Developing a culture of safety: regulation or education?

To help, or at least to do no harm

by

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Abstract

A culture of safety is important for protecting patients from harm. Developing a culture of safety entails changing health professionals’ attitudes and behaviour from reticence and defensiveness about medical error and injury to openness and learning. It is not easy to change people’s attitudes, but both regulatory and educational means have proved effective in the past. This thesis assesses two potentially positive influences on the development of a culture of safety in New Zealand health care settings: New Zealand’s distinct medical regulatory structure and a patient safety educational tool. Instead of the more typical tort-based malpractice system, New Zealand has a no-fault accident compensation scheme, which bars suing for compensatory damages, and separate medical professional accountability processes. In 2005, ‘no-fault’ compensation reforms shifted the focus of the compensation scheme from identifying fault to rehabilitation and injury prevention.

This thesis focuses on professional attitudes and diverse evidence about patient safety in primary care. It is therefore not suitable for hypothesis testing but is amenable to a qualitative and discursive assessment of, firstly, the punitive nature of New Zealand’s medical regulatory system; secondly, changes in both punishment and medical professional accountability following the 2005 no-fault compensation reforms; thirdly, the patient safety data generated under the reformed compensation scheme; fourthly, whether these data can be analysed to identify learning for patient safety; and, fifthly, whether a UK safety culture educational tool could be adapted to the New Zealand general practice context and used to improve safety culture.

Findings suggest that because punishment lies in both the process and the penalty, New Zealand’s medical regulatory system may not be perceived as less punitive than a malpractice system. Punitive outcomes for doctors decreased following the no-fault reforms but patient complaints increased, making the environment not less punitive (subjectively) overall. The increase in patient complaints reflects increased demand for accountability, but following the no-fault reforms medical professional accountability decreased, as indicated by fewer doctors being referred by ACC to the Medical Council, fewer complaints being investigated by the Health and Disability Commissioner, and fewer doctors being held to account by either the performance review or disciplinary
processes. It is not possible to say from this analysis whether doctors are adequately held to account under New Zealand’s current medical regulatory structure.

More patient safety data are generated under the reformed compensation scheme, suggesting that the reforms have engendered openness about medical injury. These data are generated without relying on health professionals to report incidents and although they lack information about injury preventability, they may be analysed to identify lessons for patient safety. Analysis of treatment injury claims and ACC harm reports data confirms medication as the major threat to patient safety in primary care, but most medication events from this no-fault compensation perspective are not associated with error. This suggests that to improve patient safety in primary care, we may need to look beyond reducing medication error to reducing medication treatment overall (where possible). Provider feedback about ACC reported events yielded helpful suggestions for improving patient safety but also revealed a continuing tendency, in some organisations, to focus on individual blame.

The UK safety culture tool seemed to adapt well to the New Zealand general practice context and its use is supported by New Zealand’s medical regulatory structure. The tool educates practice personnel about the dimensions of patient safety culture and facilitates communication about patient safety issues.

The influence of New Zealand’s distinct medical regulatory structure on health care ethics and practice is not yet fully understood, but findings from this project suggest that the no-fault accident compensation scheme engenders openness about medical injury and creates novel opportunities for learning to improve patient safety.
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<tbody>
<tr>
<td>ACA</td>
<td>Accident Compensation Act 2001</td>
</tr>
<tr>
<td>ACC</td>
<td>Accident Compensation Corporation</td>
</tr>
<tr>
<td>ACE</td>
<td>angiotensin converting enzyme</td>
</tr>
<tr>
<td>CARM</td>
<td>Centre for Adverse Reactions to Medication</td>
</tr>
<tr>
<td>CME</td>
<td>continuing medical education</td>
</tr>
<tr>
<td>CPD</td>
<td>continuing professional development</td>
</tr>
<tr>
<td>CQI</td>
<td>continuous quality improvement</td>
</tr>
<tr>
<td>DGH</td>
<td>Director General of Health</td>
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<tr>
<td>DHB</td>
<td>District Health Board</td>
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<tr>
<td>DHS</td>
<td>drug hypersensitivity syndrome</td>
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<tr>
<td>DRESS</td>
<td>drug rash with eosinophilia and systemic symptoms</td>
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<tr>
<td>DVT</td>
<td>deep vein thrombosis</td>
</tr>
<tr>
<td>FNA</td>
<td>fine needle aspiration or biopsy</td>
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<tr>
<td>FTE</td>
<td>full time equivalent</td>
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<tr>
<td>GST</td>
<td>goods and services tax</td>
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<tr>
<td>HDC</td>
<td>Health and Disability Commissioner</td>
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<tr>
<td>HPCA</td>
<td>Health Practitioners Competence Assurance Act 2003</td>
</tr>
<tr>
<td>HPDT</td>
<td>Health Practitioners Disciplinary Tribunal</td>
</tr>
<tr>
<td>HQ&amp;SC</td>
<td>Health Quality and Safety Commission</td>
</tr>
<tr>
<td>IHI</td>
<td>Institute for Healthcare Improvement</td>
</tr>
<tr>
<td>ITP</td>
<td>idiopathic thrombocytopenic purpura</td>
</tr>
<tr>
<td>IUUD</td>
<td>intrauterine contraceptive device</td>
</tr>
<tr>
<td>MaPSaF</td>
<td>Manchester Patient Safety Framework</td>
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<td>MARC</td>
<td>Medicines Adverse Reactions Committee</td>
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<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>MCNZ</td>
<td>Medical Council of New Zealand</td>
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<tr>
<td>MENZ-B</td>
<td>meningococcal B vaccination</td>
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<tr>
<td>MOPS</td>
<td>Maintenance of professional standards programme</td>
</tr>
<tr>
<td>N/A</td>
<td>not available</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
</tr>
<tr>
<td>NSAID</td>
<td>non-steroidal anti-inflammatory drug</td>
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<td>NZMA</td>
<td>New Zealand Medical Association</td>
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<tr>
<td>NZ-MaPSaF</td>
<td>New Zealand version of MaPSaF</td>
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<tr>
<td>PCC</td>
<td>Professional Conduct Committee</td>
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<tr>
<td>PHO</td>
<td>Primary Health Organisation</td>
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<tr>
<td>QIC</td>
<td>Quality Improvement Committee</td>
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<tr>
<td>RNZCGP</td>
<td>Royal New Zealand College of General Practitioners</td>
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<tr>
<td>UK</td>
<td>United Kingdom</td>
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<td>US</td>
<td>United States of America</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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<td>years of age</td>
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1 INTRODUCTION

This thesis assesses two potentially positive influences on the development of a culture of safety in New Zealand health care settings with a particular focus on general practice. The two influences assessed are, firstly, New Zealand’s distinct medical regulatory framework and, secondly, an educational means of enhancing safety culture. The questions addressed are whether New Zealand’s medical regulatory structure, shaped by the law, supports the development of a culture of safety while maintaining medical professional accountability for harm; and whether a UK safety culture tool could be adapted to the New Zealand general practice context and used to measure and improve safety culture through educational means.

1.1 Why this topic

The harm caused by health care has been identified as one of the most important public health problems in the developed world.\textsuperscript{1-3} It is important to improve patient safety, not only because it is morally wrong to harm people when they seek help, but also because the harm caused by health care places an avoidable strain on limited health care resources.\textsuperscript{4}

The traditional professional approach to medical error and injury has involved a focus on professionalism: on individual competence and probity. But this approach has been found wanting. Despite doctors long having been committed to help, or at least to do no harm,\textsuperscript{5} each year many thousands of patients are harmed and even killed by the health care that is intended to help them. Despite the best of intentions, the same problems keep recurring: the wrong medicine is prescribed, the right medicine is prescribed in the wrong dose, the right medicine is prescribed in the right dose but the wrong medicine is dispensed, the wrong injection is given correctly, the right injection is given incorrectly, communication breaks down and patients fall between the cracks, a doctor misperceives a patient’s signs and symptoms and misses a cancer diagnosis, a test result is lost and a cancer diagnosis is delayed, a referral letter is lost and treatment is delayed, and so on. It is estimated that 75,000 hospitalisations occur in the United States (US) each year due to preventable adverse events in outpatient settings resulting in 4839 serious permanent injuries and 2587 deaths.\textsuperscript{6} A hospital records review in New Zealand identified that 13% of hospital
admissions involved an adverse event, each adding an average of over nine days to the expected hospital stay. Nearly one fifth of these adverse events arose outside the hospital.

Failures in health care usually arise from the complexity of systems, not from incompetent or purposefully harmful individuals. Since most patient harm is caused by highly trained professionals who are already trying to do the right thing, it is unlikely that the traditional professional approach of yet more training and ‘trying harder next time’ will solve the problem. A new approach is required.

1.2 A culture of safety

Today, many safety experts recommend a systems approach to safety: developing safe systems of care within a culture of safety. A culture of safety is about the “shared values, attitudes, perceptions, competencies and patterns of behaviour” that underlie how people perceive and act upon safety issues. Developing a culture of safety entails changing the attitudes and behaviour of health care providers: from fear and defensiveness about things that go wrong in health care, to an attitude of openness and a readiness to learn and make changes. The topic of how to promote a culture of safety in medicine has become a crucial one. While it is not easy to change peoples’ attitudes and behaviours, both legislative reform and educational means have proved effective tools in the past.

If doctors are to be open and share information about medical error and injury, at the very least they need to be supported rather than punished for doing so. A culture of safety is not likely to thrive in a punitive regulatory environment. Yet in many countries a punitive medical regulatory environment remains the norm. Most countries use a tort-based medical malpractice system, under which patients must sue their doctor for negligence, to gain compensation for medical injury. These fault-based systems have been criticised both for their failure to deter error and injury, and for their potential to drive information about error and injury underground, preventing learning, for fear of a malpractice suit.

New Zealand’s medical regulatory system, on the other hand, has been praised for its non-punitive, rehabilitative focus consistent with the requirements of a culture of safety:

New Zealand has a regulatory system that is rehabilitative, rather than punitive; one that seeks to protect patients yet support doctors. It includes a number of
features consistent with modern approaches to reducing error and improving safety.\textsuperscript{20}

Instead of a malpractice system, in New Zealand there is a no-fault accident compensation scheme, which provides compensation for medical injury and bars suing for compensatory damages, and there are separate medical professional accountability processes.

The overriding goals of New Zealand’s accident compensation scheme are to minimise both the impact and the incidence of injury.\textsuperscript{21} All types of injury are covered under the scheme including general injuries, work-related injuries, and treatment (or medical) injuries. The treatment injury account is the smallest of ACC’s accounts in terms of levy revenue and claims liability, accounting for 3.5\% of ACC’s total net levy income and 7.5\% of the scheme’s total claims liability.\textsuperscript{22} The treatment injury account covers the treatment injury costs of claimants both in paid employment and not in paid employment (the majority of treatment injury costs). The account is funded by a levy on earners and by government through money collected by general taxation.

While today the accident compensation scheme provides compensation for medical injury regardless of fault, this has not always been the case. The compensation of medical injury was previously an anomaly under New Zealand’s otherwise no-fault compensation scheme as injured patients could obtain compensation by proving “medical error” or fault on the part of the doctor. Medical error, in effect, equated to medical negligence. Further, as ACC had a duty to report all findings of medical error to the Medical Council of New Zealand, the compensation claims process could result in punitive repercussions for doctors.

Legislative reforms in 2005 waived the medical error eligibility criterion and extended eligibility to all injuries caused by treatment regardless of error or injury rarity and severity. ACC’s prior duty to report findings of medical error to the Medical Council was also waived and replaced with a new duty to report “risk of harm to the public” to the “authorities responsible for patient safety”.\textsuperscript{23} These reforms gave New Zealand’s compensation scheme some of the most liberal eligibility criteria in the world. The changes also brought the compensation of medical injury into line with the overall no-fault scheme, shifting the focus of the scheme away from identifying and apportioning blame to rehabilitation and injury prevention. The reforms were consistent with the
patient safety agenda and were “expected to bolster efforts to create a culture of learning”.

Given the power of legislative reform to drive change, it is not unreasonable to expect that a change in the law regulating how the authorities respond to information about medical error and injury could bring about a change in doctors’ attitudes and behaviour regarding the sharing of such information; it is not unreasonable to expect that New Zealand’s 2005 no-fault compensation reforms could foster the development of a culture of safety. This is what this thesis is testing. This thesis assesses the influence of New Zealand’s distinct medical regulatory system on the development of a culture of safety in New Zealand health care settings, with a particular focus on the 2005 no-fault accident compensation reforms.

This thesis also assesses the influence of the reforms on medical professional accountability for harm. A non-punitive environment might be important for patient safety, but medical professional accountability for harm is also important, and accountability requires that there be some blame, some punishment. It is not known whether, in the trade-off between accountability and learning, an acceptable balance has been struck under New Zealand’s current medical regulatory system. The influence, if any, of New Zealand’s distinct medical regulatory system on health care ethics and practice, on doctors’ attitudes and behaviour, remains unknown.

1.3 My approach

In this thesis, I assess the influence of New Zealand’s medical regulatory system on the development of a culture of safety using both theoretical (or discursive) and empirical (both quantitative and qualitative) research methods. Firstly, since a culture of safety is not likely to thrive in a punitive environment, I examine the nature of punishment and then, in light of this assessment, the punitive nature of New Zealand’s medical regulatory processes. Secondly, to discover whether New Zealand’s medical regulatory system is less punitive following the 2005 reforms while maintaining medical professional accountability, I compare the number of doctors brought to the attention of the authorities (referrals to the Medical Council, and patient complaints to the Health and Disability Commissioner (HDC)), and punitive outcomes for doctors (Medical Council performance
reviews, HDC investigations, and disciplinary proceedings) for the five years before and after the 2005 no-fault compensation reforms.

To discover whether openness about medical error and injury increased following the 2005 no-fault reforms, I assess whether more patient safety data are generated under the reformed compensation scheme. I count the new claims to ACC, ACC harm reports to the authorities, and provider responses to the Director General of Health’s requests for feedback about ACC reported events. To discover whether opportunities for learning increased following the 2005 reforms, I analyse the datasets generated under the reformed compensation scheme to describe the content of the datasets to identify threats to patient safety and potential solutions.

Finally, I assess an educational influence on safety culture by assessing whether a UK safety culture tool could be adapted to the New Zealand general practice context and used to measure and improve safety culture. While it might have been interesting to quantify and compare the safety culture in New Zealand general practices before and after the 2005 no-fault compensation reforms, this was not possible as I could not retrospectively assess culture before the reforms. It might also have been interesting to measure and compare the safety culture in different jurisdictions, but this was beyond the scope of this thesis and any existing scholarship in this area. Further, this would not help in trying to understand the influence of the regulatory structure on safety culture as the perceptions and experiences of practitioners are central to that exercise and there are many factors, in addition to the regulatory environment, that influence safety culture.

This thesis examines New Zealand’s medical regulatory environment overall, but some of the methods used to explore and develop the thesis use data for treatment delivered only in primary care and outpatient settings (treatment injury claims, ACC harm reports, and provider responses) or only the general practice context (UK safety culture tool). This is because my background is in general practice, and also because, despite most people receiving most of their health care in primary care settings, to date, primary care patient safety research remains relatively under-developed. This shortfall has been recognised in recent years and efforts are now being made to discover and remedy threats to patient safety in primary care.

Despite an increasing emphasis on the importance of teams in the health care setting, the focus in this thesis is on doctors (the regulatory system as it applies to doctors, and the
attitudes and behaviours of doctors). This is because I am a doctor and also because doctors still have a pivotal role to play in protecting patients from harm. While the focus is on doctors, I sometimes refer to ‘providers’ or ‘health practitioners’ or ‘health professionals’ to encompass all types of providers of health services. ‘Provider’ is also the term used in both the Accident Compensation Act (treatment providers) and the Health and Disability Commissioner Act (health and disability services providers). The Health Practitioners Competence Assurance Act refers to health practitioners, and the Privacy Act refers to health agencies. I use the word ‘doctor’ where I can, referring to ‘providers of medical treatment’ or ‘registered medical practitioners’ because “The words we use to explain our roles are powerful. They set expectations and shape behavior” and the ‘doctor’ better encapsulates the role.

1.4 Thesis framework

The first part of the thesis comprises chapters 1 to 3. This introduction forms chapter 1. Chapter 2 provides the background including an overview of the notion of safety culture, why a culture of safety is important, how a culture of safety might be developed; and an outline of New Zealand’s medical regulatory system and how it has been praised for its non-punitive approach. Chapter 3 provides an overview of my research and the reasons why the topic is not amenable to hypothesis testing methodology. I am interested in the documents that define the New Zealand patient safety culture for general practice and the relationship between them, data about patient safety, and perceptions and experiences as reflected in professional feedback about adverse events. The general framework is approached with the following questions in mind:

- Is New Zealand’s medical regulatory system thought to be less punitive than a tort-based system?
- Is New Zealand’s medical regulatory system less punitive following the 2005 no-fault reforms and has medical professional accountability for harm been maintained?
- Have more patient safety data been generated following the 2005 compensation reforms?
- Can these data be analysed to identify learning for patient safety?
• Can a UK safety culture tool be adapted and used in New Zealand general practices to measure and improve safety culture?

The second part of the thesis comprises chapters 4 to 10. Chapters 4 to 10 all have a similar structure, namely a brief introduction, methods, results, discussion and conclusions. In chapter 4, I examine the nature of punishment using moral and legal arguments and, informed by this assessment, consider the punitive nature of New Zealand’s regulatory processes. In chapter 5, I assess whether New Zealand’s medical regulatory system is less punitive following the 2005 no-fault compensation reforms and whether medical professional accountability was sacrificed under the no-fault reforms. Specifically, I calculate whether there has been a decrease in ACC referrals to the Medical Council, total referrals to the Medical Council, Medical Council performance reviews, patient complaints, HDC investigations, and disciplinary proceedings against doctors.

In chapter 6, I assess whether more patient safety data for learning are generated under the reformed compensation scheme, by counting new claims to ACC, ACC reports to the authorities, and provider responses to the Director General of Health’s requests for feedback about ACC reported events. In chapters 7 through 9, I assess whether these data can be analysed to identify learning for patient safety. In chapter 7, I examine the content of the primary care treatment injury claims dataset 2006 to 2010; in chapter 8, I appraise the content of the dataset of ACC harm reports to the Director General of Health for primary care from 2008 to 2010; and in chapter 9, I appraise the content of the dataset of primary care provider feedback to the Director General of Health about ACC reported events from 2008 to 2010.

In chapter 10, I assess an educational means of improving safety culture by adapting a UK safety culture tool (the Manchester Patient Safety Framework (MaPSaF)) to the New Zealand general practice context and testing the modified tool (NZ-MaPSaF) for acceptability and utility in 12 randomly selected Dunedin practices.

Chapter 11 forms the discussion. Here, I summarise the main findings of my research and drawing on the information generated I reflect on the influence of New Zealand’s medical regulatory structure on the development of a culture of safety and the uptake and use of an educational safety culture tool in general practice. I also discuss the implications of my findings and make recommendations for further research and policy.
2 BACKGROUND

This background chapter sets the scene for the two main questions addressed in this thesis: does New Zealand’s distinct medical regulatory framework support the development of a culture of safety while maintaining medical professional accountability for harm, and could a UK safety culture tool be adapted and used to measure and improve safety culture in New Zealand general practices.

In this chapter, I discuss the concept of patient safety, explain the traditional approach to patient safety and why it is no longer sufficient, outline the systems approach to safety and the importance of developing a culture of safety, and then I provide an overview of New Zealand’s distinct medical regulatory system and discuss how this system might support the development of a culture of safety.

2.1 Patient safety

To believe in medicine would be the height of folly, if not to believe in it were not greater folly still, for from this mass of errors there have emerged in the course of time many truths.

Proust

Doctors have long been concerned with trying ‘to help, or at least to do no harm’, but in recent years patient safety has been identified as one of the most important problems facing modern health systems.\textsuperscript{1-3}

Illich wrote about the harm caused by medical care in the 1970s. He described three types of iatrogenesis: clinical iatrogenesis, social iatrogenesis, and cultural iatrogenesis.\textsuperscript{46} Clinical iatrogenesis includes both the harm to individuals caused by medical treatment, such as adverse drug events and hospital acquired infections, and the harm to society, such as drug resistance. Social iatrogenesis is about the medicalisation of life where every deviation becomes a medical problem, rendering us all anxious and dependent on healthcare which we expect can help. Cultural iatrogenesis is about the war that medicine rages against suffering, which Illich argued undermines our ability to face our reality, accept pain and inevitable decline.\textsuperscript{46}

More recently, publication of the Institute of Medicine report \textit{To Err is Human} in 1999\textsuperscript{2} brought the problem of patient safety to the attention of the public and policy makers and
prompted new efforts to improve patient safety. The current patient safety debate, and the focus of this thesis, is largely confined to what Illich called clinical iatrogenesis, the harm to individuals.

The Institute of Medicine defined safety as “freedom from accidental injury”. The Institute defined an adverse event as an injury resulting from a medical intervention, a preventable adverse event as an injury caused by an error, and an error as “the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim”. Not all errors result in adverse events, and not all adverse events result from error.

There are other definitions of patient safety, including those provided by the Institute for Healthcare Improvement (IHI) and the World Health Organisation (WHO). The IHI defined medical harm as the:

unintended physical injury resulting from or contributed to by medical care (including the absence of indicated medical treatment), that requires additional monitoring, treatment or hospitalisation, or that results in death.

Under the IHI definition, medical harm includes both preventable injuries (usually associated with medical error) and injuries that may not be preventable. The notion of preventability is contestable. Preventability is perhaps best considered an issue of degree. Some researchers have concluded that about one third of adverse events could be “preventable to a significant degree”, while others have argued that up to 70% of adverse events are preventable. In New Zealand, the Accident Compensation Act’s definition of treatment injury does not depend upon preventability (or error). It is: “personal injury that is suffered by a person seeking treatment or receiving treatment and caused by treatment (s.32)”.

The WHO has defined a patient safety incident as an incident that “could have or did result in harm”, where harm implies impairment of structure or function of the body and/or any deleterious effect arising therefrom. The WHO has defined patient safety as the “reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum”, where “an acceptable minimum” refers to the collective notions of risk given current knowledge, resources available and the context in which care was delivered, weighed against the risk of non-treatment or other treatment.
The level or amount of ‘patient safety’ cannot be measured directly but a number of different datasets may be studied to assess patient safety, each providing a distinct window into patient safety. Researchers have studied datasets of malpractice claims, incident reports, patient complaints, competence and disciplinary data, and treatment injury compensation claims. Patient safety may also be assessed through records review, direct observation, provider and patient interviews or questionnaires such as the patient reported outcome measures, audit and practice assessment and accreditation processes, and by assessing the safety culture or safety climate in health care organisations. No one method of assessing patient safety provides a complete picture, and each may provide a different picture. Analyses of malpractice claims, for example, identify delay in cancer diagnosis as the most pressing problem in primary care; while analysis of the treatment injury compensation claims identifies medication as posing the greatest threat to patient safety in primary care. Patient questionnaires identify access to care as important whereas this dimension of care is missed in most other scopes of enquiry into patient safety.

Patient safety is about protecting patients from the harm caused by both acts of commission and acts of omission in health care. The ethical justification for improving patient safety and avoiding harm is twofold: utilitarian arguments dictate that medicine should strive to deliver the greatest good to the greatest number and not squander limited health resources, and the fiduciary nature of the doctor-patient relationship gives rise to a doctor’s moral obligation to help, or at least to do no harm. The harm caused by health care affects some patients directly and all patients indirectly by consuming scarce health resources.

2.2 The traditional approach to patient safety and why it is insufficient

The traditional professional approach to medical error and injury has involved a focus on professionalism; individual integrity and competence. However, the individual focus (on doctor integrity and competence) and the ethos of personal accountability and self-scrutiny are arguably anachronistic today when health systems are so complex and care is usually provided by teams. According to Gawande: "the volume and complexity of what [doctors] know has exceeded [their] individual ability to deliver its benefits correctly, safely, or reliably". In complex health systems, an individual doctor may have little control over the prevention of error and injury. Many of the factors contributing to patient
harm are outside the power of individual providers. These include, for example, working conditions, equipment and resources, communication between providers, organisational factors, patient factors (including elderly, deaf, stressed, poorly educated), task factors (such as distracting factors, demanding tasks), and team and social factors (hierarchical structure, communication barriers).

Failures usually arise from the complexity of systems, not from incompetent or purposefully harmful individuals. Despite individual best practice, patients can still be harmed. Research has identified that most harm is caused by highly trained, well-intentioned professionals, who are already trying to do the right thing. As most clinicians are already trying to do the right thing, the old strategy of punishing clinicians when things go wrong is unlikely to be effective. As most preventable harm is caused by flaws in the system rather than flaws in the individual, the traditional approach of blaming an individual and recommending further education and more intensive training is not likely to be effective. Doctors already have prolonged and intensive training; it is unlikely that yet more training and ‘trying harder next time’ will resolve the problem. The traditional professional approach to patient safety is no longer enough, if it ever was enough, and a new approach to patient safety is required.

The release of the Institute of Medicine report in 1999 highlighted the extent of medical injury and the failure of the traditional professional approach, prompting the search to find new ways to solve the problem and improve patient safety.

2.3 The systems approach to patient safety

Safety experts recommend a systems approach to patient safety. This approach has been adopted into New Zealand health policy. Under a systems approach, rather than urging doctors to take more care and punishing or re-educating them when things go wrong, the focus is on developing safe systems of care to help prevent mistakes and minimise harm. As the Institute of Medicine report stated:

> Preventing errors and improving safety for patients requires a systems approach in order to modify the conditions that contribute to errors ... lasting and broad-based safety improvements in an industry can be brought about through a systems approach.
The systems approach to safety arose from the safety improvements made in high-reliability organisations such as the aviation industry. This approach follows safety science and human factors expertise based on findings from Reason’s research on error.⁸

2.3.1 To err is human

According to Reason, failures occur due to a combination of active failures and latent conditions, as portrayed by Reason’s Swiss cheese model of accident causation.⁸ Active failures are unsafe acts or omissions committed by individuals whose actions have immediate adverse consequences and can occur through errors (e.g. picking up the wrong syringe, administering the wrong medication), risk taking or rule breaking. Latent conditions, on the other hand, are features of the existing system and lie hidden until exposed by events that lead to harm. Latent conditions may relate to working conditions and include heavy workloads, lack of training, a stressful environment and inadequate systems of communication.⁷¹ Systems of drug administration, for example, can be designed to either prevent or facilitate error.

Active failures, or errors, can be either errors of execution (correct action incorrectly executed) or errors of planning (incorrect intended action). Reason categorizes errors as slips (active errors), lapses (often omissions), and mistakes (choice of the wrong rule or misapplication of the right rule).⁸ Slips and lapses are errors of execution, while mistakes are errors of planning. Both active failures and latent conditions are influenced by the underlying safety culture of the organisation, or the level of commitment to safety.

The systems approach accepts that we are all fallible and that “it is impossible for anybody to avoid all mistakes, even avoidable ones.”⁷²

2.3.2 A culture of safety (it’s all about attitude)

According to Reason’s theory of error causation, finding fault and allocating blame has the effect not so much of deterring poor practice as of driving information about error underground and preventing learning.², ⁸, ⁶⁸, ⁷³ To enable learning, and to enable the right preventive systems to be put in place, information about the things that go wrong in health care is required. Doctors are likely to share this type of sensitive information only if they are supported rather than punished for doing so. Central to the systems approach, then, is a shift in focus from identifying fault for medical injury, towards a culture where
doctors share information about medical error and injury in a supportive, non-punitive environment.2, 8, 10, 13, 65, 67, 70, 73-80

Today, while the research is still quite weak, evidence is emerging of a link between culture and performance.76 A deficient safety culture was implicated in the Bristol paediatric heart surgery tragedy,81 and in the mid-Staffordshire scandal.82

In an organisation with a strong culture of safety, the focus is on sharing information and learning from past problems to improve patient safety, rather than seeking to identify and allocate blame when things go wrong.65, 83, 84 When an incident occurs, providers have trust to report incidents to enable learning and for changes to be made to protect patient safety.85 Aspects of a positive safety culture include communication based on mutual trust and openness, shared perceptions of the importance of safety, confidence in the efficacy of preventive safety measures, organisational learning, committed leadership and executive responsibility, and a ‘no-blame’ approach to incident reporting and analysis.

Safety culture, according to Reason, is made up of a reporting culture, where easy reporting of errors and near misses is possible; a just culture, where providers are encouraged and rewarded for reporting rather than punished, but where there is also a clear line for unacceptable behaviour; a flexible culture, which is less hierarchical; and a learning culture, where there is a willingness to learn from mistakes and to make reforms (p.195).68

A reporting culture entails openness about medical error and injury, and sharing information about medical error and injury beyond the profession so that management can implement processes to solve the problem of patient safety. To manage risk and to improve patient safety, managers need information. ‘Openness’ is not about naming (shaming and blaming) health professionals in public, and it is not about disclosing medical error and injury to patients, although openness may include disclosure to patients.

To enable openness, a non-punitive environment is required. The Institute of Medicine recommended that organisations move away from the individual blame approach and develop a systems approach:

Safety is an emergent property of systems. In order for this property to arise, health care organizations must develop a systems orientation to patient safety, rather than an orientation that finds and attaches blame to individuals (p.157).2
If doctors are to share information about medical error and injury, at the very least they need to be supported rather than punished for doing so. For a culture of safety to thrive, then, a non-punitive regulatory environment is required. Denigration and punishment for unintentional error is not only morally wrong, it also deters openness and participation in efforts to increase learning. The Institute of Medicine emphasised the necessary prerequisite of a non-punitive environment for establishing a culture of safety:

*It would be hard to overestimate the underlying, critical importance of developing such a culture of safety to any efforts that are made to reduce error. The most important barrier to improving patient safety is lack of awareness of the extent to which errors occur daily in all health care settings and organizations. This lack of awareness exists because the vast majority of errors are not reported, and they are not reported because personnel fear they will be punished. Health care organizations should establish non-punitive environments and systems for reporting errors and accidents within their organizations (p.157).*

2.4 Developing a culture of safety

Patient safety might be improved by strengthening the safety culture in health care organisations. Developing a culture of safety entails changing the attitudes of health care providers from reticence and hiding to openness about medical error and injury and a readiness to learn and change. Since attitudes influence actions, and actions can either cause or prevent patient safety incidents, patient safety might be improved by changing the attitudes and patterns of behaviour of health professionals.  

As long ago as 1983 McIntyre and Popper were calling for a new attitude in medicine. They called for a critical attitude to one’s own work and that of others; an attitude of candour about the things that go wrong, a willingness to listen to criticism and to admit that one has erred, and a readiness to learn and to change. They claimed that “*If errors are not to be repeated it is important that certain attitudes, deeply rooted in the profession, are overcome.*”

It is not easy to change people’s attitudes, and old habits die hard. The change to develop a critical attitude in medicine may not come naturally to doctors who are “*socialised to be collegial and non-confrontational*”. The following quote from Gabriel Garcia
Marquez’s book ‘Love in the time of cholera’ illustrates the difficulties faced by a young doctor coming up against the entrenched attitudes of his more experienced colleagues:

- He tried to impose the latest ideas at Misericordia Hospital, but this was not as easy as it had seemed in his youthful enthusiasm, for the antiquated house of health was stubborn in its attachment to atavistic superstitions, such as standing beds in pots of water to prevent disease from climbing up the legs, or requiring evening wear and chamois gloves in the operating room because it was taken for granted that elegance was an essential condition for asepsis. They could not tolerate the young newcomer's tasting a patient's urine to determine the presence of sugar, quoting Charcot and Trousseau as if they were his roommates, issuing severe warnings in class against the mortal risks of vaccines while maintaining a suspicious faith in the recent invention of suppositories. He was in conflict with everything: his renovating spirit, his maniacal sense of civic duty, his slow humour in a land of immortal pranksters—everything, in fact, that constituted his most estimable virtues provoked the resentment of his older colleagues and the sly jokes of the younger ones.88

There is no evidence yet to show that safety culture in hospitals can be effectively improved.89 But while it is not easy to change attitudes, both education and regulation have proved effective tools in the past.

2.4.1 Education

Educational means can be used to increase people’s understanding of an issue, which may lead to people changing their opinions and attitudes.

The notion of safety culture is still relatively new in the healthcare context and is alien to many frontline providers. The mention of ‘patient safety’ can conjure up images of blame and put providers on the defensive, and the term ‘patient safety incident’ may be poorly understood. Safety culture tools are designed to help improve understanding by frontline staff of patient safety issues. The Manchester Patient Safety Framework (MaPSaF), for example, was designed to “make the concept of safety culture accessible to frontline practice staff” and to “facilitate discussion” about safety issues.84 The MaPSaF has been endorsed for use in the UK as a team-based self-reflection and education exercise.90
Thus educational tools might be used to change people’s attitudes and to promote the development of a culture of safety in health care settings. Providers may be more willing to use such tools, to share information about medical error and injury and to learn and make changes, in a non-punitive medical regulatory structure. But, while a number of tools have been developed to measure and strengthen both safety culture and climate in hospital\textsuperscript{14, 91-100} and primary care settings internationally,\textsuperscript{40, 84, 101-104} no tools have been designed for use in New Zealand general practice.

2.4.2 Regulation

Legislative change has also proved an effective tool for changing peoples’ attitudes and behaviour. Consider, for example, the changes in attitude and behaviour that followed making wearing seatbelts compulsory. In the United Kingdom (UK) the legislative change was followed by an increase in seatbelt wearing and a 23\% drop in traffic accident fatalities (p.173).\textsuperscript{68} Today, most people consider wearing seatbelts the norm. The legislative change brought about a change in behaviour, and over time a change in attitude followed. Cognitive dissonance theory explains a change in attitude following a change in behaviour.\textsuperscript{105}

Judge Dame Silvia Cartwright, in her 1988 report of the Inquiry into the affairs at National Women’s, agreed that legislative change could be used to encourage change in attitudes and behaviours:

\textit{Past practices are not easily relinquished but there are ways of encouraging change by establishing new rules or stating existing ones in legislative form. New Zealanders have done this on many occasions in the past. The Human Rights Commission Act 1977, Status of Children Act 1969 and Race Relations Act 1971 are all examples} (p.172).\textsuperscript{106}

Legislative change can either require behaviour change, allowing a change in attitude to follow, or encourage change by removing the punitive deterrent to certain behaviours. An example of the latter is the legalisation of cremation, which first occurred in Wales. Once cremation was legal, people began to choose cremation over burial and eventually cremation became an acceptable way of disposing of the dead in Christian societies. Legislative change might be used to promote the development of a culture of safety either by requiring openness about medical error and injury (for example, compulsory reporting
of incidents), or by facilitating openness and removing the punitive deterrent to openness (for example, through a no-fault system of compensation for medical injury).

2.4.3 Praise for New Zealand’s medical regulatory system

New Zealand’s medical regulatory system, and the 2005 no-fault compensation reforms, has been praised for supporting efforts to improve patient safety:

*New Zealand has a regulatory system that is rehabilitative, rather than punitive; one that seeks to protect patients yet support doctors. It includes a number of features consistent with modern approaches to reducing error and improving safety.*

*The most significant feature of the New Zealand medico-legal system is its willingness to eschew criminal proceedings in favour of other channels which have as their focus rehabilitation not punishment and effectively learning from and addressing mistakes.*

*New Zealand medico-legal systems have as their main focus the improvement of patient safety as opposed to punishment and retribution.*

*The no-fault compensation reforms were expected “to bolster efforts to create a culture of learning”.*

When patients are injured, they not only want compensation and accountability, they also want some assurance the same thing will not happen to someone else in the future. The principal objectives of any medical regulatory system in the aftermath of an adverse event, then, should be:

*... restoration of the patient to a pre-event condition as nearly as may be, accountability for individual and institutional providers when they err, and learning – using today’s adverse outcome to help prevent tomorrow’s.*

For learning to take place, since doctors are likely to share information about medical error and injury only if they are supported rather than punished for doing so, a non-punitive regulatory environment is required. Yet in most countries, tort-based medical malpractice systems remain the norm. Under malpractice systems, patients must sue their doctor for negligence to obtain compensation for injury. Medical malpractice systems have been criticised, not only for their failure to deter error, but also for their potential to
drive information about error underground as doctors fear being sued.\textsuperscript{9, 17, 18, 68} New Zealand’s medical regulatory system, on the other hand, has been praised, not only for providing more equitable access to compensation for medical injury more efficiently than tort-based malpractice systems,\textsuperscript{111-116} but also for its non-punitive focus and patient safety potential.

In New Zealand, instead of a malpractice system, there is a no-fault accident compensation scheme to provide compensation for medical injury, which bars suing for compensatory damages for injuries covered under the scheme, and there are separate medical processes to hold doctors to account, including the Health and Disability Commissioner patient complaints system, the Medical Council’s competence and fitness to practise processes, and the Disciplinary Tribunal disciplinary process.

Under malpractice systems patients may be compensated only if they have suffered an injury caused by treatment that was negligent, but under New Zealand’s system patients may be compensated regardless of negligence and doctors may be held to account regardless of injury (under the patient complaints system). In New Zealand, compensation is determined by outcome (injury or no injury) regardless of process (negligence or not), while accountability is determined by process (negligence or not) regardless of outcome (injury or no injury). Arguably, it is appropriate that doctors are judged according to process of care rather than outcome given that the same treatment can have highly variable outcomes in different individuals.

I now describe New Zealand’s atypical medical regulatory system comprising the no-fault accident compensation scheme and separate accountability processes.

### 2.5 New Zealand’s no-fault accident compensation scheme

New Zealand’s accident compensation scheme is established under the Accident Compensation Act 2001\textsuperscript{21} and is administered by the Accident Compensation Corporation (ACC). The accident insurance scheme was introduced in 1974 following recommendations from the 1967 Woodhouse Report.\textsuperscript{21, 117, 118} The Woodhouse Report identified the founding principles of the scheme as community responsibility for those who suffer accidents, comprehensive entitlement regardless of how the accident happened, complete rehabilitation, real compensation for the duration of incapacity, and administrative efficiency.\textsuperscript{66} Underlying the scheme is a social contract between the people
and the government: the scheme provides assistance with treatment and rehabilitation costs for people suffering personal injury without the need to prove fault and, in exchange, people have given up the right to sue for damages.

The overriding goals of the accident compensation scheme are twofold and are set out in section 3 of the Accident Compensation Act:

- minimising both the overall incidence of injury in the community, and the impact of injury on the community.\(^{21}\)

The incidence of injury concerns safety. The Woodhouse Report stated that: “Safety – this needs no elaboration. Any modern compensation scheme must have a branch concerned solely with safety…”\(^{117}\) The Accident Compensation Act stipulates that a “primary function” of the ACC should be: “the promotion of measures to reduce the incidence and severity of personal injury” (s.3(a)). In fulfilment of this duty the Accident Compensation Corporation undertakes a variety of promotional activities for injuries relating to the workplace, sporting activities, and motor vehicles. ACC has processes to reduce the incidence of general injury. For example, ACC runs advertising campaigns and undertakes promotional work advising on how to prevent sporting injuries (such as doing warm ups and stretches), back injuries (how to look after your back), motor vehicle injuries (wearing seatbelts), and work related injuries (exercises and rests to prevent overuse injuries). ACC also provides free protective gear to prevent injuries, for example wrist guards for snowboarders.

The Accident Compensation Act also stipulates that the scheme’s overriding goal to minimise the overall incidence of injury in the community is to be achieved, in part, by ‘providing for a framework for the collection, co-ordination, and analysis of injury-related information’.\(^{21}\) Hence ACC collects and collates all claims data.

To date, ACC has played a limited role in reducing the incidence and severity of medical injury. The Accident Compensation Act does not specify precisely what the Corporation’s role should be with regard to minimising the incidence of medical injury and improving patient safety.

The Accident Compensation Act stipulates that the second of the goals, minimising the impact of injury, should be achieved through: “ensuring that … the Corporation’s primary focus should be on rehabilitation” (s.3(c)). In fulfilment of this goal, the
Corporation provides assistance with injury treatment and rehabilitation costs including the cost of doctors’ visits, home help, housekeeping, childcare and funerals. Entitlements include assistance with the cost of ambulance transport, treatment, urgent and elective surgery, prescription medications, dental care, hearing loss, and counselling; earnings related losses in weekly payments; lump sum payments for permanent disability; and in the case of death assistance with funeral costs, survivor’s grant and childcare costs.

Compensation is provided in the context of universal health care coverage in New Zealand where there is free public hospital care and subsidised primary health care for all residents. The scheme also provides weekly compensation for earnings related losses and, since 2002, lump sum payments for non-economic damages proportionate to the degree of impairment caused by injury.21

All types of personal injuries are covered under the accident compensation scheme including work-related injuries, sporting injuries, motor vehicle injuries, and medical injuries (including those caused by non-medical treatment providers such as nurses and dentists). The accident compensation scheme covers intentional injuries as well as unintentional injuries (or accidents), and also covers selected occupational losses such as industrial deafness. Because the scheme bars suing for compensatory damages for injuries covered under the scheme, there is no culture of suing doctors for damages in New Zealand.

There are various ACC accounts: the work account to cover work related injuries; the earner’s account to cover non-work injuries excluding motor vehicle injuries; the self-employed work account to cover work-related injuries to self-employed people and private domestic workers; the non-earners’ account to cover injuries to students, beneficiaries, retired people, and children; the motor vehicle account to cover injuries involving motor vehicle accidents on public roads; and the treatment injury account.

The medical injury account is the smallest of the ACC’s six accounts in terms of levy revenue and claims liability. Compensation for medical injury accounts for 3.5% of ACC’s total net levy income and 7.5% of the scheme’s total claims liability.22 The Treatment Injury Account derives its funds from allocations from both the Earners’ Account (in the case of earners) and the Non-Earners’ Account (in the case of non-earners).22 The earners account is funded directly by a levy on earners and is used to meet the treatment injury costs of claimants in paid employment; the non-earners account is
funded directly by government through money collected by general taxation and meets the treatment injury costs of claimants not in paid employment (the majority of treatment injury costs). About 55% is paid by New Zealanders in paid employment and the remaining 45% is paid by the government for those not in paid employment. Unlike typical liability insurance schemes, the compensation costs of treatment injury are spread via levies and taxes among both doctors and patients. Administrative costs absorb approximately 10% of the scheme’s expenditure, compared to 50-60% among malpractice systems abroad. New Zealand’s accident compensation scheme thus provides more equitable access to compensation more efficiently than tort-based malpractice systems.

2.5.1 The 2005 no-fault reforms

The Accident Compensation Act has been subject to frequent reform since it was first introduced in 1974 and until recently was called the Injury Prevention Rehabilitation and Compensation Act.

The most recent reforms regarding the compensation of medical injury, and the focus for this thesis, were in 2005: the so called ‘no-fault’ compensation reforms. These reforms shifted the focus of the scheme away from identifying fault, bringing the scheme into line with the patient safety agenda.

2.5.1.1 Eligibility for medical injury compensation

While medical injury has long been covered under the compensation scheme, the extent of cover for medical injury has varied. The eligibility criteria for compensable medical injury were not specifically defined in the legislation until 1992.

2.5.1.1.1 The prior anomaly of medical error

In 1992 a restrictive definition was introduced in response to growing concerns about the perceived unsustainable cost of medical injury compensation. In “Accident Compensation: A Fairer Scheme”, published in July 1991, the Minister of Labour stated:

In the present legislation there is no definition of either personal injury or accident. As a result, the boundaries of the scheme have been extended over the years to cover situations which most people would have difficulty in reconciling
with the common view of what an accident is. This, in turn, has led to cost increases.\textsuperscript{122}

Under the 1992 reforms, compensation for medical injury was restricted to medical misadventure, defined as either medical mishap or medical error.\textsuperscript{123} Medical mishap was defined as a “rare and severe adverse consequence” where rarity meant that the chance of the adverse consequence occurring was less than 1%, and severity meant resulting in death or hospitalisation for more than 14 days or significant disability lasting for more than 28 days.\textsuperscript{124} Medical error was defined as “the failure of a registered health professional to observe a standard of care and skill reasonably to be expected in the circumstances”. A mishap is an adverse event where a doctor has, generally speaking, acted appropriately and provided care of sufficient standard, while error, generally speaking, implied negligence or care below the expected standard.

Most medical misadventure claims were accepted as medical mishap (about 85%) and a minority as medical error (15%).\textsuperscript{112} In practice, it was not always easy for ACC personnel to differentiate between mishap and error except on the basis of the 1% incidence threshold. Rarity was usually determined to be a less than 1% chance of an event occurring. If a claim failed the rare and severe threshold, and could not be accepted as a mishap, then the claim was assessed to see if it passed the error or negligence threshold, thus whether the doctor had provided appropriate care. Medical error is where the doctor had not acted appropriately and had not provided care of a sufficient standard such that the care caused harm. Medical error, in effect, amounted to negligence. This is the only type of medical injury compensable under tort-based malpractice jurisdictions.

The 1992 definition restricted access to compensation for medical injury and kept the cost of medical injury compensation down, as intended. However, the restrictive eligibility criteria also meant many injured patients were ineligible for compensation. The restrictive cover was unfair to people suffering medical injury (as opposed to general injury), ran counter to the social contract nature of the scheme, and increased the possibility of litigation from patients not covered under the scheme. Although the scheme bars suing for damages, the inequity introduced by the scheme between the assistance provided for injury compared to illness,\textsuperscript{125} provides an impetus for those not covered under the scheme to sue for damages.
The 1992 restrictive medical injury eligibility criteria were not only unfair to patients, the error eligibility criterion created an anomaly under the otherwise no-fault compensation scheme. While compensation for general injury was provided irrespective of fault, patients suffering medical injury could obtain compensation by proving medical error or fault on the part of the doctor.

Further, as ACC was obliged to report all findings of medical error to the regulatory authorities, the compensation claims process could have punitive repercussions for doctors. Prior to 1998, ACC’s reporting obligation under the Act extended to all cases involving “negligence or inappropriate action”. This reporting duty was dropped in the Accident Insurance Act 1998, but reintroduced in a reduced capacity in 2001 when, under the Injury Prevention, Rehabilitation and Compensation Act 2001 s.284(2) as it was then called, ACC was required to report only accepted cases of medical error.

A finding of medical error implied wrong-doing and came with the possibility of disciplinary ramifications. This made some doctors reluctant to engage with the ACC and deterred participation in the compensation claims process. Doctors sometimes also contested findings of medical error to protect their reputation and avoid disciplinary proceedings, delaying compensation for injured patients and reducing the efficiency of the scheme. The restricted cover under the 1992 medical misadventure eligibility criteria reduced the cost of medical injury compensation, as intended, but also resulted in a substantial increase in common law cases in personal injury from those not covered under the scheme.

2.5.1.1.2 Treatment injury

Concern about the growing threat of litigation, the fact that compensation for medical injury was out of line with the overall no-fault compensation scheme, and growing awareness of the problem of patient safety following release of the Institute of Medicine report ‘To err is human’ in 1999, prompted revision of the medical injury eligibility criteria and eventual reform of the compensation legislation in 2005. Reason (expert on error causation and safety) was brought to New Zealand by the New Zealand Government to advise on the reform on New Zealand’s compensation legislation. According to Reason’s theory of error causation, litigation and the requirement to determine fault and prove negligence before compensation is awarded, has the effect not
so much of deterring error as of driving information about error underground and preventing learning.⁸,⁶⁸ To improve patient safety, it would be better to shift the focus away from identifying fault (medical error) and focus instead on supporting the development of a culture of openness and learning.²,¹⁰ The 2005 compensation reforms were in line with Reason’s advice.

Under the 2005 reforms, the restrictive medical error and rare and severe eligibility criteria were waived and eligibility was extended to include all personal injury caused by treatment irrespective of fault or injury severity.²⁵ Compensable medical injury was redefined as “treatment injury”:

_Treatment injury means personal injury that is suffered by a person seeking treatment or receiving treatment and caused by treatment; and not a necessary part, or ordinary consequence, of the treatment, taking into account all the circumstances of the treatment, including the person's underlying health condition at the time of the treatment; and the clinical knowledge at the time of the treatment (s.32).²¹_

‘Treatment’ is defined broadly and includes all aspects of diagnostic evaluation as well as treatment provided by all types of providers. To qualify for compensation, patients still have to demonstrate they have suffered a personal injury and that their injury was caused by treatment, but they no longer have to either suffer a rare and severe adverse event or prove medical error. Patients who experience a medical error may be eligible for compensation, but only if they suffer an injury. A patient who experiences a medical error, such as incorrect medication dispensing, but suffers no ill effect is not eligible for compensation.

What constitutes an “ordinary consequence of treatment” was not defined in the legislation and is therefore open to interpretation and challenge. An incision scar, for example, would likely be excluded from cover as it is a necessary part or ordinary consequence of an operation, but an incisional hernia is likely to be eligible for cover because it is neither a necessary nor ordinary consequence of surgery. Excluded from cover under the 2005 reforms are personal injuries which are “wholly or substantially caused by a person's underlying health condition”, “solely attributable to a resource allocation decision” or “a result of a person unreasonably withholding or delaying their consent to undergo treatment” (s.32).²¹
Examples of previously ineligible injuries that are covered under the reformed scheme include all minor injuries such as mild allergic reactions to medications, local inflammatory reactions following injections, and burns from cryotherapy; complications following surgery such as post-operative infections and blood loss; and delayed diagnoses. While previously a patient had to prove medical error to obtain compensation if their injury was not both rare and severe, under the reformed scheme there was no need to prove either rarity and severity or medical error.

The extended eligibility criteria created some of the most liberal eligibility criteria for the compensation of medical injury of any scheme in the world. The improved access to compensation was expected to curb the perceived growing threat of litigation from patients not covered under the scheme. All patients experiencing an injury in New Zealand caused by treatment, or lack of treatment, are now eligible for compensation irrespective of negligence or injury severity.

2.5.1.2 ACC reporting duties

Under the 2005 reforms, the Accident Compensation Corporation’s prior duty to report all findings of medical error to the regulatory authorities was also waived and a statutory requirement for ACC to report perceived “risk of harm to the public” to the authorities “responsible for patient safety” was instituted in its place:

If the Corporation believes, ... there is a risk of harm to the public, the Corporation must report the risk, and any other relevant information, to the authority responsible for patient safety in relation to the treatment that caused the personal injury (s.284).

The ACC may report to the authorities any claim that raises concerns about risk, regardless of whether the claim is accepted or the patient has suffered any actual injury. Risk of harm is not defined in the legislation. Risk, according to Douglas, is culturally defined; it is not only the chance of an event occurring but also the magnitude of the event’s consequences. In reality, all treatment poses a risk of harm. To quote one doctor: “Balancing risk, that is my life”. The important consideration for ACC is determining the threshold of risk of harm to report.


2.5.2 The compensation claims process

To lodge a claim for treatment injury compensation, a patient together with an ACC registered provider must complete both the general injury claim form (ACC45) and the treatment injury claim form (ACC2152) (Appendix 1). Both forms are then forwarded by the treatment provider to ACC for consideration.

A patient may lodge any type of claim with any registered ACC treatment provider, including the provider whose treatment caused an alleged treatment injury. The process to become a registered ACC treatment provider involves filing an application form and providing ACC with a copy of an Annual Practising Certificate. Any registered health practitioner can become an ACC treatment provider including doctors, nurses, physiotherapists, dentists, counsellors, occupational therapists, chiropractors, osteopaths, podiatrists, audiologists, midwives, pharmacists, medical radiation technologists, medical laboratory technologists, and speech therapists.

The general injury claim form collects information about the patient, the alleged injury, and the lodging provider. The declaration that is signed by the patient permits ACC access to relevant medical information about the claim. Only the treatment provider need sign the treatment injury claim form. The treatment injury claim form collects details about the patient, the condition that was being treated, all underlying health conditions, the alleged injury, how the injury affects the patient’s daily activities, the treatment that caused the injury, and the circumstances that led to the injury. It also collects details about the treatment provider including where the treatment was provided (for example “GP/medical centre”), the name of the treating facility “if relevant”, and the “name and occupation of the health professional(s) who provided or directed treatment”. These forms may both be analysed to identify learning to improve patient safety.

The completed and signed forms are sent to ACC where they are assessed, collated and stored. ACC assesses all claims for both eligibility for compensation (whether the patient has suffered an injury or not) and severity. ACC pays providers directly for assisting a patient to lodge a claim and for treatment on a fee for service basis. The standard fee that ACC pays a general practitioner for an injury consultation in 2012 is $32.80. There may be additional payment for additional services such as dressings, suturing, splinting fractures and surgery. The additional fees can run into the hundreds or even thousands of dollars (for example for some surgical operations). There may be little incentive for a
patient to lodge a treatment injury claim if the treatment they require is available free of charge through the public hospital system. On the other hand, there may be a strong incentive for a patient to lodge a claim for compensation if compensation enables them to bypass public hospital waiting lists by having treatment in the private system paid for by ACC (for example, such operations as hernia repairs and joint replacements).

2.5.2.1 ACC claims assessment

The ACC assesses all treatment injury claims for both acceptance (injury or no injury) and for potential consequences. Claims are assessed as having either minor, major, serious or sentinel potential consequences. A claim is assessed as minor if it results in minimal lessening of bodily function; major if it is “likely to result in short to medium term lessening of bodily function”; serious if it has the “potential to result in death or major permanent loss of function”; and sentinel if it has “resulted in death or major permanent loss of function”.

It is possible for a claim to be declined but to nevertheless be assessed as serious or sentinel if, for example, the patient suffers no injury but the claim still gives ACC reason for concern about a potential risk of harm to the public. A common example is a claim for medication dispensing or administration error where the patient suffers no adverse effect (no injury) but the claim nevertheless gives ACC concern that the same error may recur and injure a patient in the future.

ACC does not assess claims for injury preventability. Under the reformed compensation legislation, ACC is not required to make any determination on injury preventability because all treatment injuries are covered regardless of preventability.

2.5.2.2 ACC reporting

The ACC personnel must decide what “risk of harm to the public” to report to which authorities. Under current management, this duty has fallen on ACC’s Harm Panel. The Harm panel is made up of the Treatment Injury Medical Advisor, the Corporate Medical Advisor, the Corporate Legal Advisor, and a Team Manager from the treatment injury centre. The ACC Harm panel reviews all claims assessed as serious and sentinel and decides which of these to report and which authority to report them to. To date, the Harm panel has reported to the authorities all sentinel claims, and the serious claims with a
“high or moderate likelihood of recurrence”. If the panel believes there is a “serious and immediate risk of harm to the public”, the panel can make urgent notifications within 72 hours. ACC does not report the common events causing mainly minor injuries. The Harm panel makes its reports to the Director General of Health on a monthly basis in the form of ‘Harm Reports’.

2.5.2.2.1 ACC reporting to the Director General of Health

ACC forwards all harm reports to the Director General of Health. In addition, some reports are sent to other authorities, such as the registration authorities including the Medical Council, the Nursing Council, the Pharmacy Council, the Physiotherapy Board, the Dental Council of New Zealand and the Chiropractic Board; Medsafe; and the National Radiation Laboratory.

To date, the Director General of Health has responded to ACC harm reports by writing to the treating facility named in the report and requesting feedback about the ACC reported event, “to help draw out system lessons that can be generalised and shared with other providers”. Ministry of Health personnel have developed a form specifically for this purpose: the ACC Treatment Injury Event Notification Provider Feedback Form (Appendix 2). This four page form asks the provider for information about the event’s causal factors, any action the provider has taken to reduce the risk of similar future events, and any lessons that have been learnt. The treating facility has the option of completing and returning the form but cannot be compelled to do so because the Director General has no legal authority to take action in the event of non-completion.

2.5.2.2.2 ACC reporting to the Medical Council

Under the 2005 reforms, ACC retained the power to report doctors to the Medical Council, if the Corporation believes a doctor poses a risk of harm to the public (s.284). The compensation claims process thus retains a disciplinary threat to providers, albeit greatly reduced. Figure 1 shows that the Medical Council may also refer a patient to ACC, if the Medical Council believes a patient is potentially eligible for compensation.

Under current management, ACC generally reports a doctor to the Medical Council only if external peer review confirms an event raises concerns about the standard of care provided such that the doctor is considered to pose a risk of harm to the public by virtue
of providing care below expected professional standards and guidelines. According to the ACC Team Manager, ACC infrequently invokes its power to report a doctor to the Medical Council because the Corporation “aims to foster an environment of trust with the health sector”. The Corporation considers its “primary role in treatment injury is to provide cover and speedy rehabilitation” and not to be “an investigative agency in relation to harm reporting”. According to ACC personnel, the Corporation sees itself as “a safety net, not the safety net”.

ACC does not report events to the Health and Disability Commissioner, but the Health and Disability Commissioner may refer to ACC if the Commissioner considers a patient is potentially eligible for compensation. A patient may lodge both a claim for compensation with ACC and a separate complaint with the Health and Disability Commissioner.

Figure 1 outlines the relationship between New Zealand’s accident compensation scheme and medical professional accountability processes.
Figure 1: New Zealand's medical regulatory system: the accident compensation scheme and the medical professional accountability processes
2.5.2.3 Summary of reforms

The 2005 no-fault reforms, waiving both the medical error eligibility criteria and ACC’s duty to report error, shifted the focus of the compensation scheme away from identifying fault towards rehabilitation and prevention, consistent with the patient safety agenda. These changes have enabled doctors to share information about adverse outcomes with little fear of disciplinary repercussions; the changes were expected to foster provider cooperation with the compensation claims process and to “bolster efforts to create a culture of learning”. The changes also removed any need for doctors to contest findings to protect their reputation, and for this reason were expected to speed up claim decisions, lower administration costs, and expedite compensation for injured patients.

The effect of the reforms in practice is illustrated by the following example:

A patient had abdominal surgery in a private hospital paid for by his health insurance. After the surgery he had abdominal drains in situ for a couple of days. These drains are usually easily removed but on this occasion one of the drains had been inadvertently sewn to the abdominal wall and was impossible to extract. The patient had to be taken back to theatre for a second operation to have the drain untied and removed.

To get ACC to pay for the remedial surgery to remove the drain, the patient would previously have had to prove that inadvertently sewing the drain to the abdominal wall was either a medical error or a rare and severe adverse event. Since all findings of medical error were reported to the Medical Council, the surgeon may have been reluctant to promote the compensation option to the patient for fear of damaging his reputation or for fear of possible disciplinary ramifications.

However, under the reformed compensation scheme there is no punitive deterrent to the surgeon promoting the compensation option to the patient, and given the expanded eligibility criteria, the injury is likely to be covered.

2.5.2.4 Other no-fault compensation systems

New Zealand is not alone in using an alternative form of compensation to tort-based malpractice systems. The Nordic countries in particular use various forms of no-fault
compensation for medical injury. Most Nordic schemes have a more clearly defined role to play in patient safety than New Zealand’s scheme, including making better use of the claims data collected under the scheme and having greater interaction between the insurance body and the health sector.\textsuperscript{135}

The Swedish compensation system uses the avoidability test.\textsuperscript{136} In Sweden the national medical injury insurance company encourages root cause analysis of claims and regional hospitals receive regular updates of all claims originating in their hospitals. Representatives from the national medical insurance company visit hospitals on a regular basis to follow these claims and discuss the data and what can be done to avoid future similar injuries. Regular National Patient Safety conferences are also held. In Norway, there is a national strategy for improving quality and safety in health care and there are structures in place for reporting adverse drug events, but there does not appear to be any systems learning from claims data. In Finland, claims data are collected and analysed and systems exist for the reporting of adverse medication events and for the collection and analysis of patient safety indicators, but it is not clear whether institutional exchange and professional learning from such data takes place. In Denmark all claims are coded in line with international classification systems to enable research for injury prevention.\textsuperscript{135}

2.6 New Zealand’s medical professional accountability processes

I now provide an overview of New Zealand’s medical professional accountability processes.

Accountability, according to the New Zealand Oxford dictionary, is about “being required to account for one’s conduct; the concept that public organisations are accountable to the public, esp. to persons affected by their operations.”\textsuperscript{137} Accountability is similar to responsibility but while accountability implies being accountable for one’s actions, responsibility implies being morally accountable for one’s actions. Responsibility “implies ‘holding a formal role, duty or trust’ (Webster 1966). The responsibility relationship is between the agent and the intersubjectively defined goals and values that define the agent’s role and trust relationships.”\textsuperscript{138}

Accountability may be individual or collective, retrospective or prospective. Retrospective accountability is backward looking and is about holding someone to account for something (good or bad) that has happened. Retro
professional accountability processes are often concerned with outcome: doctors may be
blamed (or praised) depending on the outcome. While prospective responsibility can help
guide people to take an active role in plans for the future, retrospective responsibility
allows praise (or blame) for something good (or bad). Backward looking responsibility is
about culpability, assigning blame and holding someone responsible for past action and
present consequences. Thus a doctor is accountable to a patient when the doctor is
obliged to inform the patient about his/her (past or future) actions and decisions, to justify
these decisions, and to suffer punishment in the case of eventual misconduct.

Prospective accountability is forward-looking and is focused on the process, doing the
right thing. Prospective accountability attempts to ensure that the right thing happens
going forward, rather than looking back to assign blame. Prospective accountability is
linked to moral deliberation and extends beyond legal requirements. It is concerned with
the roles we occupy in society and the obligations these roles entail (as parents we have a
responsibility to provide for our children, as doctors we have an obligation to safeguard
the best interests of our patients and to work for the public good). Prospective
accountability is to do with setting and meeting goals.\(^{(139)}\) The focus for improving the
quality and safety of health care was traditionally on the integrity, competence and
decision-making of individual doctors, but in recent years there has been a shift to
incorporate systems thinking into ensuring quality outcomes, in-line with the patient
safety movement. Forward looking patient responsibility encourages preventive,
responsible behaviour and is about taking responsibility for present actions and future
consequences.

In New Zealand, as elsewhere, the dominant form of medical professional accountability
was originally the court of public opinion, mediated by the marketplace - reputation and
character were all important in establishing a relationship of trust.\(^{(140)}\) As Kundera wrote in
‘The unbearable lightness of being’, “A doctor (unlike a politician or an actor) is judged
only by his patients and immediate colleagues, that is, behind closed doors, man to
man.”\(^{(141)}\) From the 19th century medical professional accountability was provided through
professional codes of behaviour provided by the Medical Associations, the British
Medical Association in New Zealand and then, from 1976, the New Zealand Medical
Association. Later still, the Medical Council of New Zealand oversaw a system of
professional self-regulation. Doctors were judged on achieving standards for membership,
rather than on clinical outcomes standards. Malpractice law existed, but malpractice suits were rare until later in the twentieth century.

But as society has changed, so too has medical professional regulation and the medical professional accountability processes. As Douglas noted: “the type of society generates the type of accountability”. Further, while the contents of a doctor’s medical kit were once pretty harmless (and pretty useless), advances in the twentieth century led medicine to become more effective, more dangerous and more expensive. Ideas on professionalism and professional codes of ethics changed as views on what it meant to be a professional changed. These factors combined to create an increase in the demand for medical professional accountability and for external oversight of the medical profession. The emphasis in health care shifted from beneficence and paternalism to patient autonomy, from clinical autonomy to clinical accountability.

Today, New Zealand’s retrospective accountability processes include the Health and Disability Commissioner (HDC) patient complaints system, the Medical Council processes to deal with competence and fitness to practice concerns, and the medical professional disciplinary process. New Zealand’s prospective medical professional accountability processes include the New Zealand Medical Association’s Code of Ethics, which aim to guide professional behaviour; the Medical Council’s recertification processes to ensure all practising doctors are competent and fit to practise; the Royal New Zealand College of General Practitioners (RNZCGP) practice accreditation programme; and the guidelines developed by the (now defunct) New Zealand Guidelines Group. The ACC reporting duties, established to provide the authorities with the opportunity to remedy risk of harm to the public, could also be said to provide prospective accountability for harm.

2.6.1 The Health and Disability Commissioner patient complaints system

The HDC patient complaints system was established under the HDC Act in the mid-1990s. The system was established after medical professional self-regulation was exposed as inadequate during the ‘Inquiry into allegations concerning the treatment of cervical cancer at National Women's Hospital and into other related matters’, chaired by Judge Dame Silvia Cartwright.
2.6.1.1 The Cartwright Inquiry

The Cartwright Inquiry was prompted by an article published in Metro magazine in 1987. The Inquiry investigated the treatment provided by gynaecologist Professor Herb Green at National Women’s Hospital in Auckland to women with pre-cancerous cervical cell changes from the 1960s through to the early 1980s. Green believed (mistakenly), and was trying to demonstrate, that pre-cancerous cervical cell changes did not progress to full blown cancer and so women could safely avoid more radical treatment such as cone biopsy and hysterectomy. Green treated women by monitoring and taking regular cervical biopsy samples, for sometimes many years.

The Inquiry found that Green was mistaken in his belief, and that he did not alter this belief when evidence to the contrary became overwhelming but rather his practice continued essentially unchallenged. The Inquiry found that Green withheld conventional treatment from the women, without either their knowledge or consent and that, as a result of Green’s management (or research programme), about 40 women eventually developed invasive cancer and some women died from cervical cancer.

In her report, Dame Silvia found that “the problems ... were known but not confronted and resolved. Peer review failed and patients suffered”. Dame Silvia identified, among other factors, a “failure of peer review and consequential dominance of clinical freedom”, a collective abdication by medical staff of their collective ethical and professional responsibilities, and a “pervading atmosphere of defensiveness and even arrogance” (p.172). Dame Silvia found that medical self-regulation had failed to protect patients in National Women’s Hospital and she considered that New Zealand’s accident compensation system, which barred patients from suing doctors for damages, had possibly exacerbated the situation. In Dame Silvia’s 1988 report of the Inquiry, she found that “in a jurisdiction where the financial accountability of the medical profession has been distorted by no-fault Accident Compensation legislation, there needs to be a procedure which patients or their relations can follow if they want more information about their health problems” (p.172).

Dame Silvia recommended changes to increase awareness of patient rights and public scrutiny of the medical profession. She concluded that she could not “leave the encouragement of new habits and practices to the medical profession alone” (p.172). She noted that: “Past practices are not easily relinquished but there are ways of
encouraging change by establishing new rules or stating existing ones in legislative form. ... legislation will ... codify principles and be a rule against which ethical and medical standards can be measured (p.172).106 Dame Silvia therefore recommended an independent public body be established, headed by a Commissioner, to promote and protect patients’ rights, and that a complaints system be established to increase accountability for health professionals.106

The response of the medical profession to the findings of the Inquiry was mixed and sometimes confused. This is reflected in notes from an Extraordinary General Meeting of the Royal New Zealand College of Obstetricians and Gynaecologists, called to discuss the findings of the Inquiry in September 1988, as explained by Jones:

*Dr Gerald Duff proposed a motion ‘that the College express regret and sympathy for the women involved and abhorrence of the events’ reported in the Inquiry. The motion was lost because some College members felt an apology might have adverse medico-legal implications. Instead, a motion was passed ‘that a letter be sent to Professors Green and Bonham expressing hope for them and their families’ wellbeing’ (p.82).*"146

No doubt there are several reasons why Green’s treatment went unchecked for so many years, but underpinning these reasons was the culture present in the hospital at the time: the *shared attitudes, values, and beliefs* of the people who were there. Green was a senior figure in the hospital with a dominant, forthright personality (p.72).146 Younger colleagues had difficulty challenging his views. It was not the norm for colleagues and co-workers to challenge his authority or to question his clinical management and research ethics. Patients, also, were not in the habit of questioning their treatment and were usually in a state of semi-ignorance about their condition and treatment options. Furthermore, there was a paucity, or complete absence, of oversight and Green’s practice was never formally scrutinised, although his work had been authorised by the National Women’s medical committee, chaired by Professor Bonham, in 1966. Green was under no obligation to audit his treatment and publish the outcomes, and nor did he have to participate in any formal recertification processes. Professional self-regulation had resulted in a situation where nobody had the power to intervene and stop Green, and there were no mechanisms by which he could be called to account.
On Dame Silvia’s recommendation, the Health and Disability Commissioner Act 1994 and the Code of Health and Disability Services Consumers’ Rights 1996 were duly written and introduced. But while the Act and the Code of Rights arose directly out of the Cartwright Inquiry, the increase in external oversight of the medical profession was part of an international trend that has been coined the rise in the ‘audit society’. As part of the wave of regulatory reform, the Medical Practitioners Act was altered in 1995 to introduce lay representation on the Medical Council and to separate the registration and disciplinary functions. These changes were carried forward into the Health Practitioners Competence Assurance (HPCA) Act 2003. Under these regulatory changes in New Zealand, external scrutiny of the medical profession increased and medical professional self-regulation became a thing of the past.

2.6.1.2 The HDC Act and the Code of Health and Disability Services Consumers’ Rights

The Health and Disability Commissioner (HDC) Act 1994 provides for the establishment of the Health and Disability Commissioner (the Commissioner), the Code of Health and Disability Services Consumers’ Rights 1996 (the Code), and the patient complaints system. The purpose of the HDC Act is to:

... promote and protect the rights of health consumers and disability services consumers, and, to that end, to facilitate the fair, simple, speedy, and efficient resolution of complaints relating to infringements of those rights (s.6).

It is the role of the Commissioner to “promote and protect the rights” of patients as set out in the Code. The Code sets out ten consumer rights:

1) Right to be treated with respect
2) Right to freedom from discrimination, coercion, harassment, and exploitation
3) Right to dignity and independence
4) Right to services of an appropriate standard
5) Right to make an informed choice and give informed consent
6) Right to effective communication
7) Right to be fully informed
8) Right to support
9) Rights in respect of teaching or research
10) Right to complain.\textsuperscript{148}

2.6.1.2.1 The patient complaints process

A patient may lodge a complaint against a doctor with either the Medical Council or the Health and Disability Commissioner but, following recommendations from the Cull report,\textsuperscript{126} all complaints must now be referred to the Health and Disability Commissioner’s office in the first instance to avoid duplication of investigation processes.\textsuperscript{37} The Health and Disability Commissioner complaints process tends to focus on individual providers, but the Commissioner may also investigate and find organisations in breach of the Code of Consumers’ Rights.

The 2001 Cull report followed an Inquiry precipitated by repeated complaints and disciplinary proceedings against gynaecologist Dr Parry. The Parry case raised the issue of a possible failure of communication between the various agencies handling complaints and adverse medical events. In her 2001 report, Cull recommended providing greater powers to the Commissioner to triage complaints; better information sharing between agencies such as the ACC, the Health and Disability Commissioner office and the Medical Council; mandatory reporting by the ACC of medical error; the creation of a national claims database; and a one-stop-shop for complaints (the Health and Disability Commissioner’s office).

On receipt of a complaint, the Commissioner makes a preliminary assessment and decides what action to take. The Commissioner’s powers are limited to reporting, recommending and referring.\textsuperscript{149} Figure 2 shows that the Health and Disability Commissioner has a range of options available to him including taking no further action; referring the complaint to the doctor or to an advocate for possible remediation; referring the doctor to the Medical Council for possible performance review if, after preliminary assessment, “it appears from the complaint that the competence of a [doctor] or his or her fitness to practise or the appropriateness of his or her conduct may be in doubt” (HDC Act s.34(1)(a)); or investigating the complaint to determine whether there has been a breach of any of the rights set out in the Code.
The Health and Disability Commissioner does not have the capacity or funding to investigate every complaint. Like most statutory bodies, the HDC office has a limited budget and so must be selective. In investigating to determine whether there has been a breach of the Code, the Commissioner must investigate each complaint on its merits but may take a number of factors into consideration. The Commissioner cannot take trends of complaints against a particular doctor into account and nor can he assess a doctor’s overall competence. The Commissioner has stated that he expects high individual standards of care regardless of systems factors.\textsuperscript{150} Health professionals and patients have no right to appeal the Commissioner’s decisions on breaches of the Code of Rights.

It is possible for the Commissioner to find a breach of the Code of Rights even when the patient has not suffered any actual harm – inadequate disclosure of information, irrespective of the outcome of treatment, is in itself worthy of censure. Complaints are
judged according to process of care (breach of a Right) rather than outcome (injury), which may be appropriate given the high degree of uncertainty in medical practice and the highly variable outcomes the same treatment can have in different individuals. The Code endorses the ‘reasonable consumer’ standard of information disclosure as set in the 1992 Australian High Court case Rogers v Whittaker, and rejects the ‘reasonable provider’ or professional standard, as set in Bolam. For this reason, during the consent process, providers must decide what information the “reasonable consumer, in that consumer’s circumstances, would expect”.

If the Commissioner finds the Code has been breached, the Commissioner may refer the complaint to the Director of Proceedings for possible disciplinary action. The Director of Proceedings must assess each complaint independently and decide whether to bring a charge of professional misconduct against the doctor before the Health Practitioners Disciplinary Tribunal and/or the Human Rights Review Tribunal. In practice, the Commissioner has tended to reserve the disciplinary route for complaints raising ‘ethical’ issues, such as boundary transgressions and inappropriate relationships. The Commissioner refers few complaints to the Director of Proceedings each year, and the Director of Proceedings brings few charges of professional misconduct against doctors (five per year on average).

Complaints raising competence issues are more likely to be referred by the Commissioner to the Medical Council for possible performance review and rehabilitation. The previous Commissioner, Ron Paterson, has written that by referring complaints to the Medical Council, he aimed “not to censure, but instead to enable a comprehensive assessment of a doctor’s practice. The focus is learning, not lynching.” Commissioner Paterson stated he preferred the rehabilitative approach to the disciplinary approach, and titled his annual reports ‘Learning from complaints’. The HDC website homepage states its mission is “Resolution, protection, and learning.” The Commissioner has no power to order the Medical Council to conduct a performance review; Council must decide independently whether to conduct a review. In practice, only one in five of the Commissioner’s referrals to the Medical Council have proceeded to formal performance review.

If the Commissioner has “reason to believe that the practice of a health practitioner may pose a risk of harm to the public, the Commissioner must promptly notify the appropriate
authority” including the Director General of Health (DGH) and/or the Chief Ombudsman (HDC Act s.39(1)).

In summary, the HDC patient complaints system provides an avenue for patients to lodge complaints against health care providers to hold them to account. A complaint may result in the Health and Disability Commissioner conducting an investigation, making a finding that one or more of the Rights set out under the Code has been breached, and referring the provider to the registration authority for possible performance review or to the Director of Proceedings for possible disciplinary action. External scrutiny of the medical profession is provided through the patient complaints system.

2.6.2 The Medical Council’s competence assurance processes

As discussed in section 2.6, the medical profession was largely self-regulating under processes established by the Medical Council until the legislative reforms in the mid-1990s. While much has continued unchanged, today there is lay representation on both the Medical Council and the Health Practitioners Disciplinary Tribunal.

The Medical Council of New Zealand is established under the Health Practitioners Competence Assurance (HPCA) Act 2003. The principal purpose of the HPCA Act 2003 is to “protect the health and safety of the public by providing mechanisms to ensure that health practitioners are competent and fit to practise their professions” (s.3(1)). To this end, the Medical Council specifies scopes of practice (HPCA Act ss.8-13), sets the qualifications and experience required for registration (ss.15-25), issues annual practising certificates (ss.26-33), and approves continuing professional development programmes.

To practise medicine in New Zealand, all doctors must be registered with the Medical Council and hold a current annual practising certificate. The Medical Council may issue a doctor with an annual practising certificate if the doctor is working under supervision, in a collegial relationship, or upon satisfactory participation in an approved continuing professional development (CPD) programme. The Medical Council accepts satisfactory participation in an approved CPD programme as sufficient proof of on-going competence and fitness to practise for recertification purposes. Approved CPD programmes must include at least one clinical audit, a minimum of ten hours peer review, and a minimum of twenty hours continuing medical education per year. Approved CPD programmes in New Zealand include those developed by the professional colleges for their respective
vocationally registered members, such as the RNZCGP Maintenance of Professional Standards (MOPS) programme, and the Best Practice Advisory Centre (BPAC) Inpractice recertification programme for doctors on the general register.

If a doctor fails to satisfactorily participate in recertification processes and the Medical Council “has reason to believe that the practice of [a doctor] may pose a risk of harm to the public” then the Medical Council “must promptly” notify relevant agencies including employers, the ACC, the Director-General of Health, and the Health and Disability Commissioner (HPCA Act s.35).

2.6.2.1 Competence and fitness to practise referrals to MCNZ

The Medical Council may receive referrals raising concerns about a doctor’s competence or fitness to practise from a variety of sources, including the Colleges, colleagues, patients, the ACC, the Courts and the HDC. A concern about a doctor’s competence or fitness to practise may arise from a single serious event or significant departure from accepted standards, or a pattern of conduct over a period of time with declining standards and/or professional isolation.

Colleagues have a discretionary power to report a doctor they believe “may pose a risk of harm to the public by practising below the required standard of competence” (HPCAA s.34(1)), but the authorities have a duty to report. The Accident Compensation “must” report risk of harm (ACA s.284)\(^1\); employers “must promptly” notify the Medical Council if a doctor is dismissed or resigns “for reasons relating to competence” (HPCAA s.34(3)); the Health and Disability Commissioner “must promptly” notify the Medical Council if the Commissioner “has reason to believe that a health practitioner may pose a risk of harm to the public” (HPCAA s.34(2)); the Courts “must” refer to the Medical Council any doctor guilty of an “offence punishable by imprisonment for a term of 3 months or longer” (HPCAA 2003 s.67) (and Council “must” refer such notices to a Professional Conduct Committee); and the ACC must refer a doctor to the Medical Council if the Corporation considers the doctor “poses a risk of harm to the public”.

All referrals to the Medical Council are assessed in the first instance by the Medical Council’s Complaints Triage Team. This team is made up of Council’s Medical Advisers, Chair, Chief Executive, Registrar, Professional Standards Manager and Senior Policy Analyst. If the Medical Council has “reason to believe that the practice of the health
practitioner may pose a risk of harm to the public”, then Council “must promptly” notify ACC, the Director General of Health, the Health and Disability Commissioner, and the doctor’s employers (HPCAA s.35(1)). The doctor is given the opportunity to respond to the issues raised in the referral and then the Complaints Triage Team sits to consider the matter and to decide what action to take.

There are a variety of options open to the Complaints Triage team to respond to referrals including taking no further action; sending the matter to the full Council for referral to the Performance Assessment Committee (for possible performance assessment), the Health Committee, or the Professional Conduct Committee (for possible discipline); and /or ordering interim suspension from practice. In deciding whether to refer a doctor for a formal performance assessment (previously called a competence review), the Medical Council must take a number of factors into consideration. These include whether there is a pattern of conduct that may indicate wider competence issues, whether a particular incident was a serious departure from accepted standards, whether the doctor concerned has taken steps to prevent repeat occurrences by putting in place systems or undertaking education, and whether there were distracting factors such as health, financial or personal issues that were present at the time of the incident and if so whether such factors still exist. If there are health concerns, then the Medical Council may refer the doctor to the Health Committee instead of, or in addition to, ordering the doctor undergo a performance assessment.

2.6.2.2 Performance assessment and rehabilitation

The Medical Council’s power to take a rehabilitative response to referrals (as an alternative to discipline) was introduced in the mid-1990s and continues under section 36 of the HPCA Act. The purpose of a performance assessment is to consider whether a doctor’s “practice of the profession meets the required standard of competence” (HPCAA s.36(5)). The Medical Council website claims that a performance assessment is “designed to review and educate; it is not a disciplinary process”. Consistent with the aim to promote good quality practice rather than to identify blame, performance assessments are held in private and the results are usually kept confidential, although, if the Medical Council considers the doctor “may pose a risk of harm to the public” then Council “must promptly notify” ACC, the Director General of Health, the Health and Disability Commissioner, and the doctor’s employers (s.35(1)). The rehabilitative focus
is intended to foster referrals to the Medical Council so that Council can address problems and pre-empt harm to the public. It is considered unlikely that colleagues will report their peers if reporting results in punishment. Despite Council’s non-punitive intent, it is widely accepted that most doctors do find a recommendation that their performance be reviewed stressful and punishing. Few doctors would welcome a recommendation that their performance be assessed as an opportunity to improve.

Performance assessments are carried out by the Performance Assessment Committee which comprises two peers and one lay person. A performance assessment usually takes place at the doctor’s practice over one full day. The domains of competence the Committee considers include medical care, communication, collaboration, management, scholarship, and professionalism. The assessment process usually includes an interview, direct observation during consultation, and a case based oral examination. The doctor’s medical records are also usually reviewed and a rating from peers of the doctor is sought. Patients are not involved in the performance assessment process and nor are they informed of the outcome – even if they have initiated the performance review process. The Performance Assessment Committee scores the doctor ‘1’, ‘2’ or ‘3’ (where ‘1’ is adequate, ‘2’ means there are areas needing remediation, and ‘3’ means there are concerns) and sends a written report of its assessment to the Medical Council. The doctor is given the opportunity to comment on the report and then Council considers all the information and decides what action to take.

The options open to the Medical Council following a performance assessment include taking no further action; requiring the doctor to undertake an educational programme under supervision; imposing conditions on the doctor’s scope of practice; requiring the doctor sit an examination; requiring the doctor attend counselling; and/or suspending the doctor from practice until conditions are fulfilled.

The educational programmes the Medical Council may order are intended to address weaknesses in practice and are developed by the Council’s medical advisor in conjunction with the doctor. The Medical Council is required to inform the doctor’s employer and any person who works in association with the doctor if an educational programme is ordered. An educational programme may include a period of practical experience and/or training, examination or assessments, a specified course of instruction, working under supervision, and/or a review of the doctor’s clinical records. Educational
programmes usually run for 12 months and are supervised by educational and clinical supervisors appointed by Council who provide monthly feedback to Council. If an educational programme is unsuccessful the Medical Council may restrict the doctor’s scope of practice, impose conditions on the doctor’s annual practising certificate, or suspend the doctor’s registration.

2.6.2.3 Disciplinary charge

If a referral to the Medical Council raises concerns about a doctor’s *appropriateness of conduct or safety of practice*, the Complaints Triage Team may refer the issue to a Professional Conduct Committee (HPCAA s.68(3)) for possible discipline. The Professional Conduct Committee also usually deals with referrals from the Courts after convictions and other concerns of a more ethical nature such as relationship boundary transgressions. A Professional Conduct Committee comprises two peers and one lay member appointed by Council.

The Professional Conduct Committee’s role is to investigate referrals, determine whether the issue is related to competence or discipline, and to recommend an appropriate course of action. The options open to the Professional Conduct Committee include no further action, referral for conciliation, referral for counselling, referral for a performance review, referral to the Police, or bringing a charge of professional misconduct before the Health Practitioners Disciplinary Tribunal.

2.6.3 The Health Practitioners Disciplinary Tribunal

Disciplinary issues are no longer overseen by the Medical Council, following reform of the Medical Practitioner’s Act in the mid-1990s. Instead, an independent Health Practitioners Disciplinary Tribunal oversees disciplinary issues. The Tribunal is established under the HPCA Act 2003 “to hear and determine charges brought” against health practitioners (s.85(a)). The purpose of the disciplinary process is not to punish but to “protect the health and safety of members of the public” in line with the purpose of the HPCA Act (s.3).

A charge of professional misconduct against a doctor may be brought before the Health Practitioners Disciplinary Tribunal by either the Director of Proceedings (following a complaint to the Health and Disability Commissioner’s office) or a Professional Conduct
Committee (following a referral to the Medical Council). The grounds upon which the Tribunal may discipline a doctor are set out in section 100 of the HPCA Act. The Tribunal must be satisfied the doctor has been guilty of professional misconduct because of any act or omission that:

i. amounts to malpractice or negligence, or
ii. has brought or was likely to bring discredit to the profession, or
iii. has been convicted of an offence that reflects adversely on his or her fitness to practise, or
iv. has practised without a practising certificate, or
v. has practised outside his or her permitted scope of practice, or
vi. has failed to observe conditions imposed, or
vii. has breached an order of the Tribunal.

Malpractice and negligence are not defined in the HPCA Act. The threshold where negligence amounts to professional misconduct, whether it is ordinary or gross negligence, for example, is determined by the Disciplinary Tribunal and on appeal by the Courts. Justice Gendall provided some guidance on when negligence and malpractice amounted to professional misconduct in his 2000 decision:

Negligence or malpractice may or may not be sufficient to constitute professional misconduct and the guide must be standards applicable by competent, ethical and responsible practitioners and there must be behaviour which falls seriously short of that which is to be considered acceptable and not mere inadvertent error, or oversight or for that matter carelessness.

A Tribunal sitting to hear a charge of misconduct against a doctor consists of five members: three peers, a legal Chair or Deputy Chair, and one other lay member. The Tribunal considers the evidence placed before it and must reach a decision as to whether a charge of professional misconduct has been proven. The standard of proof required to establish a charge is the civil standard: on the balance of probabilities. The standard of proof is on a sliding scale with more serious allegations requiring a higher standard of proof nearer to the criminal burden of proof of ‘beyond reasonable doubt’. At a Tribunal hearing, the burden of proof lies with the prosecution (the Director of Proceedings or the Professional Conduct Committee) who presents his or her case first. All Tribunal hearings are held in public, pursuant to s.95 HPCA Act, unless there are grounds for the Tribunal
to order otherwise under ss.95 or 97. This is most commonly done to protect the privacy of the complainant with respect to charges of a sexual nature. The disciplinary process has been criticised for being an expensive, adversarial, and legalistic process that externalises responsibility for truth by selectively taking information out of the hands of involved parties (the patient and the doctor). \(^{139}\)

If the Tribunal finds the doctor guilty of professional misconduct, it may impose penalties as set out in section 101 of the HPCA Act. The penalties available to the Tribunal include ordering that the doctor be removed from the register, ordering the doctor be suspended for up to three years, imposing conditions on practice, censuring the doctor, imposing a fine up to $30,000, and imposing costs. \(^{37}\) Both the Medical Council and the Disciplinary Tribunal have the power to order interim suspension from practice and to impose conditions on practice (s.93(1)). The threshold for suspension is “reasonable grounds for believing that the health practitioner poses a risk of serious harm to the public by practising below the required standard of competence” (s.39). Tribunal decisions are published on the Tribunal’s website. \(^{159}\)

Having provided an overview of the main organisations providing retrospective accountability for harm in New Zealand, I now describe other organisations with a role to play in providing prospective accountability, ensuring the right thing happens going forward. Prospective accountability processes are relevant for developing a culture of safety because, although the processes seldom lead to punitive outcomes for doctors, the processes may punish by dint of their bureaucratic design.

2.6.4 The Royal New Zealand College of General Practitioners

The RNZCGP is “the professional body which provides training and on-going professional development for general practitioners ... and sets standards for general practice”. \(^{160}\) The RNZCGP has developed an approved CPD programme (the MOPS programme) for vocationally registered general practitioners to use for recertification purposes, \(^{161}\) and the Cornerstone practice accreditation programme. \(^{162}\)

2.6.4.1.1 The RNZCGP MOPS recertification programme

The Medical Council accepts satisfactory participation in MOPS as sufficient proof of a vocationally registered general practitioner’s on-going competence and fitness to practise
for recertification purposes. The MOPS programme runs on a three yearly cycle. Every three years participating vocationally registered general practitioners must take part in an endorsed level 5 resuscitation course, gain 30 continuous medical education (CME) credits, 30 continuous quality improvement (CQI) credits, and 30 peer review credits. According to the RNZCGP website, CME activities are ‘designed to enhance knowledge, skills, attitude and judgement’; CQI activities usually consist of clinical audits and involve assessment, implementation of change, and reassessment; and peer review activities usually involve such things as participation in a peer review group, a clinical performance visit, a Cornerstone practice accreditation visit, a teaching practice accreditation visit or other self-designed activity. The RNZCGP has endorsed the safety culture tool adapted as part of this doctoral study for CQI credits and made the tool available on its website for use by members.160

Under the MOPS programme, the recertification requirements are the same for part-time as for full-time doctors. Each year participating doctors must record and submit to the College a report detailing their Continuing Professional Development (CPD) activities. College audits some reports each year to check that the reports accurately reflect actual participation in continuing professional development activities.

2.6.4.1.2 The RNZCGP Cornerstone practice accreditation programme

Cornerstone may be used in general practices to assess a practice’s level of performance in relation to the standards set out in the Aiming for Excellence publication.162 Together, the Aiming for Excellence publication and the Cornerstone practice accreditation programme meet the requirements of the New Zealand Public Health and Disability Act 2000 for general practice, which focuses on the context doctors work in.163

The Cornerstone programme consists of self-assessment and external peer review processes designed to help practices meet minimum standards and implement ways to continuously improve. The Cornerstone programme is voluntary.

2.6.5 The New Zealand Medical Association

The New Zealand Medical Association (NZMA) has written a Code of Ethics, the most recent version published in 2008, “to guide the profession and protect patients” in return for “the trust patients and the community place in doctors”.164 The Code sets out 12
Principles of Ethical Behaviour that all doctors are to “acknowledge and accept”. Based on these 12 principles, the Code of Ethics makes sixty-seven “recommendations for professional behaviour” under the headings of Responsibilities to the patient, Professional responsibilities, Research, Teaching, Medicine and commerce, Medical responsibilities in prioritising care, and Medicine and industrial action.

The NZMA Code of Ethics provides recommendations and guidance only and is not legally enforceable. While it may provide some guidance concerning appropriate standards of care, it does not help to define negligence.

2.6.6 Other

There are many other organisations with a role to play in providing both prospective and retrospective medical professional accountability in New Zealand. Following is a brief overview.

The Privacy Commissioner oversees issues to do with health information privacy. The Privacy Act 1993 provides for the establishment of a Privacy Commissioner and for the Health Information Privacy Code. Central to the Privacy Act and the Health Information Privacy Code is the patient’s autonomy, similar to the Health and Disability Commissioner Act and Code of Rights. The Privacy Act gives the patient control over who should have access to their personal health information and imposes a duty of non-disclosure on health practitioners. The Health Information Privacy Code prescribes the rules which regulate the collection, storage, security and disclosure of, and access to, the health information of identifiable individuals held by health practitioners. The Code prescribes the situations where the “public interest considerations” or the “patient’s own safety” override the doctor’s duty to “protect the patient’s private information”. Rule 11 of the Code (Limits on Disclosure of Health Information) outlines the conditions under which a doctor is permitted to break patient privacy: if the doctor “believes on reasonable grounds that it is either not desirable or not practicable to obtain authorization” and “the disclosure of the information is necessary to prevent or lessen a serious and imminent threat to public health or public safety or the life or health of the individual concerned” then disclosure is “permitted only to the extent necessary for the particular purpose”. Patient complaints alleging a breach of health information privacy may be investigated by the Privacy Commissioner and may end up before the Human Rights
Review Tribunal which may award damages. Alleged harm from breach of privacy is not considered a personal injury under the Accident Compensation Act.

The Courts play only a minor role in New Zealand, in large part because the compensation scheme bars suing for compensatory damages for injuries covered under the scheme. Today the role of the Court is usually to determine disciplinary thresholds and penalties and compensation cases on appeal, although the courts can award pecuniary damages for injuries not covered under the compensation scheme or on appeal.

The early 1990s saw an increase in doctors facing criminal manslaughter charges, perhaps because of a perceived lack of accountability, but numbers decreased following the introduction of the Health and Disability Commissioner Act in 1994 which provided an alternative route for patients to hold doctors to account. Manslaughter cases further decreased following reforms in 1997 of the Crimes Act which lifted the threshold from civil, or ordinary, negligence to gross negligence (“a major departure from the standard of care expected of a reasonable person” s.150A). There have been very few cases of medical manslaughter subsequently and only one case since 2000 for a midwife’s management of a breech delivery where the baby died. This case in 2006 ended in a not guilty finding.

The Coroner of New Zealand may become involved in issues relevant to patient safety when a patient has died. The Coroner investigates the circumstances and causes of death and may make recommendations to improve public safety to prevent deaths in similar circumstances in the future. A new Coroners Act was introduced in 1988 and this gave the police and the coronial officers unprecedented access to information about deaths, which has contributed to a shift in public attitudes and increased demand for medical accountability.

The Health Quality & Safety Commission (HQ&SC) was established in 2010 to examine and improve the quality and safety of health and disability support services in New Zealand. The HQ&SC replaced the Quality Improvement Committee (QIC), although some QIC programmes continue under the HQ&SC, including the Safe Medication Management Programme, Infection Prevention and Control, Consumer Engagement and Reportable Events. The HQ&S Commission has initiated projects including the development of a medicines reconciliation process, the introduction of a nationally standardised medication chart, a focus on reducing hospital-acquired infections, and a
programme to improve consumer participation. Other priorities include learning from preventable adverse events and responding to prevent recurrence, review hospital satisfaction survey to improve the ways consumer feedback is obtained, and establishing baseline measures and indicators against which a quality health system can be evaluated. To date, both QIC and HQ&SC initiatives have focused largely on the care provided in hospitals and have had limited involvement in improving the quality and safety of primary health care.

There are various statutory bodies in New Zealand to approve, monitor and advise on medications. These include Medsafe, which is the unit of the Ministry of Health that regulates medicines and medical devices; the New Zealand Pharmacovigilance Centre and the Centre for Adverse Reactions Monitoring (CARM), which collect and evaluate reports of adverse reactions to medicines, vaccines, herbal products and dietary supplements; and the Medicines Advisory Committee (MARC), which provides advice to the Minister of Health on the safety of approved medicines. For example, MARC may recommend drug packaging be altered, or that Medsafe datasheets be updated, or that a drug be withdrawn from the market.

The Best Practice Advocacy Centre (BPAC) promotes healthcare interventions that are evidence based, cost effective and suitable for the New Zealand context. The Centre develops and distributes evidence-based resources to primary care providers to foster best practice, and has also developed an incident reporting system for primary care. However, as this reporting system, like others, relies on voluntary reporting, many events are inevitably missed.

The (recently disestablished) New Zealand Guidelines Group also promoted the use of evidence in practice and provided evidence-based guidance to help doctors make better decisions. Electronic practice management systems, such as MedTech, are now almost ubiquitous in New Zealand general practices. These systems include electronic prescribing, forcing functions, and e-alerts all designed to protect patient safety. Such systems provide an example of design based regulation.

2.7 Summary

In summary, the traditional professional approach to patient safety is insufficient to protect patients in complex modern health care systems. Patient safety experts
recommend improving patient safety by developing safe systems of care in a culture of safety. A culture of safety may be developed through both educational and regulatory means. New Zealand’s medical regulatory system has been praised for its non-punitive, rehabilitative focus consistent with the systems approach to patient safety.

Under New Zealand’s medical regulatory system, the public can have some assurance that doctors are competent and fit to practise, guided by moral codes of behaviour and evidence-based advice, and practising in a context that fosters the delivery of safe and effective health care. However, should these prospective accountability processes fail, patients may be compensated for medical injury under the no-fault accident compensation scheme and the public may hold doctors to account under the separate retrospective medical professional accountability processes.

Under such a regulatory structure, New Zealand may be better placed than most to develop a culture of safety. But there is no evidence yet to show that a culture of safety has thrived in New Zealand. Further, while New Zealand’s medical regulatory system is praised for its non-punitive focus, there is also no evidence yet to show that doctors perceive the system to be less punitive than a malpractice system or less punitive than it was before the 2005 no-fault compensation reforms. The influence, if any, of New Zealand’s distinct medical regulatory system and the no-fault compensation reforms on health care ethics and practice, and the development of a culture of safety, remains unknown.
3 METHODS

This thesis assesses two potentially positive influences on the development of a culture of safety in New Zealand health care settings, with a particular focus on the care delivered in general practice. The first influence assessed is New Zealand’s distinct medical regulatory framework. The question posed is whether New Zealand’s medical regulatory structure, shaped by the law, supports the development of a culture of safety (a culture of openness and learning) without sacrificing medical professional accountability for harm. The second influence assessed concerns education. The specific question posed is whether a UK safety culture tool could be adapted to the New Zealand general practice context and used as an educational means of enhancing safety culture, and whether New Zealand’s distinct regulatory environment supports this.

A culture of safety is not likely to thrive in a punitive regulatory environment. Therefore, in assessing the influence of New Zealand’s distinct medical regulatory system on the development of a culture of safety, I needed to understand whether New Zealand’s medical regulatory system is less punitive than the more typical medical malpractice system, and less punitive than it was before the 2005 no-fault reforms. I also needed to understand the influence of the 2005 no-fault compensation reforms on medical professional accountability for harm because, while a less-punitive environment might be important for patient safety, medical professional accountability is also important and accountability requires that there be some punishment. Since a culture of safety is about openness and learning, I also needed to understand whether the reforms have facilitated openness about medical error and injury, and created new opportunities for learning to improve patient safety.

Regarding the influence of New Zealand’s distinct medical regulatory framework on the development of a culture of safety, then, the specific research questions addressed in this thesis are:

1. Is New Zealand’s medical regulatory system less punitive than a malpractice system?
2. Is New Zealand’s medical regulatory system less punitive following the 2005 no-fault compensation reforms and has medical professional accountability been maintained?
3. Are more patient safety data generated under the reformed compensation scheme?
4. Can these data be analysed to identify lessons that can be fed back to doctors to improve patient safety?

Regarding an educational means of enhancing safety culture, the specific research question posed is:

5. Can a UK safety culture tool be adapted to the New Zealand general practice context and used to measure and improve safety culture through educational means, and does New Zealand’s regulatory environment assist this process?

A variety of methods are used to address these questions, including both theoretical and empirical methods (both qualitative and quantitative). An overview of the methods used follows, although the methods are described in greater detail in each respective chapter.

In chapter four, I use theoretical methods (both legal and moral arguments) to examine the nature of punishment and, in light of this assessment, the punitive nature of New Zealand’s medical regulatory processes.\(^42\)

In chapter five, I examine data for New Zealand’s medical professional accountability processes to discover both whether punitive outcomes for doctors decreased following the 2005 no-fault compensation reforms and whether fewer doctors overall were brought to the attention of the authorities.\(^43\) Specifically, for the five years before and after the 2005 reforms, I count the number of doctors referred by ACC to the Medical Council, the number of competence and fitness to practise referrals to the Medical Council overall, and the number of patient complaints to the Health and Disability Commissioner, and I calculate whether fewer doctors were brought to the attention of the authorities. I then assess the outcome of referrals to the Medical Council (performance review, disciplinary action), the outcome of complaints to the Health and Disability Commissioner (investigation, referral to the Medical Council for possible performance review, referral to the Professional Conduct Committee for possible disciplinary action), and the outcome of disciplinary proceedings for doctors before the Health Practitioners Disciplinary Tribunal, and calculate whether the authorities took a less punitive approach to matters.

In chapter six, to discover whether more patient safety data are generated under the reformed compensation scheme (and thus whether the reforms have facilitated openness about medical error and injury), for the five years before and after the 2005 no-fault
reforms, I count and compare the number of new claims to ACC for medical misadventure and treatment injury compensation; the number of claims referred by ACC to the authorities including the Directory General of Health, Medsafe, and the Medical Council; and the number of provider responses to the Director General of Health’s requests for feedback about ACC reported events.

To discover whether the data generated under the reformed compensation scheme can be analysed to identify learning for patient safety, I assess the data that has been generated to identify both threats to patient safety and potential solutions. It was beyond the scope of this thesis to analyse all data; I assess only those data generated in outpatient settings, excluding maternity care and treatment provided by specialist providers.

In chapter seven, I describe the content of the primary care treatment injury claims dataset for the first four years following the no-fault reform (2006 – 2009), identifying the type, frequency, severity and cause of injury in primary care settings. While it may have been revealing to have examined and compared the content of new claims data for medical misadventure claims prior to the 2005 reforms with treatment injury claims data generated after the reforms, this was not possible as I did not have access to the content of the medical misadventure claims data. In chapter eight, I analyse primary care ACC harm reports to the Director General of Health for 2008 to 2010 to identify the risk of harm to the public as identified and reported by ACC. In chapter nine, I analyse provider feedback to the Director General of Health for ACC reported primary care events 2008 – 2010. I analyse these data using the general inductive method to develop themes relating to event causal factors, remedial actions, and lessons learnt.

In chapter ten, to assess the influence of an educational means of enhancing safety culture, I test whether a UK safety culture tool could be adapted to the New Zealand general practice context and used to measure and improve safety culture. Specifically, I adapt the Manchester Patient Safety Framework (MaPSaF) to the New Zealand general practice context and test the adapted tool (NZ-MaPSaF) for acceptability and utility in twelve randomly selected Dunedin general practices.
4 NEW ZEALAND’S MEDICAL REGULATORY SYSTEM & PUNISHMENT

4.1 Introduction

In this chapter, I assess whether New Zealand is better placed than most to develop a culture of safety by dint of having a medical regulatory system that is perceived to be less punitive than the more typical tort-based medical malpractice system.\(^{42}\) I use theoretical methods, legal and moral arguments, rather than empirical methods to examine the nature of punishment and then, in light of this assessment, the punitive nature of New Zealand’s medical regulatory processes.

4.2 The nature of punishment

Punishment has particular relevance for patient safety. Patients who are harmed by health care rightly demand that those responsible be held to account and even punished,\(^{108, 109, 176}\) but because fear of punishment can drive information about error and adverse events underground, a non-punitive environment is recommended to safeguard learning and improvement.\(^{177}\) If doctors are to share information about medical error and injury to enable learning, at the very least they need to be supported rather than punished for doing so.

New Zealand’s medical regulatory system has been praised for its non-punitive focus:

- New Zealand has a regulatory system that is rehabilitative, rather than punitive; one that seeks to protect patients yet support doctors. It includes a number of features consistent with modern approaches to reducing error and improving safety.\(^ {20}\)

- ... the non-punitive, rehabilitative focus of New Zealand's medical regulatory system.\(^ {178}\)

- The most significant feature of the New Zealand medico-legal system is its willingness to eschew criminal proceedings in favour of other channels which have as their focus rehabilitation not punishment and effectively learning from and addressing mistakes.\(^ {107}\)

- New Zealand medico-legal systems have as their main focus the improvement of patient safety as opposed to punishment and retribution.\(^ {20}\)
In the words of Professor Peter Skegg, New Zealand remains one of the safest places in the world to practise medicine. 179

Given the absence of malpractice litigation in New Zealand, there is something rather self-indulgent in the response of the small minority of doctors who cry ‘Woe is me!’ 180

But while legal commentators have praised the non-punitive focus of New Zealand’s medical regulatory system, doctors have not always agreed. 181-183 The New Zealand Medical Association, for example, released this statement in 2002:

The New Zealand Medical Association is of the view that the medico-legal environment in New Zealand is a hostile one and constitutes a deterrent to good medical practice. 183

While the Medical Association may have since changed its opinion, it is possible that opposing views on the punitive nature of New Zealand’s medical regulatory system persist. This may be because of a different understanding of what constitutes punishment.

The New Zealand Oxford dictionary defines punishment as “the act or an instance of punishing; the condition of being punished; the loss or suffering inflicted in this.” 137

According to this definition, punishment lies in both that which is dealt (the act of punishing) and that which is felt (the condition of being punished, the suffering inflicted).

The idea that punishment can be more than the penalty imposed, or the punishment that is dealt, is not new. Malcolm Feeley studied cases going through the lower courts in the United States in the 1970s and published his landmark research in 1979 as ‘The process is the punishment’. 184 Feeley found that, for smaller scale crimes, the pre-trial process often served the function of punishing the defendant, and in many cases exceeded the post-trial sanction or sentence imposed by the judge. Feeley’s finding, that punishment was inflicted prior to a finding of guilt and by those other than the judge, went against the judicial ideal of a fair trial, a finding of guilt, and then the imposition of punishment. 185

Since punishment lies in both the process and the penalty, the suffering experienced during a regulatory process and any penalty ultimately imposed by an external body, the absence of malpractice litigation does not necessarily indicate a less punitive environment.
4.3 The punitive nature of New Zealand’s medical regulatory environment

To assess whether New Zealand’s regulatory system is less punitive than a malpractice system, it is necessary to assess only whether New Zealand’s no-fault compensation scheme and the patient complaints system combined are less punitive than the tort-based malpractice system. Both regulatory systems have medical professional competence assurance and disciplinary processes, and I assume these to be equally punitive.

Compared to doctors working in malpractice jurisdictions, doctors in New Zealand are rarely sued and are extremely unlikely to face a manslaughter charge, disciplinary proceedings, or even a review of their performance in their practising lifetime. Also, under New Zealand’s Health Practitioners Competence Assurance Act, information generated during quality assurance activities, such as audits, cannot be used to either prosecute or hold doctors to account (ss.52-62). This protection enables doctors to share information about adverse outcomes without fear to enable others to learn.

Doctors in New Zealand benefit from practising in such a regulatory environment by paying low indemnity premiums compared to doctors working in tort-based malpractice jurisdictions: New Zealand doctors pay around NZ$1200 (£670) per annum, compared to doctors in the United Kingdom who pay £4367 per year, and doctors in the US who can pay up to US$50,000 per year (if doing obstetrics). In New Zealand, everyone, not just doctors, contributes to the cost of medical injury compensation. As Dame Silvia said: “financial accountability of the medical profession has been distorted by no-fault Accident Compensation legislation”.

But, since the process can also be the punishment, the absence of suing and the paucity of imposed penalties may not reflect a less punitive environment. Regarding the development of a culture of safety, the determinative factor is how punitive doctors perceive the environment to be. If doctors perceive the regulatory environment to be punitive, they are less likely to share with the authorities information about medical error and injury. I now examine the punitive nature of New Zealand’s medical regulatory processes.

4.3.1 The accident compensation scheme

The compensation scheme is designed to assist injured patients. It is not designed to identify and apportion blame for injury. Following the 2005 no-fault reforms, the ACC is
not required to identify error for a patient to receive compensation, and ACC is no longer required to report findings of medical error to the Medical Council, although ACC may still report doctors to the Medical Council if ACC considers a doctor poses a ‘risk of harm to the public’. While the compensation claims process may yet result in punishment for doctors, few doctors would perceive the reformed compensation claims process to be punitive.

4.3.2 The HDC patient complaints system

The purpose of the HDC patient complaints process, under the Health and Disability Commissioner (HDC) Act, is to “promote and protect the rights of health consumers”\(^{36}\), not to punish doctors. Nevertheless, patient complaints may result in doctors being punished under the disciplinary process and, further, the complaints process itself can punish doctors regardless of the outcome (or even whether a complaint is investigated by the Commissioner).

4.3.2.1.1 The complaints process is the punishment

Commissioner Paterson has stated that complaints should be used for “learning not lynching”.\(^{150}\) The Health and Disability Commissioner publishes decisions on the HDC website and disseminates HDC investigation findings for learning. For example, the Commissioner has identified as problem areas poor follow-up of laboratory test results (see decisions 99HDC11494 and 01HDC087709) (p.153),\(^{190}\) poor communication and handover processes within larger practices, giving the wrong injection, and poor documentation.\(^{190}\) The patient complaints data can be used to provide a window into patient safety,\(^{54, 56}\) although the ability to learn from complaints data is constrained by few injured patients lodging complaints so that the complaints dataset captures only a small proportion of harm.\(^{191}\)

Despite the intention that complaints be used for learning not lynching, however, there is evidence to suggest that the effect on a doctor of a patient complaint is more lynching than learning.\(^{181, 182, 192}\) A complaint can make a doctor anxious, depressed, and angry, lose self-confidence, lose trust in patients, and have difficulty making decisions.\(^{181, 192, 193}\) For doctors, the complaints process can punish regardless of the outcome; and often the punishment felt is in excess of any sanction ultimately imposed.\(^{186, 194}\)
A complaint may even be more punishing than a malpractice claim. A patient complaint, unlike a claim under a tort-based malpractice system, is a demand for personal accountability, not a demand for monetary compensation. A complaint, being aimed at the person of the doctor, has the ability to hurt more than a malpractice claim, where the allegation of negligence is only the means to the end. Malpractice claims are usually dealt with by doctors’ indemnity insurers and/or employers. Doctors understand that malpractice claims are about the money and not a personal attack. Patient complaints, on the other hand, are a personal attack and may cause doctors to suffer, and be punished, regardless of outcome.\footnote[195]{195}

4.3.2.1.2 The complaints system might foster defensiveness

Further, the patient complaints system is widely felt, even by doctors who have not yet personally had a complaint against them.\footnote[182]{182} A general practitioner colleague (who had not received a complaint) described in an interview feeling as if the Commissioner was “always there, sitting on my shoulder watching”.\footnote[196]{196} The effect of the complaints system, then, is similar to that described by Foucault who likened modern disciplinary institutions to Bentham’s architectural panopticon with its ‘unequal gaze’ providing the constant possibility of observation. According to Foucault, modern disciplinary institutions can create \textit{docile bodies} that internalise discipline.\footnote[197,198]{197,198} While the internalised presence of the Commissioner may be a good thing to deter error and motivate doctors to improve their performance, since unobserved doctors may lower their level of care,\footnote[199]{199} there is no evidence yet to show that the complaints system has deterred poor practice or reduced error.\footnote[73,80,200,201]{73,80,200,201} It is highly unlikely, in any case, that the complaints system could ever deter error because most medical errors are unintentional and therefore not amenable to deterrence through rational reflection (p.89).\footnote[129]{129}

To assume the possibility of a complaint will motivate doctors to improve safety is to assume that doctors believe that the likelihood of a complaint is inversely related to the quality and safety of care. But most doctors do not believe this and with good reason. While complaints are not entirely arbitrary, they are not directed towards only those who pose a threat to patient safety and who therefore, perhaps, ought to suffer and be punished.\footnote[202]{202} While doctors may be motivated to do all they can to avoid a complaint, they don’t necessarily see making efforts to reduce error and improve patient safety as the best route to avoiding a complaint. Complaints do not necessarily reflect poor performance
and preventable harm (harm caused by error). Doctors may better avoid complaints by improving communication and fostering trust, than by improving patient safety. The internalised presence of the Commissioner and the fear of a complaint may not deter error so much as deter openness and learning and drive defensive practice. Fear provides a strong incentive for doctors to hide mistakes, making difficult the study of adverse events to identify learning. Patient safety research argues that systematic prevention will reduce error more effectively than deterrence through fear ever could. For this reason, safety experts advocate shifting the regulatory focus from identifying blame towards encouraging openness and learning. The punitive nature of the complaints system may counteract efforts to develop a culture of openness and learning, or safety, in New Zealand health care settings.

4.3.2.1.3 The complaints system might damage trust

In the 1990s, when the HDC patient complaints system was introduced, it was thought that increased external oversight would maintain or increase trust in the medical profession, but this is no longer such a firmly held belief. Today some bioethicists argue that the systems designed to ensure public accountability and increase trust simply deepen the mistrust they seek to remedy.

Trust is important. The therapeutic power of the doctor-patient relationship hinges on trust: "the less practitioners are trusted, the less likely it is for the benefits of specialised expertise to be realised." While external regulatory processes may help a patient to choose wisely when to place and withdraw trust, they do not do away with a patient’s need to trust. As Paul pointed out, external controls are “blunt instruments in particular cases and require a functioning internal morality to interpret them.” Ultimately, patients must still rely on doctors having a functioning internal morality; a commitment to professionalism, integrity, compassion, altruism, and continuous improvement. As philosopher Annette Baier explained:

Rights do define a sort of individualist tip of the iceberg of morality, one that takes no extra organisation to stay afloat, but that is because it is supported by the submerged floating mass of cooperatively discharged responsibilities and socially divided labour (p.241).
In conclusion, while the HDC patient complaints process is not designed to punish doctors and seldom results in penalties being imposed, and despite the Commissioner’s stated intention that complaints be used for learning not lynching, there is evidence to suggest that the effect of the complaints process is more lynching than learning. The complaints system may also foster defensiveness and damage trust. The patient complaints system is designed to promote and protect the rights of patients, but rights are not enough to protect patients – patients still rely on doctors having a functioning internal morality. It is important, then, that external regulatory processes such as the patient complaints system be designed to minimise their damage on the functioning of doctors’ internal morality and commitment to professionalism.

4.3.3 The medical professional competence and disciplinary processes

I assess the punitive nature of New Zealand’s medical professional competence and disciplinary processes to more fully describe the punitive nature of the regulatory environment in New Zealand.

4.3.3.1 The competence assurance processes

The purpose of the Medical Council’s competence assurance processes, under the HPCA Act, is to “protect the health and safety of the public” (s.3(1)), not to punish doctors. Consistent with this purpose, the competence assurance processes are designed to be rehabilitative rather than punitive. Even so, it is generally accepted that most doctors perceive the Medical Council’s performance review process to be punitive. The recertification programmes, established to ensure a doctor’s on-going competence and fitness to practise for recertification purposes, are designed to foster continuous improvement. However, by dint of their bureaucratic design, these programmes can be perceived as punitive; they can be demoralising and demotivating.

Recertification programmes have been accused of adding to the bureaucracy in practice and of measuring doctors against meaningless standards: “[Doctors] find they are required to dance to multiple tunes simultaneously, but are judged by how well they move to the tunes that are most discordant”. The constant inspection that is part of these programmes can demoralise and demotivate doctors. Doctors may not endure constant inspection, just as “a fragile plant may not endure inspection of its roots, even when they were, before inspection, quite healthy.” Michael Power, author of ‘The Audit
Society’, describes the contradictory nature of these programmes that not only fail to identify the ‘bad guys’ but also punish the good guys by dint of their bureaucratic demands:

The auditee is undoubtedly a complex being: simultaneously devious and depressed; she is skilled at games of compliance but exhausted and cynical about them too; she is nervous about the empty certificates of comfort that get produced but she also colludes in amplifying audit mandates in local settings; she fears the mediocrity of the auditors at the same time as she regrets their powerlessness to discipline the “really bad guys”; she loathes the time wasted in rituals of inspection but accepts that this is probably what “we deserve”; she sees the competent and excellent suffer as they attempt to deal with the demands of quality assurance at the same time as the incompetent and idle manage to escape its worst excesses; she hears the rhetoric of excellence in official documents but lives a reality of decline; she takes notes after meetings with colleagues “just in case” and has more filing cabinets now than she did a few years ago; she knows the past was far from being a golden age but despairs of the iron cage of auditing; she knows public accountability and stakeholder dialogue are good things but wonders why, after all her years of training, she is not trusted as an expert any more.215

Competence assurance processes have the potential to overwhelm a doctor’s professional commitment to his or her patient and stifle professionalism, the patient’s ultimate protector. As Virginia Sharpe warned:

The structure of ‘accountability’ orients an agent’s behaviour to the rules established by an oversight body. The accountability relationship is, thus, one of agent to overseer. The risk of such a relationship is that both agent and overseer will, in their attention to each other, lose sight of the original sphere of action.138

The processes established to assure competence should be designed to foster, or to at least be compatible with, professionalism, then. Freidson, who was one of the first to study and explain professionalism,216 considered the type of accountability “most compatible with professionalism [was] collegiate rather than hierarchical ... and loosely denoted by the term peer review” (p.196).217 Successful peer review entails being ‘assessed by those who are both sufficiently informed to judge what they assess and sufficiently independent to
judge it objectively’. Peer review, if it is to be effective and to identify strengths and weaknesses and determine competence, must be judgmental and demanding while also being supportive; it must also overcome self-protecting etiquette. While New Zealand recertification programmes include elements of peer review, these processes will need to be strengthened if they are to provide satisfactory accountability. It is to be hoped that the proposed practice visits are up to the task.

Together the HDC patient complaints process and the Medical Council competence assurance processes can damage the very thing they were designed to protect: trust and the doctor-patient relationship. Doctors need to demonstrate they are trustworthy, and this is what these processes set out to achieve, but the processes should seek to demonstrate that doctors are trustworthy without damaging trust and the doctor-patient relationship; the processes should seek to regulate medical practice without damaging medical practice.

4.3.3.2 The disciplinary process

Under the HPCA Act, the purpose of the disciplinary process is to protect the health and safety of the public, not to punish doctors. Nevertheless, it is accepted that the disciplinary process is punitive. The Health Practitioners Disciplinary Tribunal has the power to impose penalties, and thus to punish doctors, when a charge of professional misconduct is made out. The penalties available to the Tribunal include ordering that a doctor’s name be removed from the register, or ordering that a doctor be suspended for up to three years, imposing conditions on practice, censuring the doctor, fining the doctor up to $30,000, and imposing costs (s.101).

New Zealand’s medical regulatory system is not entirely without purposeful punishment, then, although there are very few disciplinary proceedings against doctors each year (as shown in section 5.3.2.5). In summary, the Medical Council performance review process was never intended to punish doctors, but it is generally perceived to be punitive; the processes developed to ensure all practising doctors are competent and fit to practice can demoralise and demotivate doctors by dint of their bureaucratic design; and the disciplinary process is punitive.
4.3.4 Other

4.3.4.1 Public inquiries

Another avenue of punishment for doctors in New Zealand stems from public inquiries. There have been several public inquiries into health care in New Zealand in recent years. For example, the Cartwright Inquiry, the Gisborne cervical screening inquiry, and the Southland mental health inquiry following the Burton case. While most public inquiries have called for openness to improve safety, they have themselves focused on identifying an individual to publicly name, shame, and blame: Professor Green in the Cartwright inquiry, Dr Bottrill in the Gisborne inquiry, and the psychiatrists Tom O'Flynn and Peter Fisher in the Southland mental health inquiry. Similarly, in the UK the Bristol Inquiry found fear to be “the enemy of safety” and yet identified an individual to blame.

The impact of these inquiries is widely felt throughout the medical profession. Given the traditional focus on pinning the blame on an individual, it is not surprising that doctors might be slow to believe the no-blame openness and learning rhetoric and to hold firm to their belief that New Zealand’s regulatory environment is not as non-punitive as some have claimed it to be.

In this assessment, then, New Zealand’s medical regulatory system may not be less punitive than a malpractice system. While New Zealand’s no-fault compensation scheme is surely less punitive than a tort-based malpractice system, a patient complaint to the Health and Disability Commissioner may be perceived by doctors to be more punitive than a malpractice claim.

4.3.4.2 Managerialism: redefining uncertainty and introducing blame

In recent years there has been a managerial takeover of health care; a move towards “managerial control over professional norms, values and practices”. Management gaze at the quality of medical work creating what Waring has called “a bureaucratic panopticon of surveillance.”

Under the managerial approach, what doctors have previously understood to be medical uncertainty is redefined as quantifiable clinical risk on the assumption that uncertainty (or risk) can be managed and reduced. The emphasis is shifted from coping in uncertainty, to
quantifying and reducing risk. Under this approach, there are no accidents any more, only manageable risks; there is no bad luck any more, only bad management - which is blameworthy.

Redefining uncertainty as quantifiable risk is an extension of scientism, thinking of the world as orderly and explicable, even when it is not. Redefining uncertainty as risk creates the illusion of control and raises expectations that risk can be managed. This way of understanding risk (and the world) can lead to a culture of blame: if the risk is not managed, there will be calls for someone to be held to account.\textsuperscript{223} As Douglas points out, the process of identifying risk is central to the process of accountability and allocating blame when things going wrong.\textsuperscript{224}

The managerial redefinition of uncertainty as quantifiable risk is problematic, then, because it introduces blame where previously blame did not exist; it contributes to the punitive nature of the medical regulatory environment.

\textbf{4.3.4.2.1 What is risk / error?}

There is the additional problem that this approach assumes there is general agreement as to what constitutes risk (or error) and that risk is objective and measurable. But there may be different opinions as to what constitutes error. For example, Elstein found that about 15\% of the diagnoses made by doctors were wrong,\textsuperscript{225} and this figure was corroborated by Berner.\textsuperscript{226} But when Ely asked doctors to recall their most memorable errors, most doctors struggled to remember many.\textsuperscript{31} This suggests that doctors were either unaware of their diagnostic failures, or that they did not consider a diagnostic error to be an error.

Douglas, who has made the study of risk her life's work, argues that risk is culturally determined and therefore contestable. Douglas claims that risk is not only the probability of an event but also the probable magnitude of its outcome.\textsuperscript{131, 224} She argues that whether or not a risk is acceptable depends upon the value set on the outcome; probability alone provides a poor guide to action.

While doctors work with probabilities, they treat individuals; they apply population based information to individuals. There is a difficulty in applying probabilities to individuals. For example, while there may be a 5\% risk that your pain is a heart attack, you either are (100\%) or are not (0\%) having a heart attack; a woman either is or is not pregnant, a woman cannot be a little bit pregnant. This means that inevitably there will be diagnostic
error. If the risk that patients presenting with abdominal pain are having a heart attack is 5%, then doctors would be morally right to make the most likely (95%) not-heart attack diagnosis. Doctors would be wrong, however, 5% of the time. In 5% of cases, the most likely and most reasonable diagnosis (95% not-heart attack), rather than the correct diagnosis (5% heart attack), would be made. In 5% of cases, there would be a diagnostic error.

Missing a diagnosis is frequently suggested by doctors as the worst error in practice and the most feared. Diagnostic failures usually arise from the nature of the diagnostic process, which is one of perception and trying to make sense of a myriad of information. While a novice might use the more laborious and time consuming analytical reasoning method to reach a diagnosis or answer, experienced doctors use heuristics (rapid pattern recognition processes). The difference between these two approaches is illustrated by the approach to finding the answer to 15x16=? The first time one might reach the answer by using analytical reasoning (6 x 5 = 30, put down the 0, carry the 3, 6 x 1 … = 240), but when the same problem is presented a second time (15x16=?) the answer is reached by an entirely different and more efficient pattern recognition process (240!).

There is a price to pay for the efficiency of the rapid pattern recognition process: predictable error. The pattern recognition process saves the expert time and gives the correct answer or diagnosis most of the time, but not all of the time. For example, flu-like symptoms will usually be the flu, but occasionally flu-like symptoms will be meningitis. There is a trade-off between efficiency and accuracy. As Reason says: “Our propensity for certain types of error is the price we pay for the brain’s remarkable ability to think and act intuitively.”

Missed diagnoses are usually misperceptions; they arise not so much from a lack of knowledge but from a misperception, seeing or making sense of the information in the wrong way. For this reason, the professional approach of ‘trying harder next time’ and retraining or re-educating the errant doctor is likely to be futile. Most doctors are already on the alert for meningitis, but even so meningitis continues to be missed. The systems approach, using guidelines and protocols, may also be futile to reduce diagnostic failures because if the doctor does not perceive the problem to be meningitis, the doctor is
not going to follow the meningitis protocol; if the doctor perceives the problem to be sinusitis, the doctor is not going to follow the headache protocol.

But, even though the most likely and most reasonable diagnosis is wrong, should it be called an error? A diagnosis only becomes an error with the benefit of hindsight. As a doctor in Paget’s study commented: “the errors are errors now, but they weren’t errors then”.230 Managerial orthodoxy sees no role for culture in determining what is to count as risk (or error), although different understandings of risk may undermine patient safety initiatives such as reporting systems. Incommensurable world views may doom reporting systems to failure.231

The limitations of medical knowledge, the limits of the human intellect, and the fundamental epistemological features of a science of particulars, make uncertainty irreducible and error unavoidable.232 Doctors have to make decisions and take responsibility in uncertainty.233 In health care, it is not always possible to ‘manage’ risk. Even if we recognised the possibility, we cannot investigate every patient to exclude meningitis. As a doctor in McDonald’s study said: “balancing risk, that is my life”.132 It may be easy for those who are not practising medicine to overlook just how difficult the role can be, to overlook the burden of responsibility and the difficulty of coping with having to act in uncertainty.

By redefining medical uncertainty as manageable clinical risk, the managerial approach introduces blame where previously blame did not exist. This may be counterproductive if the success of the systems approach to patient safety hinges on the development of a no-blame culture of openness and learning.

4.4 A less punitive environment may not be sufficient

It may not matter, for the development of a culture of safety, if New Zealand’s medical regulatory environment is not perceived to be less punitive because, while a culture of safety is not likely to thrive in a punitive environment, a less punitive environment, in itself, may not encourage the development of a culture of safety. The Institute of Medicine claimed that errors "are not reported because personnel fear they will be punished” (p.157),2 but doctors have been reticent about medical error long before the threat of discipline arose.234 It may not be fear of punishment alone that is preventing doctors from sharing information about medical error and injury.
4.4.1 Moral blame and shame

Sociological research suggests that the professional response to medical error and injury is not usually fear of punishment, but rather a shared sense of vulnerability (there but for the grace of God go I). Bosk studied the attitudes of surgical trainees towards adverse events in the 1970s and found the predominant response to error to be one of “forgive and remember”. The emphasis was on trying harder and doing better next time. Mizrahi studied the responses to adverse events of doctors in training and found that they used:

\[
\text{denial, discounting and distancing when dealing with mistakes: denying error by claiming uncertainty and grey areas in medicine, discounting mistakes by blaming them on the system or the patient or other factors outside their control, and finally when all else fails distancing themselves from mistakes.}
\]

Mizrahi found that these strategies notwithstanding, the doctors were left with profound doubts and feelings of guilt and shame. Feelings similar to those felt by the taxi driver in Adiga’s 2008 Man Booker prize winning book ‘The white tiger’ when he hit and killed a pedestrian:

\[
\text{He was burning with shame over what he had done - I didn't need to reproach him. And it was not his fault. Not mine either. Our outsourcing companies are so cheap that they force their taxi operators to promise them an impossible number of runs every night. To meet such schedules, we have to drive recklessly; we have to keep hitting and hurting people on the roads. It's a problem every taxi operator in this city faces. Don't blame me.}
\]

The literature emphasises the influence that uncertainty in medical practice has on the development of professional attitudes towards error and adverse outcomes. Research suggests the professional emphasis on forgiveness and learning arose because of the permanent uncertainty of the practice of medicine, which gives rise to a shared sense of vulnerability. Fox, in her early work, characterised three types of uncertainty in medicine: the incomplete mastery of available knowledge, the limitations of current medical knowledge, and the uncertainty or difficulty in distinguishing between the two. Fox argues that the permanent uncertainty of the practice of medicine, and the necessary fallibility of doctors
(to err is human), leads to a shared sense of vulnerability, to understanding and forgiveness of colleagues, rather than to criticism, accusation and blame.\textsuperscript{241} Doctors may blame themselves, or even blame the patient, but they are likely to forgive their colleagues.\textsuperscript{230}

Shame and the sense of moral blame when things turn out badly likely contribute to making doctors reluctant to discuss error and injury.\textsuperscript{67, 243} Ego, shame, moral blame, the human desire to avoid taking responsibility for bad outcomes, peer judgement, reputational harm, cultural norms, fear of loss of employment, and time pressures, might all have a role to play in inhibiting openness about error and injury.\textsuperscript{18, 182, 244, 245}

If it is not fear of punishment alone that is inhibiting openness about medical error and injury, a less-punitive environment may not be sufficient to encourage openness. Even if New Zealand’s medical regulatory environment were less-punitive, a culture of safety may not thrive.

Despite moral blame and shame possibly suppressing openness about medical error and injury and curbing the development of a culture of safety, moral blame and shame have their role to play in protecting patients from harm. As Liang warns, moral blame and shame are not safely ignored:

\begin{quote}
Preventable or negligent harm as the result of error is a moral failure, whatever its legal status may be. Moral blame and culpability are therefore unavoidable. Removing individual blame could conceivably ... mitigate the punitive atmosphere and enhance collegiality and inter-professional communication. However, despite these beneficial possibilities, there are the associated dangers of complacency and dulling of the moral sensibilities of the humans in the system when either a ‘blame-free’ approach or a ‘blame-the-system’ approach is adopted. The power of individual guilt can be constructive as often as it is destructive. Personal accountability is owed to the person who is injured. The deterrent effect of fear of shame and blame is not safely ignored.\textsuperscript{139}
\end{quote}

There is a risk that under a systems approach and a no-fault milieu that accountability is diffused so widely that nobody feels responsible: there is no need to feel shame when a medical injury is seen as a ‘systems problem’. The systems approach minimises the role of individual agency, which risks reducing motivation and eroding professionalism; a
blame-free environment could foster the development of a laissez faire attitude in medicine and allow poor performance to flourish.

There need to be some external checks in case internal morality fails. To avoid moral shirking and learned helplessness there must still be individual doctor accountability under the systems approach. Systems and professionalism need to work together. As Pellegrino says:

*Systems cannot make the professionals within them virtuous, but they can make it possible for virtuous professionals to be virtuous. Correspondingly, a defective system can discourage even the conscientious individual or reduce his or her aspirations to nothing higher than the level of the average* (p.96).246

Thus, even if moral shame and blame do stifle openness and inhibit learning, it is important they are maintained to protect patient safety and to prevent a laissez faire attitude developing. Patient safety often still relies on the motivation and professionalism of a doctor trying to do her or his best for a patient. Often as not, it is the ethical underpinnings of the practice of medicine, and moral blame and shame should things end badly, that motivates a doctor to do her or his best. It is important that professionalism and individual agency and accountability are not lost in the systems approach to patient safety.

### 4.5 Conclusion

Findings from this assessment suggest that although New Zealand’s medical regulatory system is designed to be less punitive than most, the system is not non-punitive and may not be experienced by doctors to be less punitive than a malpractice system.

Punishment lies in both the process and the penalty. Despite little punishment being overtly imposed under New Zealand’s medical regulatory system (doctors are rarely sued and seldom face disciplinary proceedings or even a review of their performance in their practising lifetime), the regulatory environment is not non-punitive. New Zealand’s system of no-fault compensation for medical injury might be less punitive than a tort-based system of compensation, but New Zealand’s patient complaints process can punish regardless of outcome, and the competence assurance processes, public inquiries, and the managerial takeover of medicine all contribute to the punitive nature of the regulatory environment.
Further, it cannot be assumed that the absence of suing reflects a less punitive regulatory system. While the adversarial medical malpractice process is no doubt punishing and may result in hefty fines being imposed on a doctor, this process is usually dealt with by lawyers and any penalty is likely to be funded by the doctor’s or employer’s insurance. Further, malpractice claims are a patient’s bid for monetary compensation; the allegation of negligence is a means to an end. A complaint, on the other hand, is a more pointed attack against the person of the doctor and may cut deep. A complaint is not about obtaining monetary compensation, but is rather a demand that an individual be held to account and punished for perceived wrong. For these reasons, a complaint may be perceived by doctors to be more punitive than a malpractice claim.

If New Zealand’s medical regulatory system is perceived to be punitive, the system may chill provider openness about medical error and injury regardless of the no-fault compensation scheme. While New Zealand’s medical regulatory system is praised internationally for its patient safety potential, it may not be the holy grail that medical malpractice reformists seek. There is no evidence yet to show that New Zealand’s regulatory system fosters the development of a culture of safety, nor that it is perceived by providers to be a less punitive system. It may be enlightening to ask providers directly how punitive they perceive New Zealand’s regulatory environment to be.

It may not matter that New Zealand’s medical regulatory system is not less punitive because, while a culture of safety is not likely to thrive in a punitive environment, a less punitive environment, in itself, may not be sufficient to encourage the development of a culture of safety. Something further may be required to overcome the sense of shame and moral blame that doctors may feel when a patient is harmed when seeking help. Regulatory change may be required to encourage openness about medical error and injury. As Dame Silvia said: “Past practices are not easily relinquished but there are ways of encouraging change by establishing new rules or stating existing ones in legislative form” (p.172). Alternatively, educational means may be used to encourage openness by raising awareness and increasing understanding.

In conclusion, I have shown through theoretical argument that because punishment lies in both the process and the penalty, New Zealand’s medical regulatory system may not be perceived to be less punitive than a malpractice system. New Zealand’s medical
regulatory system may not, then, be more likely to encourage the development of a culture of safety. In any case, while a culture of safety is not likely to thrive in a punitive environment, a less-punitive environment, in itself, likely lacks the power to overcome shame and moral blame to encourage the development of a culture of safety. Something further is likely required.

I now assess the influence of the 2005 no-fault compensation reforms on the punitive nature of New Zealand’s medical regulatory system and on medical professional accountability for harm.
5 THE NO-FAULT COMPENSATION REFORMS: punishment and medical professional accountability

In this chapter I assess whether New Zealand’s medical regulatory system is less punitive following the 2005 no-fault compensation reforms and whether medical professional accountability has been maintained.43

5.1 Introduction

Patients who are harmed by health care rightly demand that those responsible be held to account for their conduct and even punished.108, 109, 176 A no-blame culture of openness and learning might be important for patient safety, but medical professional accountability is also important and accountability requires that there be some blame, some punishment. The difficulty for any medical regulatory system is to balance the competing demands of accountability and learning: to support efforts to create a culture of learning while maintaining medical professional accountability for harm.

New Zealand’s 2005 no-fault compensation reforms were expected to decrease ACC reporting to the Medical Council (and thus punitive outcomes for doctors and medical professional accountability via ACC) and “to bolster efforts to create a culture of learning” in health care settings,24 but the effect of the reforms in practice is not yet known.

5.2 Methods

To assess whether New Zealand’s medical regulatory environment is less punitive following the reforms while maintaining medical professional accountability for harm, I calculate whether ACC reporting to the Medical Council decreased after the reforms, as expected, whether fewer doctors overall have been brought to the attention of the authorities, and whether the authorities have taken a less punitive approach to matters raised.

I obtained data for ACC reporting to the Medical Council from both the ACC and the Medical Council’s annual reports. I counted the number of doctors referred by ACC to the Medical Council for 2002 to 2010 and calculated whether fewer doctors were referred by ACC to the Medical Council after the reforms.
I also examined data for New Zealand’s medical professional accountability processes for 2001 to 2010 to identify trends in the number of doctors referred to the authorities and punitive outcomes for doctors. These data were obtained from the annual reports of the Medical Council, Health and Disability Commissioner, and from the Medical and Health Practitioners Disciplinary Tribunal websites. Specifically, I counted the number of doctors referred to the Medical Council for competence and fitness to practice concerns, the number of doctors who underwent a Medical Council performance review, the number of patient complaints to the HDC, HDC investigations, and disciplinary proceedings for doctors and their outcome. I calculated both whether fewer doctors were brought to the attention of the authorities (referrals to the Medical Council and complaints to the HDC), and whether punitive outcomes for doctors decreased (performance reviews, HDC investigations, disciplinary proceedings). Since the process can also be the punishment, I interpret a less punitive trend to be indicated by both fewer doctors being brought to the attention of the authorities, and the authorities taking a less punitive approach.

5.3 Results

5.3.1 Punishment and accountability via the compensation scheme

5.3.1.1 ACC reporting to the Medical Council

The altered ACC reporting duties under the 2005 reforms were expected to decrease ACC reporting to the Medical Council and this proved to be the case as shown in both Table 1 and Figure 3. Comparing the years before and after the 2005 reforms, ACC data reveal that ACC reporting to the Medical Council decreased from an average of 53 doctors per year to 12; while Medical Council data show that ACC reporting decreased from an average of ten doctors per year to one.22
Table 1: Doctors reported by ACC to the Medical Council 2002 - 2010 (ACC and Medical Council data)

<table>
<thead>
<tr>
<th>Year</th>
<th>Doctors reported by ACC to the Medical Council</th>
<th>ACC data (year to 30 June)</th>
<th>MCNZ data (year to 31 March)</th>
</tr>
</thead>
<tbody>
<tr>
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<td>42</td>
<td>6</td>
</tr>
<tr>
<td>2003</td>
<td></td>
<td>63</td>
<td>7</td>
</tr>
<tr>
<td>2004</td>
<td></td>
<td>53</td>
<td>18</td>
</tr>
<tr>
<td>2005</td>
<td></td>
<td>50</td>
<td>10</td>
</tr>
<tr>
<td>2006 (Risk of harm)</td>
<td></td>
<td>27</td>
<td>2</td>
</tr>
<tr>
<td>2007</td>
<td></td>
<td>9</td>
<td>3</td>
</tr>
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<td>2008</td>
<td></td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>2009</td>
<td></td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>2010</td>
<td></td>
<td>5</td>
<td>2</td>
</tr>
</tbody>
</table>

The discrepancy between ACC and Medical Council data is explained by the Medical Council’s filtering processes. The competence data reported in the Medical Council’s annual reports represents only the competence and fitness to practise referrals that are forwarded to Council’s competence section. All referrals to the Medical Council (including ACC referrals) go to the Medical Council’s complaints section for a preliminary assessment, but only those considered by the Medical Council to raise competence issues are forwarded to the Medical Council’s competence section and reported in the Council’s annual reports. The ACC referrals not passed on to the Council’s competence section are not reported in the Medical Council’s annual reports.
ACC reporting to the Medical Council expressed as a percentage of all new claims registered with ACC is more telling. ACC data reveal that prior to the reforms ACC reported to the Medical Council 6% of all new medical misadventure claims, but after the reforms ACC reported to the Medical Council only 0.2% of all new treatment injury claims.

The no-fault compensation reforms thus strengthened the barrier between New Zealand’s compensation scheme and medical professional accountability processes, as intended, decreasing accountability via ACC. Decreased ACC reporting to the Medical Council also indicates that punitive outcomes for doctors decreased, indicating a less punitive change. Doctors are now able to participate more freely in the compensation claims process, and to share sensitive information about treatment injury with ACC.

5.3.2 Punishment and accountability via the accountability processes

5.3.2.1 Referrals to the Medical Council

Table 2 shows the total number of doctors referred to the Medical Council each year for the years 2001 to 2010 and the outcome of these referrals.
Table 2: Competence and fitness to practise referrals to the Medical Council and their outcome 2001 – 2010

<table>
<thead>
<tr>
<th>Year to 31 March</th>
<th>Referrals</th>
<th>No further action</th>
<th>Performance review</th>
<th>Educational programme</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>% referrals</td>
<td>N</td>
<td>% referrals</td>
</tr>
<tr>
<td>2001</td>
<td>82</td>
<td>45</td>
<td>37</td>
<td>57%</td>
</tr>
<tr>
<td>2002</td>
<td>73</td>
<td>36</td>
<td>37</td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td>50</td>
<td>0</td>
<td>58</td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>60</td>
<td>37</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td>41</td>
<td>21</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td>35</td>
<td>28</td>
<td>19</td>
<td>58%</td>
</tr>
<tr>
<td>2007</td>
<td>38</td>
<td>20</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>2008</td>
<td>62</td>
<td>20</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>42</td>
<td>13</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>43</td>
<td>22</td>
<td>21</td>
<td></td>
</tr>
</tbody>
</table>

*Data obtained from MCNZ annual reports*

Performance reviews and educational programmes may relate to referrals in an earlier year.

Comparing the five years before and after the 2005 compensation reforms, the number of doctors referred decreased from an average of 61 per year to 44 per year. This result was not significant. Using a test for independent samples, and following results of a levene’s test showing no difference in variance (p=0.250), we used a t-test to test whether there was a difference in the number of doctors referred to the Medical Council for the five years before and after the 2005 no-fault reforms and found no difference (p=0.087). The small number of data points likely contributed to this result.

The number of doctors referred to the Medical Council each year is shown in Figure 4.
Competence and fitness to practise referrals to the Medical Council came from a variety of sources, in addition to the ACC, as shown in Table 3.
Table 3: Source of competence and fitness to practise referrals to the Medical Council 2001 – 2010 (MCNZ data)

<table>
<thead>
<tr>
<th>Year to 31 March</th>
<th>HDC (% total)</th>
<th>ACC (% total)</th>
<th>Peer</th>
<th>Employer</th>
<th>MCNZ (CAC/PCC)</th>
<th>Other</th>
<th>Total referrals</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>27 (33)</td>
<td>N/A</td>
<td>13</td>
<td>7</td>
<td>2</td>
<td>6</td>
<td>82</td>
</tr>
<tr>
<td>2002</td>
<td>26 (36)</td>
<td>6 (8)</td>
<td>12</td>
<td>5</td>
<td>18</td>
<td>6</td>
<td>73</td>
</tr>
<tr>
<td>2003</td>
<td>32 (64)</td>
<td>7 (14)</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td>2004</td>
<td>18 (30)</td>
<td>18 (30)</td>
<td>7</td>
<td>2</td>
<td>6</td>
<td>9</td>
<td>60</td>
</tr>
<tr>
<td>2005</td>
<td>14 (34)</td>
<td>10 (24)</td>
<td>5</td>
<td>4</td>
<td>7</td>
<td>1</td>
<td>41</td>
</tr>
<tr>
<td>2006</td>
<td>18 (51)</td>
<td>2 (6)</td>
<td>3</td>
<td>7</td>
<td>3</td>
<td>2</td>
<td>35</td>
</tr>
<tr>
<td>2007</td>
<td>20 (53)</td>
<td>3 (8)</td>
<td>7</td>
<td>1</td>
<td>5</td>
<td>3</td>
<td>38</td>
</tr>
<tr>
<td>2008</td>
<td>36 (58)</td>
<td>0 (0)</td>
<td>9</td>
<td>7</td>
<td>8</td>
<td>2</td>
<td>62</td>
</tr>
<tr>
<td>2009</td>
<td>23 (55)</td>
<td>0 (0)</td>
<td>7</td>
<td>8</td>
<td>2</td>
<td>2</td>
<td>42</td>
</tr>
<tr>
<td>2010</td>
<td>22 (51)</td>
<td>2 (5)</td>
<td>2</td>
<td>7</td>
<td>2</td>
<td>8</td>
<td>43</td>
</tr>
</tbody>
</table>

(Data from MCNZ annual reports)

The decrease in total referrals to the Medical Council is mainly due to the decrease in referrals from ACC following the 2005 no-fault compensation reforms. The proportion of all referrals to the Medical Council coming from ACC decreased from 19% for the five years to 2005, to just 4% for the five years after 2005.

The Health and Disability Commissioner was the dominant source of referrals, accounting for about half of all referrals to the Medical Council. The Commissioner consistently referred to Council about 24 doctors per year. Peer referrals to the Medical Council also remained steady at about six to eight referrals per year (about 13% of referrals). The willingness of doctors to report colleagues to the Medical Council did not increase, then, despite the optimism expressed by the Medical Council in its 2001 annual report:
There is an apparently greater readiness to report concerns about colleagues which is a welcome sign of awareness. There were some 13 referrals by peers during the year compared to eight the previous year. (p.22)²⁵¹

Peer referrals never again reached the heights of 13 after 2001, and for the years 2003 and 2010 peer referrals fell to a low of just two.

College recertification programmes seldom result in a doctor being referred to Council. This may be because College recertification programmes are poorly designed to identify poorly performing doctors, or because Colleges are constrained from identifying and reporting poorly performing doctors because of a conflict of interest. Colleges have a fiduciary duty to patients (to ensure competence and to identify poorly performing doctors), and also a duty to act in the interests of the College and its members (who fund the College). On the one hand it is in the Colleges’ interest to identify and deal with poor performers to maintain the reputation of the group, but on the other hand there is a danger that exposing bad apples to public scrutiny could undermine the reputation of the group as a whole.²²¹

These data show that few doctors are referred to the Medical Council each year (about one doctor per week on average), suggesting that either there are very few poorly performing doctors in New Zealand or that the Medical Council’s processes to identify poorly performing doctors are ineffective.

5.3.2.2 The Medical Council’s response to referrals

In line with declining referrals to the Medical Council, Table 3 shows that the Medical Council conducted fewer performance reviews and referred fewer doctors to its Professional Conduct Committee for possible discipline. Performance reviews reported in one year may relate to referrals received in a previous year.¹⁸⁶

Comparing the five years before and after the 2005 compensation reforms, performance reviews decreased from an average of 35 per year to 26 per year. The rate of performance review remained steady at about half of all referrals received. The steady rate of performance review suggests a consistent approach by Council to referrals. Fewer than ten doctors per year on average were required to participate in a formal educational programme.
Table 4 shows that disciplinary proceedings against doctors brought by the Medical Council decreased over the years 2001 to 2010. Charges of professional misconduct brought by a Medical Council Committee decreased from seven per year on average for the years 2000 to 2004, to five per year on average for the years 2006 to 2010. Council referrals to the Professional Conduct Committee were mostly for Court convictions (average of eight per year) or allegations of inappropriate conduct (average of eight per year). Few negligence or competence issues were referred by Council down the disciplinary route.
Table 4: Disciplinary proceedings for doctors 2000 - 2010: prosecutor and outcome of proceedings

<table>
<thead>
<tr>
<th>Year to 31 Dec</th>
<th>Director of Proceedings</th>
<th>Medical Council Committee*</th>
<th>Total disciplinary proceedings</th>
<th>Guilty outcome N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPDT 2000</td>
<td>6</td>
<td>7</td>
<td>13</td>
<td>7 (54)</td>
</tr>
<tr>
<td>2001</td>
<td>11</td>
<td>8</td>
<td>19</td>
<td>15 (79)</td>
</tr>
<tr>
<td>2002</td>
<td>4</td>
<td>5</td>
<td>9</td>
<td>8 (89)</td>
</tr>
<tr>
<td>2003</td>
<td>9</td>
<td>11</td>
<td>20</td>
<td>10 (50)</td>
</tr>
<tr>
<td>2004</td>
<td>2</td>
<td>5</td>
<td>7</td>
<td>5 (71)</td>
</tr>
<tr>
<td>2005</td>
<td>-</td>
<td>4</td>
<td>4</td>
<td>3 (75)</td>
</tr>
<tr>
<td>HPDT 2005**</td>
<td>4</td>
<td>2</td>
<td>6</td>
<td>6 (100)</td>
</tr>
<tr>
<td>2006</td>
<td>8</td>
<td>3</td>
<td>11</td>
<td>10 (91)</td>
</tr>
<tr>
<td>2007</td>
<td>3</td>
<td>3</td>
<td>6</td>
<td>4 (67)</td>
</tr>
<tr>
<td>2008</td>
<td>2</td>
<td>5</td>
<td>7</td>
<td>4 (57)</td>
</tr>
<tr>
<td>2009</td>
<td>1</td>
<td>4</td>
<td>5</td>
<td>5 (100)</td>
</tr>
<tr>
<td>2010</td>
<td>1</td>
<td>11</td>
<td>12</td>
<td>12 (100)</td>
</tr>
</tbody>
</table>

*Complaints Assessment Committee (2000-2005), Professional Conduct Committee (2005-2010)

**Both Medical Practitioners Disciplinary Tribunal (MPDT) and Health Practitioners Disciplinary Tribunal (HPDT) active in 2005

Data from MPDT and HPDT websites (MPDT 2000-2005, HPDT 2005-2010), HPDT data for medical practitioners only

The Medical Council’s power to take a rehabilitative response to referrals as an alternative to discipline was introduced in the mid-1990s (and continues under section 36 of the HPCA Act)³⁷ and caused a decline in disciplinary proceedings with a corresponding increase in performance reviews and educational programmes, reflecting a rehabilitative trend.¹²⁷ The reforms of the mid-1990s led to a change in accountability, not a decrease in accountability. In effect, under the reformed legislation, doctors were
held to account by the competence review process rather than the disciplinary process. However, this analysis identified an overall decrease in accountability as shown in Figure 5. Both Medical Council performance reviews and disciplinary charges decreased. Council seldom invoked its power to bring a disciplinary charge or to order a doctor undergo an educational programme.

ACC referrals to the Medical Council have seldom prompted a performance review (one per year on average), and no ACC referral has yet resulted in the Medical Council taking disciplinary action against a doctor. According to Medical Council personnel, most ACC referrals result in the doctor being sent an ‘educational’ letter (effectively a warning letter) usually recommending that the doctor revise his or her practice and undertake further education. Council seldom orders interim conditions unless a referral is related to a doctor’s health.\textsuperscript{252} It is perhaps not surprising that very few claims to ACC for compensation resulted in either discipline or rehabilitation since most claims were for minor injuries,\textsuperscript{44} and in general most injuries are not caused by incompetent or negligent practitioners.\textsuperscript{48}

The fact that so few poorly performing doctors are identified and dealt with each year has caused some concern and precipitated calls for the Medical Council to up its game.\textsuperscript{253} While this matters for accountability, it may not matter greatly for patient safety since the greatest threat to patient safety comes not from the few poorly performing doctors but from all doctors, the majority of whom are competent and well-intentioned but working in unsafe systems that set them up to fail.\textsuperscript{2, 9, 13, 254}
In the Health and Disability Commissioner annual reports patient complaints against all types of providers are collated and it is not possible to identify separately complaints against doctors. Data for complaints against doctors only is available, however, for the year ended 30 June 2006. These data provide an indication of the proportion of all complaints relating to doctors. These data reveal that for the 2006 year the Commissioner received 390 complaints against doctors (36% of all complaints), investigated 98 of these complaints (84% of all HDC investigations), made 48 findings of breach of the Code, and referred seven doctors for discipline (37% of all HDC referrals for discipline). If these proportions are consistent year to year, then about a third of all complaints to the HDC concern doctors, most HDC investigations concern doctors (about 80%), and about a third of all providers referred by the HDC for discipline are doctors.

Figure 6 shows that for the ten years 2001 to 2010, patient complaints to the Health and Disability Commissioner (the Commissioner) against all types of providers increased. Complaints increased from an average of 1206 per year in the five years leading up to the
compensation reforms (2001-2005), to an average of 1318 per year for the five years subsequent to the compensation reforms (2006-2010).\textsuperscript{155}

![Graph showing patient complaints from 2001 to 2010]

**Figure 6: Patient complaints to the Health and Disability Commissioner 2001 - 2010**

It is not clear why patient complaints increased, but the increase suggests an increasing demand for accountability. This may be because of increasing patient dissatisfaction with health services and/or increasing public awareness of and willingness to engage with the HDC patient complaints process. The increase in complaints is not likely due to the compensation reforms which, by improving access to compensation, if anything, might have been expected to reduce patient dissatisfaction after an adverse event and thus reduce the demand for accountability via complaint.

**5.3.2.4 The Commissioner’s response to complaints**

Figure 7 shows that, despite increasing numbers of complaints, complaints investigated by the Commissioner decreased. HDC investigations decreased from a peak of 538 in 2001, to just 51 in 2010. Investigations reported in the HDC annual report in one year may refer to a complaint lodged in a previous year.
Figure 7: Patient complaints to the Health and Disability Commissioner and investigations by the Commissioner 2001 - 2010

*HDC data, complaints against all types of health and disability service providers

Table 5 shows that over the ten study years, in line with declining investigations, the Commissioner referred fewer providers (of any type) to the Director of Proceedings for possible discipline. Referrals for discipline decreased from an average of 21 per year (2%) for the years 2001 to 2005, to 16 per year (1%) for the years 2006 to 2010.
Table 5: Patient complaints to the Health and Disability Commissioner 2001 - 2010

<table>
<thead>
<tr>
<th>Year to 30 June</th>
<th>Patient complaints against all types of providers</th>
<th>HDC investigations N (% complaints)</th>
<th>Providers referred by HDC to Director of Proceedings N (% complaints)</th>
<th>Doctors referred by HDC to Medical Council N (% complaints)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>1397</td>
<td>538 (39)</td>
<td>26 (2)</td>
<td>27 (2)</td>
</tr>
<tr>
<td>2002</td>
<td>1211</td>
<td>234 (19)</td>
<td>28 (2)</td>
<td>26 (2)</td>
</tr>
<tr>
<td>2003</td>
<td>1159</td>
<td>345 (30)</td>
<td>27 (2)</td>
<td>32 (3)</td>
</tr>
<tr>
<td>2004</td>
<td>1142</td>
<td>178 (16)</td>
<td>18 (2)</td>
<td>18 (2)</td>
</tr>
<tr>
<td>2005</td>
<td>1124</td>
<td>172 (15)</td>
<td>14 (1)</td>
<td>14 (1)</td>
</tr>
<tr>
<td>2006</td>
<td>1076</td>
<td>116 (11)</td>
<td>19 (2)</td>
<td>18 (2)</td>
</tr>
<tr>
<td>2007</td>
<td>1289</td>
<td>89 (7)</td>
<td>19 (1)</td>
<td>20 (2)</td>
</tr>
<tr>
<td>2008</td>
<td>1292</td>
<td>100 (8)</td>
<td>22 (2)</td>
<td>36 (3)</td>
</tr>
<tr>
<td>2009</td>
<td>1360</td>
<td>112 (8)</td>
<td>15 (1)</td>
<td>23 (2)</td>
</tr>
<tr>
<td>2010</td>
<td>1573</td>
<td>51 (3)</td>
<td>5 (0.3)</td>
<td>22 (1)</td>
</tr>
</tbody>
</table>

(Data from MCNZ annual reports)

N/A = Figure not available in HDC annual report

While it might be expected that the Commissioner would refer more doctors to the Medical Council for possible rehabilitation to make up for the declining referrals for discipline, Figure 8 shows this was not the case. There was no increase in referrals from the Commissioner to the Medical Council over the ten study years. HDC referrals to the Medical Council remained steady at about 24 doctors per year (2% of complaints).

The Director of Proceedings responded to declining referrals from the Commissioner by bringing fewer charges of professional misconduct against doctors before the Health Practitioners Disciplinary Tribunal. For the years 2000 to 2004, the Director of
Proceedings brought six cases per year on average against doctors, and this decreased to three cases per year on average for the years 2006 to 2010.

Figure 8: Health and Disability Commissioner investigations and referrals for rehabilitation and discipline 2001 - 2010

*HDC data (investigations and referrals for discipline refer to all types of providers, referrals for performance reviews refer to doctors only)*

These findings indicate that both the Health and Disability Commissioner and the Director of Proceedings took a less punitive approach to matters brought to their attention. It is not clear why this was so. The decrease in investigations is likely due in part to the Commissioner’s efforts to catch up on the backlog of complaints from previous years when he took office in 2000. It may also be due to the Commissioner’s stated preference for early resolution (“early resolution is usually considered in the best interests of both complainant and provider, [and so] fewer cases are concluded by formal investigation”). The change is likely also due, in part, to the reform of the HDC Act in 2003. Under the 2003 reforms the Commissioner was given new (non-investigative) options in handling complaints, including the ability to refer complaints to the Medical Council or back to the provider without investigation. Investigations are relatively time-
consuming and resource-intensive. Like most statutory bodies, the Health and Disability Commissioner has a limited budget and must use resources with discretion.

Although Commissioner Paterson stated that there had been a trend for fewer doctors to be referred for discipline and for more to be referred for competence review, this assessment identified a decrease in referrals for discipline with no corresponding increase in referrals for possible competence review.

Overall, the Commissioner investigated few complaints, and the vast majority of complaints resulted in neither referral for rehabilitation nor referral for discipline. For the five years following the 2005 compensation reforms, the Commissioner investigated less than 10% of all complaints (Figure 7). The Commissioner also referred few complaints for possible performance review (about 23 doctors per year to the Medical Council, or about 2% of all complaints). That so few complaints resulted in a doctor being referred for possible performance review suggests that the HDC patient complaints system is not an efficient way to identify poorly performing doctors. Research suggests that patient complaints identify poor outcomes better than they do poor performance. A poor outcome irrespective of good care may prompt a complaint, while a good outcome in spite of poor performance is unlikely to prompt a complaint. Outcome and complaints do not necessarily provide a good indicator of performance: in the health care context, patients can get better despite bad care and get worse (and die) despite the best care.

5.3.2.5 Disciplinary proceedings (medical)

The Health Practitioners Disciplinary Tribunal (HPDT) replaced the Medical Practitioners Disciplinary Tribunal (MPDT) in 2004 when the Health Practitioners Competence Assurance Act (HPCA Act) came into force. Under the HPCA Act, both the Health and Disability Commissioner (via the Director of Proceedings) and the Medical Council (via its Professional Conduct Committee) have the power to bring disciplinary proceedings against doctors before the Disciplinary Tribunal.

Table 4 shows that disciplinary proceedings decreased from an average of 14 per year (MPDT 2000–2004) to eight per year (HPDT 2006-2010). The number of charges against doctors brought by both the Director of Proceedings (from 6 to 3) and the Professional Conduct Committee (from 7 to 5) decreased. Although there were fewer
disciplinary proceedings, more resulted in guilty findings. Guilty findings increased from 65% in the years 2000–2005, to 83% in 2005-2009 indicating increased success for the prosecution. Even so, fewer doctors per year were found guilty of professional misconduct overall.

It is not clear why disciplinary proceedings against doctors decreased. The, at times exorbitant, cost of proceedings may be a factor or possibly a lack of confidence in the disciplinary process. Proceedings brought by the Director of Proceedings are funded out of the Health and Disability Commissioner budget, while both the Professional Conduct Committee and the Health Practitioners Disciplinary Tribunal (for cases against doctors) are funded by the Medical Council. The cost of proceedings in the last few years has been between $30,000 and $100,000-plus excluding goods and services tax (GST), not including the cost of the defence. That there are so few disciplinary cases each year means that Tribunal members are provided with little opportunity to gain experience and little opportunity to debate and determine professional standards.

Figure 9 shows that under New Zealand’s medical regulatory structure, compared to the number of complaints and claims for compensation lodged each year, there are very few performance reviews or disciplinary proceedings (punitive outcomes for doctors).
Figure 9: Comparing new claims for medical misadventure / treatment injury compensation and patient complaints to the Health and Disability Commissioner 2000 – 2010 with Medical Council performance reviews and disciplinary proceedings for doctors

(ACC data and HDC data is for all providers year to 30 June, MCNZ data is doctors only year to 31 March, HPDT data is doctors only year to 31 Dec.)

5.4 Discussion

5.4.1 Summary of findings

5.4.1.1 The compensation scheme: less punitive, decreased accountability via ACC

ACC referred fewer doctors to the Medical Council following the reforms, as expected, reflecting a less punitive change. Doctors are now able to more freely participate in the compensation claims process and to share with the authorities information about medical error and injury without fear, enabling learning and improvement.

But while decreased ACC reporting to the Medical Council has decreased the punitive deterrent to doctors’ participation in the compensation claims process, it has also decreased the punitive deterrent to injure. Doctors are substantial beneficiaries of the state
funded compensation system: ACC pays doctors (who are working in a private capacity) to both assist patients to lodge a claim for treatment injury and to treat treatment injuries. While it is doubtful any doctor would intentionally injure a patient to gain a pecuniary advantage, given the ethical underpinnings of medical practice and the professionalism that most doctors sign up to, it would be preferable if pecuniary incentives aligned with desired outcomes and behaviours. As Shaw said in the preface to his 1906 play ‘The doctor’s dilemma’:

> It is not the fault of our doctors that the medical service of the community, as at present provided for, is a murderous absurdity. That any sane nation, having observed that you could provide for the supply of bread by giving bakers a pecuniary interest in baking for you, should go on to give a surgeon a pecuniary interest in cutting off your leg, is enough to make one despair of political humanity.\(^{259}\)

Decreased ACC reporting to the Medical Council reflects decreased medical professional accountability via ACC. While this change risks leaving poorly performing doctors in practice unchecked, patient safety is not likely to be greatly compromised because ACC has retained the power to report doctors to the Medical Council, should ACC have concerns about a doctor posing a risk of harm to the public. But ACC reporting to the Medical Council is never likely to be an effective strategy for protecting patient safety. ACC has seldom identified and reported poorly performing practitioners and, in any case, the greatest threat to patient safety comes not from the few poorly performing doctors but from all doctors.\(^{2,13}\)

5.4.1.1.2 Accountability processes: both more and less punitive

Decreased ACC reporting to the Medical Council contributed to an overall decrease in the number of doctors referred to the Medical Council and, in response to declining referrals, the Medical Council conducted fewer performance reviews and brought fewer disciplinary charges against doctors. Patient complaints to the HDC increased, but the Commissioner conducted fewer investigations and referred fewer providers for discipline while maintaining steady referrals to the Medical Council. There were fewer disciplinary proceedings against doctors but more hearings ended in a guilty finding.
These changes reflect both a more and less punitive regulatory environment: more doctors were brought to the attention of the authorities following the no-fault reforms (via patient complaints), but punitive outcomes for doctors decreased. New Zealand’s medical regulatory system may not be less punitive overall, then, following the 2005 no-fault reforms, and so it may not be more likely to support the development of a culture of safety. Further work is required to more fully understand the reasons behind the less-punitive approach taken by the authorities.

5.4.1.1.3 Some diminution in medical professional accountability

Despite increased demand for accountability in the form of patient complaints, medical professional accountability overall decreased in the years after the no-fault reforms. ACC referred fewer doctors to the Medical Council, reflecting decreased accountability via ACC and indicating that some medical professional accountability was sacrificed to provide no-fault compensation for medical injury. Contemporaneously, there was a decrease in New Zealand’s medical professional accountability processes: despite increased complaints, the Health and Disability Commissioner investigated fewer complaints, and fewer doctors were held to account via the Medical Council performance review process or the disciplinary process.

The decrease in accountability identified in this analysis, along with the inability to sue for compensatory damages in New Zealand and the lack of close legal scrutiny of medical practice, raise the question of whether doctors are adequately held to account under New Zealand’s current medical regulatory framework. While patient safety is important, medical professional accountability is also important - to maintain standards, to maintain trust in the profession, and to avoid a laissez-faire attitude developing. There must be a limit to the no-blame environment; there must be individual accountability in the system and a clear line where proportionate and just punishment is dealt for unacceptable behaviour and deliberate and egregious errors. But this must be balanced against the risk of fostering fear and defensiveness and thwarting efforts to improve patient safety. The question is how much individual retribution should be tolerated, given the potential harm to others.

It is not possible to say from this analysis whether there is adequate medical professional accountability for harm in New Zealand, only that there has been a decrease in medical
professional accountability following the 2005 no-fault compensation reforms. Further work is needed to determine whether doctors are adequately held to account under New Zealand’s current medical regulatory framework and to more fully understand how New Zealand’s distinct medical regulatory environment influences health care ethics and practice. It is yet to be established whether, in the trade-off between accountability and learning, an acceptable balance has been struck under New Zealand’s current medical regulatory system.65, 111

5.4.2 Conclusions

New Zealand’s medical regulatory system is both more and less punitive following the 2005 no-fault compensation reforms: ACC has reported fewer doctors to the Medical Council and punitive outcomes for doctors overall have decreased, but patient complaints have increased. It is not clear why these changes occurred or what effect they have had on health care ethics and practice, if any. The increase in patient complaints suggests a more punitive regulatory environment and this may counteract any effect the no-fault reforms might have had making the environment less punitive. Further research is required to assess the influence of New Zealand’s medical regulatory system on professional attitudes and behaviours, and on the development of a culture of safety.

Despite increased demand for accountability in the form of patient complaints, medical professional accountability was sacrificed under the no-fault reforms. Further work is required to determine whether doctors are adequately held to account under New Zealand’s current medical regulatory framework. Notwithstanding the question of accountability, there is no evidence to suggest that poor performance has flourished in New Zealand, or that health care in New Zealand is any less safe than it is elsewhere.7, 260-262

Having presented my assessment of whether New Zealand’s medical regulatory system is less punitive following the 2005 no-fault compensation reforms and whether medical professional accountability for harm has been maintained, I now assess whether more patient safety data are generated under the reformed compensation scheme.
6 THE NO-FAULT COMPENSATION REFORMS: engendering openness?

In this chapter I assess whether the no-fault compensation reforms have facilitated openness about medical error and injury by calculating whether more patient safety data are generated under the reformed compensation scheme.

6.1 Introduction

In assessing the influence of New Zealand’s medical regulatory system on the development of a culture of safety, I need to assess the influence of the regulatory system on openness and learning. Since providers share with the authorities information about medical error and injury via the compensation claims and assessment process, the data generated under the compensation scheme reflects provider openness about medical error and injury.

The 2005 no-fault compensation reforms were expected to enhance provider cooperation with the compensation claims process, and therefore to facilitate provider openness about medical error and injury, and to enlarge the treatment injury claims dataset. ACC’s new reporting duties were also expected to generate the new patient safety datasets of ACC harm reports and provider feedback to the Director General of Health’s requests for feedback about ACC reported events.

Providers are not obliged to respond to the Director General’s requests, but many have because the Director General of Health is not a disciplinary body and has no power to take action against individual providers in response to ACC reports.

6.2 Methods

To assess whether more patient safety data are generated under the reformed compensation scheme, and thus whether the reforms have facilitated provider openness about medical error and injury, I counted new claims to ACC, ACC reports to the authorities, and provider responses to the Director General of Health’s requests for feedback about ACC reported events. I then calculated whether more patient safety data were generated after the 2005 no-fault compensation reforms.

I obtained data for new medical misadventure / treatment injury claims from the ACC annual reports 2001 to 2010. In the annual reports ‘claims registered’ refers to all new claims lodged with ACC, both accepted and declined. To discover whether more claims
data were generated following the reforms, I compared the number of new claims for medical misadventure for the five years prior to the reforms (2001 - 2005) with the number of new claims for treatment injury for the five years following the reforms (2006 - 2010).

I obtained data for ACC reports from the ACC. I counted these reports and calculated whether ACC reported fewer doctors to the Medical Council following the compensation reforms, and whether ACC reported to the authorities (the Director General of Health, Medsafe, and the Medical Council) more claims overall.

I also went to the Ministry of Health in Wellington and obtained de-identified copies of all ACC harm reports and provider feedback to the Director General of Health for the years 2008 to 2010. I analysed these data to identify the proportion of ACC reported events with provider feedback by year of injury and by provider type to discover whether provider responding increased over time and whether some types of providers were more likely to respond to the Director General’s requests for feedback.

6.3 Results

6.3.1 New medical misadventure / treatment injury claims 2001 - 2010

Table 6 shows that new claims to ACC doubled from 1434 in the year to 30 June 2005 just prior to the compensation reforms, to 2846 in the year to 30 June 2006 immediately following the reforms. A total of 22,565 new treatment injury claims were registered with ACC in the first five years following the 2005 legislative reforms.
Table 6: New medical injury claims registered with ACC and the cost of medical injury compensation 2001 - 2010

<table>
<thead>
<tr>
<th>Year to 30 June</th>
<th>New claims registered (medical injury)</th>
<th>New claims per 100 population</th>
<th>Total Expenditure* $000 (medical injury account)</th>
<th>Total Claims Paid* $000</th>
<th>Claims Liability $000</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001 medical misadventure</td>
<td>204</td>
<td>N/A</td>
<td>28,048</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>2002</td>
<td>192</td>
<td>N/A</td>
<td>29,487</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td>682</td>
<td>N/A</td>
<td>31,345</td>
<td>383,000</td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>1250</td>
<td>0.03</td>
<td>39,202</td>
<td>465,000</td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td>1434</td>
<td>0.03</td>
<td>48,633</td>
<td>644,000</td>
<td></td>
</tr>
<tr>
<td>2006** treatment injury</td>
<td>2846</td>
<td>0.07</td>
<td>56,532</td>
<td>774,000</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>3964</td>
<td>0.09</td>
<td>69,186</td>
<td>60,910</td>
<td>886,000</td>
</tr>
<tr>
<td>2008</td>
<td>5073</td>
<td>0.12</td>
<td>76,685</td>
<td>1,353,000</td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>5472</td>
<td>0.13</td>
<td>98,076</td>
<td>2,167,000</td>
<td></td>
</tr>
<tr>
<td>2010</td>
<td>5210</td>
<td>N/A</td>
<td>94,194</td>
<td>2,476,000</td>
<td></td>
</tr>
</tbody>
</table>

N/A = figure not available in ACC annual report

*In 2007 ACC reporting moved from ‘total expenditure’ to ‘total claims paid’

** Reforms came into effect 1 July 2005

Figure 10 shows that claims for treatment injury compensation increased following the 2005 reforms, although claims for medical misadventure compensation were increasing prior to the 2005 compensation reforms anyway. The number of new treatment injury claims continued to rise each year following the reforms for the first four years and then decreased slightly in the fifth year to 30 June 2010.
The increase in claims following the reforms is not likely due to an increase in treatment injuries, but more likely reflects the increase in potentially eligible injuries under the extended eligibility criteria and a greater willingness on the part of both doctors and patients to engage in the compensation claims process now that injury no longer implies wrong-doing under the reformed definition of injury. It is not clear why medical misadventure claims were increasing prior to the 2005 no-fault reforms, but this more likely reflects changes in societal expectations than changes in the incidence of injury.

### 6.3.1.1 Claims’ acceptance and potential consequences

ACC assesses all new claims for both acceptance and potential consequences. A claim may be declined (if, for example, the patient suffered no injury) but still assessed as serious or sentinel. Prior to the reforms, the average acceptance rate for new medical misadventure claims was 38% (April 1992 to June 2005). This increased to 66% in the years following the reforms. The average number of accepted claims thus increased from 426 per year in the three years prior to the reforms, to 2866 per year in the four years subsequent to the reforms. The average decision time for claims decreased from an average of five months prior to the reforms, to 13 days following the reforms.
suggests that doctors have responded to the less punitive milieu by contesting fewer claims decisions, allowing increased efficiency of the claims assessment process.

Figure 11 shows that two thirds of all new treatment injury claims (both accepted and declined) for the period 1 July 2005 to 30 September 2009 were assessed as having minor potential consequences (68%), 25% were assessed as major, 4% as serious, and 3% as sentinel.\textsuperscript{133} Of the accepted treatment injury claims, 51% were assessed as minor, 40% as major, 6% as serious, and 2% as sentinel.\textsuperscript{135} The effect of the 2005 reforms, then, has been mainly to extend compensation to previously ineligible minor injuries, not to extend compensation to an increased range of severe problems (such as birth related hypoxic brain damage).

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{potential_consequences.png}
\caption{Potential consequences of all new treatment injury claims 1 July 2005 – 30 June 2010 and of accepted claims 1 July 2005 – 30 June 2010}
\end{figure}

The treatment injuries assessed by ACC as sentinel, serious or major injury would likely have been covered under the prior medical misadventure eligibility criteria. Consistent with this notion, Figure 12 shows that the number of medical misadventure claims prior to the 2005 reforms is comparable with the number of treatment injury claims after the reforms that were assessed as sentinel, serious, and major combined. Thus, while the
2005 compensation reforms enlarged the claims dataset, it is likely that the increase in claims comprises mostly previously ineligible minor injuries. This has implications for learning from claims data to improve patient safety. The enlarged dataset might provide increased opportunities for learning, but the increased opportunities for learning concern mainly minor injuries.

Figure 12: Comparing new medical misadventure claims 2001 – 2005 with new treatment injury claims assessed as having major, serious or sentinel potential consequences 2006 - 2010

6.3.1.2 Cost of medical misadventure / treatment injury compensation

Figure 13 shows that the cost of medical injury compensation was increasing prior to the 2005 reforms, and continued to increase subsequent to the reforms, in line with the rising treatment and rehabilitation costs and with increased claims and claims acceptance rate because of the extended eligibility criteria.

(ACC reporting changed in 2007 from total expenditure to total claims paid, both figures supplied for 2007)

The total treatment injury costs doubled in the first four years following the reforms, increasing from $48 million in 2005 to $98 million in 2009. The average settlement increased from $18,300 under the prior medical misadventure standard in 2002 to an average award of $2,692 for minor injuries, $9,355 for major injuries, $36,495 for serious injuries, and $71,026 for sentinel injuries.

Table 7 shows the components of compensation costs for 2009 and reveals that the greatest expense is social rehabilitation costs. Since the increase in accepted claims following the reforms largely comprised minor injuries (which do not cost much to treat and rehabilitate), the observed increase in costs following the reforms is more likely due to an increase in treatment and rehabilitation costs than to an increase in the number of accepted claims.
Table 7: Components of treatment injury costs for 2009

<table>
<thead>
<tr>
<th>Payment type</th>
<th>$000 (ACC data)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Social rehabilitation (personal support, equipment, home/ vehicle modifications)</td>
<td>39,038</td>
</tr>
<tr>
<td>Weekly compensation non-fatal</td>
<td>24,054</td>
</tr>
<tr>
<td>Treatment (including medical, hospital, surgical, consultations, dental, counselling)</td>
<td>19,766</td>
</tr>
<tr>
<td>Lump sum/ independence allowance</td>
<td>10,262</td>
</tr>
<tr>
<td>Weekly compensation fatal</td>
<td>2,932</td>
</tr>
<tr>
<td>Vocational rehabilitation (assessments, equipment)</td>
<td>904</td>
</tr>
<tr>
<td>Other expenses</td>
<td>1,120</td>
</tr>
<tr>
<td><strong>Total costs/ Total claims paid 2009</strong></td>
<td><strong>98,076</strong></td>
</tr>
</tbody>
</table>
Figure 14 shows that claims liability increased following the reforms. Claims liability is defined on the Treasury website as the amount of funds required to be invested now, so that together with the future investment earnings on those funds ACC has enough funding to meet the estimated future payment obligations on its current claims.

The outstanding claims liability in the Treatment Injury Account increased from $644 million as at June 2005, to $2.476 billion as at 30 June 2010. This increase is more likely due to increasing treatment and rehabilitation costs than to the 2005 compensation reforms. The injuries requiring future payment for on-going treatment and rehabilitation are likely to be more severe, and therefore covered under the prior eligibility criteria. The increase in injuries following the 2005 reforms were mostly previously eligible minor injuries which, by definition, do not require on-going treatment and rehabilitation and which therefore contribute little to the increase in claims liability.

While the cost increase may be offset, in part, by reduced compliance costs (as fewer accepted claims are contested)\textsuperscript{130} and by possible future savings from improved patient safety, as the increase in compensation went mainly to patients suffering minor injuries (who were never likely to sue), it is unlikely the cost increase can be offset by forestalled
litigation costs. Patients suffering severe problems, such as birth related hypoxic brain damage, still face the hurdle of proving causation. The threat of litigation posed by patients not covered under the scheme likely remains.

The increase in the cost of medical injury compensation has caused some concern in government circles.266 ACC Minister, the Hon Nick Smith, stated in 2009:

*The change [to medical injury compensation] was supposed to add an extra $9 million to costs, but ended up adding a whopping $40 million a year to the medical-misadventure budget.*267

It was suggested in ACC’s 2009 Annual Report that “*the underlying cause [of the cost increase] has been a shift from ACC being a public insurance company to it becoming an extension of the welfare state*”.135 There may be some truth in this. Previously, public hospitals never used to lodge compensation claims but are now encouraged to do so to fund services.

There are also more claims lodged for private treatment. For example, if a patient suffered a problem following surgery in a private hospital under the prior system the surgeon would often bear the cost of treatment, such as having to take the patient back to theatre, him or herself. Under the reformed system, however, there is little to deter the surgeon from assisting the patient lodge a claim for treatment injury compensation to fund the repeat surgery. In effect, then, a private surgeon can double his or her operating list, and double the income, if the patient is injured during the initial surgery requiring repeat surgery. While it is unlikely doctors would deliberately perform poorly to increase their income, given the ethical underpinnings of medical practice and the professionalism most doctors sign up to, it does nevertheless make sense for pecuniary incentives to be aligned with desired outcomes.

Similarly patients can bypass public waiting lists and have surgery performed in the private system if they can prove an injury. For example, if patients who require a joint replacement have been on steroids in the past, ACC may fund their joint replacement in a private hospital if the patients can prove their joint problems were caused by the steroids.
6.3.2 ACC reports to the authorities 2002 – 2010

To recap, prior to the 2005 compensation reforms ACC had a duty to report all findings of medical error to the Medical Council; following the reforms ACC has a duty to report risk of harm to the public to the authorities responsible for patient safety. ACC has interpreted this new reporting duty, to date, by reporting to the Director General of Health in the form of harm reports all sentinel and some serious events. ACC has also reported some of these events to Medsafe and to the registration authorities including the Medical Council, the Nursing Council, the Pharmacy Council, the Dental Council, the Physiotherapy Board, and the Chiropractic Board.

6.3.2.1 ACC reports to the Medical Council 2002 – 2010

Chapter 5.3.1 shows that ACC reporting to the Medical Council decreased following the 2005 no-fault compensation reforms. This is not likely to affect learning to improve patient safety because referrals to the Medical Council have always been confidential and not available for general analysis to identify learning to inform efforts to improve patient safety. The Medical Council does not systematically analyse competence and fitness to practise referral data to identify learning to inform efforts to improve patient safety.\textsuperscript{268, 269}

However, following the 2005 compensation reforms, all events reported by ACC to the Medical Council are also reported by ACC to the Director General of Health and are available there for analysis to identify learning.

6.3.2.2 ACC harm reports to the Director General of Health 2006 - 2010

Table 8 shows that following the reforms ACC reported an average of 365 serious and sentinel events each year to the Director General of Health (8% of all new treatment injury claims). ACC also reported some of these events to the Medical Council and/or Medsafe.\textsuperscript{134}
Table 8: New medical misadventure / treatment injury claims registered with ACC and claims reported by ACC to the authorities 2001 – 2010 (ACC data)

<table>
<thead>
<tr>
<th>Year to 30 June</th>
<th>New claims registered with ACC</th>
<th>Claims reported by ACC (% claims)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>To the Medical Council</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>% claims</td>
</tr>
<tr>
<td>2001*</td>
<td>204</td>
<td>N/A</td>
</tr>
<tr>
<td>2002</td>
<td>192</td>
<td>42</td>
</tr>
<tr>
<td>2003</td>
<td>682</td>
<td>63</td>
</tr>
<tr>
<td>2004</td>
<td>1250</td>
<td>53</td>
</tr>
<tr>
<td>2005</td>
<td>1434</td>
<td>50</td>
</tr>
<tr>
<td>2006**</td>
<td>2846</td>
<td>27</td>
</tr>
<tr>
<td>2007</td>
<td>3964</td>
<td>9</td>
</tr>
<tr>
<td>2008</td>
<td>5073</td>
<td>8</td>
</tr>
<tr>
<td>2009</td>
<td>5472</td>
<td>5</td>
</tr>
<tr>
<td>2010</td>
<td>5210</td>
<td>5</td>
</tr>
</tbody>
</table>

*Claims for medical misadventure, reporting of medical error

**Claims for treatment injury, reporting of risk of harm to the public (new compensation legislation came into effect 1 July 2005)

N/A = Figure not available

The new harm reports dataset created following the reforms represents a new patient safety dataset available for analysis to identify learning.

Figure 15 shows that ACC reported more events overall following the reforms (to the Directory General of Health), but Table 8 reveals that ACC reported a similar proportion of claims before and after the reforms (6% to the Medical Council and 8% to the Director General of Health, respectively).
6.3.2.3 ACC reports to Medsafe

ACC reports an event to Medsafe in addition to the Director General of Health when ACC’s Harm Panel judges an event falls within Medsafe’s area of responsibility. These include events relating to identifiable medications, medical devices, equipment or prostheses. Adverse drug events arising from performance issues were not necessarily forwarded to Medsafe. 270

Table 8 shows that ACC reported about one third of events to both the Director General and Medsafe. These reports represent new opportunities for learning about threats to patient safety not previously available. Medsafe personnel advise that Medsafe collates the ACC harm reports, analyses the reports to identify trends or clusters of events relating to particular drugs, and refers some events on to the Centre for Adverse Reactions to Medicines (CARM). On occasion Medsafe or the Centre for Adverse Reactions to Medicines has brought a drug to the attention of the Medicines Adverse Reactions Committee. 271 This Committee may recommend to the Minister of Health that a drug or device be withdrawn. For example, treatment injury claims lodged by patients for both
cardiac problems subsequent to quetiapine and thunderclap headaches subsequent to selective serotonin reuptake inhibitors prompted review of these drugs by Medsafe and the Medicines Adverse Reactions Committee. This review resulted in update of the drug datasheets and warnings circulated to prescribers. Medsafe personnel consider ACC reporting useful to identify potential or actual problems with drugs that may not come to Medsafe’s attention through other reporting mechanisms (such as reporting to CARM) which rely on voluntary reporting by health professionals. The CARM advised that they would like more information on ACC’s Harm reports so they can make better use of the reports. The information they would like from ACC includes information such as the date the drug was given, time sequence of events, and other medicines the patient may have been on at the time.

6.3.3 Provider feedback about ACC reported events 2008 – 2010

To recap, the Director General of Health has responded to ACC harm reports, to date, by writing to the provider involved requesting feedback about the ACC reported event. The Director General of Health has developed a form, the ACC Treatment Injury Event Notification Provider Feedback Form, to direct provider feedback about event causal factors, action taken to reduce the risk of future similar events, and lessons learnt (Appendix 2). The Director General is not a disciplinary agency and so supplying feedback will not result in punitive repercussions for providers.

To date, Ministry of Health personnel have filed provider feedback along with the ACC harm report and no further action has been taken. Ministry officials advise they lack the capacity to analyse the ACC harm reports and provider responses to identify learning to improve patient safety.

6.3.3.1 Provider feedback by year of injury

It took the Director General of Health some time to develop processes to respond to the new ACC harm reports following the reforms, and so provider feedback about ACC reported events in the years immediately following the 2005 reforms is limited. The provider feedback dataset for the years 2008 to 2010 was the most complete available.

Table 9 shows that, for the three study years (2008 - 2010), providers supplied feedback for about half of all ACC reported events (279 responses / 557 harm reports (50%)).
Table 9: The proportion of ACC harm reports to the Director General of Health 2006 - 2010 with provider feedback by year of reported event

<table>
<thead>
<tr>
<th>Provider</th>
<th>Proportion of ACC harm reports with provider feedback per year of event</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;=2006</td>
</tr>
<tr>
<td>General practice</td>
<td>4/13</td>
</tr>
<tr>
<td>Nursing</td>
<td>0/1</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>0/0</td>
</tr>
<tr>
<td>Radiology</td>
<td>2/4</td>
</tr>
<tr>
<td>Dental</td>
<td>0/0</td>
</tr>
<tr>
<td>Chiropractor</td>
<td>0/0</td>
</tr>
<tr>
<td>Laboratory</td>
<td>1/1</td>
</tr>
<tr>
<td>Total primary care</td>
<td>7/19</td>
</tr>
<tr>
<td>111/190 (58%)</td>
<td>(37%)</td>
</tr>
<tr>
<td>Maternity</td>
<td>4/10</td>
</tr>
<tr>
<td>18/35 (51%)</td>
<td>(40%)</td>
</tr>
<tr>
<td>Hospital specialist</td>
<td>14/42</td>
</tr>
<tr>
<td>150/333 (45%)</td>
<td>(33%)</td>
</tr>
<tr>
<td>Total responses/ reports for all settings</td>
<td>25/71</td>
</tr>
<tr>
<td>279/557 (50%)</td>
<td>(35%)</td>
</tr>
</tbody>
</table>

Providers were increasingly likely to supply feedback in the years up to 2009, although the numbers were small. Figure 16 shows that response rates increased from 34% for events arising in 2007, to 76% for events arising in 2009 (the most complete years of data).
Ministry of Health officials confirm the increased provider feedback over time, advising that the response rate for hospital providers increased from about 52% in 2008 to about 70% in 2011/2012. Ministry officials attribute the increased feedback to raised awareness following the introduction of the Quality Improvement Committee’s incident reporting programme.\textsuperscript{273} This is consistent with the findings of the Federal Drug Agency in the US Drug Safety Surveillance Program: Adverse Event Reporting Trends, which identified increased reporting as awareness increased.\textsuperscript{274} Thus the increased provider feedback was more likely due to increasing awareness about patient safety issues following the introduction of reporting systems in New Zealand hospitals in 2008\textsuperscript{249} rather than increasing provider trust in the non-punitive nature of the system.

The increasing provider response rate suggests shifting attitudes and increasing readiness to share information about error and injury with the Director General of Health. However, a response rate of only 76% suggests that providers still have some way to go before fully embracing the patient safety agenda. It may take time for providers to trust that being open about error and injury will not result in punishment; or alternatively to trust that it is worth their time and effort to supply such information to the authorities.
Feedback from providers is likely to contain useful information about the causes of patient safety incidents and potential solutions from those on the scene. Increased feedback reflects increased opportunities for learning about the causes and potential solutions.

6.3.3.2 Provider feedback by provider type

Some types of providers were more likely to respond to the Director General’s requests for feedback about ACC reported events than others. It is not clear why. Table 9 shows that primary care providers supplied feedback for 111 of 190 reported events (58%), maternity providers for 18 of 35 events (51%), and hospital providers for 150 of 333 events (45%). These findings suggest that hospital providers were less forthcoming about injury, although findings are likely skewed by having all nursing care data included in the primary care data.

To assess whether ACC reporting to the registration authorities influenced provider feedback to the Director General, I compared provider feedback and ACC reporting to the registration authorities by provider type. ACC reported to the registration authorities 25 of the 190 primary care reported events (13%), and a similar proportion of maternity events (4 of the 35 maternity harm reports; 11%); but far fewer hospital events (4 of 333 hospital events; 1%). Despite ACC reporting fewer hospital providers to the registration authorities, hospital providers were less likely to respond to the Director General’s requests for feedback. ACC reporting to the registration authorities did not, then, chill provider feedback to the Director General.

Figure 17 shows that, of the primary care providers, pharmacists were most likely to be reported by ACC to the registration authorities (12; 38% of pharmacy events), followed by general practitioners (9; 13% of general practice events). While pharmacists were the most likely to be reported by ACC to the registration authorities (38%), pharmacists also showed the highest response rate at 75% (24 responses).
Figure 17: Comparing proportion of ACC harm reports 2008 – 2010 reported by ACC to the registration authorities and proportion of ACC harm reports 2008 – 2010 with provider feedback by provider type

ACC reported no nurses to the registration authorities (it is not clear why) and only 1% of hospital specialist events. The feedback response rate for nursing events was high (68%). ACC reported two chiropractors to the Chiropractic Board, and chiropractors had the lowest feedback response rate (40%), although the numbers were small (2 responses from 5 reported events). Of the nine general practitioners who were reported to the Medical Council, nearly all were for events related to diagnosis (7). ACC forwarded one third of all reported diagnostic events.

These findings suggest that ACC reporting to the authorities did not chill provider feedback to the Director General of Health.

Anecdotally, Ministry officials suggested that women were more likely to respond to the Director General's requests for feedback, while men were more likely to seek legal recourse before responding. It may be of value for educational purposes to test this impression but current reporting and feedback data do not contain information on provider sex.
6.4 Discussion

6.4.1 Summary of findings

This study suggests that more patient safety data are generated under the reformed compensation scheme: new claims for treatment injury compensation increased following the reforms although claims were increasing anyway, and the new patient safety datasets of ACC harm reports to the Director General of Health and provider feedback about ACC reported events were generated.

The data generated under the compensation system have the advantage of being generated without having to rely on providers to report incidents.

6.4.1.1 Claims

New claims increased dramatically, although claims were increasing prior to the reforms anyway. The increase in new claims likely reflects the extended eligibility criteria and increased provider willingness to participate in the compensation claims process now that compensation no longer implies fault on the part of the doctor, and now that the process is less likely to result in punishment for the doctor. The increase in claims suggests that the no-fault reforms have engendered openness about injury, and facilitated providers sharing information about medical injury with the authorities, providing new opportunities for learning about threats to patient safety.

Claims data represent pooled outcomes data that provide a novel no-fault perspective of a wide range of adverse events that is not available to researchers in tort jurisdictions. It is important to learn from outcomes data to ensure treatment causes more benefit than harm overall; to ensure that doctors are not working perfectly in a system where the whole enterprise is off course. The compensation data have the advantage of being generated without having to rely on providers to voluntarily report events and without having to establish expensive reporting systems. While the Institute of Medicine recommended that “health care organizations should establish non-punitive environments and systems for reporting errors and accidents within their organizations” (p.157), it is becoming apparent today that the cost of generating incident report datasets does not justify the limited learning they have generated.
Claims data nevertheless suffer from various limitations for the purpose of learning to improve patient safety. Despite increased claiming following the reforms, it is likely that the treatment injury claims dataset still provides an incomplete picture of adverse events - although it may provide a more complete picture than the previous misadventure claims dataset. It is likely many potentially eligible injured patients still fail to lodge a claim for compensation. Patients are unlikely to lodge a claim if they suffer a very minor injury not requiring treatment, or if the required treatment is provided free of charge in a public hospital, or if they are not aware of the assistance provided by ACC. The precise relationship between injuries and claims in the years following the compensation reforms is not known, but research prior to the reforms revealed that few injured patients lodged a claim for compensation.275

The increase in new claims mainly comprised previously ineligible minor injuries. Thus while more claims mean more data available for study, much of the data concerns minor events which may be of less interest for patient safety purposes. The enlarged dataset may not provide more information about the most severe injuries, and it may contain less useful information now that ACC is no longer required to collect information on injury preventability.

The lack of information in the claims dataset about injury preventability further limits its use for injury prevention purposes. Preventability data were necessarily sacrificed under the no-fault reforms. During the legislative change a deliberate stance was taken to move away from implications of wrong-doing and therefore to not collect information about error or injury preventability. Many claims likely pertain to events that were not associated with error and therefore not routinely preventable (for example, first exposure adverse drug reactions).

It might be enlightening to compare the content of the malpractice and treatment injury claims datasets for learning, but I did not have access to the malpractice claims data.

The increased compensation going mainly to patients suffering previously ineligible minor injuries has implications for the perceived threat of litigation. The threat of litigation may not have decreased following the reforms. New Zealand’s compensation scheme bars suing for compensatory damages for injuries covered under the scheme, but patients not covered under the scheme may still sue for damages. The prior restrictive eligibility criteria meant that many injured patients were previously ineligible for
compensation, increasing the possibility of litigation. But patients suffering minor injuries were never likely to sue because they stood to gain little. It is the patients who suffer substantial loss, and who require expensive, long-term support that stand to gain most by suing, for example, those suffering birth-related hypoxic brain damage. Compensation for these patients is not altered under the reforms; these patients still face the hurdle of proving causation. The Court of Appeal has recently confirmed that cerebral palsy following oxygen deprivation during labour is not an accident covered under the scheme because none of the three possible causes of oxygen deprivation (placental insufficiency, placental separation, and cord obstruction) fall within the definition of accident for the purposes of cover. The no-fault reforms have not removed the hurdle of proving causation and so may have extended the inequity created by the scheme between those suffering injury and those suffering illness.

6.4.1.2 ACC harm reports

Despite ACC reporting fewer doctors to the Medical Council following the reforms, ACC reported more events overall to the authorities responsible for patient safety including the Director General of Health and Medsafe. Decreased ACC reporting to the Medical Council will not decrease opportunities for learning because, firstly, referrals to the Medical Council have always been confidential and not available for researchers to study and, secondly, all events reported by ACC to the Medical Council following the reforms are also reported by ACC to the Director General of Health and are available there for learning.

The new dataset of ACC harm reports to the Director General of Health contains information about the nature of events with the most severe potential consequences, the treatment posing the greatest risk of harm to the public from the ACC’s perspective. This information is likely to be of great interest for patient safety.

The new ACC reporting duty has not only generated new datasets for researchers to analyse, it has presented the authorities with new opportunities to remedy ACC identified and reported risk.
6.4.1.3 Provider feedback

The provider feedback to the Director General of Health about ACC reported events represents a new dataset containing suggestions from frontline providers about event causal factors and potential solutions. There is no punitive deterrent to providers sharing their ideas as the Director General does not play a disciplinary role.

Some types of providers were more likely to supply feedback that others, it is not clear why. Providers were increasingly likely to respond to the Director General of Health’s requests for feedback over the years 2008 to 2010, although numbers were small. This may indicate that providers are more becoming more ready to share information about medical error and injury with the authorities.

6.4.2 Conclusion

In conclusion, more patient safety data are generated under the reformed compensation scheme. Thus, although New Zealand’s medical regulatory system may not be perceived to be less punitive following the 2005 no-fault reforms, the reformed compensation scheme does facilitate provider openness about medical error and injury and create new opportunities for learning to improve patient safety, thereby supporting the development of a culture of safety.

The data generated under the reformed compensation scheme have the advantage of being generated without having to rely on providers to report incidents, but they suffer from various limitations for injury prevention purposes, not least the lack of information about injury preventability.

Having determined that more patient safety data are generated under the reformed compensation scheme, I now assess whether these data can be analysed to identify learning to inform efforts to improve patient safety. In the following three chapters I describe the content to the datasets generated under the reformed compensation scheme for primary care: treatment injury claims (chapter 7), ACC harm reports to the Director General of Health (chapter 8), and provider feedback to the Director General about ACC reported events (chapter 9).
7  TREATMENT INJURY CLAIMS DATA: lessons for patient safety

7.1  Introduction

In this chapter I describe the content of the primary care treatment injury claims data for the years 2006 to 2009 to identify threats to patient safety in primary care.

7.1.1  A primary care focus

I assess the ACC data for events arising only in primary care because, firstly, this is the health care setting I am most familiar with and, secondly, because despite the majority of patient contacts taking place in primary care, to date, most patient safety initiatives have focused on the harm in hospitals.

7.1.1.1  What is primary care?

It is generally accepted that primary care is different to secondary or tertiary care, but the boundaries of what is and what is not primary care are not always obvious. Primary care has been variously defined according to the functions it serves, the specialty of the doctors, and the orientation of health systems. The WHO first level of contact definition is generally agreed to be a good workable definition for most purposes. The WHO came up with this definition in 1978 at an international conference on primary health care held in Alma-Ata (now Almaty), Kazakhstan:

*Primary health care is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and the country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination. It forms an integral part of both the country's health system, of which it is the central function and main focus, and the overall social economic development of the community. It is the first level of contact of individuals, the family and the community with the national health system bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process.*
This definition was updated in the 2008 WHO World Health Report, *Primary Health Care: now more than ever* to include the concepts of comprehensiveness; integration; continuity; patient empowerment; bridging personal, family, and community health; prevention and health promotion; and team-based care.$^{283}$

In New Zealand and in most developed countries the first point of contact is usually a community-based clinic, but in many developing countries the first (and often only) point of contact for medical care is the local hospital. Community clinics in New Zealand include general practices, accident and medical centres, physiotherapy clinics, dental clinics, osteopath clinics, and chiropractic clinics.

The Institute of Medicine has provided an alternative definition of primary care:

> **Primary care is the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.**$^{284, 285}$

Starfield defined ‘primary care’ according to the four essential functions it serves: providing first-contact care for new health problems, comprehensive care for the majority of health problems, continuity of person-focused care, and care coordination across providers.$^{286}$ This definition has also been updated to include system-level attributes of minimal financial barriers, reliable communication and care transitions between primary care doctors and other health providers, and local cultural and behavioural norms which encourage patients to seek care from a primary care provider.$^{287}$ According to Starfield’s research, good primary care is the bedrock of a cost-effective health care system. Starfield defined ‘primary health care’ as primary care applied on a population level; a strategy aimed at developing a population orientated set of services.

### 7.1.1.2 Patient safety in primary care

The problem of patient safety in primary care is yet to be well defined,$^{288, 289}$ but it is generally accepted that the problem is different to that in hospitals.$^{290}$ Recent efforts are working to define patient safety in primary care.$^{27-35, 52, 53, 227, 291-303}$ The WHO Patient Safety Programme recently called a meeting in Geneva of international experts in primary care patient safety research to develop an understanding of the frequency, nature, burden and preventability of unsafe care in primary care settings internationally, and to agree on
priorities for future research to guide future work on primary care patient safety research. A systematic review of the global burden of patient safety incidents in primary care was conducted for the inaugural meeting of the Safer Primary Care for All expert working group. This research group’s oral presentation reported that:

- There remains a paucity in research on tools and methods to improve patient safety in primary care.
- Where estimates were available, existing work indicated that patient safety incidents occur in no more than 2% of all primary care encounters.
- Patient safety incidents were more prevalent in certain contexts, for example errors in the medication process in elderly patients with multiple morbidities.
- The extent of harm resulting from patient safety incidents was around 10%, the majority of which harm tended to be mild and transient in nature. Overall, mild to moderate harm occurred in around 0.2% of consultations.
- Severe harm occurred mainly in relation to prescribing and misdiagnosis/delayed diagnosis.

A US study estimated that adverse events in ambulatory care resulted in 75,000 hospital admissions and over 2500 patient deaths each year. Davis has previously studied New Zealand hospital records and identified that one fifth of all identified adverse events originated outside the hospital. Of the primary care adverse events resulting in hospital admission, one third concerned a delay in diagnosis, one third related to surgery or other procedures, and about one sixth related to medication.

Most primary care patient safety research, to date, has been conducted in general or family practice settings. Other areas of concern include community pharmacies and dentistry. The focus of most research to date has been on patient safety in high income countries, while little is known about patient safety in low and middle income countries.

To date great emphasis has been paid to studying medication errors. A UK literature review in 2003 found that prescribing and prescription errors occurred in up to 11% of all prescriptions, mainly related to errors in dose. Others have found adverse drug events to be relatively common in primary care. Failure to review and manage poly-pharmacy in older people, prescribing and dispensing errors, and diagnostic errors in particular pose a risk to patients. In pharmacies, high prescription volumes, pharmacist fatigue or overwork, interruptions to dispensing, similar or confusing drug names, lack of systematic
dispensing workflow and regulatory guidelines all contributed to dispensing errors. The WHO group recommended that in future a greater focus is required on other types of errors, especially those that can result in severe harm such as diagnostic errors.

The key gaps in the existing primary care patient safety literature identified by the WHO group included terminology, context, types of errors, focus, and quality of the evidence. Regarding terminology, there has been little consistency across studies, making comparison difficult, although the LINNAEUS group has made progress towards the development of a widely accepted taxonomy specific to patient safety in primary care. The LINNAEUS group developed a taxonomy for classifying errors in primary care in the early 2000s to improve consistency between the terms used for describing errors in primary care, enabling comparison between studies. The LINNAEUS taxonomy is becoming accepted for use in primary care patient safety research. This taxonomy uses two discrete categories to classify errors: process errors and knowledge and skill based errors.

Process errors are the more common (70%) and include errors of office administration, investigations, treatments, communications and payment. Thus while threats to patient safety in primary care are diverse, key patient safety issues include process errors in diagnosis, prescribing, communication (including follow-up after discharge from hospital and follow-up of test results), policy and administration. Knowledge and skill based errors (caused by deficiencies in the knowledge and skills of health professionals) are less common (30%) and include errors in the execution of a clinical task, misdiagnosis, and wrong treatment decision.

Given the scale of primary care, even if the injury rate were low, the burden of harm is potentially great; even if only one in 550 prescriptions were in error, considering the number of prescriptions written in primary care each year, the burden of harm from incorrect prescriptions could be high. Addressing the problem of patient safety in primary care is made more urgent by the shift to delivering more health care in primary care. This shift is the result of the increasing cost of hospital care and the increasing problem of chronic conditions, such as diabetes, that need managing rather than curing.

In this chapter, I assess whether treatment injury claims data can be analysed to identify learning for patient safety in primary care. Specifically, I describe the content of the primary care claims dataset for 2006 to 2009, to identify threats to patient safety in
primary care. To date, there has been no systematic analysis of New Zealand’s compensation claims data to identify learning to inform efforts to improve patient safety. While researchers have recently begun to study the claims dataset, and ACC has disseminated to providers regular treatment injury case studies, this study has provided the only attempt to systematically analyse claims data to identify learning for patient safety in primary care.

7.2 Methods

In assessing whether the treatment injury claims data can be analysed to identify learning for patient safety, I analyse the content of the primary care claims dataset 2006 to 2009 to describe the content of the dataset and thereby draw conclusions about the learning opportunities such analyses can provide.

7.2.1 Primary care claims data 2006 – 2009

The Accident Compensation Act stipulates that ACC must provide for ‘a framework for the collection, co-ordination, and analysis of injury-related information’. To this end, ACC collects and collates treatment injury claims.

For the purposes of this study, ACC provided de-identified treatment injury claims data for all claims lodged the first four years following the introduction of the reformed scheme (1 July 2005 - 30 June 2009) pertaining to events arising in primary care as identify by ACC. ACC defined primary care settings to include general practice/family medicine clinics, dental clinics, physiotherapy rooms, chiropractic rooms, osteopath rooms, community pharmacies, community laboratories, radiology rooms and rest homes. These settings may differ from those included under other definitions of primary care.

To recap, to lodge a claim for treatment injury compensation, a patient must complete both the general injury claim form (ACC45) and the treatment injury claim form (ACC2152) (Appendix 1). These forms collect information about the patient, the alleged injury and alleged causal treatment, the lodging provider, and the treatment provider. The forms are sent to ACC and ACC personnel assess the claims for both eligibility (accept/decline) and for ‘potential consequences’ (minor, major, serious or sentinel). Table 10 provides the ACC datafield descriptions.
Table 10: ACC definitions and data field descriptions

<table>
<thead>
<tr>
<th>Potential consequence</th>
<th>An assessment of whether the outcome of this event was sentinel, serious, major or minor.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sentinel</td>
<td>An event during care or treatment that has resulted in an unanticipated death or major permanent loss of function not related to the natural course of the claimant’s illness or underlying condition, pregnancy or childbirth</td>
</tr>
<tr>
<td>Serious</td>
<td>An event, or related events, that has the potential to result in death or major permanent loss of function not related to the natural course of the claimant’s illness or underlying condition</td>
</tr>
<tr>
<td>Major</td>
<td>An event which results in short-to-medium lessening of bodily function (sensory, motor, physiologic or intellectual) unrelated to the natural course of the illness and differing from the expected outcome of patient management</td>
</tr>
<tr>
<td>Minor</td>
<td>An event which results in minimal lessening of bodily function and which may require an increased level of care, review and evaluation, further investigation or referral to another clinician.</td>
</tr>
<tr>
<td>Treatment context</td>
<td>The overarching type of treatment that the claimant was receiving when the alleged injury occurred. Corresponds to occupation of health professional, for example general practice, dental, acupuncture, chiropractor, laboratory, osteopathy, pharmacy, physiotherapy, podiatry, radiology, appearance medicine, equipment, phlebotomy, nursing, pharmacy, podiatry, screening and other.</td>
</tr>
<tr>
<td>Treatment facility</td>
<td>Physical setting where treatment provided</td>
</tr>
<tr>
<td>Event</td>
<td>The specific treatment that the claimant was receiving when the alleged injury occurred. Corresponds to ‘What events or circumstances led to the injury?’ For example, removal of skin lesion, medication administration, delay/ failure to diagnose...</td>
</tr>
<tr>
<td>Primary injury</td>
<td>Category of injury being claimed for, for example abscess, cellulitis, wound infection, allergic reaction</td>
</tr>
<tr>
<td>Did injury result in death?</td>
<td>An indication of whether or not it is known that the claimant died as a result of the injury.</td>
</tr>
</tbody>
</table>
ACC administrative personnel enter claims data into an electronic claims database. Claims data include date of birth; age and sex of patient; date of injury; age at date of injury; claim lodgement date; lodging provider; claim decision; whether patient died; injury place; District Health Board (DHB) region; facility category; treatment context; treatment facility; facility unit; potential consequences; primary injury; injury being covered; and event. ACC uses the term ‘event’ rather than ‘treatment’ to include injuries caused by failure to diagnose and failure to treat. Injuries are classified using both ICD10 and Read classification systems.

ACC makes no assessment of injury preventability. This is because preventability usually has something to do with error or fault and the 2005 compensation reforms took a deliberate move away from ACC identifying error. Prior to the 2005 reforms ACC did make an assessment of preventability (whether or not there had been a medical error) but under the reformed compensation legislation all treatment injuries are covered irrespective of error. Regarding its injury prevention duties, ACC considers prevention in terms of groups of claims.

Neither the individual health provider nor the type of provider (such as doctor, nurse, or physiotherapist) is identified in the dataset. This is in line with the no-fault focus of the scheme which seeks to avoid attributing blame to individuals and to create an atmosphere of openness and learning with respect to adverse events and injuries in health care settings. Nevertheless, the type of treatment provider can often be inferred from the event and the treatment context. Thus, for example, ‘spinal/neck manipulation’ provided in ‘rooms physio’ can be assumed to have been provided by a physiotherapist; while ‘spinal/neck manipulation’ provided in ‘rooms chiropractor’ can be assumed to have been provided by a chiropractor.

For the purposes of this study, ACC provided de-identified data for all treatment injury claims arising in primary care and lodged in the first four years following the 2005 legislative reforms (1 July 2005 to 30 June 2009). Lodgement years were the 12 months from 1 July to 30 June. The first claims were lodged on the day the reforms came into effect, 1 July 2005, and the last claim was lodged on 19 June 2009. Four data years were included in the study even though a few remaining open claims will eventually be added to the fourth year, ending 30 June 2009.
The settings defined by ACC as primary care included general practice/family medicine clinics, dental clinics, physiotherapy rooms, chiropractic rooms, osteopath rooms, community pharmacies, community laboratories, radiology rooms and rest homes. Claims arising from care provided in hospitals, in private specialist clinics and by maternity providers were excluded. Maternity claims were excluded because it was not possible for ACC to differentiate the maternity claims arising in primary care from those arising in public hospital settings. Sometimes, for instance, a home birth might be planned but end in a hospital delivery making it difficult to assess whether any resultant injury should be included as a primary care or a hospital treatment injury.

For this study, the eight lodging provider types in the dataset were aggregated into three categories: (1) DHB; (2) general practice (N = 2,040) and community clinics (N = 14); and (3) other (including private clinic (N = 460), ambulance (N = 79), other (N = 21), private hospital (N = 8), and the ACC Accidental Death Unit (N = 3)). Twenty five accepted claims (0.6%) had no lodging provider identified.

There was some inconsistency in data field entry and this had to be sorted before the data could be analysed. For example ‘cryotherapy’ and ‘liquid nitrogen’ were entered as separate ‘event’ categories while they are different names for the same treatment; triamcinolone was sometimes entered as kenacort but they are different names for the same drug and, when causing septic arthritis, the ‘causal event’ was sometimes entered as ‘medication’ and sometimes as ‘injection’.

### 7.2.2 Data analysis

I analysed the claims data to describe the content of the dataset, in particular to describe the type, incidence, severity and cause of events from the no-fault compensation perspective. The analytic approach to the data was mainly descriptive because the aim of the study was to determine the content of the dataset and its ability to inform providers about the nature of threats to patient safety in primary care and to guide injury prevention initiatives.

I calculated the proportion of claims that were accepted, and the proportion of claims assessed as having minor, major, serious, and sentinel potential consequences. Standard statistical tests were used to investigate probabilities of a claim being accepted by age and
sex (t-tests and chi-square tests). These data were then described by various patient and provider characteristics and by treatment type.

All claims were analysed to discover claims’ acceptance rate and potential consequences, settings where claims arose, and the age and sex distribution of claimants. Accepted claims (treatment injuries) were analysed to identify the type, incidence, severity and cause of injury. Serious and sentinel injuries were analysed to identify the events that caused injury which resulted in, or had the potential to result in, ‘death or major permanent loss of function.’ Declined serious and sentinel claims were analysed to identify the events assessed by ACC as having the potential to cause ‘death or major permanent loss of function’ (even though in this instance no injury resulted).

No independent assessment of injury causation was made. ACC’s acceptance of a claim was taken as indicative of a causal association between the treatment and the injury. By definition a treatment injury is a ‘personal injury suffered by a person seeking treatment or receiving treatment and caused by treatment...’ (s.32).21

In this analysis the sentinel and serious claims were collated and analysed together. Sentinel and serious claims are those assessed by ACC as, respectively, “resulting in” or “having the potential to result in” death or major permanent loss of function. In this study most analyses were of accepted claims (injuries), but declined serious and sentinel claims were also included in some analyses because, even though no actual injury occurred, these claims can provide insights into potential sources of the most severe harm. For example, a claim for a medication dispensing or administration error may be declined because no injury occurred, and yet assessed by ACC as ‘serious’ because the claim raises concerns about a potential risk of harm to the public.

Some injuries were caused by more than one type of event. An event is defined by ACC as the “treatment that the claimant was receiving when the alleged injury occurred”. For example, pneumothorax was caused by both acupuncture and fine needle biopsy; nerve injury was caused by injection, venepuncture and spinal manipulation; and stroke was caused by both neck manipulation and oral contraceptive medication. To better inform injury prevention initiatives, the focus of the analysis was not so much on the injury as on the causal ‘event’.
Data about treatment were analysed to identify the burden of injury associated with particular treatments, including screening and preventive treatments. The focus was on treatment rather than ‘treatment context’ or ‘treatment provider’ because some treatments are provided in more than one context and by more than one type of provider. For example, acupuncture was provided in general practice, physiotherapy and chiropractic rooms. For injury prevention purposes, the information generated about a particular type of treatment is of interest to all providers of that treatment irrespective of their professional affiliation. That said, some treatments and treatment contexts are specific to some types of providers and the lessons generated are specific to them. For example dentists can be assumed to be providing the treatment provided in dental rooms; and doctors to be prescribing the medication in general practice rooms. Data about claimants were also analysed to identify patient groups at particular risk of injury.

Approval for this study was obtained through the University of Otago ethical approval process.

7.3 Results: threats to patient safety in primary care

7.3.1 New claims for treatment injury compensation

Data from ACC annual reports reveal there were 17,355 new treatment injury claims registered with ACC in the first four years following the introduction of the extended eligibility criteria (1 July 2005 - 30 June 2009). Of the 17,355 new claims, 6007 were identified by ACC as having arisen in primary care settings as outlined above (35%). Only about one third of all treatment injury claims lodged with ACC over the four study years arose in primary care settings, then. This is despite most health care contacts in New Zealand occurring in primary care: the Ministry of Health 2006/7 health survey revealed that about 80% of children and 85% of adults had contact with primary care services over a 12 month period, compared to only 8% of both children and adults for Emergency Department services and 18% for other public hospital services.

Most primary care claims were lodged in general practice (3328; 55%). The remainder were lodged by DHB providers (1346; 22%), in private clinics (764; 13%), or by other or unspecified providers (10%).
Figure 18 shows that the number of new primary care treatment injury claims registered with ACC increased each year over the first three years, and then dropped slightly in the fourth year. The decrease in claims in the final study year is mostly likely due to missing data as there were a few claims from this year still to be added to the dataset when ACC supplied the data. The increase in claims likely reflects increasing awareness about the extended eligibility criteria, and also suggests greater willingness on the part of providers to engage in the compensation claims process and to promote the scheme to patients.

![New claims 2006-2009](image)

**Figure 18: New primary care treatment injury claims 2006 - 2009**

### 7.3.1.1 Claims acceptance

ACC accepted nearly two thirds of the primary care treatment injury claims as being treatment injuries (3853; 64%); this is in line with the overall acceptance rate of 66% for all treatment injury claims. Table 11 shows that a similar number of primary care claims were lodged and accepted in each of the four study years.

Of the 2154 declined claims, most were declined because there was ‘no injury’ (1247; 58%); 18% were declined because there was ‘no causal link’, 12% because the alleged injury was a ‘necessary part or ordinary consequence of treatment’, 11% because the alleged injury was caused by ‘underlying health condition’, and 1% for ‘other’.
Table 11: Claim decision by lodgement year for primary care treatment injury claims 2006 - 2009

<table>
<thead>
<tr>
<th>Claim decision</th>
<th>Lodgement year post legislative reform</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Accepted</td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>Accepted - Section 20(2)d*</td>
<td>714 (58.9)</td>
<td>826 (53.7)</td>
<td>999 (58.6)</td>
<td>927 (59.8)</td>
<td>3466 (57.7)</td>
<td></td>
</tr>
<tr>
<td>Total Accepted Claims</td>
<td>792 (65.3)</td>
<td>923 (60.0)</td>
<td>1112 (65.2)</td>
<td>1026 (66.2)</td>
<td>3853 (64.1)</td>
<td></td>
</tr>
<tr>
<td>Declined - No Injury</td>
<td>245 (20.2)</td>
<td>343 (22.3)</td>
<td>321 (18.8)</td>
<td>338 (21.8)</td>
<td>1247 (20.8)</td>
<td></td>
</tr>
<tr>
<td>Declined - No Causal Link</td>
<td>57 (4.7)</td>
<td>94 (6.1)</td>
<td>119 (7.0)</td>
<td>115 (7.4)</td>
<td>385 (6.4)</td>
<td></td>
</tr>
<tr>
<td>Declined - Necessary part or ordinary consequence of treatment</td>
<td>72 (5.9)</td>
<td>77 (5.1)</td>
<td>76 (4.4)</td>
<td>38 (2.4)</td>
<td>263 (4.4)</td>
<td></td>
</tr>
<tr>
<td>Declined - Underlying Health Condition</td>
<td>44 (3.6)</td>
<td>90 (5.8)</td>
<td>66 (3.9)</td>
<td>28 (1.8)</td>
<td>228 (3.8)</td>
<td></td>
</tr>
<tr>
<td>Declined - Other</td>
<td>3 (0.02)</td>
<td>12 (0.08)</td>
<td>12 (0.07)</td>
<td>4 (0.03)</td>
<td>31 (0.06)</td>
<td></td>
</tr>
<tr>
<td>Total Declined Claims</td>
<td>421 (34.7)</td>
<td>616 (40.0)</td>
<td>594 (34.8)</td>
<td>523 (33.8)</td>
<td>2154 (35.9)</td>
<td></td>
</tr>
<tr>
<td>Total Claims Made</td>
<td>1213 (100.0)</td>
<td>1539 (100.0)</td>
<td>1706 (100.0)</td>
<td>1549 (100.0)</td>
<td>6007 (100.0)</td>
<td></td>
</tr>
</tbody>
</table>

The injury results from treatment provided for an injury already covered by ACC

### 7.3.1.2 Potential consequences

ACC assesses all claims, both accepted and declined, for potential consequences. ACC assesses a claim as having ‘major’ potential consequences if ACC considers the event
could result in ‘short-to-medium lessening of bodily function’. Claims that either have ‘the potential to result in death or major permanent loss of function’ or that ‘have resulted in death or major permanent loss of function’ are assessed by ACC as serious or sentinel respectively. All sentinel claims (both accepted and declined) and those serious claims considered by ACC to have a high or moderate likelihood of recurrence are reported by ACC to the Director-General of Health in fulfilment of ACC’s statutory duty to report perceived ‘risk of harm to the public’ (s.284).21

Figure 19 shows that most primary care treatment injury claims (both accepted and declined) in the four study years were assessed as minor (4976; 83%); 12% were assessed as major (729), 4% as serious (244) and 1% as sentinel (58). These figures compare with treatment injury claims overall where, of the total 31,103 claims for the period 1 July 2005 – 30 June 2010, 68% were assessed as minor (21,042), 25% were assessed as major (7959), 4% were serious (1293), and 3% sentinel (809).133

![Figure 19: Proportion of accepted and declined primary care treatment injury claims 2006 – 2009 that were assessed as having minor, major, serious and sentinel potential consequences](image)
The more severe claims were more likely to be accepted; only 58% of minor claims were accepted (2885) compared with 96% of major claims (701), 84% of serious claims (204) and 95% of sentinel claims (55). Most accepted primary care claims (injuries) were also assessed as minor (2885; 75%); 18% were assessed as major (700), 5% as serious (204) and 1.5% as sentinel (56). Most declined claims were also assessed as minor (97%); but 1% were assessed as major, and 2% were assessed as either serious or sentinel.

### 7.3.1.3 Claimants

All four study years had similar distributions of claimants by age and sex. Similar proportions of claims were accepted from male and female claimants (65% of males and 63% of females: \( p = 0.21 \)). Figure 20 shows that claimants ranged in age from 0-101 years. The mean overall age was 45 years.

![Figure 20: Age distribution of claimants and the injured for primary care treatment injury claims 2006 - 2010](image)

Nearly two thirds of all claimants were female (62%), and females experienced 62% of all primary care treatment injuries. Women experienced all of the injuries caused by
contraceptives such as oral contraceptive pills (10), depo-provera injections (9), and IUCDs (21). Women experienced the majority of injuries caused by screening procedures: mammograms caused 35 injuries and fine needle aspiration of breast lumps caused six injuries; cervical smears caused five injuries (1 sentinel and 1 major). Appearance medicine procedures caused 14 injuries, all in women; laser resurfacing or hair removal (8), botox (2), collagen (2), teeth whitening (1) and dermabrasion (1). Treatment with iron caused 14 injuries (1 serious). Women also suffered all of the serious injuries (strokes) caused by neck manipulation. It is not possible to say whether this is because women are particularly vulnerable to this type of injury, or whether women are simply more likely to access this type of treatment.

Primary care claims lodged by the elderly were more severe and more likely to be accepted (76%) than primary care claims overall (64%). Despite lodging only 6% of all primary care claims, those aged 80 years or older were involved in 11% of serious or sentinel claims. Most of the serious and sentinel injuries in the elderly were caused by medication (39; 75%), and most of these were in relation to use of either antibiotics (12; 31%) or warfarin (7; 20%). Serious and sentinel medication injuries included tendonitis from ciprofloxacin or norfloxacin (5), pulmonary fibrosis from nitrofurantoin (2), a gastric bleed caused by arcoxia plus aspirin, two steroid injection injuries (ischaemia from injection of the ulna artery, and septic arthritis), morphine overdose (2), digoxin toxicity, prednisone overdose resulting in gastritis, myopathy and rhabdomyolysis from simvastatin, neutropenia from spironolactone, Stevens-Johnson syndrome from terbinafine, and intracerebral bleed from warfarin (5), methotrexate (1), and one case of pancreatitis from ezetimibe. Other serious and sentinel injuries in the elderly included decubitus ulcers (2), falls resulting in subdural and subarachnoid bleeds (2), shoulder injury during transfer, failure to diagnose (2) (giant cell arteritis and another unspecified condition resulting in blindness in one eye), injuries from injections (4) including ischaemia and septic arthritis, and Volkmann’s contracture from plaster cast.

Most of the major injuries in the elderly were also caused by medication (35; 39%). Injuries including allergic reactions to antibiotics, angio-oedema secondary to ACE inhibitors, one avascular necrosis femoral head requiring hemiarthroplasty following steroid use. Other major injuries were caused by ear syringing (11), removal of lesions/corns (7), cryotherapy (5), and injections and vaccinations combined (7). Physiotherapy
caused dislocations (shoulder and hip) and chiropractic treatment caused two major injuries (fracture and contusion).

Just 292 primary care treatment injuries (7%) occurred in children under the age of 10 years. Most injuries in children were caused by medication (130) and vaccination (107), but there were also injuries caused by dental treatment (10), cryotherapy (10), delay in diagnosis (8), and circumcision (7). Most medication injuries in children were caused by antibiotics (104): all were allergic reactions, 11 of which were major but none serious or sentinel. It was not possible to identify any medication injuries in children caused by incorrect dosing of medication. Four of the injuries in children were assessed as sentinel, all for delay in diagnosis; 14 were serious, mostly related to vaccination; 38 were assessed as major, caused by vaccination, medication, circumcision and delay in diagnosis. The diagnoses that were missed included meningitis, congenital glaucoma, chronic renal failure, congenital dislocation of the hip, oesophageal foreign body, and septicaemia.

7.3.2 Events causing treatment injuries

By definition, an accepted treatment injury compensation claim indicates that a person has suffered an injury caused by treatment (as assessed by ACC). Of the 3853 accepted primary care treatment injury claims (injuries) in this study, there were 179 different types of injury. Just ten types of injury accounted for 66% of all primary care injuries. The most common injury was “allergic/ adverse drug reaction” (1334; 35% of accepted claims), then “wound infection” (416; 11%), “haematoma” (231; 6%), and nerve damage (199; 5%). This compares with injuries in the complete claims dataset where wound infection was the most common injury, followed by allergic reaction, then haematoma/ bruising and nerve damage. It makes more sense, for injury prevention purposes, to focus on the causal event rather than the resultant injury (for example, reducing injury caused by acupuncture rather than reducing pneumothoraces which may be caused by a number of different types of treatment). Some injuries were caused by more than one type of event (for example, pneumothorax was caused by both acupuncture and fine needle biopsy), and some events caused more than one type of injury (for example, anti-inflammatory medication caused both renal failure and peptic ulcer).
Table 12 shows that, while injuries in primary care were caused by 119 different events, just ten events caused 75% of all injuries. Medication caused most injuries in primary care overall (1457; 38%), followed by dental treatment (626; 16%), then vaccinations and injections (392; 10%). This compares with the overall claims dataset (including hospital specialist and maternity care) where medication was also the leading cause of injury, followed by hip and knee surgery or replacement, and then intravenous cannulation.

Table 12: Events in primary care causing injuries and injuries assessed by ACC as having serious or sentinel potential consequences 2006 - 2009

<table>
<thead>
<tr>
<th>Causal event</th>
<th>Injuries (%)</th>
<th>Serious and sentinel injuries (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>1457 (38)</td>
<td>155 (60)</td>
</tr>
<tr>
<td>Dental treatment</td>
<td>626 (16)</td>
<td>9 (4)</td>
</tr>
<tr>
<td>Injection or vaccination</td>
<td>392 (10)</td>
<td>23 (9)</td>
</tr>
<tr>
<td>Venepuncture</td>
<td>237 (6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Removal of skin lesion</td>
<td>222 (6)</td>
<td>4 (2)</td>
</tr>
<tr>
<td>Cryotherapy</td>
<td>175 (5)</td>
<td>1 (0)</td>
</tr>
<tr>
<td>Physiotherapy</td>
<td>168 (4)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Ear syringing</td>
<td>108 (3)</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Chiropractic</td>
<td>99 (3)</td>
<td>5 (2)</td>
</tr>
<tr>
<td>Delay in diagnosis</td>
<td>77 (2)</td>
<td>39 (15)</td>
</tr>
<tr>
<td>Podiatry</td>
<td>56 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>IUCD</td>
<td>21 (1)</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>12 (0)</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Other</td>
<td>195 (4)</td>
<td>18 (7)</td>
</tr>
<tr>
<td>Total</td>
<td>3853 (100)</td>
<td>260 (100)</td>
</tr>
</tbody>
</table>
7.3.2.1 Events causing serious and sentinel events

In this analysis, serious and sentinel claims were considered together. There were 303 claims assessed by ACC as having either serious (245) or sentinel (58) potential consequences. ACC accepted 260 (86%) of these claims as being treatment injuries, 205 serious and 55 sentinel. Most of the serious and sentinel injuries arose in general practice settings (201; 77%).

Figure 21 shows that medication was the leading cause of serious and sentinel injuries (60%), followed by delay in diagnosis (15%), then injection/ vaccination (9%).

![Chart showing percentages of serious and sentinel injuries by primary care causal event](chart.png)

Figure 21: Serious and sentinel injuries 2006 – 2009 by primary care causal event

7.3.2.1.1 Declined serious and sentinel claims (no injury)

A claim may be declined and yet assessed as either serious or sentinel if, for instance, no actual injury occurred but ACC assessors nevertheless considered the claim gave rise to concerns about risk of harm to the public as the event had the potential to result in death or major permanent loss of function. Thus, even the declined claims, where no injury occurred, can identify potential threats to patient safety that may need addressing.
In this analysis, 43 claims were declined but assessed by ACC as having either serious (40) or sentinel (3) potential consequences. Most of these claims related to medication (35: 81%): medication dispensing in pharmacies (16), medication administration in rest homes (13), and medication ‘other’ in general practice (6), further highlighting the potentially dangerous nature of medication therapy and identifying the steps in the medication pathway where injuries can arise. Of the remaining declined serious and sentinel claims, three were associated with vaccination, two with injection, and one each with neck manipulation, diagnostic delay, and dental treatment.

7.3.2.2 Events causing major injuries

In this analysis, nearly all claims assessed as major were accepted (96%). Most of the 700 accepted major claims (injuries) arose in general practice settings (62%).

Table 13 shows medication was the leading cause of injury assessed as major (37%), followed by dental treatment (25%), then injection/ vaccination (11%).
Table 13: Events in primary care causing injuries assessed by ACC as having major potential consequences 2006 - 2009

<table>
<thead>
<tr>
<th>Event</th>
<th>Major injuries N=700 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td>259 (37)</td>
</tr>
<tr>
<td>Dental treatment</td>
<td>174 (25)</td>
</tr>
<tr>
<td>Injection / vaccinations</td>
<td>76 (11)</td>
</tr>
<tr>
<td>Removal of skin lesions</td>
<td>31 (4)</td>
</tr>
<tr>
<td>Ear syringing</td>
<td>31 (4)</td>
</tr>
<tr>
<td>Physiotherapy</td>
<td>26 (4)</td>
</tr>
<tr>
<td>Chiropractic</td>
<td>17 (2)</td>
</tr>
<tr>
<td>Spinal / neck manipulation</td>
<td>16 (2)</td>
</tr>
<tr>
<td>IUCD</td>
<td>13 (2)</td>
</tr>
<tr>
<td>Cryotherapy</td>
<td>13 (2)</td>
</tr>
<tr>
<td>Delay in diagnosis</td>
<td>12 (2)</td>
</tr>
<tr>
<td>Vasectomy</td>
<td>10 (1)</td>
</tr>
<tr>
<td>Venepuncture</td>
<td>8 (1)</td>
</tr>
<tr>
<td>Biopsy</td>
<td>7 (1)</td>
</tr>
<tr>
<td>Circumcision</td>
<td>6 (1)</td>
</tr>
<tr>
<td>Mammography</td>
<td>5 (1)</td>
</tr>
</tbody>
</table>

7.3.2.3 Events causing injuries that resulted in death

Twenty seven injuries resulted in death. Although death is probably the worst outcome from an injury, death does not necessarily imply the worst or most severe injury. A frail patient, for example, may die following a slight injury, while a robust patient may survive the worst injury.
The mean age of claimants who died was 48 years and the median age 58 years. One was an infant, five were aged less than 40y, ten were aged between 40y and 65y and three were aged over 80y. Nineteen were male (70%) and eight female (30%).

Twenty three of these injuries (85%) were classified sentinel, one major and three minor. The major injury was a thigh abscess following routine five month immunisations; the three minor injuries were allergic reactions to aspirin (61y), and co-trimoxazole (56y), and a decubitus ulcer leading to septicaemia (70y). Most of the injuries resulting in death occurred in general practice (20 claims); four were in rest homes, one in a laboratory and two occurred at home and resulted from delay/ failure to diagnose or monitor.

‘Delay/ failure to diagnose or treat’ was the most common cause of injury resulting in death (13; 50%). The delayed diagnoses included cardiac conditions (myocardial infarctions 58y, 62y and ‘other’ 38y); cancer (3) (lymphoblastic leukaemia 43y, peripheral T-cell lymphoma 28y, lung cancer 67y); infection (3) (staphylococcal pneumonia 20y, varicella pneumonia 40y, and septicaemia 3y); asthma (27y); pulmonary embolism (67y); and another unstated condition (39y).

Medication treatment was implicated in nine deaths. Many different drugs were involved including warfarin (3 deaths 71y, 80y, 86y); morphine (incorrect administration 78y); and six different drugs that caused fatal allergic/adverse reactions (allopurinol 47y, aspirin 61y, clozapine 50y, co-trimoxazole 56y, methotrexate 89y, and simvastatin 63y).

Other injuries resulting in death included falls during transfer, and decubitus ulcer leading to septicaemia.

### 7.3.3 Causal events by treatment context

The type of provider was not identified in the dataset but the treatment context was. Figure 22 shows that most primary care claims arose in general practice settings (62%), followed by dental clinics (22%), then physiotherapy rooms (5%), laboratories (4%) and chiropractic rooms (3%). Most primary care treatment injuries also arose in general practice settings (2573; 67%); followed by dental clinics (626; 16%), laboratories (171; 4%), physiotherapy rooms (167; 4%), chiropractic rooms (99; 3%) and radiology rooms (95; 3%). Only 32 injuries arose in residential care settings (0.1%).
Figure 22: Percentage of all primary care claims and injuries (accepted claims) 2006 - 2009 by treatment context

7.3.3.1 Events causing injury in general practice

As could be expected, causal events varied according to primary care treatment context. Some events caused injury in more than one setting; for example, medication caused injury in general practices, dental clinics, pharmacies and rest homes; acupuncture caused injury in general practice, physiotherapy and chiropractic rooms; spinal/neck manipulation caused injury in physiotherapy and chiropractic rooms; and venesection caused injury in general practice rooms, laboratories and rest homes. Some treatments were unique to some settings, for example, dental treatment was unique to dental clinics, and mammography was unique to radiology rooms.

Medication was the leading cause of injury in general practice (56%), followed by vaccination and injection combined (11%), minor surgery (removal of lesion or toenail wedge resection) (10%), cryotherapy (7%), and ear syringing (4%).
Of the serious and sentinel injuries in general practice, medication was also the leading cause (72%), followed by delay/failure to diagnose or treat (16%), injection and vaccination combined (6%), IUCDs (1%) and ear syringing (1%).

### 7.3.3.2 Medication

Medication was the leading cause of injury in the primary care claims dataset, causing 38% of all injuries (1457), 35% of the major injuries (255), and 60% of the serious and sentinel injuries (155). Most medication injuries arose in general practice settings but some arose in other settings including dental rooms (73), pharmacy (dispensing) (23), and rest homes (medication administration) (6).

Sixty-four different medicines were implicated. Table 14 shows the top ten medications causing injury in primary care.
Table 14: Medications in primary care causing injury and serious or sentinel injury 2006 - 2009

<table>
<thead>
<tr>
<th>Medication</th>
<th>Injuries N=1406 (100%)</th>
<th>Serious and sentinel injuries N=149 (100%)</th>
<th>Type of injuries with serious or sentinel potential consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotics</td>
<td>843 (60)</td>
<td>42 (28)</td>
<td>Allergic reaction, hepatitis, tendinitis</td>
</tr>
<tr>
<td>Steroids</td>
<td>146 (10)</td>
<td>22 (15)</td>
<td>Avascular necrosis (8), cataracts (3), gastritis (2), septic arthritis (5), ischaemia (2)</td>
</tr>
<tr>
<td>NSAIDs</td>
<td>146 (10)</td>
<td>19 (13)</td>
<td>Renal failure (8), gastro-intestinal bleed (6), allergy (3), septicemia (1), neuropraxia (1)</td>
</tr>
<tr>
<td>ACE-inhibitors</td>
<td>45 (3)</td>
<td>2 (1)</td>
<td>Adverse reaction</td>
</tr>
<tr>
<td>Anti-emetics</td>
<td>22 (2)</td>
<td>1 (1)</td>
<td>Adverse reaction</td>
</tr>
<tr>
<td>Opiates</td>
<td>20 (1)</td>
<td>4 (3)</td>
<td>Coma, death</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>20 (1)</td>
<td>2 (1)</td>
<td>Adverse reaction</td>
</tr>
<tr>
<td>Hormonal contraceptives</td>
<td>19 (1)</td>
<td>4 (3)</td>
<td>Stroke (3), DVT (1)</td>
</tr>
<tr>
<td>Terbinafine</td>
<td>15 (1)</td>
<td>6 (4)</td>
<td>Drug hypersensitivity syndrome (DHS)</td>
</tr>
<tr>
<td>Warfarin</td>
<td>14 (1)</td>
<td>10 (7)</td>
<td>Haemorrhage, death</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>12 (1)</td>
<td>4 (3)</td>
<td>Myopathy, death</td>
</tr>
<tr>
<td>Proton pump inhibitors</td>
<td>12 (1)</td>
<td>2 (1)</td>
<td>Interstitial nephritis</td>
</tr>
<tr>
<td>Allopurinol</td>
<td>11 (1)</td>
<td>4 (3)</td>
<td>DHS, death</td>
</tr>
</tbody>
</table>
Figure 23: The medications in primary care that caused injuries and injuries assessed by ACC as having serious and sentinel potential consequences 2006 - 2009

Figure 24: The medications in primary care that caused injuries assessed by ACC as having serious and sentinel potential consequences 2006 - 2009 (N=149)
Figure 23 shows that antibiotics caused the most medication injuries (841; 60%), followed by steroids (146; 10%), and anti-inflammatory drugs (146; 10%). Figure 24 shows that antibiotics (28%), steroids (15%), and anti-inflammatory drugs (13%) were also the leading cause of serious and sentinel medication injuries. Both steroids and anti-inflammatory drugs also caused injury via injection. Steroids caused 22 serious and sentinel injuries; 15 in relation to the medication such as avascular necrosis (8), cataracts (3), and gastritis (2), and 7 in relation to the injection process including septic arthritis (5) and ischaemia (2). Anti-inflammatory drugs caused 19 serious and sentinel injuries; 17 including renal failure (8), gastro-intestinal bleed (6), and allergy, and two related to the injection administrative route (septicaemia and neuropraxia).

7.3.3.2.1 Antibiotics

Antibiotics caused most medication injuries (843; 60%), most major medication injuries (138; 57%), and most serious and sentinel medication injuries (42; 28%), reflecting both the incidence of antibiotic use in primary care and the dangers of antibiotic use. Overall, antibiotics caused about one fifth of all primary care treatment injuries (843; 22%), and about one sixth of all serious and sentinel primary care treatment injuries (42; 16%).

Figure 25 shows that penicillins caused most of the antibiotic related injuries, followed by cephalosporins, and then sulphonamides. Penicillins also caused most of the serious and sentinel injuries (allergic reaction and hepatitis), followed by fluoroquinolones (tendonitis), and then macrolides.
Figure 25: The antibiotics in primary care that caused injuries, and the antibiotics that caused injuries assessed by ACC as having either serious or sentinel potential consequences 2006 - 2009

Table 15 shows the antibiotics that caused serious and sentinel injuries. Fluroquinolones (Ciprofloxacin and Norfloxacin combined) caused 49 injuries including 12 cases of tendonitis/ tendon rupture (8 serious); Nitrofurantoin caused 12 injuries, including seven cases of pneumonitis (5 serious and one major); and Co-trimoxazole caused 55 injuries, mainly allergic reactions including three cases of Stevens-Johnson or drug hypersensitivity syndrome.
Table 15: The antibiotics in primary care that caused injuries assessed by ACC as having serious or sentinel potential consequences, and the type of injury these medications caused 2006 - 2009

<table>
<thead>
<tr>
<th>Antibiotic</th>
<th>Serious &amp; sentinel injuries N=42 (100%)</th>
<th>Type of injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penicillins</td>
<td>18 (43%)</td>
<td>Allergic reaction (12), hepatitis (6)</td>
</tr>
<tr>
<td>Fluroquinolones</td>
<td>8 (19%)</td>
<td>Tendonitis (8)</td>
</tr>
<tr>
<td>Macrolides</td>
<td>7 (17%)</td>
<td>Hepatitis (2), renal failure (2), allergic reaction (2), and hearing loss (1)</td>
</tr>
<tr>
<td>Nitrofurantoin</td>
<td>5 (12%)</td>
<td>Interstitial lung disease (5)</td>
</tr>
<tr>
<td>Co-trimoxazole</td>
<td>3 (7%)</td>
<td>Allergic reaction (2), interaction with warfarin leading to stroke (1)</td>
</tr>
</tbody>
</table>

Drug hypersensitivity syndrome (DHS) was also caused by penicillin (2), erythromycin, and trimethoprim. DHS is a severe adverse drug reaction which may occur up to two months after drug exposure; it is characterized by fever, widespread blistering of the skin and ulceration of the mucous membranes, and internal organ derangement including hepatitis, myocarditis, nephritis and pneumonitis. DHS has a mortality rate of about 8%.\(^{313}\) DHS was sometimes referred to in the dataset as DRESS (Drug Rash with Eosinophilia and Systemic Symptoms) or Stephen-Johnson syndrome.

Hepatitis was caused by augmentin (6), erythromycin (2), flucloxacillin, and roxithromycin (also diclofenac and terbinafine).

7.3.3.2.2 Steroids

Steroids (prednisone, kenacort, and triamcinolone) caused 143 injuries (10% of medication injuries). Of these, 50 were assessed as major, 21 serious, and one sentinel. Some injuries were caused by the medication and some by the injection process (112), including infection (septic arthritis (20), cellulitis, abscess), nerve damage (13), tissue atrophy (34), bruising, and ischaemia. Steroid injections for carpal tunnel syndrome
caused 12 nerve injuries (mainly median nerve, but also three ulna nerve) and two ischaemic injuries (ulna artery).

7.3.3.2.3 Anti-inflammatory drugs

Anti-inflammatory drugs (NSAIDs) caused 136 injuries (10% of medication injuries); nineteen were assessed as either serious or sentinel. Injuries included renal failure (9), gastro-intestinal bleed (16), and injection related injuries (12) including abscess (5) and nerve damage (5).

7.3.3.2.4 Antihypertensive drugs

Antihypertensive drugs caused 4% of all medication injuries (53); but only two were assessed as serious (both allergic reactions to ACE inhibitors), and seven as major (allergic reactions).

A 40 year old woman died after taking amiloride/ hydrochlorothiazide which caused “hypokalemia which resulted in cardiac arrest and hypoxic encephalopathy”. The 'hypokalemia' is probably a data entry error because this drug combination is more likely to result in hyperkalemia. The amiloride/hydrochlorothiazide drug combination has subsequently been withdrawn.

7.3.3.2.5 Warfarin

Warfarin caused 1% of all medication injuries (14), but a disproportionate number of the serious and sentinel medication injuries (10; 7%). Warfarin caused 4% of serious and sentinel injuries overall. Injuries were mainly bleeds in the elderly and included cerebral haemorrhage (7), subarachnoid haemorrhage (2), and one each of subdural haematoma, epidural haematoma, and haemarthrosis. Three warfarin related injuries resulted in death (71y, 80y, 86y).

7.3.3.2.6 Other drugs

Omeprazole and pantoprazole combined caused 14 injuries (1% of medication injuries). Omeprazole caused two cases of interstitial nephritis (one serious and one major) and one case of bilateral leg oedema; pantoprazole caused one sentinel case of Stevens-Johnson syndrome in a 38 year old woman. The remaining injuries were allergic reactions.
Terbinafine, commonly prescribed in primary care for fungal infections such as onychomycosis, caused 15 adverse drug reactions. Six of these injuries were serious, including six cases of DHS. Allopurinol caused 11 injuries, one sentinel (death of a 47y woman), three serious and one major. Injuries included four cases of DHS. Simvastatin caused 12 injuries including 11 cases of myopathy (four serious or sentinel including death of a 63y man), and three major. The analysis also identified several toxicity-related injuries, in relation to digoxin, methotrexate, morphine, and carbamazepine, which are all likely to be highly preventable.

Hormonal combined oral contraceptives or progesterone caused 17 injuries including five deep vein thrombosis and/or pulmonary embolism, and four strokes (26y, 35y, 35y and 36y). These were classified sentinel (2), serious (4), major (2), and minor (9).

Other medication injuries of note included DHS caused by carbamazepine (5); terbinafine (4) and one each by clozapine (which resulted in the death of a 50 year old woman), ezetimibe, lamotrigine, phenytoin, fluconazole, diazepam, carbimazole and dapsone; three cases of digoxin toxicity; three cases of methotrexate toxicity (one fatal); three serious burns from imiquimod; and two cases of foetal valproate syndrome (physical deformity and global developmental delay) caused by sodium valproate taken during pregnancy. Sodium valproate is contraindicated in pregnancy for this reason.

The injection of iron caused six hyper-pigmentation injuries in addition to haematomas, infections and nerve damage. There was one case where an unspecified herbal medication caused cushingoid changes and an osteoporotic rib fracture in a 45 year old woman.

7.3.3.3 Delay or failure to diagnose, follow-up, treat, or refer

Delay or failure to diagnose, follow-up, treat, or refer accounted for only 150 of the primary care treatment injury claims (2%); and only 1% of injuries (56). Only 37% of claims for this type of event were accepted, compared to 64% for primary care claims overall. Although delay/ failure to diagnose caused few injuries overall (56; 1%), the injuries were disproportionately severe, accounting for 15% of all serious and sentinel events injuries (39). Claims for delay or failure to diagnose, follow-up, treat, or refer arose in general practice, laboratories and radiology rooms.
Table 16 shows that cancer was the most commonly missed diagnosis (16); there were two cases each of cancer of the cervix, breast, bowel and skin and one each of bone, lung, and blood. There were five cases of missed testicular torsion resulting in orchidectomy; two missed ectopic pregnancies; two fatal myocardial infarctions; and five infections including meningitis, necrotising fasciitis, pneumonia and appendicitis. Uncommon congenital conditions such as congenital dislocation of the hip and congenital glaucoma were also missed. There were two cases where incorrect diagnosis had led to unnecessary surgery including hysterectomy and removal of skin lesion. Some diagnostic failures resulted in death: myocardial infarction (58y, 62y), cardiac failure (38y, 67y), pneumonia (20y, 40y), pulmonary embolism (67y), asthma (27y) and septicaemia (3y).

Table 16: The conditions that gave rise to treatment injury claims in primary care for delay or failure to diagnose 2006 - 2009

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer (16)</td>
<td>Bowel (50y, 64y, 65y); breast (48y, 51y, 53y); cervix (24y, 40y, 44y); blood (leukaemia 43y, lymphoma 23y); skin (squamous cell carcinoma 53y, 74y; melanoma 33y); lung (67y); bone (sarcoma 60y)</td>
</tr>
<tr>
<td>Infection (5)</td>
<td>Viral pneumonia (20y, 40y); necrotising fasciitis (26y); meningitis (1y); appendicitis (49y); pelvic infection (15y); intra-abdominal sepsis (3y); septic arthritis (52y, 72y)</td>
</tr>
<tr>
<td>Testicular torsion (5)</td>
<td>(Resulting in orchidectomy - 12y, 12y, 13y, 14y and 21y)</td>
</tr>
<tr>
<td>Cardiac conditions (4)</td>
<td>Myocardial infarction (58y, 62y); cardiac failure(38y, 67y)</td>
</tr>
<tr>
<td>Congenital conditions (2)</td>
<td>Glaucoma, dislocation of the hip</td>
</tr>
<tr>
<td>Ectopic pregnancy (2)</td>
<td>(Resulting in salpingectomy - 23y and 33y)</td>
</tr>
<tr>
<td>Giant cell arteritis (2)</td>
<td>(77y)</td>
</tr>
<tr>
<td>Other</td>
<td>Pulmonary embolism (67y); chronic renal failure; bowel obstruction (56y); ischaemic foot (39y); cervical disc protrusion (42y); oesophageal foreign body (4y); wrist dislocation (21y); fractured fibula and macula damage (30y).</td>
</tr>
</tbody>
</table>
7.3.3.4 Procedures and physical examination

Removal of skin lesions caused 222 injuries (6%), and 1% of serious and sentinel events. Most injuries were minor wound infections and dehiscence (200) but there were also ten arterial bleeds and five nerve injuries (peroneal, sural and accessory nerves). There were two serious injuries (one keloid scar and one dehiscent scalp wound) and 25 major injuries.

Vasectomy caused 23 injuries; including haematoma (16), chronic epididymitis (4), scrotal abscess (1), wound infection (1) and testicular nerve damage (1). Ten of these injuries were major. Circumcision caused eight injuries; six classified as major, mainly scarring and phimosis. Catheterization caused one major urethral injury necessitating suprapubic catheterization in a 41 year old. Intrauterine contraceptive devices (IUCD) caused 21 injuries; one sentinel, one serious and 13 major. Injuries included uterine perforation (12), bowel perforation (1), and pelvic infection (5) resulting in tubal occlusion and infertility. Cervical smears caused four injuries including vaginal laceration requiring surgical repair, lumbar sprain, thigh burn, and urethral contusion.

Physical examination caused 15 injuries, mostly minor strains of knees, thumbs, shoulders and toes, a torn biceps tendon, a traumatic anal fissure, and dislocation of the hip. There was also one dislocation of the elbow (radial head) during blood pressure measurement. Plaster casts caused one sentinel Volkmann’s ischaemic contracture, one trigger thumb and two pressure ulcers. Sclerotherapy of varicose veins caused three ulcers (two minor and one major) and two minor allergic reactions; laser treatment for varicose veins caused one major sural nerve injury. Laser skin treatment caused six burns and two major hypo-pigmentation injuries; collagen injection caused two allergic reactions – one minor and one major; botox caused two major injuries – one wound infection and one case of facial palsy. Acupuncture caused 12 injuries in total; mostly in physiotherapy rooms (9), but two occurred in general practice and one in chiropractic rooms. Injuries included infections, haematomas, strains, and three pneumothoraces (33y, 35y, 48y). Podiatry treatment caused 56 injuries (1%); most were minor infections (34) and lacerations (17), but there were two major infections.
7.3.3.5 Nursing care

7.3.3.5.1 Injections and vaccinations

Most vaccination injuries related to the injection process (local inflammatory reactions, infection, nerve damage, and tendonitis/capsulitis injuries) and so, for this analysis, it made sense to analyse injections and vaccinations together. Coding inconsistencies made it difficult to make precise determinations about injuries and injury causation and to determine, for example, whether an injury was a local inflammatory reaction or a systemic allergic reaction.

Injections and vaccinations combined caused 12% of all primary care treatment injuries (458). Most of the injuries were minor (331; 72%); but there were 94 major (21%), and 33 serious (7%) injuries. Injuries included infection (166; 36%) (cellulitis, abscess, wound infection, septic arthritis and septicaemia); allergic reactions (57; 12%); haematoma/bleeding (55; 12%); nerve damage (41; 9%) (sciatic, ulna and median nerves); tissue atrophy (34; 7%); and tendon damage (7; 2%). The injection of depo-provera caused three sciatic nerve injuries (one serious), three abscesses (one major), and one other haematoma.

Five of the vaccination injuries were caused by the wrong diluent being used to reconstitute the infanrix-hexa vaccine. That this event arose in different sites suggests that a change in packaging, or a solution other than ‘further education and training’, is warranted. The influenza vaccine caused Guillain-Barre syndrome, transverse myelitis, and frozen shoulder. The meningococcal-B vaccination (MENZB) caused idiopathic thrombocytopenic purpure (2).

There was one sentinel accepted treatment injury claim for hepatitis C infection following administration of anti-D to a rhesus negative woman in 1998. Screening of blood products for hepatitis C was introduced in New Zealand in the 1990s. While unsafe blood products cause a number of adverse events worldwide, there are few occasions where blood products are administered in primary care in New Zealand and so it is not surprising that few blood product related injuries were identified in this analysis.
7.3.3.5.2 Other nursing

Venepuncture (220) and intravenous cannulation (17) combined caused 6% of all primary care treatment injuries (237). Most injuries were assessed as minor (97%); the remaining seven were assessed as major (3%). Injuries included nerve damage (75) (mainly median nerve, but also ulna and radial nerves); bruises and infections.

Treatment with liquid nitrogen caused 175 injuries (5%). Most of these injuries were minor (161; 92%) and included wound infections, cellulitis, and ulcers. There was one serious full thickness burn and 13 major injuries (ulcers and infections).

Ear syringing caused 108 (3%) injuries, including 78 perforated ear drums and 29 ear canal injuries. Most injuries were minor (75; 69%), but 31 were major (29%) and two were serious (2%).

7.3.3.6 Residential care

Few injuries overall occurred in residential care settings (32, 1%); but the injuries were disproportionately severe. There were 12 serious or sentinel injuries (38%) and three major (1%). The serious and sentinel injuries were caused by medication administration (4), patient transfer (3), injection (2), and inadequate nursing care (2).

There were 17 serious or sentinel claims relating to medication administration in rest homes. Only four of these claims were accepted as a treatment injury, involving the medications morphine (2), oxycontin (1) and one unstated drug. Most of the medication administration claims involved a patient being given someone else’s medication.

Other injuries in residential care settings were caused by ‘inadequate nursing care’ (14 decubitus ulcers or skin damage), and ‘fall during patient transfer’ (4 fracture injuries and one fatal subarachnoid haemorrhage).

7.3.3.7 Dental treatment

In this analysis, all treatment provided in dental clinics has been combined as ‘dental treatment’. Treatment in dental settings includes claims where the treatment facility was coded as “rooms dental”, the facility unit as “dentist”, or the treatment context as “dental”. This treatment is such a distinct entity in primary care, with very little or no cross over
with treatment provided in other primary care settings, and so has been grouped together as a type of treatment.

Dental clinics were the second most common source of primary care claims, reflecting both the potential danger of dental treatment and the greater pecuniary incentive to claim for dental care - dental care for adults is not subsidised in New Zealand.

There were 1100 primary care treatment injury claims that arose in dental rooms; 627 of these were accepted as treatment injuries (57%). Thus claims arising in dental rooms were less likely to be accepted than primary care claims overall (64%). Dental treatment was the leading event precipitating a claim that was declined and assessed as minor (490; 24%). This perhaps reflects the financial incentive for patients to lodge claims to assist with the cost of dental treatment.

Treatment provided in dental clinics caused 16% of all primary care treatment injuries (626), but only 4% of the serious and sentinel injuries. Most injuries in dental settings were caused by ‘dental treatment’ (268), tooth extraction (181), and medication (73); but root canal treatment (41), local anaesthetic (13), and orthodontic treatment (11) were also reasonably common causes of injury in dental settings. Injuries included allergy/ anaphylaxis (91), nerve damage (67), tooth chip/ damage (66), temporo-mandibular joint dysfunction (60), fistula (51), infection/ abscess/ cellulitis/ wound infection (49), sprain (46), laceration (31), perforation - root canal (31), haematoma/ bruising/ bleeding (19), burn (15), and foreign body (15).

Most injuries from dental care were minor (70%), but 177 were major (28%), and 13 were serious (2%). None were classified sentinel. The major injuries were caused by dental treatment (80; 45%), tooth extraction (59; 33%), root canal treatment (13; 7%) and medication (11; 6%). Injuries included fractured mandible or maxillary sinus (4); ingestion of foreign body (5); dislocated mandible (1); temporo-mandibular strain (17); infection (23) including osteomyelitis (2) and septicaemia (1); lacerations (3), nerve damage (23); oro-antral fistula (30); and wrong site surgery (2).

The serious injuries were caused by dental treatment (6), medication (3), tooth extraction (2), orthodontic treatment (1), and root canal (1). Injuries included infection (2)
(necrotising fasciitis, and endocarditis requiring heart valve replacement), wrong site surgery (2), tooth damage (4), laceration (1), and adverse drug reactions (3).

### 7.3.3.8 Manual therapy

Manual therapy, exercise therapy, and spinal/neck manipulation caused injury in both physiotherapy and chiropractic clinics. Although the provider type is not listed in the claims dataset, it can be assumed that treatment provided in physiotherapy rooms is provided by physiotherapists (168 injuries) and treatment in chiropractic rooms by chiropractors (99 injuries).

Manual and exercise therapy caused 117 injuries; most were minor (92; 79%), but 25 were major (21%). Spinal/neck manipulation caused 77 injuries, mostly in chiropractic rooms (78%). Most injuries were minor strains (59; 77%) but there were 14 major injuries including lumbar and cervical nerve root injuries, and five serious or sentinel injuries including arterial dissection and strokes in women aged 33y, 39y, 52y, and 62y.

#### 7.3.3.8.1 Physiotherapy

There were 168 injuries in physiotherapy rooms (4%). Most injuries were minor but there was one sentinel and one serious injury (both strokes from neck manipulation). Other injuries caused by physiotherapy included dislocations of the hip (4) and shoulder (3); nerve root injuries (3); ruptured achilles tendon (2); meniscal tears (4); and other strains (98). Physiotherapy also caused strapping injuries, skin damage and one pneumothorax from acupuncture.

For the year to 31 March 2009, the Physiotherapy Board issued 3815 annual practising certificates. The number of treatment injuries generated per registered physiotherapist over the four study years was therefore 168/3815 = 0.04.

#### 7.3.3.8.2 Chiropractic

There were 99 injuries in chiropractic rooms (3%), all presumably caused by chiropractic treatment. 17 injuries were major, seven were serious, but none were sentinel. Injuries included two strokes from neck manipulation (33y, 39y); a transient ischaemic attack (60y); eight fractures (ribs 44y, 53y, 57y, 62y, 80y, 82y and teeth 36y, 53y); one serious
pneumothorax from acupuncture; ten nerve root injuries (cervical and lumbar disc injuries and sciatica from spinal manipulation); two burns and other strains. Of the declined claims, chiropractic treatment gave rise to two serious events caused by spinal/neck manipulation and failure to diagnose, and one major event associated with ‘underlying health condition’.

For the year to 31 March 2009, the chiropractic board issued 384 annual practising certificates. The number of treatment injuries generated per registered chiropractic provider over the four study years was therefore 99/384 = 0.26. In this analysis, then, chiropractic treatment is almost six times as likely as physiotherapy to result in an accepted treatment injury claim.

7.3.3.8.3 Osteopathy

There was only one injury in the primary care treatment injury claims dataset arising in “Rooms osteopath” – a minor chest contusion. For the year to 31 March 2009, the Osteopathic Council issued 335 practicing certificates. In this analysis, the motivation to claim remaining the same, osteopathic treatment appears a comparatively safe option.

7.3.3.9 Other settings

7.3.3.9.1 Laboratories

There were 171 injuries in laboratories (4%); most were minor (155; 91%), but 11 injuries were assessed as major (haematoma, nerve damage, and cellulitis relating to venepuncture or biopsy); one as serious and four as sentinel (all five relating to diagnostic failure). Venepuncture caused most laboratory injuries (89%). Other injuries included pneumothorax from fine needle aspiration of breast lumps (2); and diagnostic failures (including failure to diagnose cancer (3) (two cervix and one leukaemia) and incorrect diagnosis of cancer leading to unnecessary surgery (2) (skin and cervix)).

7.3.3.9.2 Radiology rooms

There were 95 injuries in private radiology rooms (3%); mostly minor strains from positioning. There were 17 major injuries; three assessed as serious and two as sentinel for failure to diagnose cancer of the breast (2) and bowel (2), and for a new-born intracranial haemorrhage caused by ultrasound. The major injuries included adverse
reactions to injected contrast material, ruptured implants, strains and infections. Mammography caused 34 injuries; including five ruptured breast implants and other strains, bruises, and lacerations.

7.3.3.9.3 Pharmacies

There were 48 claims arising in pharmacy settings, 23 of these were accepted as treatment injuries. Most injuries in pharmacy were caused by “medication dispensing”. Although pharmacy dispensing caused only 1% of all primary care treatment injuries, the injuries were disproportionately severe - 14 were serious (61%) and three were major (13%). The medications involved in pharmacy dispensing claims included prednisone (7), methadone (4) and morphine (1), imiquimod (3), clonazepam (2). There were also 16 pharmacy dispensing claims that were declined but still assessed as serious. Medications involved included prednisone, warfarin, morphine, methadone, clonazepam, and tramadol, among others.

7.4 Discussion

Findings from this analysis suggest that treatment injury claims data can be analysed to identify learning to inform efforts to improve patient safety.

7.4.1 Summary of findings

This was the first study to analyse the claims dataset to identify the type, frequency, severity and cause of injury in primary care. One third of all new treatment injury claims over the four study years arose in primary care. Most primary care claims (62%) and injuries (66%) arose in general practice, consistent with where most primary care contacts occur in New Zealand. Most primary care claims, as most claims overall, were assessed by ACC as having only minor potential consequences (83%), consistent with previous primary care patient safety research. While events with only minor potential consequences may be of less interest to injury prevention initiatives, the number of new primary care claims nevertheless confirms the importance of addressing patient safety concerns in primary care.
7.4.1.1.1 Women

Two thirds of primary care claims were lodged by females, consistent with previous research on claiming behaviour. The greater presence of women in the claims dataset suggests that women may be at greater risk of harm. This may be partly explained by women’s greater use of the health system; women taking more drugs, having more cosmetic surgery, participating more in cancer screening, and experiencing more over-diagnosis than men. Thus, while the patient safety movement has been mainly concerned with what Illich called clinical iatrogenesis, this analysis suggests that social and cultural iatrogenesis may also be a problem. To improve patient safety, in addition to delivering care more accurately, we may need to withhold (potentially dangerous or futile) treatment. We may need to shift the focus, then, from reducing what Illich called clinical iatrogenesis to reducing social and cultural iatrogenesis.

7.4.1.1.2 The elderly

The elderly are known to be particularly vulnerable to injury in healthcare settings and so could have been expected to feature more strongly in the treatment injury dataset. While only 14% of claimants (852) were 70 years or older, the injuries suffered by the elderly were disproportionately severe. The lack of showing in the dataset by the elderly may be explained by under-claiming. This may be due to a lack of awareness or a lack of motivation to claim when treatment and rehabilitation may be provided free of charge in public hospitals. It may also be because some injuries common in the elderly, such as falls, may be lodged as a general injury instead of as a treatment injury. If lodged as a general injury, a fall would not appear in the treatment injury claims dataset. The entitlements are the same for both types of claim, but it is easier to lodge a general injury claim as it requires the completion of only one form.

The elderly were particularly vulnerable to serious and sentinel medication injuries. Potentially inappropriate medication is known to cause injuries in the elderly and to lead to avoidable hospital admissions. Simvastatin, for example, which is widely prescribed in New Zealand to prevent cardiovascular disease, caused injuries to people in their 80s. Findings from this study support research demonstrating that many medications in the elderly can be discontinued, leading to improvement in quality of life.
Few claims arose in residential care settings but this should not be taken as indicative of the relative safety of these settings. Injuries from residential settings may be under-represented in the claims dataset because only a small percentage of the population live in residential care settings or because of a low rate of claiming. The injuries that were identified were those known to be common in rest homes, including decubitus ulcers (15), medication administration incidents (5), and falls (5). Many of these injuries are highly preventable with adequate staffing levels, preventive administration systems and improved training.

7.4.1.1.3 Medication

Allergic reaction was the most common injury in the primary care claims dataset, compared with the overall claims dataset where wound infection was the most common injury, followed by allergic reaction, haematoma or bruising, and then nerve damage.

Medication was identified as the dominant threat to patient safety in primary care, causing 38% of primary care treatment injuries and 60% of the injuries assessed by ACC as serious and sentinel. This reinforces previous research findings and confirms the importance of addressing medication as a source of harm in primary care settings.

The predominance of medication injury reflects both the frequency of medication use in primary care (67% of general practice patient visits result in a prescription) and the potentially dangerous nature of medication treatment.

Antibiotics caused most of the medication injuries (841; 60%), consistent with previous research findings. This was followed by steroids (oral and injected) (146; 10%) and anti-inflammatory drugs (146; 10%). Antibiotics, steroids, and anti-inflammatories also caused most of the serious and sentinel medication injuries (28% (42); 15% (22), and 13% (19) respectively). Medication injuries do not mirror prescribing rates as, although in 2001/02 antibiotics were the most commonly prescribed drugs in primary care (15%), steroids were only 11th (2%) and anti-inflammatory drugs were sixth (3.5%).

Warfarin was an outstanding cause of medication harm in the primary care claims dataset, causing 5% of all serious and sentinel events (10) including three deaths, despite lessons from research extending over more than a decade providing information on how to manage warfarin use more safely. This analysis draws attention to the risks of...
warfarin therapy in the community, which may be different to the risks apparent during controlled trials, and confirms the need for further translational research in this area. Findings also support the need for prescribers to frequently reassess a patient’s ability to cope with the close monitoring and frequent dose adjustments required for warfarin therapy.

It is not possible to tell from the treatment injury claims dataset which of the medication injuries were preventable. While it is likely many injuries arose from properly prescribed and administered medication, at least some injuries occurred as a result of medication error. Research has identified that medication errors occur mostly at the ordering and dispensing stage. The situation may be different in New Zealand where, in contrast to other countries, general practitioner prescribers have been using electronic medical records for at least the last decade, which should have reduced ordering and dispensing errors, although there is no published research yet to show this.

The number of severe injuries caused by medication used for prevention or to treat non-life-threatening conditions highlights the need for caution and for informed decision-making based on proper risk: benefit assessments. Simvastatin, for example, caused five serious and sentinel injuries, some in people over 80 years. Proton pump inhibitors (omeprazole and pantoprazole) caused 14 injuries, one sentinel (38y), one serious, and four major. Allopurinol, which is used to prevent gout, caused four severe DHS reactions including one resulting in the death of a woman in her forties. Terbinafine, which is commonly used in primary care to treat onychomycosis (a very common and largely harmless toenail infection previously left untreated) caused seven serious and sentinel injuries (DHS). During this study period, the pharmaceutical company producing terbinafine took advantage of New Zealand’s direct-to-consumer advertising laws to promote both the drug and the condition to the New Zealand public, resulting in a dramatic rise in terbinafine dispensing.

The extent of the medication-related harm identified in this analysis supports calls to better manage drug therapy, or alternatively to reduce prescribing overall. While the lack of information on injury preventability makes it impossible to differentiate events caused by the proper prescribing of appropriate medication from those caused by errors in prescribing and dispensing, this analysis suggests that to improve patient safety we may
be better to reduce prescribing overall rather than seeking to reduce medication errors. This may be especially so for antibiotics, which were identified in this analysis as the leading cause of medication-related harm, while antibiotic over-prescribing in primary care is a well-recognised problem.\textsuperscript{362-366} This analysis may also be used to guide prescribing choices. For example, both nitrofurantoin and trimprim are recommended as first line choices for the treatment of urinary infections in primary care,\textsuperscript{367} but in this analysis there were six serious injuries caused by nitrofurantoin (interstitial pneumonitis/pulmonary fibrosis) while trimethoprim caused only minor allergic reactions. Trimethoprim thus appears safer than nitrofurantoin and, all else being equal, would make be a better first choice.

Pharmacy medication dispensing and rest home medication administration accounted for most of the declined serious and sentinel claims (37\% and 35\% respectively), highlighting the potentially dangerous nature of these activities and identifying these activities as possible targets for injury prevention initiatives.

7.4.1.1.4 Diagnosis

Analysis of the treatment injury claims dataset identified comparatively few claims (2\%) and few injuries (56; 1\%) caused by delay or failure to diagnose, follow-up, treat, or refer. Not surprisingly, claims for injury caused by diagnostic delay were more likely than other claims to be declined for reasons that the alleged injury was “wholly or substantially caused by a person's underlying health condition” (s.32).\textsuperscript{21}

The injuries that were identified were disproportionately severe, accounting for 9\% of serious injuries and 50\% of sentinel injuries. The diagnoses that were missed were those well known to present a diagnostic challenge in primary care. Cancer was the most commonly missed diagnosis (16),\textsuperscript{368} followed by infection (9) (viral pneumonia, necrotising fasciitis and meningitis), testicular torsion (5),\textsuperscript{369} cardiac conditions (4), ectopic pregnancy (2),\textsuperscript{370} pulmonary embolism, giant cell arteritis,\textsuperscript{371} congenital glaucoma, and congenital dislocation of the hip.

It is unclear why diagnostic delay or failure is so underrepresented in the treatment injury claims dataset. The anomaly is not likely to be explained by New Zealand primary care practitioners being unusually good diagnosticians. It is more likely to be explained by a
lower rate of claiming for this type of injury (it is counterintuitive to claim for an injury caused by treatment when one has not received any treatment subsequent to a missed diagnosis). This suggests increasing awareness about the scheme and the eligibility criteria may increase future claiming.

Diagnosis is a key function of primary care and diagnostic failures feature prominently in other primary care patient safety research. It is always going to be difficult to avoid diagnostic failures, especially for rare conditions, given the complexity of practice and the vast number of possible diagnoses (13,000), but avoiding diagnostic failures through lost test results is a potential target area for improvement. Also, although not identified in this analysis, over-diagnosis is increasingly being recognised as a source of harm in health care, serving as a reminder to providers of the dangers of responding to the fear of missing a diagnosis by ordering more tests.

7.4.1.1.5 Injections and vaccinations

Injections and vaccinations caused 10% of all primary care treatment injuries, confirming injections as an important source of harm in primary care. As the harm caused by injections is thought to be highly preventable through improved injection technique, such as using longer needles for immunisations, this analysis supports calls to target injury prevention initiatives at reducing injection related harm.

Injections by both doctors and nurses caused injuries. Although the provider type is not identified in the dataset, it is likely that doctors performed most of the joint injections and injections for carpal tunnel syndrome. Joint injections resulted in septic arthritis (20), and carpal tunnel injections caused nerve injuries (12), identifying target areas for improvement. Of particular concern, there were injuries in the claims dataset caused by the injection of both iron (13) and anti-inflammatory drugs (12), when the injection route is generally not indicated for these medications because safer alternative administrative routes are usually available.

7.4.1.1.6 Procedures

Hospital studies have found surgical adverse events more preventable (and more common) than medical adverse events. If this also holds true for primary care, then events other than those caused by medication might be easier targets for injury prevention.
initiatives. Procedures such as the removal of skin lesions (6%), venepuncture (6%), cryotherapy (5%), and ear syringing (3%) were common causes of injuries in the primary care claims dataset (mostly minor). These events, and the majority of patient safety incidents, were not captured in the previous claims dataset when eligibility was confined to rare and severe injuries or to injuries caused by medical error. The new enlarged treatment injury claims dataset provides a more inclusive view of patient safety incidents, containing information about the most severe events but also about the most common minor events.

Screening and investigative procedures, including mammography and cervical smears, caused injuries highlighting the importance of informed consent and risk: benefit discussions.\textsuperscript{389,390}

7.4.1.1.7 Dental treatment

Dental treatment gave rise to 22% of all primary care claims, but just 16% of injuries. A greater proportion of claims arising in dental settings were declined (45%) than claims overall (34%), possibly reflecting the greater pecuniary incentive to claim because dental treatment, unlike general practice care, is not subsidized for adults in New Zealand. Children in New Zealand get free dental care and 80% of children have at least one contact with an oral health care worker annually.\textsuperscript{311}

Dental injuries were mostly minor. Despite causing 16% of all primary care injuries, dental treatment caused only 4% of the serious and sentinel injuries.

7.4.1.1.8 Manual therapy

Manual therapy caused 7% of all primary care treatment injuries (physiotherapy 4% and chiropractic treatment 3%). Of particular concern, neck manipulation caused a disconcerting number of arterial dissections and strokes in young women (4).\textsuperscript{391-393} Most of these injuries are highly preventable with adequate risk assessment and proper technique. The elderly suffered a disproportionate number of injuries caused by manual therapy, reflecting the vulnerability of this population to this type of therapy. Acupuncture resulted in only 12 injuries, but as some were serious this finding serves as a reminder of the potential danger of this type of treatment in some hands.\textsuperscript{394}
7.4.2 Strengths and weaknesses

New Zealand’s treatment injury claims dataset provides a novel no-fault perspective of a wide range of health care adverse events that is not available to researchers in tort jurisdictions. The dataset offers a number of advantages for patient safety research, including that the generation of claims data does not rely on provider compliance with reporting requirements, or on efforts to prove negligence, but is driven by patients’ desire for assistance with treatment and rehabilitation costs.  

The claims dataset represents pooled outcomes data. Analysis of outcomes data is essential to ensure that health care is delivering more benefit than harm overall. While analysis of process data (such as competence and some claims data) can identify whether care is delivered properly, it cannot ensure that doctors are not striving to work perfectly in a system that is heading off course. Analysis of outcomes data is necessary to ensure that doctors are not striving to work perfectly in a system that is heading seriously off course, as Kazuo Ishiguro’s butler was in ‘The remains of the day’. Only analysis of outcomes data can answer Lantos’s question:

*Are doctors also working perfectly within a system that is spinning off into increasing irrelevance, powerless to participate in the larger events of the day?*

Analysis of claims data identified that the greatest threat to patient safety in primary care was medication. Much of the medication harm in this analysis was not associated with error, suggesting that, to improve patient safety, we may be better to shift the focus from reducing medication error to reducing medication treatment overall. The greatest threat to patient safety may not be improperly delivered care, but the nature of the care itself. This comes back to Illich’s theories about the different types of iatrogenesis. The patient safety movement is mainly concerned with clinical iatrogenesis, but it may be that what Illich called social and cultural iatrogenesis are the greater problem. This is also illustrated by the finding that women were particularly vulnerable to treatment injury, not because they needed more treatment to be as well as men, but because they received more treatment despite likely being as fit and well as men. The goal for improving patient safety, then, should be to reduce harm overall, not just to reduce error. There is no point doing what we do better, if what we do causes more harm than benefit.
Despite its advantages, like all datasets used to study adverse events, the claims dataset has some limitations. The claims dataset was developed primarily to process insurance claims and, as is often the case with such data, there were some inconsistencies in data classification and some fields were idiosyncratically completed.

Interpretation of study findings is constrained by the limited information collected on the ACC treatment injury claim form. The claims dataset lacks some information of interest for patient safety research purposes, including information on the provider and the health care organisation (for example, accreditation status).

A major limitation of the claims dataset is that the data lack information on injury preventability; information about what could have been done differently to avoid injury. The dataset contains insufficient information for any reliable assessment of preventability to be made for the purposes of this study. It is not possible, for example, to determine from the dataset whether an allergic drug reaction was a first exposure reaction or whether it was a known drug allergy.

Preventability usually has something to do with error, or something in the process of care that could have been done differently to avoid injury. The 2005 reforms waived any requirement for ACC to identify error or make any determination on injury avoidability in a deliberate move to foster provider collaboration with the claims process and expedite compensation for patients. Preventability usually has something to do with error (the right plan incorrectly carried out or the wrong plan correctly executed) and the 2005 legislative reforms were intended to move compensation away from fault and implications of wrong-doing.

The issue of preventability is complex and is perhaps better considered as one of degree, rather than being a question of preventable or not. The question is not was this delay in diagnosis avoidable, but rather how much of a delay in diagnosis is acceptable; not was this adverse drug event avoidable, but how much drug related harm is acceptable. The degree of preventability may be determined by a combination of factors including consensus of expert medical opinion, case complexity, appropriateness of management, co-morbidity, and urgency and risk of management. Some injuries are not preventable (such as first exposure allergic drug reactions to essential medications); some injuries have low preventability (such as the delayed diagnosis of rare conditions); and some
injuries are highly preventable (such as those caused by poor injection technique or medication dispensing or administration errors). This concept of preventability encompasses the notion that ‘to err is human’, and also the realisation that although the incidence of injury may be reduced, it may never be reduced to zero.

One third to one half of all adverse events are thought to be preventable and caused by error. If this proportion carries through to the claims dataset, two thirds of the dataset concern adverse events may have low preventability. These claims may still be of use for learning to improve patient safety. For example, although many claims in this analysis likely related to unavoidable first exposure allergic reactions to antibiotics, the number and severity of claims relating to this type of ‘unavoidable’ injury may inspire efforts to reduce antibiotic over-prescribing or to guide prescribing choices.

Interpretation of study findings is further limited by the incomplete picture of primary care adverse events provided through the selection of this claims dataset. The dataset did not include claims arising from maternity care, for example, even though much maternity care is provided in primary care settings in New Zealand. This gap arose because it was not possible for ACC to provide data for claims relating only to primary care maternity services while excluding hospital maternity claims. It was difficult for ACC to draw dividing lines between what was and what was not primary care with respect to many types of treatment. Claims arising from dental treatment were included, for example, when usually dental treatment is not included in analyses of primary care treatment. The importance of dentists in primary care is thought to be underestimated, supporting the inclusion of dental care in this analysis. Identifying only ‘primary care’ treatment injury data called for the artificial and almost arbitrary drawing of dividing lines.

Interpretation of claims data is complicated by missing data introducing bias. The claims dataset presents an incomplete picture of treatment injury as patients probably still fail to lodge a claim for compensation for many potentially eligible treatment injuries. One hospital record review study found that prior to the 2005 compensation reforms only about 3% of patients who suffered an injury lodged a claim for compensation with ACC. Claiming has increased more than fourfold following the 2005 reforms, but it is likely the claims dataset still fails to capture many treatment injuries. Both underclaiming (falls, diagnosis) and selective claiming (dental) likely occurred because of a lack of awareness about the scheme and eligibility (for example, for diagnosis-related
injuries or for injuries resulting in death and contribution to funeral costs), and because of a lack of motivation to claim. The elderly, in particular, were under-represented in the claims dataset, perhaps because much of their required treatment is provided free in hospital. Dental events may have been over-represented in the dataset because dental treatment is expensive and not funded for adults in New Zealand, creating an incentive for people to get dental treatment covered by ACC. Claims arising in dental clinics were more likely to be declined, suggesting that the rate of claiming may be higher in these settings. Some injuries, such as falls, may be claimed as either a treatment injury or a general injury, but as it is easier to lodge a claim for general injury and the compensation entitlements are the same, it is likely many falls are claimed under the general injury criteria. Increasing awareness over time may lead to an increase in claiming, and so future trends in claims cannot be taken as indicative of trends in injury. But even though the claims dataset provides a restricted and biased view of adverse events, it offers a more inclusive view than some other datasets. The complaints dataset, for example, provides an even more restricted view of adverse events: even fewer patients who suffered an injury lodge a complaint with the Health and Disability Commissioner (0.4%).

Interpretation of study findings is further limited by the lack of a denominator for the number of treatments provided, meaning that relative risk cannot be determined. Thus, while medication was identified as the dominant threat to patient safety in primary care, it is not possible to say whether medication featured so prominently because medication is the most dangerous treatment or because medication is the most common treatment in primary care (or both). And, while both neck manipulation and hormonal contraception caused four strokes in women, it is not possible to say which treatment is more dangerous; and although women suffered all of the strokes caused by manipulation, it is not possible to say whether this was because women were more vulnerable to injury from manipulation than men, or whether women simply had their necks manipulated more often. It is possible only to say that these treatments are risky for women and to draw attention to the need for adequate training and an adequate risk: benefit assessment prior to treatment.

These reservations aside, analysis of the claims data does hint at the relative safety or danger of treatments. Chiropractic treatment, for example, appears more risky than
physiotherapy treatment because, although physiotherapy caused nearly twice as many injuries as chiropractic treatment, there were ten times as many physiotherapists registered to practice in New Zealand during the four study years.\textsuperscript{317, 318}

### 7.4.3 Conclusion

Findings from this study suggest that the enlarged claims dataset can be analysed to identify learning for patient safety. This analysis contributes new knowledge to a developing body of work on patient safety in primary care. Analysis of the treatment injury claims dataset provides a novel no-fault perspective of threats to patient safety in primary care and confirms medication as the dominant threat to patient safety in these settings. Given many of the medication events in this analysis were likely not associated with error, findings suggest that patient safety in primary care may be better improved by shifting the focus from reducing medication error to reducing medication overall.

Despite the enlarged treatment injury claims dataset providing increased opportunities for learning, the data suffered from various limitations. The increase in claims data comprised mainly events assessed by ACC as minor, the claims dataset also provided an incomplete picture of the nature of threats to patient safety, and the data lacked information concerning injury preventability. Despite these limitations, analysis of the claims dataset revealed valuable insights into the nature of threats to patient safety in primary care from a novel no-fault compensation perspective.

This analysis confirmed previous research findings identifying medication as the dominant threat to patient safety in primary care. Antibiotics featured prominently as a cause of medication events, followed by steroids and anti-inflammatory drugs. Medication prescribing, dispensing and administration were all identified as areas for improvement, but many of the adverse drug events were not associated with identifiable errors and so may have low preventability. Both the prevalence and severity of medication events reinforces the need to improve medication safety. Many adverse drug events in this study were likely not associated with error, suggesting we may be better to shift our focus from reducing medication error to reducing the over-prescribing of non-essential medications in primary care (such as statins, anti-fungal medication and proton pump inhibitors). The range and severity of medication injury in the elderly, in particular,
serves as a reminder to providers to rationalise drug use and to consider withdrawing drugs when the risks may begin to outweigh the benefits.

Findings from this study may also be used to guide prescribing choices, avoiding medications associated with more adverse events when safer alternatives are available. Findings from this analysis also suggest that, in addition to improving the delivery of medication, we also need to pay attention to conducting a proper risk: benefit analysis for all medication treatment and reduce non-essential medication.

Injections and vaccinations were identified as another potent threat to patient safety in primary care, as were other nursing procedures such as venesection, ear syringing and liquid nitrogen therapy. Spinal and neck manipulation were also identified as threats, causing a disproportionate number of severe injuries. Events relating to delay in diagnosis were under-represented in the dataset, which is perhaps not surprising given the compensation eligibility criteria and the counter-intuitive nature of considering the progression of a disease consequent of a failure to diagnose (and therefore also a failure to treat) being an injury caused by treatment. The events relating to diagnosis that were identified in the dataset were disproportionately severe, reinforcing the importance of addressing diagnostic failure in primary care.

In conclusion, the treatment injury claims dataset can be analysed to identify threats to patient safety. The lessons identified can be fed back to frontline providers to guide prescribing choices, and to reinforce messages regarding the importance of avoiding over-prescribing and of withdrawing non-essential medication, especially in the elderly. Lessons from this analysis can serve as reminders for general practitioners about diagnostic challenges, and also be used to inform patients about the potential risks of treatments (for example, neck manipulation).

Having described the content of the treatment injury claims dataset, I now present my analysis of the second dataset generated under the reformed compensation scheme: ACC harm reports to the Director General of Health.
8 ACC HARM REPORTS: lessons for patient safety

In this chapter I analyse ACC harm reports to the Director General of Health to identify learning for patient safety. Specifically, I describe the content of the primary care ACC harm reports data 2008 to 2010 to discover the events identified and reported by ACC as posing a “risk of harm to the public”.

8.1 Introduction

Under the Accident Compensation Act, ACC has a duty to report “risk of harm to the public” to the “authorities responsible for patient safety”. To date, ACC has interpreted this duty by reporting to the Director General of Health all events assessed as sentinel and those assessed as serious with a “high or moderate likelihood of recurrence”. In addition, ACC reports some of these events to the registration authorities and/or Medsafe.

ACC reports events to the Director General of Health in the form of paper harm reports. The ACC harm reports are stored in filing cabinets in the Ministry of Health’s Wellington offices.

8.2 Methods

8.2.1 ACC harm reports to the Director General of Health 2008 – 2010

I visited the Ministry of Health in Wellington and obtained de-identified photocopies of all ACC harm report data along with any provider feedback for the three years 1 January 2008 to 31 December 2010. Ethical approval for this project was obtained through the University of Otago ethics approval process (Appendix 12).

For this study, I analysed the ACC harm reports pertaining only to primary care, which included all care provided in general practice by both doctors and nurses (including medication, minor surgery, diagnosis, joint injection, insertion of intrauterine contraceptive device, injections and vaccinations, liquid nitrogen therapy); all nursing care provided in residential care settings (such as medication administration, and care resulting in falls and pressure ulcers); and all care provided in dental clinics, laboratories, pharmacies (medication dispensing), chiropractic and radiology rooms. All nursing care was included even though some of the nursing care was likely provided in hospitals because the delineation between primary care and hospital care was not clear cut, and it
was not always possible to differentiate from the ACC harm report data the care that was provided in community residential settings from that provided in hospital settings.

Excluded were data from maternity care, and data from hospital specialist care. Hospital specialist care encompassed intensive care, urology, neurosurgery, vascular surgery, ophthalmology, emergency department, cardiology, cardiothoracic surgery, oncology, gynaecology, ear, nose and throat, orthopaedics, general medicine, general surgery, anaesthesia, plastics and burns, neurology, radiotherapy, paediatrics, and paediatric surgery.

Harm reports are usually one page long and contain information about the patient, the alleged injury, the alleged causal treatment, and the name of the treating facility but not the name of the individual treatment provider.

8.2.2 Data analysis

The ACC harm reports data were analysed to describe risk of harm to the public in primary care as identified and reported by ACC. The analytic approach to these data was mainly descriptive; the reports were described by provider type and by treatment event. This is because the aim of the study was to determine the content of the harm reports dataset and its ability to identify the most serious threats to patient safety.

8.3 Results: “risk of harm to the public” in primary care

I identified 555 ACC harm reports in the Ministry of Health filing cabinets for the three study years (2008 - 2010). This compares with reporting figures supplied by ACC which reveal that the ACC reported to the Director General of Health 1052 events for the years 2008 to 2010. This indicates that nearly half of all ACC harm reports were missing from the harm reports data I obtained from the Ministry of Health filing cabinets. This discrepancy is unexplained.

Table 17 shows that one third of the 555 identified ACC reports arose in primary care (190); the remainder arose from either hospital medical and surgical care (330), or from maternity care (35).
Table 17: ACC harm reports to the Director General of Health and to the registration authorities 2008 – 2010 and provider feedback about the ACC reported events by provider type

<table>
<thead>
<tr>
<th>Treatment context / event</th>
<th>ACC harm reports to the Director General of Health</th>
<th>ACC harm reports to registration authorities (% reports)</th>
<th>Provider feedback (% reports)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GP - medication</td>
<td>40</td>
<td>1 (3)</td>
<td>12 (30)</td>
</tr>
<tr>
<td>GP - diagnosis</td>
<td>23</td>
<td>7 (32) (1 unknown)</td>
<td>12 (50)</td>
</tr>
<tr>
<td>GP - minor surgery</td>
<td>4</td>
<td>1 (25)</td>
<td>4 (100)</td>
</tr>
<tr>
<td>GP - other</td>
<td>5</td>
<td>0 (0)</td>
<td>3 (60)</td>
</tr>
<tr>
<td><strong>Total GP</strong></td>
<td><strong>72</strong></td>
<td><strong>9 (13)</strong></td>
<td><strong>31 (43)</strong></td>
</tr>
<tr>
<td>Nurse - medication administration</td>
<td>26</td>
<td>0 (0) (2 unknown)</td>
<td>20 (77)</td>
</tr>
<tr>
<td>Nurse - pressure ulcers</td>
<td>16</td>
<td>0 (0)</td>
<td>8 (50)</td>
</tr>
<tr>
<td>Nurse - injection/vaccination</td>
<td>7</td>
<td>0 (0) (1 unknown)</td>
<td>4 (57)</td>
</tr>
<tr>
<td>Nurse - other</td>
<td>7</td>
<td>0 (0)</td>
<td>6 (88)</td>
</tr>
<tr>
<td><strong>Total nursing</strong></td>
<td><strong>56</strong></td>
<td><strong>0 (0)</strong></td>
<td><strong>38 (68)</strong></td>
</tr>
<tr>
<td>Pharmacy - dispensing</td>
<td>32</td>
<td>12 (38) (4 unknown)</td>
<td>24 (75)</td>
</tr>
<tr>
<td>Radiology</td>
<td>13</td>
<td>0 (0)</td>
<td>8 (62)</td>
</tr>
<tr>
<td>Dental</td>
<td>8</td>
<td>2 (25) (1 unknown)</td>
<td>4 (50)</td>
</tr>
<tr>
<td>Chiropractor</td>
<td>5</td>
<td>2 (40)</td>
<td>2 (40)</td>
</tr>
<tr>
<td>Laboratory</td>
<td>4</td>
<td>0 (0)</td>
<td>4 (100)</td>
</tr>
<tr>
<td><strong>Total primary care</strong></td>
<td><strong>190</strong></td>
<td><strong>25 (13)</strong></td>
<td><strong>111 (58)</strong></td>
</tr>
<tr>
<td>Maternity care</td>
<td>35</td>
<td>4 (11)</td>
<td>18 (51)</td>
</tr>
<tr>
<td>Hospital specialist care</td>
<td>330</td>
<td>4 (1)</td>
<td>145 (44)</td>
</tr>
<tr>
<td><strong>Total for all settings</strong></td>
<td><strong>555</strong></td>
<td><strong>33 (6)</strong></td>
<td><strong>274 (49)</strong></td>
</tr>
</tbody>
</table>
8.3.1 General practice

Table 17 shows that the largest proportion of reported primary care events arose in general practice (72; 38%).

8.3.1.1 Medication

Table 17 also shows that most of the general practice events concerned medication (40; 56%).

Many of the reported medication events were severe adverse drug reactions not associated with any identifiable error. Table 18 shows the types of adverse drug reactions identified that were not associated with error.

Table 18: ACC reported medication events with no identifiable error

<table>
<thead>
<tr>
<th>Medication/ s</th>
<th>Reported injury/ ies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allopurinol</td>
<td>Toxic epidermal necrolysis, multi-organ failure</td>
</tr>
<tr>
<td>Co-trimoxazole, phenytoin, carbamazepine</td>
<td>Stevens-Johnson syndrome</td>
</tr>
<tr>
<td>Statins</td>
<td>Rhabdomyolysis, myositis</td>
</tr>
<tr>
<td>Norfloxacin</td>
<td>Tendinitis, tendon rupture</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>Hepatitis</td>
</tr>
<tr>
<td>Anti-inflammatories</td>
<td>Renal failure, perforated stomach ulcers</td>
</tr>
<tr>
<td>Nitrofurantoin</td>
<td>Interstitial fibrosis</td>
</tr>
<tr>
<td>Prednisone</td>
<td>Avascular necrosis</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>Hearing loss, liver failure</td>
</tr>
<tr>
<td>Spironolactone, clozapine</td>
<td>Agranulocytosis</td>
</tr>
<tr>
<td>Provera, tranexamic acid</td>
<td>Thromboembolism</td>
</tr>
<tr>
<td>Warfarin</td>
<td>Cerebral bleeds</td>
</tr>
</tbody>
</table>
Some reported medication events were associated with identifiable prescribing errors. For example, anaphylaxis to "prescription of an antimicrobial that she was known to be allergic to"; digoxin toxicity and cardiac arrest following "incorrect starting dose"; dystonic reaction in a child following "excessive dose" of metoclopramide; burn from acetic acid when 100% solution was prescribed instead of 2% solution; thyrotoxic crisis when "prescribed thyroxine despite having florid hyperthyroidism"; and renal failure after given "overdose" of vitamin D.

8.3.1.2 Diagnosis

Twenty three of the primary care ACC harm reports concerned diagnostic events (12%). These reports identified a number of conditions known to pose a diagnostic challenge in general practice including, ectopic pregnancy, temporal arteritis, testicular torsion, appendicitis, congenital dislocation of the hip, varicella pneumonia, and cancers of the breast, rectum, prostate, lung, skin, lymphatic system, and brain.

8.3.1.3 Other

There were four reports concerning surgical procedures in general practice (bleeding and scarring); two reports concerning septic arthritis following joint injections; and one report each for IUCD insertion (uterine perforation and sepsis), acupuncture (pneumothorax) and liquid nitrogen therapy (severe burn requiring admission to hospital).

8.3.2 Nursing care

Fifty five of the reported primary care events arose from nursing care (29%) (Table 17). The nursing events were mostly associated with care provided in residential care settings, for example medication administration (26), pressure ulcers (16), and falls (2). There were seven nursing events associated with injection/vaccination in general practice including administration of pre-used vaccines and the administration of an incorrect injection (adrenalin instead of vitamin B12).

8.3.3 Other

Thirty two of the primary care harm reports arose from pharmacy dispensing (15%). Pharmacy dispensing incidents caused patients to suffer a range of symptoms including drowsiness, dry retching, vomiting, immobility, shortness of breath, sweating.
clamminess, weakness, light-headedness, dry mouth, urinary retention, visual impairment, headache, bruising, loss of vision, thirst, rash, tremor, chest pain, palpitations, agitation, flushing, numbness and tingling, and haematuria. Not all pharmacy dispensing incidents resulted in injury.

13 of the ACC reported primary care harm reports arose in radiology settings. These mainly concerned diagnostic incidents, reactions to medication such as dye, and trauma or falls. There were eight reported dental events, including bacterial endocarditis, tooth damage, adverse drug reaction, and wrong site surgery. There were five events associated with chiropractic treatment, mostly from neck manipulation (4) some of which resulted in arterial dissection and stroke. There were three reported laboratory events, all relating to delay in diagnosis.

8.4 Discussion

Findings from this study suggest that the ACC harm reports can be analysed to identify learning to inform efforts to improve patient safety. This analysis revealed risk of harm to the public as identified and reported by ACC.

8.4.1 Summary of findings

One third of all identified ACC harm reports to the Director General of Health 2008 to 2010 arose in primary care. Analysis confirmed medication as posing the greatest risk of harm to the public in primary care, at least in terms of the number of harm reports (98/190; 52%). Risk of harm from medication arose from medication prescribing, dispensing, and administration, and from the nature of medication itself. Diagnosis caused only about one third as many events, and was an issue in general practice, radiology, and laboratory settings.

8.4.2 Strengths and weaknesses

Study findings are limited by the incomplete nature of the harm reports dataset. I estimated that nearly half of all ACC harm reports were missing from the Ministry of Health data. A possible explanation may have something to do with the data I obtained coming from the early years following the legislative change. ACC did not previously report to the Director General of Health and so the Ministry of Health personnel had to
develop new processes to deal with the ACC reports. No funding followed the legislative change, and so any changes had to come from within existing Ministry budgets.

Of the data that were obtained, some were incomplete. For example, for some provider feedback there was no corresponding ACC harm report. The absence of avoidability data constrains the use of the harm reports data for injury prevention purposes, as it does for the treatment injury claims dataset. The harm reports data also lacked some potentially useful information, for example data about the provider (age, sex, experience, country of graduation) and the organisation (group or solo practice, accredited practice).

Interpretation of study findings is also limited by not knowing how ‘ACC reported risk’ relates to risk overall. The “risk of harm to the public” that ACC should report is not defined in the compensation legislation. Risk, according to Douglas, is culturally determined, it is not only the potential severity of an event but also the likelihood of an event occurring. In reality, all treatment poses a risk of harm to the public.

### 8.4.3 Conclusion

In conclusion, despite the shortcomings of the ACC harm reports data, analysis confirmed medication as posing the greatest threat to patient safety in primary care, and hinted that diagnosis posed more of a threat than indicated by analysis of claims data. Findings from this analysis confirm that, to improve patient safety in primary care, the focus needs to be on reducing the risk posed by medication and secondarily the risk posed by difficulties in diagnosis.

I now examine the third dataset generated under the reformed compensation scheme: the provider feedback to the Director General of Health about ACC reported events.
9 PROVIDER FEEDBACK: lessons for patient safety

In this chapter I assess whether provider feedback to the Director General of Health about ACC reported events can be analysed to identify learning to inform efforts to improve patient safety. Specifically, I describe the content of the provider feedback dataset for ACC reported primary care events 2008 to 2010 to identify event causal factors and potential solutions.

9.1 Introduction

The Director General of Health has responded to the new ACC harm reports, to date, by writing to providers requesting feedback about the ACC reported events. Providers are not legally obliged to respond to the Director General’s requests for feedback but many have (chapter 6).

9.2 Methods

I visited the Ministry of Health in Wellington and obtained de-identified photocopies of all provider responses to the Director General of Health’s requests for feedback about ACC reported events 2008 to 2010.

In seeking feedback, the Director General sends to the provider a four page paper ‘ACC Treatment Injury Event Notification Provider Feedback Form’. This form states that the purpose of provider feedback is to assure the Ministry of Health “that action has been taken to reduce further risk” and “to help draw out system lessons that can be generalised and shared with other providers”. The form also states that the “Ministry will produce an annual review of these events, including the lessons that have been learned in terms of reducing the risk of recurrence”.

There are seven questions on the form:

1. Does the event require an internal review by your organisation?
2. Please list all the causal factors identified as being involved in the event:
3. Which of the above factors is (are) considered to be the root cause(s) of the event?
4. What actions have been taken (or will be taken) to reduce the risk of similar events in your organisation?
5. What is your estimate of the risk (i.e. the likelihood of future events and their consequences) that still remains after the actions have been taken?
6. What are the lessons from this event and the actions taken to reduce risk that could be shared with other providers?

7. Any further comments?

I analysed the primary care provider feedback data for 2008 to 2010. I use the general inductive method to develop themes relating to event causal factors, remedial actions, lessons learnt, and potential solutions.

9.3 Results: event causal factors and potential solutions

Table 17 shows that primary care providers supplied feedback to the Director General of Health for 111 of the 190 ACC reported primary care events 2008 – 2010 (58%). The provider feedback comprised free text answers to the questions on the ACC Treatment Injury Event Notification Provider Feedback Form. This included feedback about event causal factors, action taken to reduce the risk of future similar events, and lessons learnt.

9.3.1 General practitioner feedback

Table 17 shows that general practitioners provided feedback for 31 of the 72 ACC reported events arising in general practice (43%).

9.3.1.1 Medication

There was feedback for 12 of the 40 reported medication events in general practice (30%). A dominant theme to emerge from this feedback was the need for greater awareness of potential risks and a call for further education and training, especially relating to prescribing combinations.

*All medical staff made aware of possibility of colonic as well as upper GI effects of NSAIDs.*

There were also suggestions for the Medtech practice management prescribing programme to be changed to help prevent prescribing errors.

*Doctor has contacted Medtech and advised them of the potential for mishap. There may be value in removing or highlighting the preparation [100% acetic acid].*

There were also suggestions to improve communication both between doctors, between doctors and pharmacists, and between doctors and patients.
9.3.1.2 Diagnosis

There was feedback for 12 of the 23 reported diagnostic events (50%). Fatigue was identified as a contributing factor to diagnostic events, as was "complicated" diagnosis and "very rare" diagnosis. The perceived need to avoid referring patients to hospital too readily was also identified as a contributing factor.

Over-influenced by perceived parental desire to avoid hospitalisation; increased duty load and hours; tired; sense that should not refer to hospital too readily.

Regarding the prevention of diagnostic incidents, common themes running through the feedback were again the need for greater vigilance, and for further education and training. Other ideas for improvement included setting workload limits, improving communication between providers, and reviewing referral criteria and protocols.

Failure of lost test results has occurred previously.

Need improvement in communicating medical information between practices.

There were also suggestions concerning the handling of test results by practice management systems.

Computer software should be set so that when a result is electronically filed (even electronically) [sic] it can be immediately retrieved.

There has been education and greater emphasis on the use of the task facility in Medtech to help the efficient handling of results.

9.3.1.3 Other events in general practice

Regarding surgical events in general practice, the main suggestions for improvement were again further education and training. There were also calls for protocols and checklists to be developed for procedures. Improved sterile technique and further training were suggested to reduce the risk of adverse events following joint injections.

Doctor now started using an iodine swab additional to alcohol swab with the non-touch technique. Increased vigilance.... Practice discussed at clinical governance committee the use of iodine with steroid injections; heightened awareness within the practice.

One doctor, whose patient experienced uterine perforation and septic shock following insertion of a Mirena IUCD, wondered whether the unusually complicated insertion technique for Mirena IUCDs contributed to perforation. The doctor suggested changing to a "two appointment approach to insertion of all IUCDs".
Technique of insertion for the mirena is so different - I wonder if the risk of perforation is higher with mirena.

9.3.2 Nurses / nurse manager feedback

Provider feedback was obtained for 38 of the 56 reported nursing events (68%). Much of this feedback appeared to have come from nurse managers rather than the nurse directly involved in the ACC reported event.

9.3.2.1 Medication administration

There was feedback for 20 of the 26 reported nursing medication administration events. Common themes to emerge from this feedback were the need for greater vigilance and checking, and for avoiding distraction while dispensing medications.

A number of responses identified the solutions to be increased competence, education and training, and supervision.

Person administering medication did not follow the medication policy ... person who wrongly administered the medication underwent competency review.

Staff member was stood down from giving medication until she completed another Medication Competency course

it was explained to her she was not to give medication unless supervised and she had completed another drug competency satisfactorily

Analysis of the feedback for nursing events identified individual blame for events. Discipline and even dismissal were seen as potential solutions. This type of feedback suggests an immature safety culture in some organisations.

To help reduce risk, staff member immediately taken off the duty

After internal investigation, a number of disciplinary steps taken with the individuals directly involved

Nurse given a verbal warning ... Copies of the documentation resulting from this error will be held on the personnel files of the staff involved for a period of six months.

No longer have this nurse assigned to our facility

Some nurses had given up their positions following the reported medication administration incident.

Nurse failed to adhere to the drug administration procedure relating to identifying the resident. ... resigned her position and is no longer nursing
The rest home lost a very good and caring assistant as a result of the incident: an ACE trained level 3 employee with several years of experience who became anxious over her abilities to administer medications despite management support.

There were more constructive suggestions for reducing the risk of medication events including updating protocols, using blister packs, and re-dispensing blister packs with changes in prescription.

**Blister packs now returned to pharmacy for re-dispensing after changes in medication**

Medication aprons or vests were suggested to prevent interruptions while on medication administration duty.

*had several interruptions ... policy reviewed to include the wearing of a medication apron*

*a number of distractions during the medication round (mobile phone) ... in future nurse will put her business mobile on answer phone to prevent distractions during medication*

'Medication round - do not interrupt' vests purchased ... nurses have been encouraged to pass the duty phone to another member of staff during the medication round

'caregivers now wearing 'Do not disturb' pinafore while administering medications

**Further staff training re avoiding distraction during drug rounds.**

The use of only 1mg warfarin tablets and two-person checking were identified as strategies to reduce errors administering warfarin - a known complex task involving frequent changes in dose over time.

*warfarin now checked by two people into named envelope with date, time and dose to be administered ... will only use 1mg tablets.*

*warfarin administration must be done by two staff*

Other suggested solutions for medication administration incidents included the use of robotics, and placing patient photo identification on bedroom doors.

**Change to robotics in rest home to further minimise future risk.**

*All residents to have a named laminated photo placed behind their bedroom door to enable accurate identification of the resident by all staff members.*

A most thoughtful suggestion discussed the introduction of multi-disciplinary review of medications for patients taking a number of drugs.

**In partnership with Community Geriatric Service, and with resident and interdisciplinary team involvement, we are reviewing all medications for residents**
who take over nine regular medications per day. This has not only resulted in positive benefits for the residents, but has resulted in a team that are [sic] better informed and knowledgeable. In many instances the number of medications administered has been adjusted and rationalised which in itself has reduced the complexity of the task.

9.3.2.2 **Injections/ vaccinations**

Nurses provided feedback for four of the seven reported injection/ vaccination events.

All responses stressed the importance of following protocols, avoiding distraction and recommended further education and training. Two responses were about giving a pre-used vaccine when vaccinating two related patients at the same time. Suggested solutions included refusing to vaccinate two people at the same time, avoiding distractions, using separate kidney dishes for used and un-used vaccines, and discarding needles immediately after use.

*We will not succumb to pressure from patients - we will insist on their coming back at an appointed time; we will have one patient in the room at a time; we will have separate kidney dishes for loaded and used syringes ...*

9.3.2.3 **Other nursing events**

Feedback regarding other nursing events offered similar suggestions for the cause and prevention of injury. Common themes running through the contributing factors were a heavy workload, distractions, and a lack of adequate resources such as appropriate mattresses to prevent pressure ulcers. Most suggestions for improvement included increasing staff numbers, raising awareness and further education and training.

9.3.3 **Pharmacy feedback**

Pharmacists had the highest response rate to the Director General’s requests for feedback, providing feedback for 24 of the 32 reported pharmacy dispensing events (75%).

The suggested causal factors for dispensing incidents and the suggested solutions were similar to those suggested by nursing personnel for medication administration events, that is avoiding distractions and interruptions, following protocols, checking, being vigilant, and having further education and training.

*Dispensary staff aren't to be rushed; do not interrupt pharmacist when checking prescriptions; increased staffing numbers need to concentrate ...*
at all times other than when there is a sole pharmacist working in the dispensary, the roles of typing, counting and checking the prescription shouldn't be carried out by the same staff member. Where there is only a sole pharmacist - dispense, complete another task and come back with 'fresh eyes'.

Patient identification could be problematic for pharmacists, and communication difficulties were identified as contributing to the difficulty of correct dispensing.

Patient speaks Mandarin Chinese and his English was very poor.

Pharmacist mistook client to be a different methadone patient - dispensed other patient's medication dosage. Introduced photographing methadone patients and getting clients to say aloud name, address, methadone usage prior to receiving medication

Similar drug names were identified as increasing the chance of error. Suggested solutions included separating similar drugs on the shelf, labelling and highlighting medication boxes.

Erroneous dispensing of Frumil instead of Frisium tablets. Since this incident we have separated our frumil and frisium on the shelf and put a cautionary warning ...
We have included a list of similar sounding/looking drugs attained from Pharmacy Council newsletter dated May 2005

two different strengths of same medication stocked side by side
Reminder for staff to highlight with a marker packaging changes or similar looking bottles.
enalapril and epilim ... both items now have a Pharmaceutical Society 'check names' sticker on them.
keeping dispensary shelves and bench orderly ... Stock on shelf checked to ensure all facings showing neatly ... STOP sign added to Verapamil as a prompt reminder

Even after identifying the correct medication box, however, problems could still arise for pharmacists:

400mg Tegretol tablets were placed in a 200mg box. The 200mg and 400mg tablets look very similar. The checking pharmacist checked the box but did not check the tablets inside.

Another suggestion to reduce pharmacy dispensing incidents was to educate patients and engage them on the quest to improve medication safety.

We see great value in educating patients to contact us should they notice anything different in appearance of medicines - i.e. number, colour, shape etc.
9.4 Discussion

Findings from this study suggest that the provider feedback can be analysed to identify learning for patient safety. Providers made a number of helpful suggestions about event causal factors and also possible actions to reduce the risk of future similar events.

9.4.1 Summary of findings

Event causal factors identified by providers included heavy workload, fatigue, distraction and interruptions, a lack of adequate resources, and difficulties in communication both between providers, and between providers and patients. Of concern, the perceived need to avoid hospitalisation was identified as a causal factor for diagnostic incidents.

Providers rarely cited ‘lack of education and training’ as a factor in injury causation, but they frequently suggested ‘further education and training’ as a potential solution. Similarly, increased vigilance and awareness was also commonly suggested as a solution. These suggestions are not likely to be successful, however, as most preventable harm is caused by providers who are already highly trained and trying to do the right thing.

Other potential solutions identified were changes to computerised practice management systems to both reduce prescribing errors and to ensure that test results were not overlooked, updating of protocols and the development of checklists, and the wearing of special alert aprons during drug administration duties. There were calls for more staff to be employed and for workload limits to be imposed. Some providers suggested educating patients and engaging them in the quest to improve safety. One of the more potentially helpful solutions was the introduction of multi-disciplinary review of patients taking several medications.

Analysis also revealed a continuing focus in some organisations on identifying individual blame for events. While the relatively high response rate for nursing events (68%) suggests nursing personnel are open and willing to share information about injury, the focus on identifying individual blame suggests there is some way to go yet in these organisations regarding the development of a culture of openness and learning. The focus on blame suggests an immature safety culture despite New Zealand’s less punitive regulatory environment.
9.4.2 Strengths and weaknesses

Interpretation of study findings is constrained by the small dataset and the potential bias introduced by missing data. Many ACC harm reports were missing from the Ministry of Health data, and many of the identified harm reports lacked provider feedback. Bias might also be introduced by providers feeling constrained about sharing sensitive information with the Director General of Health.

These limitations aside, analysis of provider feedback identifies helpful suggestions from frontline providers, those closest to the source of risk, about how to reduce risk and improve patient safety.

9.4.3 Conclusion

Despite the Ministry of Health provider feedback form stating that the “Ministry will produce an annual review of these events, including the lessons that have been learned in terms of reducing the risk of recurrence”, to date, this has not happened. Findings from this assessment suggest that provider feedback data can be analysed to identify event causal factors and potential solutions. The lessons identified could and should be fed back to frontline providers to inform efforts to improve patient safety and to guide changes in practice.

If there is to be on-going analyses of these data, funding needs be made available. Regular analysis of the provider feedback to identify learning and the dissemination of learning to frontline providers, as stated on the form, might help to encourage providers to supply feedback. Provider feedback might be increased and improved if the Ministry’s 'ACC Treatment Injury Event Notification Provider Feedback Form' was made more user-friendly.

In conclusion, there are many ways to assess patient safety, including by studying patient complaints, competence and fitness to practice data, disciplinary proceedings, malpractice claims, incident reports, patient reports, and medical records, and by assessing an organisation’s safety culture or climate. Each method offers a distinctive, albeit limited, perspective of patient safety, and none provide the complete picture. New Zealand’s reformed compensation scheme generates
data that provides yet another perspective of patient safety incidents – a novel no-fault compensation perspective.\textsuperscript{12, 24, 44, 308}

Having described the content of the three patient safety datasets generated under the reformed compensation scheme, I now assess an educational influence on the development of a culture of safety in New Zealand general practices.
10 A UK SAFETY CULTURE TOOL: educating in New Zealand?

10.1 Introduction

In this chapter I assess whether a UK safety culture tool could be adapted to the New Zealand general practice context and used as an educational tool to measure and improve safety culture. Specifically, I adapt the Manchester Patient Safety Framework (MaPSaF)\textsuperscript{15} to the New Zealand general practice context, and test the adapted tool (NZ-MaPSaF) for acceptability and utility in twelve Dunedin general practices.\textsuperscript{45}

10.1.1 A general practice focus

I base my study in general practice because I am familiar with this setting having worked as a doctor in general practice in New Zealand for twenty years, and also because the study of safety culture in this setting is novel. While a number of tools have been developed to measure and strengthen safety culture and climate in both hospital\textsuperscript{14,91-100} and primary care settings internationally,\textsuperscript{40,84,101-104} no tools have been designed for use in New Zealand general practice.

10.1.1.1 General practice in New Zealand

The dominant model for general practices in New Zealand is the small owner-operated business.\textsuperscript{407} According to a 2007 RNZCGP survey, 45% of New Zealand general practices were jointly owned, 39% were privately owned, and 46% of general practitioners reported they were self-employed.\textsuperscript{408} Corporate ownership of practices is becoming increasingly common today, as are alternative ownership models through Maori providers and Community Trusts.

Government funding for general practice is distributed via District Health Boards, to Primary Health Organisations, and then to general practices. Funds are determined on a capitation basis, according to the number of patients enrolled with a practice. While the care provided in New Zealand public hospitals, including Emergency Departments, is free of charge, the care provided in general practice is only partially subsidised by the government and patients usually have to contribute a partial payment.
The profit imperative in New Zealand general practice means that most practice activity is geared toward profit-generating activities, seeing patients and providing services, rather than non-profit generating activities such as addressing safety culture.

10.1.1.2 General practice is different

The care provided in general practice is different to that provided in hospitals in a number of ways. A major difference lies in the nature of the doctor-patient relationship. While hospitals have a more disease specific orientation, general practice is oriented towards the whole person. In general practice there is often greater continuity in the doctor-patient relationship, with episodic contact over a long period of time. The nature of the care is intermittent, rather than continuous, with many separate but interrelated, sequential presentations occurring over many years and often in multiple locations. Three quarters of patients leave the consultation with unanswered questions. The average consultation time in New Zealand general practice is 15 minutes.

In general practice the focus is not only on diagnosing and curing illness but also on managing chronic conditions (such as diabetes), screening (for example breast and cervical cancers) and prevention (through vaccination, provision of lifestyle advice, and treatment of cardiovascular risk factors). In general practice, there are long feedback loops and it may take days, weeks or even months for results of investigations to filter back. This may be especially problematic for the care of complex patients where responsibility may be shared by multiple providers, in many institutions.

Cassell warns that it is a common error to see general practice as entry-level medicine and thus rudimentary medicine. He argues that counter-intuitively the higher we go on the scale of a specialist training, the less complex the medical problem becomes. In general practice, he argues, the great challenge is not only to identify serious illness but also to decide whether something is serious or not, and knowing when you don’t know requires sophisticated knowledge from general practitioners.

In general practice the signal-to-noise ratio is low, complicating diagnosis but also contributing to general practitioners’ attitude to risk. In general practice the focus may not be so much on identifying and reducing risk, as on acknowledging and absorbing risk and on providing reassurance where possible. It is not always possible to eliminate the risk, or uncertainty, that is at the heart of medical practice. In addition to diagnosing and
treating patients, Heath described the purpose of general practice to be “to acknowledge and witness the suffering brought about by illness”. 411

In hospitals people usually work in teams, but in general practice much still takes place between a patient and a doctor behind a closed door. The structure of general practice means that many doctors work in a degree of isolation from their peers, so perpetuating the view of doctors as ‘autonomous artisans’. 412-414 General practitioners are often considered more independent and more contrarian, with greater intrinsic scepticism, than their hospital counterparts. There may also be greater hierarchy in general practice as doctors often own the business and employ the nursing and reception staff. There is no career pathway or structure in general practice, no ladder to climb to motivate doctors to higher performance.

Patients in general practice are also different. Usually they are not as sick and so may be able to play a greater role in injury prevention than their (usually sicker) hospital counterparts. Patients in general practice have greater autonomy and higher levels of freedom, and are able to be active participants in their health care and more involved in decisions. They also have greater discretion with regard to following (or not) treatment plans. In general practice patients can choose not to take prescribed medications and may be able to recognise incorrect prescribing or dispensing of medication, but they can also misunderstand label instructions and take the wrong dose. 415, 416

The regulatory and legislative requirements are also different between hospital based and general practice based care. While hospitals are required to maintain certain staffing ratios and to be accredited, general practices are under no such obligation. In New Zealand, practice accreditation is voluntary and requires considerable investment in time and money. No pecuniary or other incentive is provided.

10.1.1.3 Patient safety in general practice may be different

These differences have implications for patient safety. The patient safety agenda and current models of improvement are based on acute care models of health care delivery, designed for implementation in hospitals. While this approach may translate well to some aspects of health care, such as anaesthetics, intensive care, and surgery, general practice is different: the scale is different, the nature of the work is different, the philosophy is different, and the people and their relationships are different. 277 These differences raise
questions about the transferability of current models of improvement to the more complex and less mechanised world of general practice.290

Much of the patient safety debate is framed in managerial terms that are foreign to those in general practice working with minimal managerial support. Many general practices in New Zealand do not have a manager let alone a safety officer; the doctor may double as the manager and the IT person who updates the computers. Much of general practice remains at its heart a ‘cottage industry’.413, 414, 417 Further, safety improvement usually requires investment and while large hospitals have staff whose specific purpose may be to monitor and improve patient safety, resources are often limited in general practice and there is a need to make a profit. In general practice, the systems mind-set is usually less well developed. Quality has traditionally been based on the ‘craft-based’ model where individual performance and decision-making are considered the main determinant of quality and patient outcomes.

These differences will need to be borne in mind when developing a tool to improve safety culture in general practices.

10.2 Methods

To assess the influence of an educational means of developing a culture of safety in general practice, I adapted a UK safety culture tool (the MaPSaF) and tested the adapted tool (NZ-MaPSaF) for acceptability and utility in 12 Dunedin general practices.

Ethical approval for this study was provided by both the University of Otago Research Ethics Review Committee (Appendix 3) and the World Health Organisation Research Ethics Review Committee (Appendix 4).

10.2.1 Adapting the MaPSaF to the New Zealand general practice context

The Manchester Patient Safety Framework (MaPSaF) was developed and validated by a UK research group based at the National Primary Care Research and Development Centre at Manchester University. The MaPSaF was developed to assess and strengthen safety culture in UK Primary Care Trusts.15, 84 It was designed to "make the concept of safety culture accessible to frontline practice staff" and to "facilitate discussion" about safety issues.84 The MaPSaF has been endorsed by the UK’s National Patient Safety Agency for use as a team-based self-reflection and education exercise.90
Table 19 presents the nine dimensions of patient safety defined in the MaPSaF.

**Table 19: The MaPSaF nine dimensions of patient safety**

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Overall commitment to quality</td>
<td>How much is invested in developing the quality agenda? What is seen as the main purpose of policies and procedures? What attempts are made to look beyond the practice for collaboration and innovation?</td>
</tr>
<tr>
<td>2. Priority given to patient safety</td>
<td>How seriously is the issue of patient safety taken within the practice? Where does responsibility lie for patient safety issues?</td>
</tr>
<tr>
<td>3. Perceptions of the causes of patient safety incidents and their identification</td>
<td>What sort of reporting systems are there? How are reports of incidents received? How are incidents viewed, as an opportunity to blame or improve?</td>
</tr>
<tr>
<td>4. Investigating patient safety incidents</td>
<td>Who investigates incidents and how are they investigated? What is the aim? Does the practice learn from the event?</td>
</tr>
<tr>
<td>5. Team learning following a patient safety incident</td>
<td>What happens after an incident? What mechanisms are in place to learn from the incident? How are changes introduced and evaluated?</td>
</tr>
<tr>
<td>6. Communication about safety issues</td>
<td>What communication systems are in place? What are their features? What is the quality of record keeping communicating about safety like?</td>
</tr>
<tr>
<td>7. Staff management and safety issues</td>
<td>How are safety issues managed in the practice? How are staff problems managed?</td>
</tr>
<tr>
<td>8. Staff education and training about safety issues</td>
<td>How, why and when are education and training programmes about patient safety developed? What do practice personnel think of them?</td>
</tr>
<tr>
<td>9. Team working around safety issues</td>
<td>How and why are teams developed? How are teams managed? How much team working is there around patient safety issues?</td>
</tr>
</tbody>
</table>
For each dimension, the MaPSaF provides five statements describing the dimension at increasing levels of safety culture maturity as shown in table 20. The most immature stage of safety culture is pathological (A). At this level of safety culture maturity information is hidden, failure is covered up, new ideas are crushed, and sharing information and learning is actively discouraged. The most mature stage of safety culture is generative (E). At the generative level, information is actively sought, new ideas are welcomed and failure prompts inquiry rather than cover-up or blame.

<table>
<thead>
<tr>
<th>Score</th>
<th>Level of safety culture maturity</th>
<th>Attitude reflecting the maturity of safety culture</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Pathological</td>
<td>why do we need to waste our time on patient safety issues?</td>
</tr>
<tr>
<td>B</td>
<td>Reactive</td>
<td>we take patient safety seriously and do something when we have an incident</td>
</tr>
<tr>
<td>C</td>
<td>Bureaucratic</td>
<td>we have systems in place to manage patient safety</td>
</tr>
<tr>
<td>D</td>
<td>Proactive</td>
<td>we are always on the alert for patient safety issues that might emerge</td>
</tr>
<tr>
<td>E</td>
<td>Generative</td>
<td>managing patient safety is an integral part of everything we do</td>
</tr>
</tbody>
</table>

The MaPSaF process is led by a facilitator from within the practice. For each of the nine MaPSaF dimensions of patient safety, participating practice personnel read the five statements describing the dimension at increasing levels of safety culture maturity. Participants then choose the statement they think best reflects the situation in their practice (A, B, C, D, or E). Participants do this for each dimension individually and without discussion. After all participants have rated their practice on each of the nine dimensions, a team discussion is held to choose a consensus score for each of the nine dimensions of patient safety. Each participant reveals and justifies his or her score before the practice team decides on a consensus score for each dimension in turn. By giving each
participant an opportunity to reveal and justify their score, the MaPSaF helps to overcome hierarchies within the team and helps everyone to have a voice.

I adapted the MaPSaF to the New Zealand general practice context in two stages. Initially I reviewed the language used in MaPSaF descriptions and removed or replaced phrases unique to the UK setting. For example, I replaced “solicitor” with “Health and Disability Commissioner”. I chose words carefully. The choice of language is important when researching a sensitive topic like patient safety. The notion of safety culture is relatively alien to many working in general practice in New Zealand, and for many the term ‘patient safety’ still conjures up images of blame and shame. Words like ‘error’ and ‘mistake’ imply fault or wrong-doing and can make participants ill at ease, but phrases like ‘patient safety incident’ are foreign and sound managerial.

I also shortened the five descriptions for each of the nine dimensions so that the MaPSaF process would take no longer than one hour (including reading all five descriptions for each dimension, choosing individual scores, discussing the score and the dimensions, and choosing a practice consensus score for each dimension). Table 21 shows the shortened NZ-MaPSaF description for dimension 4 at maturity level D, compared to the original MaPSaF description.
Table 21: MaPSaF and NZ-MaPSaF descriptions of Dimension 4 at maturity level D

<table>
<thead>
<tr>
<th>Dimension 4: Investigating patient safety incidents</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MaPSaF: description D</strong></td>
<td><strong>NZ-MaPSaF: description D</strong></td>
</tr>
<tr>
<td>Investigations occur in order to gain an independent perspective. The staff involved in incidents are involved in their investigation, which uses robust methods like root cause analysis and significant event audit to identify the contributory factors and system problems that led to the incident. The aim of investigations is to learn from incidents and disseminate the findings widely. Data from investigations are used to analyse trends, identify ‘hot spots’ and examine training implications. It is a forward-looking, open organisation. Patients are involved in the investigation process and their perceptions, experience and recommendations are sought.</td>
<td>Investigations occur in order to gain an independent perspective. The staff involved in incidents are involved in their investigation, and help to identify the contributory factors and system problems that led to the incident. The aim of investigations is to learn from incidents and disseminate the findings widely.</td>
</tr>
</tbody>
</table>

Secondly, as the pilot progressed and the NZ-MaPSaF was used in the study practices, I made further changes to the descriptions as participants drew attention to phrases or concepts that either did not resonate with them or were unclear. For example, I had initially left in the term “root cause analysis” but I later removed this term as it became obvious many participants were unfamiliar with it. Table 22 shows the five NZ-MaPSaF descriptions for Dimension 3. All NZ-MaPSaF dimensions and descriptions are provided in Appendix 6.
Table 22: NZ-MaPSaF Dimension 3 described at five increasing levels of safety culture maturity

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Incidents are seen as ‘bad luck’, occurring as a result of staff errors or patient behaviour. Ad hoc reporting systems are in place but the practice is largely in ‘blissful ignorance’ unless serious incidents occur or letters of complaint are received. There is a strong blame culture.</td>
</tr>
<tr>
<td>B</td>
<td>The practice sees itself as a victim of circumstances. Individuals are seen as the cause and the solution is ‘retraining’ and punishment. There is an embryonic reporting system. Minimum data on the incidents is collected but not analysed. There is a blame culture, so staff are reluctant to report incidents.</td>
</tr>
<tr>
<td>C</td>
<td>There is a recognition that ‘systems’ contribute to incidents and not just individuals. A reporting system is in place. Attempts are made to encourage staff to report incidents (including those that did not lead to harm), though staff do not feel safe reporting the latter.</td>
</tr>
<tr>
<td>D</td>
<td>It is accepted that incidents are a combination of individual and system faults. Reporting of patient safety incidents is encouraged and they are seen as learning opportunities although learning is not always disseminated. Accessible, ‘staff friendly’ electronic reporting methods are used. The practice has an open, fair and collaborative culture.</td>
</tr>
<tr>
<td>E</td>
<td>‘System’ failures are noted, although staff are also aware of their own professional accountability in relation to errors. It is second nature for staff to report patient safety incidents as they have confidence in the investigation process and understand the value of reporting. The practice has a high level of openness and trust.</td>
</tr>
</tbody>
</table>
10.2.2 Testing the NZ-MaPSaF for acceptability and utility

10.2.2.1 Recruiting practices and participants

The Dunedin city boundary encloses large areas of rural land as well as high-density urban locations. Dunedin has a population of 120,000 and has 32 general practices. 15 practices were randomly selected by applying a random numbers table to the list of 32 practices in the Dunedin telephone book. These 15 practices were approached by letter, email and telephone to recruit the 12 study practices (Appendix 7). Three declined to participate. Participants were all practice personnel present on the day of data collection who agreed to participate.

10.2.2.1.1 RNZCGP endorsement of the NZ-MaPSaF process

To aid recruitment for this study, I sought and obtained RNZCGP endorsement for use of the NZ-MaPSaF tool as an approved Continuous Quality Improvement (CQI) activity for the RNZCGP’s recertification programme MOPS (Appendix 8).

All doctors in New Zealand must participate in a Medical Council approved recertification programme to maintain their certificate to practice. The RNZCGP has designed a recertification programme for use by vocationally trained general practitioners (MOPS). General practitioner participants in the MOPS programme must earn 30 CQI credits each triennium. CQI activities comprise cycles of audit to measure practice performance, action to make improvement, and then retesting to measure change.

The RNZCGP may provide endorsement of a CQI activity for use in the recertification programme on application. Approved CQI audit cycles usually involve the quantitative assessment of an area of care, the institution of change, and then a second round of assessment to measure improvement.

The application process involved an explanation of the activity, why the activity is important, how the process works, and how the activity will involve the practice team and benefit the practice. Most College approved audits use quantitative methods and involve quantitative measures of an area of care, the implementation of change, and then another round of audit to measure improvement. However, as safety culture refers to the 'shared attitudes, beliefs, values and assumptions', it is a concept best assessed using qualitative
rather than quantitative methods. The MaPSaF provides a (qualitative) measure of safety culture and also improves safety culture by its processes.

I had some difficulty explaining to the RNZCGP the use of the MaPSaF as a tool to both provide a valid qualitative audit of safety culture and to implement change (stimulate improvement in safety culture). These hurdles were eventually overcome and the NZ-MaPSaF process was ultimately approved by the College for use as a tool to provide both a measure of safety culture (using qualitative methods) and a stimulus for change to improve safety culture.

College endorsement of the NZ-MaPSaF process provided an incentive for doctors to use the tool in their practice, and to give up their time to participate in this pilot study. General practitioner participants in this study were able to claim ten MOPS CQI credits for each round of the NZ-MaPSaF study. The College also agreed to make the NZ-MaPSaF available on its website for members to use in their practices to strengthen safety culture. General practitioners who use the tool are now able to claim ten MOPS CQI credits each time they use the NZ-MaPSaF in their practice as part of their continuing professional development programme for recertification purposes (Appendix 9).

10.2.2.2 Data collection

The data collection process was held in each practice at baseline and again at three months. Data collection generally took place over a one hour lunchtime meeting, although some meetings were held over morning or afternoon tea, or at the beginning of the day. Signed informed consent for participation in the study was obtained from each individual participant prior to data collection.

I gave each participant a printout of the NZ-MaPSaF tool comprising the nine dimensions of patient safety described at five different levels of safety culture maturity. I then instructed participants to read the five descriptions for each dimension in turn, and to rate their practice for each dimension by choosing the description (A, B, C, D or E) that they thought best reflected their practice. I asked participants to do this individually and without discussion, and to write their scores on a card (Appendix 10). When all participants had individually rated their practice on each of the nine dimensions, a group discussion was held during which each participant in turn discussed each of the nine
dimensions, the score they had chosen, and the reasons for their choice. The practice group then chose a practice-wide consensus score for each dimension (Appendix 11). The individual participant and the consensus score cards were collected. The discussions were recorded and later transcribed *verbatim*.

This process was repeated at a second visit at three months. At the second visit participants were asked additional questions to discover their views about the acceptability and utility of the NZ-MaPSaF process, and whether it had stimulated any change in thinking about safety issues or had led to any changes in practice processes.

Supplementary data about the practices and participants were collected including practice size (N patients and N staff), urban/rural location, and whether the practice was Cornerstone-accredited or involved in teaching.

### 10.2.2.3 Data analysis

The quantitative data consists of both the individual participant scores and the practice-wide consensus scores rating the maturity of safety culture in their practice (on a scale of A to E, where A is immature and E mature) on each of nine safety dimensions.

The scores selected by individual participants and the practice consensus scores were assigned a categorical code from 1 – 5 (where 1 is immature and 5 mature). Frequency distributions of these categories were computed for the set of study practices. The Wilcoxon signed-rank test was used to compare the average scores of visit 1 and 2 for each dimension. The Wilcoxon signed rank test is the non-parametric equivalent of the dependent samples t-test. Both can be used to compare the difference in scores before and after some sort of intervention and in this case between the first and second visits. A non-parametric test was chosen because initial analysis showed that the distribution of differences between scores was generally not normal, which means that the t-test is not appropriate. An average score was calculated as the mean value of all ‘dimensions of patient safety culture’ scores and included in the analysis.

The qualitative data comprised the recorded team discussions about each of the nine dimensions of patient safety as the practice team discussed their individual scores and chose a consensus score for each dimension at visit one and visit two. The analytic approach to these data involved immersion in the data and identification of themes relating to acceptability and utility of the NZ-MaPSaF in study practices, and changes in
views or practice processes following the first visit. Further themes arose from data analysis. As the study’s aim was practically oriented—to test NZ-MaPSaF for acceptability and utility—theory-building and philosophical development were not analytic goals. There were no predetermined categories relating to acceptability and utility that guided discussions: these categories emerged from data analysis. All quotes from transcripts were organised into categories under the main themes and representative quotes were chosen to demonstrate the main findings.

10.3 Results

10.3.1 Practices and participants

Table 23 shows that the 12 study practices ranged in size from a solo practice with 1100 registered patients to a large group practice with 12 full-time equivalent doctors and 18,000 patients. The study sample included rural, suburban and student health practices and an Accident and After Hours centre. Study practices were representative of all Dunedin practices in terms of their size (number of full-time equivalent (FTE) doctors, nurses, and administration staff) and their patient population (age, sex, and race of enrolled population). Some practices were Cornerstone accredited and some were not, some took students and some did not. Study participants were all practice personnel present in the practice on the day of data collection.
Table 23: Data for study practices and participants

<table>
<thead>
<tr>
<th>Practice</th>
<th>Enrolled patients</th>
<th>Doctors</th>
<th>Nurses</th>
<th>Admin</th>
<th>Cornerstone accredited*</th>
<th>Teaching</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>FTE N</td>
<td>FTE N</td>
<td>FTE N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1100</td>
<td>1 3</td>
<td>0.6 1</td>
<td>0.4 2</td>
<td>Never</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>2301</td>
<td>1.2 1</td>
<td>1.2 2</td>
<td>1.5 2</td>
<td>Lapsed</td>
<td>Nursing</td>
</tr>
<tr>
<td>3</td>
<td>2930</td>
<td>2 6</td>
<td>2 3</td>
<td>1 4</td>
<td>Never</td>
<td>Medical</td>
</tr>
<tr>
<td>4</td>
<td>(0)**</td>
<td>8.6 14</td>
<td>7.2 9</td>
<td>8.8 9</td>
<td>Accredited</td>
<td>Medical, Psychology</td>
</tr>
<tr>
<td>5</td>
<td>3384</td>
<td>2 2</td>
<td>1 2</td>
<td>1.5 4</td>
<td>Never</td>
<td>Medical</td>
</tr>
<tr>
<td>6</td>
<td>2725</td>
<td>2 4</td>
<td>2 3</td>
<td>2.5 3</td>
<td>Never</td>
<td>-</td>
</tr>
<tr>
<td>7</td>
<td>2613</td>
<td>2 2</td>
<td>0.7 1</td>
<td>1 1</td>
<td>Never</td>
<td>Medical</td>
</tr>
<tr>
<td>8</td>
<td>1800</td>
<td>1.7 3</td>
<td>1 1</td>
<td>1.5 2</td>
<td>In process</td>
<td>Medical</td>
</tr>
<tr>
<td>9</td>
<td>(0)**</td>
<td>1.5 5</td>
<td>2 5</td>
<td>4 6</td>
<td>Never</td>
<td>Medical, Nursing</td>
</tr>
<tr>
<td>10</td>
<td>18,000</td>
<td>12 18</td>
<td>12.6 19</td>
<td>11.5 16</td>
<td>Reaccredited</td>
<td>Medical, Nursing</td>
</tr>
<tr>
<td>11</td>
<td>3000</td>
<td>2.3 4</td>
<td>2.3 3</td>
<td>2 3</td>
<td>Reaccredited</td>
<td>Medical, Nursing</td>
</tr>
<tr>
<td>12</td>
<td>1300</td>
<td>1 4</td>
<td>1 1</td>
<td>1 2</td>
<td>In process</td>
<td>Nursing</td>
</tr>
</tbody>
</table>

*RNZCGP Cornerstone practice accreditation programme

** Two practices worked under different funding arrangements and did not have enrolled patients.
Figure 26 shows that there were between four and 23 participants at each NZ-MaPSaF meeting, and that participants included general practitioners, nurses, managers, receptionists, counsellors, dentists, registrars and student nurses.

**Figure 26: Occupation of study participants**
10.3.2 Self-rated scores for the nine dimensions of patient safety

The quantitative data consisted of both the individual participant scores and the practice-wide consensus scores for each of nine dimensions of patient safety (A, B, C, D, E).

Figures 27, 28 and 29 show that the most commonly chosen score by all participants and on consensus in both visit 1 and visit 2 was ‘D’. This is the score reflecting the second most mature safety culture description, the pro-active level of safety culture maturity. The next most commonly chosen score was ‘E’ reflecting the generative level of safety culture maturity. Few participants rated their practice 'A' or 'B', scores reflecting pathological and reactive levels of safety culture maturity respectively.

![Combined scores for all participants and practices across all dimensions](image)

**Figure 27: Combined scores for all participants and practices across all dimensions**
Figure 28: Frequency of individual responses visit 1

Figure 29: Frequency of individual responses visit 2
Figure 30 shows there were significant differences in scores from visit 1 to visit 2 for dimensions 1, 2, 3, 4, 6, and 9. No significant difference in scores from visit 1 to visit 2 was found for dimensions 5 (Team learning following a patient safety incident), 7 (Staff management and safety issues), and 8 (Staff education and training about safety issues).

No significant differences were found between the scores given by different provider groups: medical, nursing and administrative personnel were thus in general agreement.

![Figure 30: Average scores for each dimension at visit 1 and visit 2](image)

It was not possible to draw valid conclusions about the maturity of safety culture from analysis of the self-rated scores. While the individual scores decreased for some dimensions between visits 1 and 2 (indicating decreasing maturity), analysis of the qualitative data indicated increased awareness about patient safety issues and an increasingly mature safety culture. Counter-intuitively, increased understanding about patient safety issues and a strengthening of the safety culture, led some participants to rate their practice at a lower level of maturity on the second visit. The higher score at the first visit may have indicated a state of blissful ignorance rather than a more mature safety culture, while the lower score at the second visit indicated increasing awareness and greater understanding about the dimensions of patient safety and hence a more mature
safety culture. The NZ-MaPSaF cannot, then, be used to provide a quantitative measure of safety culture for comparison purposes.\textsuperscript{45}

‘D’ was the most common score chosen by participants, but the main reason proffered for this choice was not that participants thought their practice had a pro-active level of safety culture maturity, but rather that participants felt they were ‘trying their best, and generally did pretty well, but that there was always room for improvement’. The quantitative data (self-rated scores) are subjective measures only and do not necessarily reflect actual levels of practice safety culture maturity.

10.3.3 Acceptability of the NZ-MaPSaF

The qualitative data comprised the recorded team discussions about each of the nine dimensions of patient safety as the practice team discussed their individual scores and chose a consensus score for each dimension. Analysis of these data revealed that most participants enjoyed the NZ-MaPSaF process and said they found the process thought-provoking and useful. Most indicated a willingness to use the NZ-MaPSaF again in the future. Most found the one-hour format reasonable although timing was tight and some participants wanted to spend more time reading through the descriptions and choosing their scores. Other participants expressed concerns about time pressures and indicated that they would need protected time to undertake the process and that this time was hard to come by in the pressures of daily practice life. Some participants expressed concerns about being too busy in general practice to take part in non-patient contact activities such as the NZ-MaPSaF. This may be due, in part, to New Zealand’s fee-for-service environment where practice viability depends on maintaining adequate patient turnover. Most practice activity is therefore geared towards profit generating activities.

Practice 5: \textit{We just got busier and busier and the paperwork got greater and greater… there’s not the time to do it…} (Doctor)

While the structure and timing of the NZ-MaPSaF process was generally appropriate and the MaPSaF descriptions resonated with New Zealand participants, I further modified some descriptions as the study progressed and it may be that some descriptions would benefit from further modification yet, in particular to make the NZ-MaPSaF more acceptable for use in smaller practices. Some participants from smaller practices commented that the NZ-MaPSaF was weighted towards larger organisations which led to
unfair scoring. In particular they noted that some of the systems advocated in the NZ-MaPSaF were not necessary in smaller practices.

Practice 5: See I wonder about that whole sort of um... I mean they’re really based around large organisations, and so it’s an unfair tool in that sense. (Doctor)

Practice 4: We just basically talk about it don’t we? I mean we’re a small team... (Receptionist)

Well, we don’t discuss it in an ‘open forum’... An ‘open forum’ sounds like something large. ... It’s more over a cup of tea, or at the front desk. Certainly ‘the process exists to share learning’ because we talk about things. (Nurse)

Practice 7: Often everyone’s involved in some incident too, so you have to know about them... In a little place... you can talk to each other, so you don't have quite the same... We have discussion but we don't actually have the systems in place. (Doctor)

Some participants expressed scepticism about some of the ideas in the generative level descriptions such as patient involvement in safety initiatives. Few of the study practices had processes to involve patients in safety initiatives.

Practice 7: Because we did offer them a patient questionnaire and the thing just said, “We love you.” (Doctor 1)

Not very meaningful feedback. (Doctor 2)

It is positive but if you’re looking at what goes on, what happens and how do we change ... It's sort of like you've gone through all the effort of doing it, for what?... A pat on the back. (Doctor 1)

Some participants expressed reservations about overcoming defensive attitudes even though the study took place in a ‘safe’ environment (the participants' practice) and the NZ-MaPSaF provided a framework for participants to talk about patient safety issues without having to reveal personal details or incriminating events.

Practice 5: And were we defensive? Too bloody right. (Doctor)

This is a ‘learning tool’. (Nurse)

But it is natural to be defensive... But it’s also a learning experience as well... Everyone sort of says ‘Oh we’re not defensive, it’s learning’... Of course we’re defensive. I think everyone is defensive. (Doctor)
10.3.4 Utility of the NZ-MaPSaF

10.3.4.1 Educating participants about patient safety

The NZ-MaPSaF introduced the concept of safety culture to practice participants in an accessible format and, by breaking down patient safety into nine constituent dimensions, helped participants to understand this complex concept. The NZ-MaPSaF helped participants to recognise that patient safety incidents were different to occupational safety and health issues, and also that patient safety incidents need not be only rare egregious incidents or blameworthy incidents.

Practice 2:  *We actually do, do that... at every meeting we ask if there are any ‘health and safety issues’.* (Manager)

*The ‘health and safety issues’, they were often about the building.* (Nurse 1)

*They are ‘health and safety’ issues, yeah, which is slightly different from ‘patient safety incidents’...* (Nurse 2)

Some participant responses reflected poor understanding about patient safety issues and indicated that practices were at an early stage of safety culture development.

Practice 5:  *I found difficulty with this because we don’t ... haven’t had a situation that I can recall...* (Doctor)

10.3.4.2 Facilitating team communication about patient safety issues

The NZ-MaPSaF process provided a useful forum for discussion about safety issues; the process directed team discussion about safety issues. Most participants said that they found the process stimulated thought and discussion about patient safety issues within their practice:

Practice 2:  *I think it’s definitely stimulated us to think about it more ... we’re more conscious about how all the communication channels work and affect us ... we’re getting to maybe talk about it a bit more than we did.* (Receptionist)

*I think it was quite thought provoking after last time. It was good.* (Nurse)

The NZ-MaPSaF facilitated team discussion and empowered less outspoken team members to air their concerns:
Practice 2:  Well, I find the staff meetings are too far apart. Like they’re not often enough. Often stuff might not be dealt with because there’s too many other things to do. I’ve had … a problem which is seen as not an issue because … but I’m not actually being heard … it would be quite nice to know what was actually… what’s on the agenda, or if you want to actually put something to the management meetings so that it can be discussed. … But what is actually discussed there at the staff meeting? (Nurse)

Practice 7:  Umm, the ‘equally valued’ and ‘free to contribute’… (Receptionist)

So, what do you mean by that, do you feel that people aren’t equally valued? (Researcher)

Sometimes, yes. (Receptionist)

In what way? (Researcher)

Just mainly attitudes really. (Receptionist)

From patients or from other staff or…? (Researcher)

Mostly other staff… I’m aware of times when it doesn’t feel equally valued. (Receptionist)

10.3.4.3 Stimulating change

The generative level descriptions of the dimensions of patient safety provided an ideal for participants to work towards, and provided ideas for change that participants could implement in their practices, such as having regular practice meetings with ‘patient safety’ on the agenda.

Practice 2:  Well, we could bring it up in the practice meeting? That would be the forum I think. (Nurse)

Have it on the agenda: ‘safety’. Okay. (Doctor)

That’s a very good idea. We should include that on our agenda, just that… a line on safety, if there are any issues or anything like that… I think that’s a great idea. (Nurse)

The NZ-MaPSaF stimulated some practices to make changes, reflecting increased safety culture maturity.

Practice 6:  We’ve started a patient called ‘Mr Patient Safety’ and we’ve recorded a fair number of incidents. We had a meeting recently… so that has
improved things, it’s made us more aware. To my mind it’s improved the score… The other thing we have done is to instigate a meeting to try and develop commonality of approach to patients and to discuss, I was going to use the word ‘difficult’ patients but I don’t mean it in that way, I mean patients that are complex patients. And we really want to develop a uniform approach to managing those complex problems. And that’s happened since our last meeting. (Nurse)

10.4 Discussion

10.4.1 Summary of findings

Findings from this study suggest that the MaPSaF can be adapted and used in the New Zealand general practice context to both measure safety culture (through qualitative means) and improve safety culture through educational means. New Zealand’s distinct medical regulatory framework might support the uptake and use of the tool. The lack of punitive outcomes for doctors also enables providers to participate freely in the educational process, sharing information about the things that go wrong, without fear of punitive repercussions, and the RNZCGP’s endorsement of the tool for CQI points provides an incentive for general practitioners to use the tool in their practices.

Participants found the NZ-MaPSaF process both acceptable and useful. The NZ-MaPSaF introduced the concept of safety culture, helped to facilitate communication about patient safety issues, and led to changes being made in some practices. The NZ-MaPSaF can be added to the toolkit, then, for improving patient safety in New Zealand general practices.

Improving patient safety in general practice will likely take a many-pronged approach. Researchers are working towards developing a toolkit for patient safety in primary care. Some of the patient safety tools that have been tried so far include safety culture tools, including the Manchester Patient Safety Framework, and safety climate tools; local reporting systems, which can help to raise awareness and to motivate people to take action; practice accreditation programmes, for example the RNZCGP Cornerstone programme in New Zealand, the Royal Australian College of General Practitioners’ quality improvement and continuing professional development programme and other tools to improve general practice care, Healthcare Improvement Scotland's patient safety programme in primary care, and the Safe-care organisation's five levels of accreditation programme in Africa, team training packages such as the Agency for
Healthcare Research and Quality’s TEAM STEPPS package;\textsuperscript{426} and patient safety office checklists, such as that developed by the American Medical Association.\textsuperscript{427}

\subsection{10.4.2 Strengths and weaknesses}

The quantitative data cannot be used to provide a measure of safety culture maturity, but the qualitative data can provide an assessment of safety culture maturity, revealing the attitudes and underlying assumptions held by practice personnel. It is perhaps not surprising that the qualitative data better revealed the maturity of safety culture given safety culture refers to the \textit{shared values, attitudes, perceptions, competencies and patterns of behaviour},\textsuperscript{14} which are concepts best studied by qualitative rather than quantitative methods. Analysis of the qualitative data suggests that the development of a culture of safety in some practices may be in its infancy. Further work is needed to confirm this.

This study was conducted in one New Zealand city, but study findings are likely to be transferable at least within New Zealand because of the diversity of the participating practices. Participating practices included both large and small practices; rural, urban and suburban practices; accredited and non-accredited practices; and teaching and non-teaching practices. The results may also be transferable to other countries where small primary care practices are common and where discussion about patient safety is in its infancy.

The use of an external facilitator (the researcher) is a source of bias in this study. The MaPSaF tool was designed to be used within practices using a facilitator from within the practice. The presence of an external facilitator may have influenced responses and the outcome of the NZ-MaPSaF process and introduced a socially desirable response bias. While an external facilitator can be helpful to break established practice hierarchies and foster discussion, she may also intimidate participants and inhibit discussion about patient safety – which remains a sensitive topic for some providers. On the plus side, the external facilitator was able to act as a vector, transmitting ideas from one practice to the next. Further research is required to determine whether using a facilitator from within the practice would yield different results.

While the self-rated scores (quantitative data) did not provide a valid measure of safety culture maturity, the process of choosing the scores was useful. The need to come up with
a score provided an incentive for participants to read the five descriptions for each of the
nine dimensions, and the scores provided a good starting point for the discussions.
Analysis of the qualitative data provided a more valid measure of safety culture maturity.

There is currently no requirement for New Zealand general practitioners to address the
safety culture in their practices. However, if strengthening practice safety culture can be
shown to improve patient safety then general practitioners would have a moral obligation
to take up the challenge.4, 76, 428, 429 There is no punitive deterrent to using the tool in New
Zealand, but some participants still expressed reservations about setting aside time for the
process. It is likely participants would need some incentive to overcome barriers and to
use the NZ-MaPSaF regularly in their practices. An incentive has been provided by the
Royal New Zealand College of General Practitioners’ endorsement of the NZ-MaPSaF as
an approved Continuous Quality Improvement (CQI) activity. General practitioners can
now claim 10 CQI points towards the College’s recertification programme each time they
use the NZ-MaPSaF in their practice (out of a total of 30 points required per triennium).
The College has made the NZ-MaPSaF available on its website for members to download
and use in their practice: (https://www.rnzcgp.org.nz/the-manchester-patient-safety-
framework-mapsaf).160

10.4.3 Conclusion

Findings from this pilot study suggest that the MaPSaF can be adapted and used as an
educational tool in New Zealand general practices to both assess safety culture using
qualitative methods and to strengthen safety culture by educating participants about
patient safety issues and facilitating team communication.

Study findings are likely to be transferable to other countries where small primary care
practices are common and where discussion about patient safety is in its infancy. While
endorsement of the tool by the Royal New Zealand College of General Practitioners
provides an incentive for the use of the tool in general practice, it remains unclear
whether New Zealand’s distinctive medical regulatory environment overall supports the
uptake and use of the tool.
I now discuss what my findings say about the influence of both New Zealand’s distinct medical regulatory framework and an educational tool on the development of a culture of safety in New Zealand health care settings.
11 DISCUSSION

In this thesis I assessed two potentially positive influences on the development of a culture of safety in New Zealand health care settings: New Zealand’s distinct medical regulatory structure and an educational means of enhancing safety culture.

A culture of safety concerns the shared attitudes and assumptions that underlie how people perceive and act upon safety issues. Developing a culture of safety entails changing health professionals’ attitudes and behaviours, from reticence and defensiveness to openness and learning. While it is not easy to change people’s attitudes, both regulation and education have proved effective tools in the past.

In developing the thesis that New Zealand’s medical regulatory system supports the development of a culture of safety while maintaining professional accountability for harm, I assessed whether New Zealand’s medical regulatory system is perceived to be less punitive than a tort-based malpractice system; whether it is less punitive following the 2005 no-fault compensation reforms while maintaining medical professional accountability; whether the reformed compensation scheme engenders openness about medical injury; and whether the data generated under the reformed scheme can be analysed to identify learning that can be fed back to frontline providers to improve patient safety. In assessing an educational means of enhancing safety culture, I assessed whether a UK safety culture tool could be adapted to the New Zealand general practice context and used to improve safety culture by educating practice personnel and facilitating team communication about patient safety issues, and whether New Zealand’s medical regulatory structure supports the use of the tool in practices.

11.1 New Zealand’s medical regulatory system

The influence of New Zealand’s distinct medical regulatory structure on the development of a culture of safety is not yet fully understood, but findings from this research suggest that, on balance, New Zealand may be better placed than most to develop a culture of safety in health care settings.

11.1.1 Not necessarily less punitive

New Zealand’s no-fault compensation scheme prevents the development of a culture of suing but, because punishment lies in both the process and the penalty, New Zealand’s
medical regulatory system overall may not be perceived as less punitive than an adversarial medical malpractice system. Patient complaints are often keenly felt by doctors, while malpractice claims may be more about money and are handled by the lawyers. While punitive outcomes for doctors decreased following the no-fault compensation reforms, patient complaints increased, making the regulatory environment not less punitive (subjectively) overall.

It may not matter that New Zealand’s medical regulatory environment is not less punitive because, while a culture of safety is not likely to thrive in a punitive environment, a less punitive environment, in itself, is not likely to encourage the development of a culture of safety and overcome the sense of shame and moral blame that doctors may feel when patients are harmed while seeking help.

11.1.2 Some diminution in medical professional accountability

ACC referred fewer doctors to the Medical Council following the no-fault reforms, as expected, reflecting decreased accountability via ACC. This change contributed to an overall decrease in medical professional accountability in New Zealand as indicated by the HDC investigating fewer complaints, and fewer doctors being held to account by either the performance review or disciplinary processes. The decrease in accountability occurred despite increased demand for accountability in the form of increasing patient complaints.

It is not possible to say from this analysis whether doctors are adequately held to account under New Zealand’s current medical regulatory structure and whether, in the trade-off between accountability and learning, an acceptable balance has been found in New Zealand. There is no universally agreed level of accountability.

11.1.3 Engendering openness and creating new opportunities for learning

Findings from this doctoral project suggest that the reformed compensation scheme does facilitate openness about medical injury, creating new opportunities for learning to improve patient safety. In this way the reformed compensation scheme supports the development of a culture of safety in New Zealand health care settings.

Findings suggest that while the data generated under the reformed scheme suffer from various limitations for patient safety purposes, including the lack of information about
injury preventability, the data can nevertheless be analysed to identify learning to inform efforts to improve patient safety.

11.1.3.1 Lessons from claims data

One third of all new treatment injury claims arose in primary care settings, confirming the importance of addressing patient safety concerns in primary care. Analysis of the primary care treatment injury claims dataset confirmed medication as the major threat to patient safety in primary care, reflecting both the use of medication in primary care and the danger of this type of treatment. Antibiotics caused most medication related harm. Warfarin was an outstanding cause of severe medication injuries, drawing attention to the risks of warfarin therapy in the community. Analysis also drew attention to the possible over-prescribing of non-essential medications such as statins in the very elderly, proton pump inhibitors, and antifungal medications. Of particular concern was the number of severe injuries caused by heavily promoted non-essential medications (such as terbinafine, used in general practice predominantly to treat generally harmless toenail infections).

It was possible to identify some prescribing, dispensing, and administration errors in the dataset. However, for many medication events there was no suggestion of error (for example, adverse reactions to drugs properly given). To improve patient safety in primary care, then, we might be better to shift the focus from reducing medication error, to reducing medication treatment overall (where possible).

While more claims are generated under the reformed compensation scheme increasing opportunities for learning, these data suffered from various limitations for injury prevention purposes, not least the lack of information about injury preventability. Further, the increase in claims mainly concerned events assessed as minor. The dataset provides an incomplete picture of threats to patient safety, and the missing data introduce bias. Claiming is largely driven by the desire for assistance with treatment and rehabilitation costs and it is likely many patients still fail to lodge claims for some injuries. The elderly, for example, who are known to be particularly vulnerable to injury, were under-represented in the claims dataset. This may be because of a lack of awareness about the scheme, a lack of motivation to claim when treatment is available free of charge in hospital, and because some injuries common to the elderly, such as falls, may be claimed as a general injury rather than as a treatment injury. Claims for delay in diagnosis were
under-represented in the dataset, perhaps because of a lack of awareness about the eligibility criteria and the counter-intuitive nature of disease progression due to a failure of diagnosis and the consequent lack of treatment, being considered an ‘injury caused by treatment’. The lack of a denominator for many treatment events made it not possible to say whether medication featured so prominently in the dataset because medication is the most dangerous treatment or because medication is the most common treatment in primary care (or both).

11.1.3.2 Lessons from ACC harm reports

Analysis of the ACC harm reports dataset also confirmed medication as posing the greatest risk of harm to the public in primary care, although numbers were small. Also many reports were potentially missing from the dataset. Some reported events were unpredictable severe adverse reactions, but many were potentially preventable events associated with medication prescribing, dispensing, and administration errors.

Diagnosis featured more strongly in the harm reports dataset than in the claims dataset, identifying conditions known to present a diagnostic challenge in primary care: ectopic pregnancy, temporal arteritis, some cancers, and rare congenital conditions. Surgical procedures, joint injections, neck manipulation and IUCD insertions were also identified as posing a risk of harm to the public in primary care.

11.1.3.3 Lessons from provider feedback

Analysis of the provider feedback about ACC reported primary care events identified helpful, but not ground-breaking, suggestions for averting event causal factors and identifying potential solutions. Providers identified as contributing factors heavy workload, fatigue, distraction and interruptions, lack of adequate resources, and difficulties in communication both between providers and between providers and patients. While lack of education and training and lack of effort were seldom identified as contributing factors, suggested solutions frequently included a call for ‘more education and training’ and ‘trying harder next time’. Other solutions suggested included changing computerised practice management systems and medication dispensing and administration processes, introducing protocols and checklists, wearing alert aprons when on medication administration duty, increasing staff ratios, reducing workload limits,
reviewing charts with multiple medications, and educating patients and enlisting them in the cause.

Analysis also revealed a concerning focus in some health care organisations on identifying individual blame for events. This was particularly so for residential care settings, indicating that there is some way to go yet towards developing a culture of safety in these settings.

11.2 A UK safety culture educational tool in New Zealand

Findings suggest that the MaPSaF adapts well to the New Zealand general practice context and can be used to help strengthen safety culture in practices. The NZ-MaPSaF educates practice participants about the dimensions of patient safety culture and facilitates team communication about patient safety issues.

The MaPSaF did not live up to expectations for quantitatively measuring safety culture, but the tool can be used to provide a qualitative measure of safety culture. Analysis of the qualitative data suggests that the notion of patient safety is still relatively novel for many practice personnel, and that the development of a culture of safety may still be in its infancy in some Dunedin practices.

New Zealand’s medical regulatory framework supports the uptake and use of the NZ-MaPSaF in practices. RNZCGP endorsement of the NZ-MaPSaF as an approved CQI activity provides an on-going incentive for College members to use the NZ-MaPSaF in their practices to strengthen safety culture.

11.3 Further research and policy

11.3.1 Understanding the influence of New Zealand’s medical regulatory system

Further work is needed to confirm and expand on the findings of this research. In particular, to better understand the influence of New Zealand’s distinct medical regulatory structure on health care ethics and practice. For example, it is not yet known whether New Zealand’s system encourages learning and improvement or fosters a laissez-faire attitude in medicine, or neither. It is also not yet known what influence the system has, if any, on the problem of over-diagnosis and over-treatment in medicine. If over-diagnosis is driven, in part, by doctors' fear of litigation then over-diagnosis might be less
of a problem under New Zealand’s no-fault jurisdiction. Any research to confirm the value of New Zealand’s approach to medical regulation is likely to be complicated by the myriad of factors influencing doctor behaviour.

**11.3.1.1 Determining the adequacy of New Zealand’s medical professional accountability processes**

The decrease in medical professional accountability identified in this analysis raises concerns about the adequacy of the processes to identify and deal with poorly performing doctors in New Zealand. Work needs to be done to determine whether doctors are adequately held to account in New Zealand and whether, in the trade-off between accountability and learning, an acceptable balance has been struck under New Zealand’s current medical regulatory framework.\(^{430}\)

Findings from this project support calls for New Zealand’s accountability and oversight arrangements to be improved.\(^{255}\) Compared to the number of patient complaints and claims for treatment injury compensation, very few doctors are held to account under either the performance review or disciplinary processes. However, while regulatory regimes can drive change by setting standards, incentives and deterrents, they can also threaten patient safety by damaging the doctor-patient relationship, undermining trust, and disenfranchising and demotivating doctors. Therefore, accountability processes should be designed to foster, or at least not to damage, professionalism. Peer review processes are probably best placed to do this. While most recertification programmes in New Zealand include elements of peer review, these processes will need to be strengthened if they are to provide satisfactory accountability. It is to be hoped that the proposed regular practice review visits are up to the task.\(^{431}\)

The number and severity of treatment injuries identified in this analysis demonstrates the extent of the problem of patient harm. However, while medical injury causes suffering and places a drain on already stretched health care resources, there is no collective or institutional accountability. Work needs to be done to explore ways of providing collective accountability for medical injury.
11.3.2 Defining ACC’s role in improving patient safety

One of the overriding goals of the compensation scheme is to minimise the incidence of injury,\textsuperscript{21} but ACC’s role in minimising the incidence of \textit{treatment} injury remains ill-defined.\textsuperscript{432,433} ACC has established processes to minimise the incidence of general injury but, to date, ACC has not invested to the same extent to minimise the incidence of treatment injury. Under the current leadership team, the ACC sees its role largely as collecting and collating treatment injury compensation claims data, assessing the data for both eligibility and potential consequences, and reporting to the authorities perceived ‘risk of harm to the public’.

ACC does publish monthly ‘treatment injury case studies’,\textsuperscript{263} but the claims dataset is likely to have more to offer for injury prevention purposes. ACC is not legally obliged to analyse the compensation data to identify learning for patient safety. It is not clear whose responsibility it is to provide on-going analyses of the data. The Accident Compensation legislation provides little guidance. The 2005 compensation reforms provided a good opportunity for legislators to define ACC’s role in minimising the incidence of treatment injury, but this opportunity was passed over at the time.\textsuperscript{434}

It is necessary to clarify and define the roles of both ACC and the Director General of Health in minimising the incidence of treatment injury. It may be possible for the Medical Council, ACC, the Director General of Health, and the professional colleges to find ways to work together to improve patient safety,\textsuperscript{130} but it may be that the role of these organisations will always be limited. Institutional reforms, such as improved staffing levels or hours of work, efficient computer systems, safety campaigns, the use of educational tools, and finding ways to reward doctors for withholding inappropriate investigations and unwarranted treatments,\textsuperscript{382} may all have a greater role to play.\textsuperscript{13,31}

11.3.2.1 Considering a levy

Doctors are substantial beneficiaries of the accident compensation scheme. The pecuniary incentive for doctors to injure could be, but currently is not, counteracted by a levy on providers. Under current ACC management, treatment providers are not levied to fund treatment injury compensation costs.\textsuperscript{128} If doctors bore the cost of treatment injury, then this might provide an incentive for them to make efforts to reduce injury.\textsuperscript{109} Section 230
of the Accident Compensation Act allows for funds to be derived from a levy paid by treatment providers, but to date this provision has never been applied. A levy on individual treatment providers may not help to reduce injury in any case. Given the systems understanding of error and injury causation, individual providers may not have much power to control risk and reduce injury. But those who might have the power, those who design and operate the organisational and institutional systems under which the doctors operate, could be levied. It may be worth ACC exploring the option of introducing financial incentives to minimise the incidence of treatment injury, such as enterprise liability or an organisational levy. The difficulty with any such option would be that while a levy might provide an incentive to reduce injury, it also provides a deterrent to claiming, which goes against the social contract nature of the scheme (to provide assistance with treatment and rehabilitation in exchange for foregoing the power to sue). It may also be counterproductive to introduce a levy because any levy may be more likely to deter openness and thwart efforts to improve safety than to deter injury.

11.3.3 Learning from the compensation data

11.3.3.1 Funding for on-going analyses

This doctoral project identified that claims data, ACC harm reports, and provider feedback all contain information that can be used to inform patient safety initiatives. The compensation data are generated without having to rely on providers to report patient safety incidents and are available in an accessible format for researchers to study to identify learning for patient safety. To date, the opportunities for learning from the compensation data have not been fully realised. No funding has been made available to resource on-going analyses of the data. If there is to be on-going analyses of the data, a secure source of funding is required. Research funds should be channelled in this direction. Learning from mistakes should take precedence over the acquisition of new information, as McIntyre and Popper recommended as long ago as 1983. Analyses can be used to identify and monitor threats to patient safety to inform patient safety initiatives; to identify variation in claiming across regions, patient groups or provider types; and to identify the most severe or most common injuries regarding particular treatments or patient groups. Regular analyses of the data and dissemination of findings would not
only support learning, it would also likely encourage providers to supply feedback about ACC reported events.

Both funding and capacity are also needed if the ACC and the Director General of Health are to act to remedy identified risk and improve patient safety. To date, the authorities have had to resource any action to remedy ACC reported risk from within existing budgets because no funding followed the legislative change.

Work is needed to understand the reasoning behind ACC reporting decisions, also to understand whether women are more likely than men to provide useful feedback about ACC reported events, as was suggested by Ministry of Health officials. There is also a need to define the denominator for treatment events to enable the proper assessment of risk of harm from analysis of the compensation datasets. Work has been done to determine the relationship between injuries and claiming in hospital patients prior to the 2005 legislative reforms, but there is a need to update this work and to extend it into the primary care setting.

11.3.3.2 Modifying the forms

Both the ACC215 ‘Treatment injury claim’ form and the ACC ‘Treatment injury event notification’ form could be altered to improve data collection for injury prevention purposes. It would be helpful to include data about the provider, such as age, sex, year and country of graduation; and data on the health care organisation or general practice, such as the type of practice (solo or group), and whether the practice is Cornerstone accredited. It would also be helpful if more data on the alleged injury and event were included, such as contributing factors, how essential the treatment was, and what other medication the patient was taking. CARM officials advise that, to make better use of the harm reports, they need data such as the date a drug was given, the time sequence of events, and any other medication the patient was taking. While it would be useful if ACC collected data about injury preventability, the benefits of collecting this type of information may be out-weighed by the risk of alienating providers and deterring their participation in the compensation claims process.

The Director General might consider making changes to the Ministry of Health's “ACC treatment injury event notification provider feedback form”. This form could be adjusted to make it more user-friendly for both providers and researchers. It would be helpful if
the form could be completed electronically, for example, and changes could be made to encourage provider feedback by emphasising that the purpose of feedback is to garner suggestions for the causes of and possible solutions to ACC reported *risk of harm to the public*, not to apportion blame.

**11.3.4 Reducing inequities under the compensation scheme**

ACC could do more to promote the scheme to under-represented groups, such as the elderly, and to increase awareness about the extended eligibility criteria, in particular regarding under-represented injuries such as those caused by delay in diagnosis. Promotion of the scheme to both patients and providers would likely improve access to compensation and enhance the utility of the claims dataset for injury prevention purposes.

The ethics of the compensation scheme in the wider context of health resource allocation in New Zealand also needs to be more thoroughly debated. This study identified that most of the compensated injuries were minor injuries. There needs to be an assessment of whether this is a proper use of limited resources in the overall scheme of things, specifically, whether the right sort of injury is being compensated and whether compensating mainly minor injuries is an ethical use of public funds. This is important because patients with greater disability have needs that are not currently being adequately met in New Zealand.\(^{125}\)

**11.3.5 Improving patient safety in primary care**

**11.3.5.1 Primary care patient safety research**

Primary care patient safety research still lags behind that in hospitals, but findings from this doctoral project suggest that patient safety in primary care is also a concern. While this project has provided a foundation for further patient safety research in New Zealand primary care settings, the burden of harm in primary care (both financial and human costs) needs to be more accurately defined. We need to know the proportion of injuries in primary care caused by both error and by over-treatment (or questionable clinical decisions).\(^{435}\)

Work still needs to be done to discover patterns of injury causation and preventability, and to identify, implement, and monitor, effective injury prevention initiatives in primary care. Given the differences between hospital based care and primary care, this will entail
more than merely translating effective hospital initiatives, such as checklists, into the primary care context.\textsuperscript{9} In primary care, patients are often in a better position to both prevent and to cause treatment injuries, for example, by identifying medication dispensing errors and making medication administration errors.

To date, New Zealand’s Health Quality and Safety Commission has focussed its attention largely on hospital based care. There is an urgency to address patient safety issues in primary care because of the greater volume of healthcare provided in primary care settings and the increased opportunity for patient safety incidents. The Commission needs to include patient safety in primary care in its areas of interest.

\textbf{11.3.5.2 Shifting the focus of patient safety initiatives}

Findings from this research project suggest that, to improve patient safety in primary care, we may need to look beyond the harm caused by error, to include the harm caused by over-prescribing, over-investigating, and over-treating.\textsuperscript{390} Findings draw attention, in particular, to the need for providers to constantly reassess the risks and benefits of treatment,\textsuperscript{436} especially medication treatment.\textsuperscript{361} Antibiotics are a case in point. Antibiotic over-prescribing is a well-recognised problem in primary care.\textsuperscript{362-366} Antibiotics were identified as the leading cause of medication related harm in this analysis. Thus, to reduce harm from antibiotics, we may be better to focus on decreasing antibiotic prescribing rather than improving the delivery of antibiotics.

Thus work needs to be done to not only identify and reduce preventable medication injury (that associated with error), but also to reduce medication exposure overall. This will require a two-pronged approach, targeting both the demand for medication and the supply of medication. It is not yet clear how best to reduce public demand for medication. Demand may be curtailed by educational schemes (in schools, for example) and also by removing direct-to-consumer advertising of drugs.\textsuperscript{361} Parliament could consider legislative change to remove direct-to-consumer advertising from New Zealand.\textsuperscript{359} It is also not yet clear how best to reduce supply. If we are to reduce harm from over-treatment and questionable clinical decisions, we need to better understand and address the factors driving over-diagnosis, over-investigation and over-treatment, including commercial and professional vested interests, cultural issues and legal incentives.\textsuperscript{390}
Further research is required to find ways to encourage and reward practitioners for not prescribing drugs.

11.3.5.3 Defining patient safety priorities

Any patient safety initiative will consume limited health resources. Therefore, there will need to be some prioritisation of injury prevention initiatives. It is not obvious from this analysis what the priorities should be. It is not obvious whether the few sentinel injuries should take priority over the bulk of mostly minor injuries; and whether the focus should be on reducing treatment error or reducing treatment exposure.

Further work is needed to identify the priorities for injury prevention initiatives, and to agree upon the basis on which the priorities are set.

11.3.5.4 Developing reliable channels of communication

Better feedback loops need to be developed to disseminate patient safety lessons to frontline providers in a format that providers find accessible. A recent edition of the local Otago Daily Times newspaper illustrates the importance of having reliable channels of communication in the aviation industry to disseminate safety lessons:

*A pilot and his passenger died in a Robinson R22 helicopter crash in the Mt Aspiring National Park in 2006. An inquiry revealed the helicopter crashed because the helicopter door detached while the helicopter was in flight, damaging the rotor and causing irreversible loss of control in the air.*

*The door likely detached because of the absence of a cotter pin in the door’s lower hinges. The absence of the cotter pin had been identified as a safety risk in Robinson R22 helicopters twelve years previously, following a similar R22 helicopter crash in the UK in 1994. This crash had prompted the UK Civil Aviation Authority to require all R22 helicopters in the UK to be fitted with revision H-compliant door hinges.*

*The problem of the absent cotter pin had been known by the UK Civil Aviation Authority and the helicopter manufacturer for twelve years, but the problem had never come to the attention of the Civil Aviation Authority in New Zealand.*

The primary care network is widely distributed, making the transfer of information between providers particularly problematic. Clear and reliable communication pathways
need to be developed for sharing patient safety lessons with frontline providers, and also between health care organisations, and within health care teams. Frontline providers then need to find ways to integrate learning into daily practice.

Dissemination of learning to providers might not only enhance learning and enable providers to make changes to improve patient safety, it might also convince providers of the value of supplying patient safety information to the authorities.

There also needs to be a way for general practitioners to recommend changes to be made to practice management systems to improve, for example, prescribing and the handling of test results.

11.3.5.5 Regular use of the MaPSaF

The RNZCGP has endorsed the NZ-MaPSaF as an approved CQI activity and made the tool available on its website for members to download and use. More could be done to promote regular use of the NZ-MaPSaF in general practices to strengthen safety culture.

11.4 Conclusions

Developing a culture of safety entails changing health professionals’ attitudes and behaviours. While it is not easy to change attitudes and behaviours, both regulatory and educational means have been found effective in the past. Findings from this project suggest that both regulatory and educational means can be used to overcome reticence and defensiveness about medical error and injury, to encourage the development of a culture of safety in New Zealand health care settings.

There is no evidence to suggest that New Zealand’s medical regulatory system is perceived to be less punitive than a medical malpractice system or less punitive following the 2005 no-fault compensation reforms but this may not matter for the development of a culture of safety. While a culture of safety is not likely to thrive in a punitive environment, a less punitive environment in itself is not likely to encourage the development of a culture of safety, or openness and learning.

Findings from this doctoral project suggest that openness about medical error and injury may be engendered through legislative change, such as that instituted under New Zealand’s 2005 no-fault compensation reforms, and through educational means, such as the use of the safety culture tool examined as part of this thesis. Providers shared more
information about medical injury following the no-fault compensation reforms, as indicated by the increase in claims and provider feedback.

However, the increased openness came at the cost of some diminution in medical professional accountability for harm. ACC reported fewer doctors to the Medical Council following the reforms, contributing to an overall decrease in medical professional accountability as indicated by fewer complaints being investigated and fewer doctors being held to account by either the performance review or disciplinary processes. Further work is needed to discover whether doctors are adequately held to account in New Zealand and whether, in the trade-off between accountability and learning, an acceptable balance has been struck under New Zealand’s current medical regulatory framework.

The data generated under the reformed compensation scheme are generated without having to rely on providers to report incidents and can be analysed to identify lessons for improving patient safety. While the data suffer from various limitations for injury prevention purposes, they nevertheless provide a novel no-fault compensation perspective of patient safety incidents. Analyses of the data confirmed medication as the major threat to patient safety in primary care but, from the no-fault compensation perspective, most medication events were not associated with error. This suggests that to improve patient safety in primary care we may need to look beyond reducing medication error to reducing medication treatment overall (where possible).

Study findings suggest that a UK safety culture tool can be adapted and used in New Zealand general practices to strengthen safety culture and that New Zealand’s regulatory environment supports the uptake and use of the tool. The adapted tool helps to educate practice personnel about the dimensions of patient safety culture and to facilitate communication about patient safety issues.

In conclusion, while the influence of New Zealand’s distinct medical regulatory system on health care ethics and practice is not yet fully understood, findings from this research suggest that the reformed compensation scheme engenders openness about medical error and injury, and creates novel opportunities for learning to improve patient safety. Regardless of the patient safety potential, however, the improved access to compensation for medical injury and the absence of a culture of suing in New Zealand create an environment that is arguably preferable for both patients and providers.
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