](http://www.jointcommission.org/assets/1/18/hot%20topics%20transitions%20of%20care.pdf)>

Kaiser Permanente, 'History of Kaiser Permanente' <<http://share.kaiserpermanente.org/article/history-of-kaiser-permanente/>>

— — 'Patient Safety' <<https://healthy.kaiserpermanente.org/health/care/consumer/center/>>

Liebman C and Hyman C, 'Medical Error Disclosure, Mediation Skills, and Malpractice Litigation: A Demonstration Project in Pennsylvania.' (2005) <[www.pewtrusts.org/our work report detail.aspx?id=24398](http://www.pewtrusts.org/our%20work%20report%20detail.aspx?id=24398)>

Lilley R, Samaranyaka A and Weiss H, *International Comparison of International Labour Organisation Published Occupational Fatal Injury Rates: How does New Zealand Compare Internationally? Commissioned Report for the Independent Taskforce on Workplace Health and Safety* (New Zealand: 15 March 2013) <<http://hstaskforce.govt.nz/documents/comparison-of-ilo-published-occupational-fatal-injury-rates.pdf>>

Lunge R and Martin A, *Report on Impact of Vermont Malpractice Reform Act 171 of 2012, Section 24e* (State of Vermont Agency of Administration, 29 August 2014.) <<http://www.leg.state.vt.us/reports/2014ExternalReports/302733.pdf>>

Medical Mediation Foundation, 'Evelina Resolution Project' <<http://www.medicalmediation.org.uk/evelina-resolution-project/>>

National Health Service, 'NRLS Quarterly Data Workbook' (22 October 2014) <<http://www.nrls.npsa.nhs.uk/resources/collections/quarterly-data-summaries/?entryid45=135304>>

— — 'Report a Patient Safety Incident' <<http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/>>

National Patient Safety Agency, 'National Framework for Reporting & Learning from Serious Incidents Requiring Investigation' <www.nrls.npsa.nhs.uk/patientsafetydirect>

— — 'Seven Steps to Patient Safety in General Practice.' <<http://www.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?allId.43743.>>

New York State Department of Health, 'Professional Misconduct and Physician Discipline' <<http://w3.health.state.ny.us/opmc/factions.nfs>>

NHS Commissioning Board, *Serious Incident Framework* (March 2013) <www.england.nhs.uk/wp-content/uploads/2013/03/sif-guide.doc>

NHS England, *Guide to Good Handling of Complaints for CCGs* (13 May 2013) 13 <<http://www.england.nhs.uk/wp-content/uploads/2012/03/20130513-Good-complaints-handling-for-CCGs-FINAL-version-for-publication.pdf>>

Ofri D, 'The Emotional Resistance to Admitting Error Cannot be Legislated Away' (KevinMD, 13 September 2010) <<http://www.kevinmd.com/blog/2010/09/emotional-resistance-admitting-error-legislated.html>>

PARI-MP. *Collective Agreement*. 1 July 2011 to 30 June 2014. [Art 17(b)]. <www.cdha.nshealth.ca/system/files/sites/834/documents/professional-association-residents-maritime-provinces.pdf>

PARIM and Winnipeg RHA. *Collective Agreement*. 1 July 2014 to 30 June 2018. [Art 13.02 (d)]. <<http://www.parim.org/wp-content/uploads/2015/06/PARIM-Collective-Agreement-2014-2018-OSB.pdf>>

- Paul M, 'Moving from Blame to Accountability' (2016) <<https://thesystemsthinker.com/moving-from-blame-to-accountability/>>
- Sebelius K, *Memorandum Decisions* (22 May 2014) <<http://www.citizen.org/documents/2211%20Enclosure.pdf>>
- Sorry Works!, 'Making Disclosure a Reality for Healthcare Organizations' <<http://www.sorryworks.net/apology-laws-cms-143>>
- — 'Book 2.0.' <<http://sorryworkssite.bondwaresite.com/what-is-the-problem-cms-44.>>
- WHO Collaborating Centre for Patient Safety Solutions (International Steering Committee), *Nine Patient Safety Solutions* (Geneva: World Health Organization, April 2007) <<http://www.ccforspatientsafety.org/Patient-Safety-Solutions/>>
- — 'Look-Alike, Sound-Alike Medication Names' (Geneva: World Health Organization, 2007) <<http://www.who.int/patientsafety/solutions/patientsafety/PS-Solution1.pdf>>
- WHO Regional Office for Europe, 'Patient Safety' (Denmark: World Health Organization, 2013) <<http://www.euro.who.int/en/health-topics/Health-systems/patient-safety/patient-safety>>
- World Health Organization, 'Clean Care is Safer Care' <<http://www.who.int/gpsc/en/>>
- — 'Education and Training' <<http://www.who.int/patientsafety/safesurgery/en/>>
- — 'Patient Safety Checklists' <<http://www.who.int/patientsafety/implementation/checklists/en/>>
- — 'Patient Safety: What are Patient Safety Solutions?' (World Health Organization, 2013) <http://www.who.int/patientsafety/implementation/solutions/patientsafety/solutions_explained/en/index.html>
- — 'Safe Surgery' <<http://www.who.int/patientsafety/safesurgery/en/>>
- — 'Vincristine Sulphate' <<http://www.who.int/patientsafety/activities/technical/vincristine/en/>>
- — *Glossary of Patient Safety Concepts and References* (January 2009) <http://www.who.int/patientsafety/taxonomy/icps_technical_annex2.pdf>

Newspaper Articles

Altman L and Grady D, 'Hospital Accreditor will Strictly Limit Hours of Residents' *New York Times* (New York, 13 June 2002) <<http://www.nytimes.com/2002/06/13/health/13RESI.html>>

Andrews L, 'I Was Juror No. 6, the Lone Dissenter in the Libby Zion Case' *New York Times* (New York, 21 February 1995) <<http://www.nytimes.com/1995/02/21/opinion/1-i-was-juror-no-6-the-lone-dissenter-in-the-libby-zion-case-219095.html>>

Boffey D, 'NHS Litigation Claims Double Under Coalition' *The Guardian* (London, 13 December 2014) <<http://www.theguardian.com/society/2014/dec/13/nhs-litigation-claims-double-under-coalition>>

Culliton G, 'HSE: EWTD Obligations "Unaffected"' *Irish Medical Times* (Dublin, 17 July 2015) <<http://www.imt.ie/news/2015/07/hse-ewtd-obligations-unaffected.html>>

Cullen P, 'New Law to Bring Private Hospitals Under Remit of HIQA' *Irish Times* (Dublin, 20 June 2017) <<https://www.irishtimes.com/news/health/new-law-to-bring-private-hospitals-under-remit-of-hiqa-1.3126568>>

Devlin M, 'Why the New Duty of Candour Could be Detrimental to the NHS' *The Guardian Professional* (London, 8 April 2014) <<http://www.theguardian.com/healthcare-network/2014/apr/08/duty-of-candour-nhs>>

Houston M, 'Drugs Mixture Poses Serious Risks to Health' *Irish Times* (Dublin, 12 April 2011) <<http://www.irishtimes.com/news/health/drugs-mixture-poses-serious-risks-to-health-1.570160>>

Lerner B, 'A Case That Shook Medicine' *Washington Post* (Washington DC, 28 November 2006) <<http://www.washingtonpost.com/wp-dyn/content/article/2006/11/24/AR2006112400985.html>>

— — ‘A Life-Changing Case for Doctors in Training’ *New York Times* (New York, 14 August 2011) <http://www.nytimes.com/2009/03/03/health/03zion.html?_r=0>

Letter to the Editor, ‘When Doctors Hide Medical Errors’ *New York Times* (New York, 9 September 2006) <http://www.nytimes.com/2006/09/09/opinion/09sat4.html?_r=0>

Lynch S, ‘State facing fines up to €100m after finding on doctors hours’ *Irish Times* (Dublin, 19 March 2015) <<http://www.irishtimes.com/news/health/state-facing-fines-up-to-100m-after-finding-on-doctors-hours-1.2145306>>

Madden D, ‘Saying Sorry for Medical Mistakes’ *Irish Examiner* (Cork, 03 February 2014) <<http://www.irishexaminer.com/ireland/saying-sorry-for-medical-mistakes-257419.html>>

Sack K, ‘Doctors Say “I’m Sorry” Before “See You in Court”’ *New York Times* (New York, 18 May 2008) <<http://www.nytimes.com/2008/05/18/us/18apology.html?fta=y>>

Sanford D, ‘Why Bristol is So Important’ *BBC News* (London) <<http://news.bbc.co.uk/1/hi/health/1443081.stm>>

Tickle L, ‘Why Mediation Training Should be Offered in Hospitals.’ *The Guardian Professional* (London, 10 December 2014) <<http://www.theguardian.com/healthcare-network/2013/dec/10/mediation-training-offered-hospitals>>

Woods A, ‘Medical Residents Needs Shorter Work Shifts, Many Say.’ *The Toronto Star* (Toronto; Montreal, 30 September 2012) <http://www.thestar.com/news/canada/2012/09/30/medical_residents_needs_shorter_work_shifts_many_say.html>