Learning from claims and complaints: 
an epidemiological approach to medical regulation

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Abstract

This collection of works examines patterns in medico-legal claims and complaints to help improve decision-making by regulatory agencies. The contribution to medical knowledge is threefold: first, we provide new evidence on patient harm as seen through the eyes of medico-legal agencies in Australia and New Zealand; second, we demonstrate new ways to apply epidemiological methods to medico-legal data; and third, we inform the development of evidence-based regulatory policies to better protect the public from harm.

Over the centuries, as medicine has evolved, so too have the risks it entails. In the wake of serious preventable patient harm, calls for stronger regulation by medico-legal agencies are common. By 2012, both Australia and New Zealand had established a medico-legal system that rested on three core pillars: national health practitioner regulation boards with strong lay representation, independent health complaints commissioners, and a commitment to compensating patients who are seriously injured by medical care. The approach of these agencies is at the forefront of medical regulation internationally. Yet, both patients and practitioners express dissatisfaction with current processes.

A review of the literature suggests that the case-by-case, reactive, process-driven nature of medico-legal agencies is dulling their ability to hear the voices of patients and practitioners and to see broader patterns of concern. We applied methods drawn from epidemiology to data collected from insurers, health complaints commissioners, and health practitioner regulation boards. We sought to understand: Who takes medico-legal action and what remedies do they seek? Where do hot-spots of medico-legal risk occur? How can we identify high-risk practitioners earlier?

Our findings show that most patients who are injured by medical care do not claim or complain. Worryingly, the odds of complaining are significantly lower for patients who are elderly, of Māori ethnicity, or live in the most deprived areas. Those who do complain have a complex array of needs that are only partially met by current medico-legal processes. It seems that certain factors ‘supercharge’ a healthcare interaction for a medico-legal complaint.

While medical practitioners may feel that they all practice under a medico-legal cloud, we found that just three percent of all doctors accounted for nearly half of all complaints. The number of prior complaints a doctor had experienced was a strong predictor of
subsequent events: doctors named in a third complaint had a nearly 60% probability of being named in a further complaint within two years.

Mandatory reporting offers one potential way to identify high-risk practitioners. However, early data from Australia’s new mandatory reporting regime suggests that some groups of practitioners remain reluctant (or unsure of their obligations) to report concerns regarding the health, conduct or performance of another health practitioner.

Medico-legal agencies find themselves at the confluence of several growing ideas: patient safety, responsive regulation, empirical legal studies, and ‘big data’ analyses of consumer information. Our findings should encourage medico-legal agencies to use epidemiological methods as a way of ‘sharpening their senses’: to hear the voices of patients and practitioners in new ways and to see patterns that might help prevent future harm.
Many colleagues, friends, family members and patients have encouraged me in researching and writing this collection of works. I offer them my heartfelt thanks. First and foremost, I thank my husband Matthew Bismark who has loved, supported, and inspired me through the last decade of working, researching, marriage, and parenting. Our three children, Finn, Stella, and Zoe, were babies when I began my research in this field. Over the last ten years it has been my greatest joy to watch them grow into bright, beautiful, curious and compassionate young people. My parents, Louw van Wyk and Margriet Theron, gave me my love of learning and a warm, encouraging place to write.

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Finally, I express my deepest gratitude to the many patients and families who share their stories each year in the hope of protecting others from harm. In particular, my heartfelt thanks go to Dale Ann Micalizzi and Jen Morris. Their courage, compassion, and commitment to a safer healthcare system light the path ahead.
# Table of contents

Abstract ........................................................................................................................................i

Acknowledgements .................................................................................................................. iii

Chapter One: Introduction .......................................................................................................... 1
  1.1 Context .................................................................................................................................. 2
     1.1.1 Adverse events .............................................................................................................. 2
     1.1.2 Regulatory responses ................................................................................................. 3
     1.1.3 Regulation has proven to be a blunt instrument ......................................................... 4
     1.1.4 Three common concerns ............................................................................................. 5
  1.2 Aim and scope of study ......................................................................................................... 8
     1.2.1 Research problem and study questions ...................................................................... 8
     1.2.2 Scope and boundaries .................................................................................................. 9
     1.2.3 Significance of the study ............................................................................................. 9
  1.3 Methods ............................................................................................................................... 10
     1.3.1 Epidemiological approach ........................................................................................... 10
     1.3.2 Setting and sources ...................................................................................................... 11
     1.3.3 Data collection and analysis ....................................................................................... 13
  1.4 Chapter overview ................................................................................................................. 15

Chapter Two: Collection of works ............................................................................................... 17
  2.1 Relationship between complaints and quality of care ...................................................... 18
  2.2 Claiming behaviour in no-fault system of medical injury .................................................. 24
  2.3 No-fault compensation in New Zealand ............................................................................ 28
  2.4 Motivations for medico-legal action .................................................................................. 34
  2.5 Accountability sought by patients following adverse events .......................................... 51
  2.6 Realising the research power of complaints data ............................................................. 57
  2.7 Remedies sought and obtained ......................................................................................... 63
  2.8 Informed choice: law, medicine and person-centred care .............................................. 67
  2.9 Legal disputes over informed consent for cosmetic procedures .................................... 72
  2.10 Legal disputes over duties to disclose to disclose treatment risks .................................. 79
  2.11 Prevalence and characteristics of complaint-prone doctors ........................................... 85
  2.12 Identification of doctors at risk of recurrent complaints ............................................... 89
  2.13 Mandatory reporting of concerns ................................................................................... 98
  2.14 Mandatory reporting of impaired medical practitioners .............................................. 103
  2.15 The legacy of the Cartwright Report .............................................................................. 108
Chapter Three: Discussion

3.1 Summary ................................................................. 113
  3.1.1 Findings ............................................................... 113
  3.1.2 Themes ............................................................... 116
  3.1.3 Limitations ......................................................... 117

3.2 Contribution ............................................................ 118
  3.2.1 Development of knowledge ...................................... 118
  3.2.2 Development of methods ....................................... 119
  3.2.3 Impact on policy and practice ................................ 120

3.3 Recommendations ..................................................... 122
  3.3.1 For legislators and regulators .................................. 122
  3.3.2 Practitioners and educators ................................... 123
  3.3.3 Patients, families and consumer advocates ................. 123

3.4 Further research ....................................................... 124

3.5 Conclusions ............................................................. 125

References ........................................................................ 127
Chapter One: Introduction

The very first requirement in a hospital is that it should do the sick no harm.

- Florence Nightingale

Calls for improved regulation of medical practitioners are not new. As far back as 1421, the parliament of King Henry V was petitioned over concerns that unqualified practitioners were causing "great harm and slaughter of many men."2

As the tremendous power of modern medicine to do good has grown,3 so too has its potential to cause inadvertent harm.4-5 Researchers estimate that, in modern medical systems, around one in ten patients admitted to hospital suffers an adverse event caused by medical care rather than their underlying disease.6-10 From these findings has grown a burgeoning patient safety movement,11 12 along with louder calls for regulators to provide injured patients with remedies, and to protect other patients from future harm.13

The failures of traditional medical malpractice litigation in achieving these twin goals of restoration and prevention are well described. Tort law is rigid, slow, and expensive, and its adversarial focus on finding fault runs counter to the culture of openness and learning required for safer care.14 Less studied is the effectiveness of alternative medico-legal systems, such as those in Australia and New Zealand, which include insurers, complaints commissioners, and medical boards. While these systems have some clear advantages over negligence litigation,15 they too have been criticised for their reactive and process-driven focus on case-by-case resolution. To date, there has been a dearth of empirical evidence to assess the validity of such concerns.16

Over a decade of research at Harvard University and the University of Melbourne, I worked with colleagues to understand and inform the ability of medico-legal agencies in New Zealand and Australia to hear the voices of patients who have been harmed in care, to see patterns of concern, and to ‘sniff out’ early warning signs that practitioners might be running into trouble. Our methods are multidisciplinary, drawing from law, ethics, medicine, and biostatistics. However, our most valued tools come from the field of epidemiology. The discipline has
evolved over 350 years from being only the science of epidemics, to an indispensable approach for finding effective ways of preventing health harms.\textsuperscript{17}

Our aims were threefold: to provide new evidence on the nature of patient harm as seen through the eyes of medico-legal agencies, to demonstrate the potential for methods drawn from epidemiology to be applied to medico-legal data, and to inform the development of policies and practices that will better protect the public from harm. In essence, the research presented in this collection of works seeks to facilitate a shift among medico-legal agencies from behaving as “regulatory philosophers” towards thinking as “regulatory scientists”.\textsuperscript{18}

1.1 Context

1.1.1 Adverse events

“First, do no harm” is a central tenet of medical practice.\textsuperscript{19} Since the time of Hippocrates, doctors have sworn: “I will use my power to help the sick to the best of my ability and judgment; I will abstain from harming or wronging any person by it.”\textsuperscript{20,21} This obligation of non-maleficence is central to medical ethics,\textsuperscript{22,23} and we even have a word—“iatrogenic”—to describe those illnesses that were "brought forth by the healer".\textsuperscript{24}

Over the centuries, as medicine has evolved, so too have the risks it entails. Highly specialised surgeries, complex medical procedures, and inter-disciplinary systems of care require humility, teamwork, and consistency to be delivered safely. Yet medicine has been slow to relinquish traditional values of autonomy, independency, and self-sufficiency.\textsuperscript{25} Rates of burn-out and impairment among practitioners are worryingly high,\textsuperscript{26} the work of skilled and dedicated practitioners is jeopardised by unsafe systems,\textsuperscript{5} and speaking up about risks to patient safety remains difficult for many.\textsuperscript{27}

The true magnitude of preventable medical harm associated with modern medicine was not fully appreciated until the 1990s when researchers at Harvard quantified the proportion of patients in Utah, New York and Colorado harmed and killed by medical errors.\textsuperscript{6,7} Their findings, as reported in the landmark report To Err is Human,\textsuperscript{13} suggest that more people die in a given year as a result of medical errors than from motor vehicle accidents or breast cancer. Shocked by the findings, and concerned about the extent to which they might hold true in other healthcare systems, researchers sought to replicate the Harvard methodology in other countries, including New Zealand,\textsuperscript{8} Australia,\textsuperscript{9} Canada,\textsuperscript{10} and the United Kingdom.\textsuperscript{28} The results were sobering. Across the developed world, around one in ten patients
experiences a prolonged hospital stay, or disability after discharge, resulting from medical care itself, rather than the underlying disease. Among these adverse events, around half are judged to be preventable.

From these findings grew a burgeoning patient safety movement, focused on addressing problems with quality and safety in healthcare. This movement has created a plethora of tools for reporting, analysis and investigation of healthcare quality and safety, and practitioner and health service performance. It has also spawned interventions that span the continuum from highly technical efforts to re-engineer devices, through to broad efforts to reform the “club culture” of medicine.

1.1.2 Regulatory responses

As concerns about patient safety grew, questions were also being asked about whether the medical profession could be trusted to regulate itself. A series of high-profile inquiries into apparent failures of the profession to do so effectively turned a spotlight on the role of external legal and regulatory mechanisms. In New Zealand, the 1987 Cartwright Inquiry into unethical conduct at National Women’s Hospital led to sweeping reforms, including the world’s first legislated code of patients’ rights, the establishment of an independent network of patient advocates, and the appointment of a health complaints commissioner. In Australia, high-profile inquiries into the harm caused by errant doctors Jayant Patel and Graeme Reeves questioned the profession’s willingness or ability to deal with poor performance among its own. Major reforms included the establishment of the Australian Health Practitioner Regulation Agency and the introduction of mandatory reporting of concerns about the health, performance, and conduct of practitioners. Events in the United Kingdom had an impact too: as governments in New Zealand and Australia watched the inquiries into deaths caused by Harold Shipman and at the Bristol Royal Infirmary, they asked themselves: “Could it happen here? Could it happen now?”

Self-regulation carries with it an obligation to ensure the competence and trustworthiness of the members of the profession. But these scandals, and others, suggested that perhaps the medical profession had been enjoying the benefits of a highly regarded profession without fulfilling all of the obligations attached to self-regulation. Health ministers and officials, acting on behalf of the public, responded with new measures designed to protect patients’ rights, provide public accountability, and achieve a better balance between professional freedoms and responsibilities.
By 2012, both Australia and New Zealand had established a medico-legal system that rested on three core pillars: national health practitioner regulation boards with strong lay representation, independent health complaints commissioners, and a commitment to compensating patients who are seriously injured by medical care. A key difference between the two systems is that, in Australia, tort law remains the primary source of compensation (though a no-fault medical injury insurer is likely to be established in Australia for serious treatment injuries.\(^{41,42}\) In New Zealand, compensation is provided through a no-fault insurer, the Accident Compensation Corporation (ACC).\(^ {43}\) The role of each agency is described in more detail in the section on Setting and Sources below and in the papers set out in Chapter 2.

### 1.1.3 Regulation has proven to be a blunt instrument

The intent of regulatory systems like those in Australia and New Zealand is that medico-legal agencies (rather than the courts alone) should provide remedies to patients who have been harmed in care, and improve the quality of future care through deterrence and learning. Unfortunately, the reality is more complicated. As outlined below, an initial reading of the discourse surrounding medico-legal agencies suggests that we may have achieved “the worst of both worlds”: a system of regulation that goes too far on one hand, and on the other does too little.

#### Regulation goes too far

Medical practitioners and their professional bodies have argued that the actions of medico-legal agencies lead, at various times, to “futility, perversity, and jeopardy” (to borrow from the words of Albert Hirschman).\(^ {45}\) The argument of futility rests on the premise that the healthcare system and medical culture are complex systems and that the simplistic levers exercised by medico-legal agencies do little to alter the underlying status quo. In practice, the values and norms that are intrinsic to the practice of medicine will often preside over “clumsy and unsatisfactory” external controls.\(^ {46}\)

The argument of perversity suggests that, in some cases, medico-legal action will produce an outcome opposite to that which was intended. For example, practitioners commonly voice concerns that mandatory reporting of impaired practitioners to regulators may drive those with health concerns further underground.\(^ {47}\) Or in another example, negligence claims may lead to defensive medicine, whereby practitioners order unnecessary tests, or decline to see high risk patients, resulting in poorer care than would otherwise be provided.\(^ {48}\)
And finally, the argument of jeopardy claims that while medico-legal actions may have some beneficial consequences, they also result in unintended harms in other parts of the health sector. For example, some practitioners have argued that revalidation takes time and resources away from more pressing priorities in the health sector.\textsuperscript{49}

\textbf{Regulation does too little}

In contrast, many patients, families and their advocates believe that current systems of medico-legal regulation do not go far enough. They feel frustrated and unheard by medico-legal processes that feel difficult to access, slow to act, impersonal in their response.\textsuperscript{50} And all too often, those processes seem to ‘miss the point’ of the patient’s claim or complaint. It is not unusual for a complaint to lodge a claim or complaint, only to conclude: ‘this isn’t the type of process I was looking for’.\textsuperscript{50}

Patients and families also resent the ‘wall of silence’ that seems to exist around many medico-legal processes. We live in a world where information on the most esoteric of subjects is available at the touch of a screen. Consumers are able to access real-time information on the quality and safety of travel guides, chefs, airline pilots, and funeral directors. Yet, when it comes to choosing a doctor, or following the progress of a notification to the Medical Board, medico-legal agencies offer little meaningful information. Indeed, the identities of those who have been subject to complaints and disciplinary proceedings are often shielded behind opaque processes and orders for name suppression.\textsuperscript{51}

\subsection*{1.1.4 Three common concerns}

On their surface, the criticisms expressed by patients and practitioners take quite different forms. However, deeper analysis suggests that they are connected by three, broader concerns. These are: a case-by-case focus that sometimes misses the bigger picture, a reactive rather than proactive approach, and a process-driven system that, at times, values ‘doing it the right way’ over ‘doing the right thing’.

\textbf{Case-by-case focus}

The first common concern is that the ‘visual field’ of individual staff working within medico-legal agencies is largely restricted to the individual cases that come before them. This is a problem for two reasons. First, without a coherent and principled understanding of how an individual case fits into a broader decision-making framework, decisions may be disproportionate or inconsistent. Under current approaches, medico-legal agencies are
blinkered in their ability to see how a complaint fits in with a particular practitioner’s history, wider feedback from other patients and peers; and information held by other agencies. This is of concern to both practitioners and patients, as it can result in two kinds of errors: overlooking legitimate risks, or taking regulatory action against practitioners who do not pose a risk.

Secondly, and of more concern to the broader public, processing cases one-by-one does not encourage, nor leave much time for, higher level thinking and analysis. Therefore, opportunities to develop systemic and lasting solutions are lost. Recommendations for improvement tend to occur in an incremental and piecemeal fashion, lacking a sense of wider vision. In essence, medico-legal agencies offer reactive solutions to immediate problems, while paying little attention the systemic problems underlying them.

Unfortunately, even if medico-legal agencies do wish to see a bigger picture, the necessary information is often difficult to access and gather. Insurers, commissioners, and regulatory boards typically only hear the voices of patients and practitioners whose cases are brought before them. Yet, international research suggests that under-reporting of adverse events is rife. Without such denominator data, it is hard for any agency to even recognise its own blind spots. Where data is available, agencies may not have the skills or knowledge to make maximal use of it.

The same is likely to be true in healthcare. For example, it is well-established that malpractice lawsuits, complaints, and disciplinary proceedings tend to cluster among relatively small groups of doctors. Yet, regulators know little about the characteristics of such practitioners beyond anecdote and intuition.

Consequently, the medico-legal sector remains a reactive one, dealing primarily with the aftermath of adverse events and behaviours. For patients, this is problematic because they remain at risk of harm until appropriate action is taken. For practitioners, it is problematic
because, without proactive support and early intervention, minor health and competence issues can evolve into full-blown impairments, jeopardising their careers and wellbeing.

Regulatory expert Malcolm Sparrow urges regulators to “pick important problems and fix them.” And indeed, many agencies would like to take a more proactive approach. In the words of former New Zealand Health and Disability Commissioner, Ron Paterson, health complaints commissioners would prefer to be “the fence at the top of the cliff, rather than the ambulance at the bottom.” However, to date, agencies have lacked the tools to proactively identify and intervene proactively with high-risk groups of practitioners. Instead, they continue to live with the fear that one day a patient will die after red-flags were overlooked and someone will ask “why didn’t you act sooner?”

**Process-driven systems**

The final stream feeding into the critiques described above is the process-driven nature of medico-legal agencies. In practice, the time and efforts of medico-legal agencies are overwhelmingly focused on receiving, prioritising, and handling cases in a procedurally correct manner. This in turn means that communications are shaped by workflows and precedents, rather than human relationships or outcomes. And remedies are largely determined by what the agency routinely offers, rather than the resolution that would be most effective at protecting patients while supporting practitioners back into safe practice.

The consequence is a process that is both stressful and uncertain for patients and practitioners. A recent review of AHPRA processes found that people dealing with the agency wanted to be able to say:

> The agency understood, heard me, believed me, responded (“took me seriously”), acted, kept me informed, explained reasons, I dealt with the same staff, who communicated with me in a personal way.

Both patients and practitioners would benefit from a more outcome-focused approach: with less reliance on pro-forma responses and more attention to the voices of patients and practitioners. However, in order to achieve resolutions that better meet patients’ needs, agencies first need a clear understanding of what those needs are and where existing gaps arise.
1.2 Aim and scope of study

1.2.1 Research problem and study questions

In the wake of serious preventable patient harm, calls for stronger regulation are common. The medico-legal systems in Australia and New Zealand have many advantages over traditional court-based systems (acknowledging that tort law still plays a role in the Australian system.) Yet, both patients and practitioners are dissatisfied with current processes. A review of the literature in this area suggests that the case-by-case, reactive, process-driven nature of the medico-legal enterprise is dulling the ability of regulators to hear the voices of patients and practitioners, to see patterns of concern, and to ‘sniff out’ emerging concerns. Working with colleagues, I sought to better understand patterns of claims and complaints to medico-legal agencies, in order to help these agencies better protect patients from harm.

To address this research problem we needed an approach that was well suited to making sense of large volumes of data, and allowed us to compare the characteristics of different groups of patients and practitioners. The medico-legal process is not designed for such analyses. But the science of epidemiology is.64

Using well-established methods from epidemiology, relocated to the setting of medico-legal cases, we sought to explore the following questions:

- Who brings claims and complaints to the attention of medico-legal agencies following an adverse event, and who does not?43 65-67
- What forms of accountability do patients seek from medico-legal agencies, and what remedies do they actually obtain?68 69
- When do monetary forms of compensation matter to patients, and when are non-monetary remedies more appropriate?68
- Where do ‘hot-spots’ of medico-legal risk occur within different reporting mechanisms, such as mandatory reports of concerns by peers?70 71
- Why do some issues, such as consent to cosmetic procedures, result in more medico-legal actions than others?72 73
- How can medico-legal agencies identify high-risk practitioners earlier, to protect future patients from harm?62 74

Our aim was threefold: to provide new evidence on patient harm as seen through the eyes of medico-legal agencies; to demonstrate new ways to apply epidemiological methods to
medico-legal data; and to inform the development of evidence-based regulatory policies to better protect the public from harm.

1.2.2 Scope and boundaries

The role of medical regulation in improving patient safety is a vast topic, and we are mindful that our contribution only addresses a small part of a much broader challenge. Our research focused in on the agencies that provide three key medico-legal functions in Australia and New Zealand:

- Compensation (via the NZ ACC and claims to indemnity insurers)
- Complaints resolution (via health complaints commissioners)
- Competence assurance (via the Australian Health Practitioner Regulation Agency and the regulatory boards that fall under its umbrella).

I use the terms medico-legal agencies and regulators interchangeably to refer to these organisations, recognising that not all would agree with my characterisation of litigation as a form of regulation, nor of complaints commissioners as medico-legal agencies. We did not seek to address the education and registration functions of these agencies—important topics in their own right. Nor did we consider the role of numerous other agencies that have a medico-legal role: health information privacy commissioners, hospital audit and accreditation systems, coroners, and the criminal justice system.

For this collection of works, I have selected only those papers on which I was a first author, and which are directly relevant to the research problem. Some papers on which I was a second or later author are cited in the discussion. My research on related topics, such as the role of governing boards in improving the quality and safety of care, and open disclosure of adverse events, falls outside the scope of this thesis.

1.2.3 Significance of the study

This collection of works contributes to the field of medicine in three main ways.

First, we develop knowledge about medico-legal events by describing the epidemiology of claims and complaints across three types of medico-legal agencies in New Zealand and Australia. Medico-legal agencies are a valuable source of data on risks to patient safety, because they concentrate cases of serious preventable adverse events from populations of millions. We bring insights from those cases to light through our analyses and use of illustrative case studies. We also help develop a conceptual understanding of issues such as
patient motivations for medico-legal action through the development and application of new taxonomies.

Second, our program of research offers innovative methods, applying tools developed in the field of public health to regulatory problems. Currently, clinical leaders, risk managers, liability insurers and regulators all lack reliable methods for systematically determining which doctors would benefit from assistance and preventive action, before they acquire troubling track records. Our research findings challenge the conventional wisdom that the risk of future medico-legal events cannot be predicted within acceptable levels of accuracy.

Third, and perhaps most importantly, our research findings offer some tangible solutions and policy-relevant recommendations to problems that have plagued the field of medical regulation for decades. In practical terms, our application of epidemiological methods to medico-legal actions strengthens the ability of medico-legal agencies to “find important problems and fix them.” These findings have obvious relevance to medico-legal agencies in New Zealand and Australia. They may also be of interest to regulators and policy-makers in other countries, who are interested in the promise of no-fault compensation, health complaints commissioners, and mandatory reporting as an alternative to medical malpractice litigation.

1.3 Methods

1.3.1 Epidemiological approach

My work as a researcher is shaped and informed by many years of practical experience in the health sector. I have worked for three years as a junior hospital doctor (1997–2000), four years as an advisor to New Zealand’s Health and Disability Commissioner (2001–2004), and four years as a senior lawyer in the litigation team of a leading health law firm (2006–2009). I also have nearly a decade’s experience as a non-executive director of a number of health sector companies, including the board of New Zealand’s Accident Compensation Corporation (2006-2010).

As Sparrow notes “the topic of regulatory reform touches an alarming number of established academic disciplines.” My overall research approach is interdisciplinary, drawing from my training in law, medicine, bioethics and public health. However, the research methods in this series of papers are predominantly empirical, taking techniques familiar to public health and applying them in an unconventional setting. This approach was chosen because the tools of
epidemiology are ideally suited to uncovering differences between groups of individuals, and identifying risk factors for harm. This public health focus is reflected in the location of my Law and Public Health group within the University of Melbourne School of Population and Global Health.

Our work connects with the emerging field of empirical legal research, which uses quantitative and qualitative methods, rather than traditional legal analyses to make sense of legal and regulatory data. In particular, we build on the foundations laid by medico-legal researchers in the United States, including the group at the Harvard School of Public Health. We have adapted some of their methods to answer questions specific to the Australasian setting. Indeed, many of the papers presented here were co-authored with members of that group, including Professors David Studdert, Troy Brennan, and Atul Gawande.

The methods adopted in each study are described in the papers set out in Chapter Two. In the paragraphs that follow, I provide a brief summary of our data sources to help orient the reader, and highlight some key features of our approach to data collection and analysis.

1.3.2 Setting and sources

Our research involved three types of medico-legal agencies—insurers, complaints commissioners, and regulatory boards—in both Australia and New Zealand. We also included two additional forms of denominator data in our analyses: adverse event data from a large sample of hospital admissions in New Zealand and workforce data from the medical register in Australia.

Insurers

In Australia, Avant Mutual Group Limited (Avant) is Australia’s largest provider of medical indemnity insurance, providing coverage to more than half of the country’s registered medical practitioners. By screening nearly 8,000 medical malpractice claims lodged over a seven-year period, my colleague Andrew Gogos and others identified 481 informed consent disputes for analysis. These disputes included 263 malpractice claims brought against doctors insured by Avant in three states (New South Wales, Victoria and Queensland). I conducted more detailed file reviews of cases within this sample, focused on cosmetic procedures and disputes over risks that were not disclosed.

In New Zealand, medical malpractice litigation is effectively barred. Instead, the Accident Compensation Corporation awards compensation on a no-fault basis. We collected data from
ACC on all claims relating to medical injuries that occurred in 1998, the year of the New Zealand Quality of Healthcare Study. During the study period, claims were deemed to be compensable if they involved a medical mishap (a rare consequence of treatment properly given) or a medical error (a failure to provide treatment with reasonable care and skill). The criteria for compensation were subsequently broadened to include all treatment injuries.\textsuperscript{85}

**Health practitioner regulation boards**

Since 2010, Australia has brought over 72 health practitioner regulation boards together under the umbrella of the Australian Health Practitioner Regulation Agency (AHPRA). Each profession still has its own board, appointed by the Minister of Health, which includes lay members, as well as members of the relevant profession.

By law, practitioners, employers and education providers must report certain concerns about the health, conduct or performance of a health practitioner to AHPRA.\textsuperscript{36} We reviewed all 819 such mandatory reports made to AHPRA over a thirteen month period (November 2011 to December 2012).

**Complaints commissioners**

Health complaints commissioners are statutory agencies established in New Zealand and each of Australia’s six states and two territories. Commissions are responsible for receiving and resolving patient complaints about the quality of healthcare services, and strive to use complaints as a catalyst for improving patient safety.\textsuperscript{86} Patients or their advocates must initiate complaints in writing, but the process is free, and legal representation is optional. Compared with litigation, the process is highly accessible.

In New Zealand, I collected data on all complaints received by the Health and Disability Commissioner’ office, by June 2004, that were associated with a public hospital admission in 1998. In Australia, we used the data bases of the commissioners in each State and Territory (apart from New South Wales and South Australia) to assemble a sample of nearly 19,000 formal healthcare complaints lodged between 2000 and 2010.

**Denominator data**

In addition, we obtained denominator data from two sources. The authors of the New Zealand Quality of Healthcare Study provided us with data on all adverse events arising from a sample of nearly 7,000 patients discharged from publicly-funded acute care hospitals in 1998.\textsuperscript{8}
Australia, AHPRA provided us with a copy of the medical register, which includes basic demographic data on all registered medical practitioners in Australia.

1.3.3 Data collection and analysis

Data collection

Over the ten year period covered by this research, the availability of electronic data steadily improved. In 2004, when data collection commenced, we were still heavily reliant on paper files, archived in a document warehouse. By the time we collected the data for our mandatory reporting study in 2012 many more documents and variables were available in an electronic form.

Administrative files were assessed by reviewers with either medical or legal training. For all but two of the papers set out below, I was the lead reviewer with responsibility for training and overseeing the work of any research assistants. To test the reliability of the reviews, a second reviewer independently coded a random subsample of files. Agreement between reviewers was found to be satisfactory, and any discrepancies in coding were discussed and consensus reached.

Analyses

Four features of our analyses are worthy of note. The first is our use of denominator data. A weakness of many medico-legal studies is the use of a floating numerator, where the number of cases is not related to an appropriate ‘at risk’ population. For example, most complaints against doctors involve general practitioners. However this tells us little about the relative complaint risk of general practitioners compared with other doctors, because general practitioners account for the bulk of the medical workforce. For this reason, we sought to use appropriate denominator data where possible—such as the underlying number of adverse events, or the characteristics of medical workforce. To continue with our earlier example, once one accounts for the number of doctors in each speciality, it becomes apparent that surgeons are actually at significantly higher risk of complaints than general practitioners.

Second, due to the innovative nature of our work, we found a paucity of established taxonomies for coding certain variables of interest. Where necessary, we developed such taxonomies ourselves. These included taxonomies for classifying motives for medico-legal action, and disputes over duties to disclose treatment risks.
Third, in our more recent work, we progressed beyond standard bivariate and multivariate analyses to more sophisticated statistical methods. For example, we used a time-to-event method of analysis to determine the characteristics of doctors likely to incur recurrent complaints, and to estimate each practitioner’s risk of recurrence at specific time points. For the technical aspects of these analyses I am indebted to my colleagues, Dr Matthew Spittal and Professor David Studdert.

A final strength of our analytic approach is our ability to understand medico-legal cases from both a legal and medical perspective. While our research methods were primarily epidemiological, a close familiarity with clinical medicine, quality improvement principles, and processes of legal decision-making was needed to interpret our results. In order to ensure that our findings were relevant and meaningful to both the legal and medical professions, we worked closely with regulators, clinicians, and health consumer advocates throughout the research process.

**Contributions**

For each of the papers included in this collection of works, I was the lead author. I had primary responsibility for liaising with research partners to define the study question, developing the study design, obtaining ethics approval, and interpreting results. For each of the studies reported in this collection of works, I led the collection of data from our partner agencies, spending weeks-to-months on-site extracting data, reviewing files, and supervising the work of any other team members involved in data collection. While at Harvard University I conducted most of my own statistical analyses using SAS; at the University of Melbourne I carried out the initial descriptive analyses while Dr Matthew Spittal and Professor David Studdert conducted our more advanced statistical analyses.

As first author I wrote the draft manuscripts and co-ordinated the process of collating input from other authors before submission for publication. I also took responsibility for ensuring the effective dissemination of our research findings—presenting widely to international conferences, communicating with senior clinicians and hospital managers, briefing politicians, holding workshops with regulatory bodies, writing blog posts, and speaking with the media.  

Research is rarely an isolated endeavour. I acknowledge the valuable contribution of five groups of colleagues to the papers in this collection. First, my mentors Professors David Studdert, Ed Dauer, and Ron Paterson, served as senior authors on a number of these works.
They provided valuable intellectual guidance at every stage from conception of research ideas through to influencing policymakers. Second, several practising clinicians lent their clinical expertise to the coding of clinical records, the interpretation of findings, and the communication of results to specialist clinical groups. They include trauma surgeon, Associate Professor Russell Gruen, respiratory physician Dr Chris Clarke, plastic surgeon, Mr David McCombe, neurosurgical trainee, Dr Andrew Gogos, and endocrine surgeon Professor Atul Gawande. Thirdly, in recent years, I have been privileged to have the support of two able research assistants, Laura Thomas and Tessa Plueckhahn, who assisted with literature reviews, data collection and coding. The fourth group of colleagues who contributed to these papers are the statisticians who provided expert technical assistance on study design and complex analyses of data. In particular, I note the contribution of Dr Matthew Spittal to our analyses of complaint-prone practitioners.

Finally, I record with thanks the contribution of two healthcare consumers who were themselves seriously harmed by medical care. Dale Ann Micalizzi and Jen Morris opened my eyes to new perspectives, challenged my thinking, contributed a fresh and honest style to the writing of manuscripts, and encouraged me to publish in open access journals so that other consumers could have access to our research findings.

All authors made substantial contributions to study design and interpretation of data, and contributed important intellectual content to manuscripts.

**Ethics:** Each study was approved by the relevant ethics committee: the Wellington Ethics Committee, the Harvard Institutional Review Board, or the University of Melbourne Human Ethics Committee. In presenting this research, we usually reported results in aggregate form. Where case studies are used, identifying details are changed to protect anonymity.

### 1.4 Chapter overview

This collection of works includes selected scientific contributions from a decade of research on regulatory responses to patients’ claims and complaints. Chapter One situated our research in related literature and provided an overview of our research methodology. In Chapter Two, I present our research in the form of fifteen papers published in peer-reviewed journals. These papers fall into four broad groups. Papers 2.1 to 2.5 explore patients’ motives for medico-legal action and the ‘gap’ between what they desire and receive. Papers 2.8 to 2.10 offer a deeper dive into a common area of medico-legal concern: informed consent. Papers 2.11 to
2.14. focus on how we might be able to identify high-risk practitioners in order to prevent harm. 2.15 looks to the future, 25 years on from New Zealand’s Cartwright Inquiry. Finally, Chapter Three contains the discussion and implications for practice, and suggests future research agendas.
# Chapter Two: Collection of works

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<th>No.</th>
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<td>Journal of Bioethical Inquiry</td>
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</table>

$^1$ Thomson Reuters Journal Citation Reports for 2014

$^2$ Health Issues is a consumer-focused journal that, for 30 years, has been publishing papers on topical issues in health policy

$^3$ Meaningful citation numbers are not yet available for papers published in 2014
2.1 Relationship between complaints and quality of care

Relationship between complaints and quality of care in New Zealand: a descriptive analysis of complainants and non-complainants following adverse events

M M Bismark, T A Brennan, R J Paterson, P B Davis, D M Studdert

Objectives: To estimate the proportion and characteristics of patients injured by medical care in New Zealand public hospitals who complain to an independent health ombudsman, the Health and Disability Commissioner ("the Commissioner").

Design: The percentage of injured patients who lodge complaints was estimated by linking the Commissioner’s complaints database to records reviewed in the New Zealand Quality of Healthcare Study (NZQHS). Bivariate and multivariate analyses investigated sociodemographic and socioeconomic differences between complainants and non-complainants.


Population: Patients who lodged claims with the Commissioner (n = 398) and patients identified by the NZQHS as having suffered an adverse event who did not lodge a complaint with the Commissioner (n = 847).

Main outcome measures: Adverse events, preventable adverse events, and complaints lodged with the Commissioner.

Results: Among adverse events identified by the NZQHS, 0.4% (3/850) resulted in complaints; among serious, preventable adverse events 4% (2/48) resulted in complaints. The proportion of injured patients to complain increased steeply with the severity of the injury: odds of complaint were 11 times greater after serious permanent injuries than after temporary injuries, and 18 times greater after deaths. Odds of complaining were significantly lower for patients who were elderly (odds ratio [OR] 0.2, 95% confidence interval [CI] 0.1 to 0.4), of Pacific ethnicity (OR 0.3, 95% CI 0.1 to 0.9), or lived in the most deprived areas (OR 0.3, 95% CI 0.2 to 0.6).

Conclusion: Most medical injuries never trigger a complaint to the Commissioner. Among complaints that are brought, severe and preventable injuries are common, offering a potentially valuable “window” on serious threats to patient safety. The relatively low propensity to complain among patients who are elderly, socioeconomically deprived, or of Pacific ethnicity suggests troubling disparities in access to and utilisation of complaints processes.

There is growing international interest in harnessing patient dissatisfaction and complaints to address problems with quality in health care. The value of complaints as a marker of threats to patient safety depends on the answers to several questions. Do complaints track injuries, or are they prompted by more subjective concerns? Are complaints the “tip of the iceberg” in terms of quality of care problems and, if so, how representative are they of broader quality problems? The longstanding obstacle to addressing these questions is methodological in nature and concerns the elusiveness of an appropriate metric against which to measure the prevalence and reasonableness of complaints.

In New Zealand, injury compensation and complaints against healthcare professionals are dealt with in distinct settings. An innovative accident compensation system compensates injured patients on a “no fault” basis. An independent health ombudsman, the Health and Disability Commissioner ("the Commissioner"), has statutory responsibility for resolving patient complaints about quality of care, acts as a gatekeeper to disciplinary proceedings, and strives to use complaints as a catalyst for improving patient safety.

In this study we linked information on quality of care complaints lodged with the Commissioner with adverse event data gathered in the New Zealand Quality of Healthcare Study (NZQHS). Together, these two datasets permit estimation of how frequently adverse events led to complaints, and a description of the characteristics of patients who did and did not complain to the Commissioner.

METHODS

The Wellington Ethics Committee and the Harvard Institutional Review Board approved the study.

Baseline data on a random sample of patients who had experienced adverse events came from the NZQHS. As previously described, the NZQHS used a two stage sampling process to develop a representative sample of 6579 medical records of patients discharged from publicly funded acute care hospitals in 1998, excluding psychiatric and same day discharges. Trained reviewers assessed each episode of care for the presence of an adverse event and, when an adverse event was detected, rendered a judgment on whether it was preventable. Following previous research in the United States, adverse events were defined as unintended injuries caused by healthcare management, rather than the underlying disease process, that resulted in disability. The study included all adverse events detected during or responsible for the index admission, as well as those occurring during the index admission that were detected on a subsequent
admission. Serious adverse events were those which caused death or permanent disability.

The Commissioner provided data on all complaints received by his office that were associated with a public hospital admission in 1998 (n = 398). To determine which of these complaints involved adverse events and preventable adverse events, an investigator with medicolegal expertise (MMB) reviewed the relevant administrative information using the NZQRS process of structured implicit review. A second investigator (TAB), also a medicolegal expert, independently reviewed a random subsample of 98 complaints, a quarter of the sample. Inter-rater reliability for determination of whether an adverse event had occurred was high (k = 0.84); reliability for preventability judgment was moderate (k = 0.50), although slightly higher than previous estimates of reliability for preventability determinations.

We matched the NZQRS records to complaints probabilistically using national hospital number, date of birth, sex, and date of injury. Clinical data from the medical record review was then compared with claims data to confirm that the NZQRS patient and complainant was the same person and that the complaint related to the same episode of care. Two investigators (MB, DS) reviewed potential matches and reached consensus on whether sufficient information existed to confirm a match with a high degree of certainty. Among 18 candidate matches, nine were determined not to be matches and two were excluded on the grounds that there was insufficient information to confirm a match.

The analyses are descriptive. We compared characteristics of patients who lodged complaints with the Commissioner after experiencing an adverse event (“complainants”) with characteristics of patients from the NZQRS who experienced an adverse event and did not file complaints (“non-complainants”). Matched cases—that is, patients from the NZQRS sample whose care involved an adverse event and who subsequently complained about that instance of care—were classified as complainants. Figure 1 shows the derivation of the two populations which were combined for the multivariate analysis.

Data were analysed using the SAS 9.0 statistical software package (Cary, NC, USA) Stata 8.0/SE (Stata Corp, College Station, Texas). We used t tests and χ² tests to conduct bivariate comparisons of the characteristics of complainants and non-complainants. We investigated predictors of failure to complain despite having experienced an adverse event using multivariate logistic regression. The dependent variable in the regression analysis distinguished complainants from non-complainants. The independent variables were sex, ethnicity (Maori, Pacific, Non-Maori/non-Pacific), patient age (<1 year, 1-17 years, 18-44 years, 45-64 years, >65 years), disability due to adverse event (temporary, permanent with <50% impairment, permanent with >50% impairment, death), and whether or not the event was preventable. An additional covariate provided a measure of the patient’s socioeconomic status using the New Zealand Index of Deprivation Score. This index, based on mesh blocks, combines nine census variables reflecting aspects of material and social deprivation; following previous studies, index scores were separated into quintiles for analysis.

To account for the stratified two stage cluster sampling design in the NZQRS, the bivariate and multivariate analyses were weighted. The weighting had negligible effects on our estimates.

RESULTS

The Commissioner received 398 complaints related to care delivered in public hospitals in 1998, 234 of which (64%) related to an episode of care in which the patient had experienced an adverse event. For 51% of the complaints the adverse event was judged to be preventable. The NZQRS review identified 850 adverse events, as previously reported, of which 315 were preventable, 124 were serious, and 48 were both serious and preventable. Patients themselves instigated 105 (41%) of the 254 complaints involving adverse events (fig 2). Third party complaints were commonly laid by family members, primarily the patient’s child (17%), parent (16%), or spouse (13%). A total of 79% (313/398) of complaint letters and 75% (191/254) of the adverse event complaint letters expressed concern about a health professional’s attitude or communication either during the index admission or after the adverse event.

There were seven matches between the complaint sample and the full NZQRS sample (n = 6579). NZQRS reviewers judged three of these matches to involve adverse events (one preventable death, one preventable permanent disability, and one unpreventable temporary injury); the rest did not involve adverse events. (Besides injuries, the Commissioner also has jurisdiction to hear complaints relating to informed consent, discrimination, and a variety of other bases of dissatisfaction with care.) Hence, 0.4% (3/850) of the patients in the NZQRS sample who experienced adverse events complained. Among NZQRS patients judged to have experienced adverse events that were serious and preventable, 4% (2/48) complained.

Figure 1 Identification of injured complainants and non-complainants.
Box 1 Case studies of injured patients who did and did not complain

Adverse event with no subsequent complaint
Mrs A, an elderly woman with a history of hyperthyroïdism, asthma, left ventricular failure, hypertension, and gastro-oesophageal reflex disorder was admitted to hospital with diaphoresis and vomiting. She was dehydrated with low sodium (113 mEq/L, normal range 135–145). Her list of 13 medications prescribed by her general practitioner included frusemide 80 mg a day and spironolactone 100 mg twice a day. She was diagnosed with hypotension secondary to an excessive dose of diuretics. She was rehydrated and discharged 8 days later on a reduced frusemide dose of 40 mg/day. Mrs A did not complain.

Complaint following adverse event
Mr D, a middle aged farmer, sustained a penetrating injury to his right eye while cutting firewood. As a result of this injury Mr D suffered a detached retina. He was referred to an ophthalmologist who offered to reattach the retina using an operation he had recently learned in the United Kingdom. The scrub nurse was unfamiliar with the proposed operation which involved the use of diluted SF6 gas. The theatre supervisor was on a meal break because the operating schedule was running late. Due to a breakdown in communication between the nurse and the surgeon, the gas was not diluted and 100% gas was administered to Mr D’s eye, resulting in total blindness in that eye. He is no longer able to run his farm due to the loss of depth perception. Mr D’s complaint was upheld and his claim for no-fault compensation was accepted.

Complaint with adverse event
Mr N, a young man, was admitted to hospital with a severe crush injury to his right middle finger. A senior orthopaedic registrar with extensive plastic surgery experience assessed Mr N and discussed the case with his consultant. They agreed that it would be inappropriate for the registrar to attempt to preserve Mr N’s finger. The registrar stabilised the soft tissue with loose sutures and administered an antithrombotic prophylactic, dextran, to try to prevent thrombosis of the artery. Another orthopaedic registrar, who had not been involved with Mr N’s initial care, told Mr N that crush injuries should never be sutured, causing him considerable anxiety. Following discharge, the hospital tried to arrange a follow up appointment for Mr N but he insisted on going on holiday to a remote region of New Zealand and did not contact a general practitioner as had been agreed. His fingertip became infected and later required partial amputation. The Commissioner found that Mr N had received an appropriate standard of care.

Box 1 provides case studies of three patients. The first patient complained following an adverse event. The second patient suffered an adverse event and did not complain. The third patient complained but, because the poor outcome he experienced was attributable to the condition for which care was sought rather than the medical care itself, it was not an adverse event.

Table 1 shows the characteristics of the patients in the full NZQHS sample, the subset of patients who experienced adverse events (except for the three who complained), and the complainants who experienced adverse events. The average age of the complainants was 47 years and 59% were female. Among complainants for whom ethnicity data were available, 14% were Maori and 3% were Pacific. In general, complainants’ injuries involved were quite severe, with 31% resulting in permanent injury and 28% in death. Most of the injuries (79%) were preventable. 44% (110/254) of complaints involved an injury that was both permanent and preventable.

Bivariate analyses showed several significant differences between injured complainants and injured non-complainants (Table 1). Compared with complainants, non-complainants were significantly older (52 v 47 years, p = 0.003) and more likely to live in deprived socioeconomic areas. Complainants, on the other hand, were significantly more likely to have sustained injuries that led to permanent disability or death, and preventable adverse events were twice as common in this group (79% v 37%, p < 0.001).

These differences persisted in multivariate comparisons of the complainants and non-complainants (Table 2). Injury severity was a strong predictor of complaining, with odds of complaining increasing with injury severity. Compared to patients with temporary disability, the odds of complaining for patients with a permanent disability resulting in >50% impairment were 11.4 times greater (95% CI 5.9 to 22.1) and for patients who died they were 17.9 times greater (95% CI 9.3 to 34.2). There was also a strong independent correlation between preventability and odds of complaining (odds ratio (OR) 7.6, 95% confidence interval (CI) 3.0 to 11.6).

In addition, several sociodemographic factors were associated with propensity to complain after an adverse event. Odds of complaining for patients in the most deprived quintiles were one third those for patients in the most privileged quintile (OR 0.3, 95% CI 0.2 to 0.6). Elderly patients were significantly less likely than their younger counterparts to complain following an adverse event (OR 0.2, 95% CI 0.1 to 0.4). Odds of complaining for patients of Pacific ethnicity were lower than for non-Maori/non-Pacific patients (OR 0.3, 95% CI 0.1 to 0.9). The difference was not statistically significant for Maori patients, perhaps because of the relatively small numbers in this category.

**DISCUSSION**

**Principal findings**

This study is the first to match epidemiological data on medical injuries to complaints about quality of care lodged with a national health ombudsman. Three findings are noteworthy. Firstly, while the right to an appropriate standard of care is one of the ten patient rights enforced by the Commissioner, most complaints involved an adverse event, often a serious one. Secondly, our results suggest that approximately one in 200 injured patients complain about their care to the Commissioner. Among patients who experience injuries that are both serious and preventable, one in 25 complain. Thirdly, the “under-complaining” phenomenon was not spread uniformly across the patient population: elderly patients and socioeconomically disadvantaged patients were especially unlikely to complain despite having suffered an injury, and propensity to complain increased steeply with the severity of the injury sustained.

**Legitimacy of complaints**

Although New Zealand doctors appear to support the use of complaints as a quality assurance tool, concerns abound in the medical community about their prevalence and reasonableness of many complaints brought before the Commissioner. However, the 2001 survey by Cunningham and colleagues suggested that doctors’ attitudes toward complaints found general support for a forum for hearing and investigating complaints, but considerable scepticism about the legitimacy of complaints actually lodged with the Commissioner. Only one in 10 doctors agreed with the statement that most complaints were warranted, and half disagreed with the statement that most complaints are about errors and actual wrongdoing.
Table 1  Characteristics of all patients, non-complainants, and complainants

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<th></th>
<th>All patients in NZQHS, n (%)</th>
<th>Injured non-complainants, n (%)</th>
<th>HDC complainants, n (%)</th>
<th>p value†</th>
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<tr>
<td></td>
<td>(n = 65579)</td>
<td>(n = 847)</td>
<td>(n = 254)</td>
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<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Male</td>
<td>2970 (45)</td>
<td>379 (45)</td>
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<td>42.6</td>
<td>52.0</td>
<td>46.6</td>
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<td>661 (80)</td>
<td>160 (65)</td>
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<tr>
<td>Maori</td>
<td>1013 (16)</td>
<td>135 (16)</td>
<td>26 (10)</td>
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<td>Pacific</td>
<td>240 (4)</td>
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<td>Depreditation quintile</td>
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<td>1 (least deprived)</td>
<td>874 (13)</td>
<td>96 (11)</td>
<td>47 (20)</td>
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<td></td>
<td>907 (14)</td>
<td>128 (15)</td>
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<td>1354 (21)</td>
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<td></td>
<td>1583 (24)</td>
<td>205 (24)</td>
<td>49 (21)</td>
<td></td>
</tr>
<tr>
<td>5 (most deprived)</td>
<td>1834 (28)</td>
<td>227 (27)</td>
<td>38 (16)</td>
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<tr>
<td>Disability</td>
<td></td>
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<td>&lt;0.001</td>
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<td>Temporary</td>
<td>–</td>
<td>685 (85)</td>
<td>105 (41)</td>
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<td>Permanent &gt;50%</td>
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<td>Death</td>
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<td>37 (5)</td>
<td>71 (28)</td>
<td></td>
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<tr>
<td>Preventability</td>
<td></td>
<td>313 (37)</td>
<td>201 (79)</td>
<td>&lt;0.001</td>
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</table>

HDC, Health and Disability Commissioner.

*Percentages were calculated using non-missing values as denominators. Ethnicity data were missing for 19 non-complainants (2.3%) and 65 complainants (25.6%). Depredation scores were missing for seven non-complainants (0.8%) and 17 complainants (6.7%); disability information was missing for 40 non-complainants (4.7%) and one complainant (0.4%).†p values were calculated for the difference between complainants and non-complainants using t test or χ² test as appropriate. Hospitals were weighted to account for NZQHS cluster sampling methodology.

The second of these opinions is partially correct as a matter of law. The Commissioner’s obligations extend beyond classic violations of quality. New Zealand law sets forth a variety of other rights, including rights to be treated with respect and to be free from discrimination or financial exploitation. Perceived breaches of all such rights are legitimate bases for complaint.20

Nonetheless, our analysis suggests that doctors’ attitudes about the reasonableness of complaints are at odds with reality, at least among the subset of complaints related to public hospital care. Nearly two thirds of the complainants in the study sample had experienced adverse events, of which 79% were preventable and 60% involved permanent injury or death; 93% of the adverse events were either preventable or serious injuries.

It is incorrect to interpret these results as evidence that complaints are usually triggered by doctors’ wrongdoing. The causes of adverse events in medicine are often multifactorial, involving a complex interplay between individual and system factors. On the other hand, the prevalence of adverse events—especially preventable and serious ones—refutes the notion that most complaints over quality of care are groundless.

Table 2  Multivariate odds of complaint among patients who experienced an adverse event

<table>
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<tr>
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<th>Odds of complaint (n = 1101)</th>
<th>95% CI</th>
<th>p value</th>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>0.75</td>
<td>0.49 to 1.12</td>
<td>0.16</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Infant 0-1</td>
<td>1.06</td>
<td>0.50 to 2.22</td>
<td>0.9</td>
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<tr>
<td>1-17</td>
<td>0.82</td>
<td>0.50 to 1.34</td>
<td>0.08</td>
</tr>
<tr>
<td>18-44</td>
<td>1.0</td>
<td>0.55 to 1.00</td>
<td>0.92</td>
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<tr>
<td>&gt;65</td>
<td>1.41</td>
<td>0.24 to 2.48</td>
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<td>2</td>
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<td>3</td>
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<td>17.86</td>
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<td>Death</td>
<td>7.60</td>
<td>4.98 to 11.60</td>
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Relationship between complaints and quality of care

Complaint rates
Complaint rates were low. The finding that only 0.4% of adverse events and 4% of serious preventable adverse events triggered complaints is consistent with crude estimates of 0.3% (254/85 000) and 2.3% (110/4800) obtained using the number of complaints as the numerator and an extrapolation of adverse event rates to the national level as the denominator.

In an earlier analysis of the same survey data, Cunningham and colleagues found that one in three doctors had experienced a complaint at some time in their career; the study estimated a complaint rate of 5.7% per doctor per year and used these data to conclude that there was a "high incidence" of complaints. From the perspective of busy practitioners, this may be so. But from a health policy perspective, the prevalence of poor quality care rather than the number of physicians is the appropriate baseline against which to measure complaint frequency. Using this metric, we reach the opposite conclusion: complaints are rare in the sense that the vast majority of preventable adverse events never trigger one.

Why are complaint rates so low? Felstein and colleagues conceptualisation of the evolution of disputes through a process of "naming, blaming, and claiming" helps organise the most likely explanations. First, many patients may not be aware that they have sustained an injury from medical care. Disentangling medical injury from the progression of underlying illness is not straightforward, especially in the inpatient setting where that illness may be severe.

Secondly, patients may recognise their injury but be unaware of the Commissioner's services, or unwilling to commit the time and energy needed to take action. In theory, the complaints process should pose few barriers—patients can lodge a complaint by writing a letter or by making a free phone call (0800 11 22 33); a lawyer's assistance is not required. However, in perception or reality, it may not be straightforward for some aggrieved patients. The complaints process has been described as "confusing, cumbersome, difficult to access, and costly, both financially and emotionally." Moreover, health professionals are provided with a copy of the letter of the complaint, including the patient's name, so some patients may hold back out of concern that such action will bring tension into their relationship with their doctor.

Thirdly, despite both recognising their injury and understanding the complaint option, some patients may simply adopt the attitude that "what's done can't be undone", put the event down to bad luck, and move on. Alternatively, they may elect to take action, but not with the Commissioner. Several other options are available to injured patients seeking redress or accountability following an adverse event. Monetary compensation is available through the national no-fault compensation scheme. Patients seeking an apology, an explanation, or system change to protect others from suffering a similar harm can have those interests met by bringing their concerns directly to the attention of their healthcare provider by using free independent patient advocacy services, or by lodging a complaint with the hospital.

Disparities in use of complaints
A study by Tapper and colleagues of complaints against surgeons found that they were more likely to be brought by women and patients in older age groups. Again, analyses of complaints that do not calibrate their frequency to the underlying rate and patterns of injury can be misleading. Women and the elderly are leading users of the healthcare system; they are also over-represented among injured patients. Calibrating complaints to baseline data on injury, we found no sex differences in complaint behaviour. Elderly patients, on the other hand, were one quarter as likely as their younger counterparts to complain following an adverse event.

Similarly, socioeconomic disparities in complaint behaviour are not readily apparent from a discrete analysis of complaint data. The incidence of complainants is fairly evenly distributed across the five deprivation quintiles, but multivariate regression analysis controlling for the presence and severity of injury showed that patients from the most socioeconomically deprived areas were significantly less likely to complain. These results echo studies of malpractice litigation in the United States in which both old age and lower socioeconomic status have been correlated with lower propensity to sue.

Severity of injury
The strong relationship we identified between severity of injury and propensity to take legal action is also consistent with findings from medicolegal research from the United States. Although the Commissioner's complaint processes attract only a small proportion of adverse events, the odds that an injury will materialise as a complaint increase steeply with severity of the injury; the odds are also substantially greater if the injury is preventable. There is thus a clear "bias" in the severity and types of injuries that come before the Commissioner. Complaints data should not be construed as representative of general patterns of medical injury. On the other hand, the skew towards serious and preventable events is precisely what policymakers might hope for from a system whose goals are to protect consumers from the most serious safety hazards and identify opportunities for quality improvement.

Limitations of study
Our study has several limitations. Firstly, complaints relating to episodes of care in 1998 may have been (or might be) lodged later than 30 June 2004, the date our complaints sample was drawn, although this is unlikely because virtually all complaints are filed within 2 years of the date of the alleged injury (mean 10 months, median 5 months). The 5.3 year window for complaints that we allowed is therefore conservative.

Secondly, estimating adverse event rates through medical record review has recognised limitations. In our review of complaint files, inter-reviewer agreement on the preventability judgment was only fair. To the extent that complaints were judged not to involve preventable adverse events and they did, our regression analysis will underestimate the predictive value of preventability in complaining.

Thirdly, several of the variables used in our analyses were suboptimal. Ethnicity data were missing for one quarter of complainants, and miscategorisation of ethnicity is a recognised problem. The use by the New Zealand Index of Deprivation of small area-based measures to assign socioeconomic characteristics at the individual level creates the potential for measurement error. The direction and magnitude of potential biases stemming from these data limitations are unknown, but we know of no reason why they would differ systematically between complainants and non-complainants and thus affect the results of our analyses.

Conclusion
Given the absence of tort remedies and the availability of a free independent complaints mechanism, it might be expected that patients in New Zealand would frequently lodge complaints following adverse events. Indeed, some physicians in New Zealand feel under siege by complaints processes and the medicolegal environment has been
described as one of the “most hostile” in the world. Yet when complaints to the Commissioner are set against the underlying rate of injury, it becomes apparent that they represent only the tip of an iceberg of adverse events. That tip misrepresents what is beneath the surface in two important ways. Firstly, the relatively low propensity to complain among patients who are elderly, socioeconomically deprived, or of Pacific ethnicity suggests troubling disparities in access to and utilisation of complaints processes. Further research is required to better understand and address these disparities. Secondly, the probability of a complaint increases steeply with severity of injury, and preventable events are much more likely to lead to a complaint than unpreventable ones. In this regard, complaints offer a valuable portal for observing serious threats to patient safety and may facilitate efforts to improve quality.

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Competing interests: none.

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2.2 Claiming behaviour in no-fault system of medical injury

MEDICINE AND THE LAW

Claiming behaviour in a no-fault system of medical injury: a descriptive analysis of claimants and non-claimants

Marie M Bismarck, Troyen A Brennan, Peter B Davis and David M Studdert

ABSTRACT

Objectives: (i) To determine the proportion of patients in New Zealand who claim compensation from the national no-fault compensation program after experiencing a compensable injury; and (ii) to identify characteristics of injured patients who are least likely to claim despite having sustained a compensable injury.

Design: We estimated the percentage of eligible patients who claim no-fault compensation by linking a national claims database (Accident Compensation Corporation) to records reviewed in the New Zealand Quality of Healthcare Study (NZQHS). Bivariate and multivariate analyses were used to investigate socioeconomic and sociodemographic differences between claimants and injured non-claimants.

Participants and setting: Patients who experienced an adverse event associated with care in NZ public hospitals in 1998 and claimed compensation with the ACC, the national no-fault insurer (n = 741). Patients identified by the NZQHS as having sustained an adverse event associated with hospital care in the same year who did not file a compensation claim (n = 839).

Main outcome measures: Adverse events, compensable adverse events, and compensation claims.

Results: Among patients judged by NZQHS reviewers to be eligible for compensation, 2.9% (6/210) claimed. Odds of claiming after an adverse event were significantly lower for patients who were elderly (odds ratio [OR], 0.20; 95% CI, 0.14–0.28), from the most deprived areas (OR, 0.36; 95% CI, 0.23–0.57), or of Maori or Pacific ethnicity (OR, 0.47; 95% CI, 0.32–0.69 and OR, 0.26, 95% CI, 0.11–0.58).

Conclusions: Despite few apparent institutional or economic barriers, the proportion of injured patients in NZ who seek compensation after sustaining a compensable injury is very low. Hence, substantial underclaiming occurs in both negligence and no-fault systems. The disproportionately low propensity of elderly, poor and minority patients to seek compensation also appears to be pervasive.

MJA 2006; 185: 203–207

Critics of medical negligence litigation frequently decry its excesses. However, medical research into the relationship between iatrogenic injury, negligence, and litigation highlights a serious problem of a different kind: the vast majority of patients who sustain injury due to negligent medical care never sue,1–3 and certain subgroups of injured patients — primarily, patients who are elderly, poor, and uninsured — are especially unlikely to seek damages.4–6 The reasons for this “underclaiming” phenomenon are unclear. One commonly cited explanation is that, in negligence-based systems, patients who desire compensation confront a variety of barriers, including difficulties finding or paying for legal representation, time costs associated with litigation, and secrecy among providers about errors and their consequences.7

The prospect of fewer such barriers, and better linkage of compensation to injuries, has fuelled interest in alternative approaches to medical injury compensation.6–7 Commentators in Australia,8,9 the United States,6,7,10 including the Institute of Medicine,11 and the United Kingdom12 have eyed New Zealand’s no-fault system of compensation13 as a promising alternative. In Australia, a major review of medical indemnity arrangements in the mid 1990s rejected the no-fault model,13 a more recent review of the law of negligence noted that a significant body of opinion supports implementation of such a system, but made no recommendation.14 There has been little empirical assessment of the performance of no-fault systems in fulfilling their central promise of providing faster and fairer compensation to more patients. In this study, we linked a national dataset of compensation claims with chart review data from the NZ Quality of Healthcare Study (NZQHS). This permitted estimation of how frequently compensable adverse events, as determined by physician reviewers, led to compensation claims. We also analysed the “compensation gap” by comparing injured non-claimants with injured claimants.

METHODS

Baseline data on a random sample of patients who had experienced adverse events came from the NZQHS. As previously described,15 NZQHS used a two-stage sampling process to develop a representative sample of 6579 medical records of patients discharged from publicly funded acute care hospitals in 1998, excluding psychiatric and same-day discharges. Trained reviewers assessed each case for the presence of an adverse event. Following previous research in the US,17,18 Australia,15 and NZ,16 adverse events were defined as an unintended injury caused by health care management, rather than the underlying disease process, that resulted in disability.

The Accident Compensation Corporation (ACC), the government agency responsible for adjudicating and paying claims for compensation of medical injuries in NZ, provided data on all claims alleging an injury that occurred in 1998. Since 1974, eligibility for compensation has not been predicated on proof of provider negligence.

The compensation criteria have changed over time. Between 1992 and 2005, injuries were compensable if they met either of two criteria:13,15 (i) a “medical mishap”, defined as a consequence of treatment properly given that is rare (occurring in no more than 1% of cases) and severe (hospitalisation for more than 14 days, significant disability lasting more than 28 days, or death); or (ii) “medical error”, defined as a failure to provide treatment with reasonable care and skill. On 1 July 2005, “medical mishap” and “medical error” were replaced with a new concept of “treatment injury”.21,22 This change broadened coverage to include all personal injuries sustained while receiving treatment from health professionals. Our study was conducted before the legislative change, and compensability determinations focused on the mishap/error criteria.

Claims relating to episodes of care in 1998 may have been (or might be) filed later than 30 June 2004, the date the claims data were extracted, although this is unlikely. Virtually all claims are filed within 2 years of
the date of the alleged injury; and the adjudication frame time averages 6 months, with a statutory time limit of 9 months. Therefore, the 5.5-year claiming window we allowed is conservative.

We matched adverse events to claims using the national hospital number (a unique national identifier) and birth date: 14 matches were identified. Two of us (M.M.B., D.M.S.) compared clinical data from the medical record review with claims data to confirm that the NZQHS patient and the complainant were the same person and that the complaint related to the same episode of care.

The analyses are descriptive. We compared characteristics of patients who filed a claim for compensation ("claimants") with characteristics of patients from the NZQHS who experienced an adverse event and did not claim ("non-claimants"). The overlapping or "match" patients — that is, patients from the NZQHS sample whose care involved an adverse event and who subsequently claimed compensation for that event — were classified as claimants. Box 1 shows the derivation of the two populations.

A determination of "compensability" was available within both the NZQHS and the ACC data. For each adverse event identified in NZQHS, reviewers had judged whether it met the statutory criteria for compensation. Among claims, compensable events were those so judged by the ACC. A pilot study established good inter-rater reliability between NZQHS and ACC determinations of compensability ($\kappa$, 0.66).24

Data were analysed using the SAS statistical software package, version 9.0 (SAS Institute Inc, Cary, NC, USA), and Stata, version 8.0 (Stata Corp, College Station, Tex, USA). We used t tests and \(\chi^2\) tests to conduct bivariate comparisons of characteristics of the claimant and non-claimant groups. We investigated predictors of failure to claim despite having experienced an adverse event using multivariate logistic regression. The dependent variable in the regression analysis distinguished claimants from non-claimants. The independent variables were sex, ethnicity (Māori, Pacific, non-Māori/non-Pacific), patient age (<1 year, 1–17 years, 18–44 years, 45–64 years, and ≥65 years), disability (temporary, permanent with <50% impairment, permanent with ≥50% impairment, death), and whether or not the event was compensable. An additional covariate provided a measure of the patient’s socioeconomic status using the NZ Index of Deprivation Score.25,26 This index, based on small area mesh blocks (a micro-level breakdown of geographic boundaries), combines nine census variables reflecting aspects of material and social deprivation; as has been done previously,27 index scores were separated into quintiles for analysis.

To account for the stratified two-stage cluster sampling design in the NZQHS, the bivariate and multivariate analyses were weighted. Weighting made little difference to the estimates.

Ethics review boards in Wellington, NZ, and at the Harvard School of Public Health, USA, approved the study.

RESULTS

The ACC received 1148 claims relating to injuries allegedly sustained in 1998, 741 (65%) of which were associated with admissions to acute care public hospitals. Forty-six per cent (338/741) of the hospital-related claims were accepted and received compensation. The mean time between the event and filing of the claim was 12 months (median, 4 months; range, 0–78 months).

As previously reported, NZQHS investigators’ review of 6579 admissions identified 850 adverse events; 210 of these were judged to be compensable under the statutory standard (Box 1). This corresponds to a rate of 3.2 compensable adverse events per 100 admissions under NZ’s no-fault standard, which is about three times greater than the frequency of compensable events previously detected in the US using the negligence standard (Box 2).

There were 14 matches between the NZQHS and claims populations. NZQHS reviewers had judged six of these to be compensable adverse events, which suggests that 2.9% (6/210) of compensable adverse events led to claims. In Box 2 the claiming rate among compensable adverse events in NZ is compared with corresponding rates from malpractice systems in New York and Utah/Colorado. Among the rest of the matches, five were judged by NZQHS reviewers to be adverse events that did not meet the compensation criteria, and three were judged not to be adverse events.

For the 14 matches, we observed both the NZQHS reviewers’ judgments about compensability and the ACCs actual compensation determination. NZQHS reviewers were more restrictive. The ACC, which typically
has more information on which to base compensation decisions than the medical record used by NZQHS reviewers, determined that 10 claims met the statutory criteria and awarded them compensation. Based on the ACC's compensability judgment rather than the NZQHS reviewers' judgments, therefore, 4.8% (10/210) of compensable adverse events led to claims. In summary, sensitivity analyses that account for differing thresholds in the compensability determinations suggest that 2.5%–4.8% of compensable adverse events in NZ led to claims.

Box 3 gives baseline measures of patient characteristics from the NZQHS's representative sample, and then compares characteristics of claimants and non-claimants (Box 4). Claiming propensity decreased with deprivation; the odds of claiming among injured patients in the most deprived quintile were a third the odds of claiming among injured patients in the most privileged quintile (odds ratio [OR], 0.36; 95% CI, 0.23–0.57). Elderly patients were significantly under-represented among claimants (OR, 0.20; 95% CI, 0.14–0.29), as were patients of Māori and Pacific ethnicity (OR for Māori, 0.47; 95% CI, 0.32–0.69; OR for Pacific peoples, 0.26; 95% CI, 0.12–0.58). The model controlled for disability and eligibility for compensation, both of which were significant predictors of claiming (OR for permanent disability >50% impairment, 5.2; 95% CI, 2.9–9.3; OR for compensable event, 2.8; 95% CI, 2.1–3.8).

Confining the model to ACC cases and NZQHS cases that were judged compensable had the effect of dropping Māori ethnicity and deprivation quintiles 3 and 4 from significance. It did not affect the significance of any other predictors and had only trivial impacts on the magnitude of coefficients in the model.

**DISCUSSION**

Our study is the first to match epidemiological data on medical injuries to claims for compensation in a no-fault environment. Only a small minority (2.9%–4.8%) of patients who suffered an injury and were eligible for compensation claimed it. The strongest risk factors for not claiming in our analyses were old age, Māori and Pacific ethnicity, socioeconomic disadvantage, and injury resulting in temporary disability or death.

Both the ACC and NZQHS data we used have some limitations. Ethnicity is missing for 119 patients (7.5% of the study sample), and misclassification is a well-recognized problem with data of this type. The NZ Index of Deprivation's use of small area-based measures to assign socioeconomic characteristics at the individual level creates the potential for measurement error. The direction and magnitude of the impact of these data limitations on our findings are unknown, but we know of no reason why they would differ systematically between claimants and non-claimants, and thus affect the main results of our analyses.

The claiming rate we estimated is consistent with Davis and colleagues' crude estimate (based on adverse event and claims data from one region of NZ) that compensable events outstrip claims in NZ by a factor of 30 to 1. It is also consistent with the estimated claiming rate of 3.6% obtained by using all claims as the numerator and an extrapolation of compensable event rates to the national level as the denominator (749/21,000).

However, our claiming rate estimate should be interpreted as a lower bound for two reasons. First, patients who experience falls or fractures in a health care facility usually have their claims processed as general accidents rather than medical injuries, and our dataset was confined to the latter. Second, the claims volume for 1998 (n = 1146)

| 3 Characteristics of patients in New Zealand Quality in Healthcare Study (NZQHS), injured non-claimants in NZQHS, and claimants with the Accident Compensation Corporation (ACC) |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| **Full NZQHS sample** (n = 6579) | **NZQHS Injured non-claimants** (n = 839) | **ACC claimants** (n = 741) | **P** |
| **Sex** | | | | | |
| Male | 2970 (45%) | 376 (45%) | 287 (39%) | 0.02 |
| Female | 3609 (55%) | 463 (55%) | 454 (61%) | |
| **Age (years)** | | | | <0.001 |
| Mean | 42.6 | 52.1 | 42.4 | |
| **Ethnicity** | | | | <0.001 |
| Non-Māori/non-Pacific | 5131 (80%) | 654 (80%) | 571 (79%) | |
| Māori | 1013 (16%) | 134 (16%) | 58 (8%) | |
| Pacific | 240 (4%) | 32 (4%) | 12 (2%) | |
| **Depression quintile** | | | | <0.001 |
| 1 (least deprived) | 824 (13%) | 95 (11%) | 118 (18%) | |
| 2 | 907 (14%) | 127 (15%) | 138 (21%) | |
| 3 | 1354 (21%) | 181 (22%) | 140 (21%) | |
| 4 | 1583 (24%) | 204 (25%) | 139 (21%) | |
| 5 (most deprived) | 1834 (28%) | 225 (27%) | 118 (18%) | |
| **Disability** | | | | <0.001 |
| Temporary impairment | — | 677 (85%) | 313 (54%) | |
| Permanent < 50% impairment | — | 65 (8%) | 192 (33%) | |
| Permanent > 50% impairment | — | 19 (2%) | 49 (9%) | |
| Death | — | 30 (5%) | 22 (4%) | |
| **Compensation eligibility** | | | | <0.001 |
| ACC criteria met | 210 (3%) | 204 (24%) | 338 (46%) | |
was unusually low, with 33% fewer claims filed compared with the 5-year period 1997–2001 (mean, 1717; range, 1148–2133). Why fewer claims arose from injuries in 1998 is unknown. Our findings do not suggest that a considerably larger proportion of injured patients who are eligible for compensation will actually obtain it in a medicolegal environment like NZs, where negligence has been eliminated as the basis of determining eligibility for injury compensation. As in the US, patients who sustained injuries were much more likely to claim compensation than uninjured patients. But despite few apparent barriers to seeking compensation in NZ — for example, lawyers are not necessary and few claimants use them — the vast majority of eligible patients (97%) did not claim. The proportion that did claim was very close to the proportion estimated from tort systems in New York in the late 1980s26 and Utah and Colorado in the late 1990s.3

Our findings are also consistent with estimates from Denmark, another country with a comprehensive no-fault system. A recent review of 1573 patient records from a surgery department in Copenhagen found only two no-fault compensation claims among 209 potentially compensable events.30 The problem of chronic underclaiming appears to be quite insensitive to the structure of the compensation system.

What explains the low claim rates? There are several plausible possibilities. First, many patients may not be aware that they have sustained an injury from medical care. Disentangling medical injury from the progression of underlying illness is not straightforward, especially in the inpatient setting where that illness may be severe.

One hope for efforts to promote disclosure of medical injuries is that greater transparency may attenuate this identification problem. In theory, the blame-free atmosphere of a no-fault environment is better placed to realise this goal. In practice, NZ’s continued use of medical error as one of the bases of eligibility for compensation has meant its scheme has retained some of the fault and blame elements that characterise tort systems. These vestiges have almost certainly inhibited disclosure.31 The recent changes to the scheme, replacing “medical mishap” and “medical error” with “treatment injury” are explicitly designed to eliminate fault-finding from the compensation inquiry, promote disclosure, and reinforce the system’s no-fault mission.23

Second, injured patients and their families have many interests besides money,32,33 though it is essentially the only remedy available in a tort system. The NZ system offers monetary compensation for economic losses, and offers alternative processes for responding to patients’ other needs. Patients who seek an apology, an explanation, or system change to protect others from similar harm can have those interests met by using free, independent advocacy services or filing a complaint with the national Health and Disability Commissioner.34

Third, other sources of service and financial support for injured patients may diminish the economic importance of compensation in NZ, relative to a country like the US. For example, hospital care is free, and primary care is heavily subsidised. This hypothesis finds support in the fact that claims for dental injuries during anaesthesia are a leading category of medical injury claims to ACC; dental care is one area in which NZ patients face significant out-of-pocket expenses.

A related point is that the awards themselves tend to be modest relative to damages paid in tort. Forty-six per cent (338/741) of the claims in this study were compensated, receiving an average of NZ$23,245 by the time of the study (median, $4305; range, $23–$504,609). As compensation is paid weekly for as long as is required, these figures cannot easily be compared with a lump-sum award.

Non-economic damages are not compensated. Older patients and people representing children may be discouraged from claiming because significant earnings-related compensation is not available to them.34 A disproportionate degree of underclaiming among those groups is consistent with the results of our comparisons of non-claimants with claimants.

The negative correlation of both temporary injury and death with claiming propensity probably reflects the economic realities of compensation: successful claims for these levels of harm typically attract relatively little compensation, decreasing incentives to bring them forward. The remaining risk factors demonstrate the inverse relationship between social disadvantage and propensity to claim. Although injury compensation systems are designed to reduce social disparities, they may amplify them in the area of medical injuries.

Our findings related to social deprivation are consistent with previous research.35,36 Burston and colleagues found that poor, elderly and uninsured patients in New York were significantly less likely to sue for malpractice, even after controlling for the presence of medical injury. Similarly, Studdert and colleagues’ analysis of adverse events and lawsuits in Utah and Colorado found that sociodemographic risk factors for being members of the “worthy but uncompensated” group included being poor, uninsured, a Medicare or Medicaid beneficiary, and 75 years of age or older.3
COMPETING INTERESTS
None identified.

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28
2.3 No-fault compensation in New Zealand

UPDATE

UPDATE: INTERNATIONAL REPORT

No-Fault Compensation In New Zealand: Harmonizing Injury Compensation, Provider Accountability, And Patient Safety

Injury compensation systems meet patients’ financial needs only and must be complemented by other forms of accountability.

by Marie Bismark and Ron Paterson

ABSTRACT: In 1974 New Zealand jettisoned a tort-based system for compensating medical injuries in favor of a government-funded compensation system. Although the system retained some residual fault elements, it essentially barred medical malpractice litigation. Reforms in 2005 expanded eligibility for compensation to all “treatment injuries,” creating a true no-fault compensation system. Compared with a medical malpractice system, the New Zealand system offers more timely compensation to a greater number of injured patients and more effective processes for complaint resolution and provider accountability. The unfinished business lies in realizing its full potential for improving patient safety. [Health Affairs 25, no. 1 (2006): 278–283]

In 1974 New Zealand adopted a government-funded system for compensating people with personal injuries (operated by the Accident Compensation Corporation, or ACC), replacing its former tort-based system. A generation of New Zealanders has now grown up knowing the ACC as the primary method of dealing with personal injury claims, including medical injuries, and avoidance of litigation is widely regarded as a social gain.1 Reforms in 2005 removed the final fault element from the compensation criteria for medical injuries, making it a true no-fault system.

Contextual differences in health funding, social security, and community values limit generalization of the New Zealand experience to other countries. Nevertheless, this system merits close consideration for its efforts to compensate injured patients quickly and equitably, while offering accountability mechanisms focused on ensuring safer care rather than assigning individual blame. Exhibit 1 lists some of the features of the New Zealand system in comparison with the U.S. system.

The trouble with torts. The failings of the U.S. tort-based medical malpractice system have been well described. Most injured patients do not qualify for compensation, because their injuries were not negligently caused. And even negligently injured patients, especially those who are poor or elderly, are unlikely to sue and receive compensation.2 Yet,
EXHIBIT 1
Comparison Of The United States Medical Malpractice And The New Zealand No-Fault Systems

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<th>United States</th>
<th>New Zealand</th>
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<td>Expert advisers</td>
<td>Appointed by parties</td>
<td>Appointed by ACC</td>
</tr>
<tr>
<td>Decisionmaker</td>
<td>Lay jury</td>
<td>Administrative panel</td>
</tr>
<tr>
<td>Time to resolve a claim</td>
<td>Years</td>
<td>Weeks to months</td>
</tr>
<tr>
<td>Administrative costs</td>
<td>High (&gt;50%)</td>
<td>Low (&lt;10%)</td>
</tr>
<tr>
<td>Average payment</td>
<td>High</td>
<td>Low (average payment &lt; US$30,000)</td>
</tr>
<tr>
<td>Physician indemnity insurance</td>
<td>High</td>
<td>Very low (&lt; US$1,000, regardless of specialty)</td>
</tr>
<tr>
<td>costs</td>
<td></td>
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<tr>
<td>Links to quality improvement</td>
<td>Theoretical deterrent effect</td>
<td>Claims analysis informs efforts to improve patient safety</td>
</tr>
<tr>
<td>processes</td>
<td></td>
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</tr>
</tbody>
</table>

**SOURCE:** Authors' analysis.  
**NOTE:** ACC is Accident Compensation Corporation.

Paradoxically, most lawsuits arise out of appropriate care. This creates confusing signals about quality of care, and although some doctors adopt a defensive mode of practice, there is little evidence of a true deterrent effect.

**Thirty years of government-funded compensation.** New Zealand’s compensation system arose not in response to concerns about medical malpractice but through far-sighted workers’ compensation reforms. A Royal Commission, established in 1967, concluded that accident victims needed a secure source of financial support when deprived of their capacity to work. Skeptical of the ability of a liability-based system to provide such support, the commission recommended no-fault compensation for personal injury. At around the same time, the United States, Australia, and the United Kingdom also debated the merits of no-fault compensation, but the idea of a comprehensive approach to injury by accident failed to gain traction.

In the New Zealand system, injured patients receive government-funded compensation through the ACC. In exchange, they give up the right to sue for damages arising out of any personal injury covered by the accident compensation legislation. This prohibition applies even when a person chooses not to lodge a claim or is not entitled to compensation. It remains possible to bring actions for exemplary damages, but the courts have found that not even gross negligence warrants such damages unless there is some element of conscious or reckless conduct.

**“Medical error” and “medical mishap.”** Historically, health care–related injuries have made up 0.05 percent of all claims made to the ACC, with around 2,000 such claims received in an average year from a population of four million. Under the original legislation, personal injury by accident included “medical, surgical, dental or first aid misadventure,” without further definition. At the time, claims against health professionals were uncommon, and for several years doctors remained uncertain about the extent to which the specter of liability had been removed.

In 1992, the concepts of medical error and medical mishap were formally introduced into the ACC legislation. Medical error was defined as the failure to observe a reasonable standard of care and skill—civil negligence by another name. Before 2002 medical error could not be attributed to an organization; this focus on individual error, combined with the threat of disciplinary action, hindered open communication and delayed compensation, as doctors sought to challenge error findings.

The second category, medical mishap, was defined as a rare (occurring in less than 1 percent
of cases) and severe (disability or prolonged hospitalization) adverse consequence of properly given treatment. The mishap concept allowed recovery for non-negligent injuries and accounted for the majority of accepted claims. Yet the definition was a clumsy one, with the rarity and severity criteria criticized for being confusing and arbitrary. Here is an example of a medical mishap compensation claim:

A young woman underwent laparoscopic surgery to confirm a diagnosis of endometriosis. Post-operatively, she was readmitted with abdominal pain and found to have peritonitis associated with a bowel perforation. She required a temporary colostomy and spent three weeks in critical care.

The ACC’s independent expert advised that the complication was a rare and severe consequence of treatment properly given and met the definition of medical mishap. The woman was awarded a compensation package worth around US$28,000 (for pharmaceuticals, home help, and lost earnings). Under the new 2005 compensation criteria, this injury would be compensated as a form of “treatment injury.”

■ 2005 reforms. Criticisms of the compensation criteria—particularly the inconsistency between medical error and the no-fault basis of the wider ACC system—prompted an interagency review in 2002. The review found overwhelming support for new coverage criteria and almost no suggestion of returning to a right-to-sue—a reflection on the extent to which the ACC system is embedded in New Zealand culture and support for the proposition that “even an imperfect administrative compensation system [is] an improvement over the...medical malpractice system.”

Consequently, on 1 July 2005, medical mishap and medical error were replaced with a new concept of treatment injury. This change broadened coverage to include all personal injuries suffered while receiving treatment from health professionals. A causal link between treatment and injury is still required. Injuries that are a necessary part or ordinary consequence of treatment (such as chemotherapy hair loss) are not covered. Clarification of what constitutes “a necessary part” will be critical. As before, there is no coverage where the injury is solely the result of resource allocation decisions.

A key objective of the change is to encourage health professionals to assist injured patients to make claims earlier, thereby facilitating timely provision of ACC assistance. Claimants are informed of the availability of independent processes for resolving concerns about the quality of care, and the ACC is required to report any “risk of harm to the public” to the responsible authority. A new Patient Safety team analyzes claims data and works with the health sector and researchers to help improve patient safety.

■ Claims process. The ACC system is one of the simplest in the world for patients to navigate, and although the eligibility criteria have changed, the decision-making process remains much the same. Claims are decided in the ACC’s national claims unit, based on information provided by patients and their providers, and advice from independent clinical advisers. Straightforward claims can be processed in weeks, with a statutory requirement for decisions to be made within nine months. Historically, the ACC has accepted around 40 percent of all claims. Dissatisfied claimants may request a review of the decision, and if this fails, they have a right of court appeal.

The ACC is financed through general taxation and an employer levy. A fixed award schedule means that claimants with similar disabilities receive similar compensation. Entitlements fall into four categories. (1) Treatment and rehabilitation includes the cost of pharmaceuticals, disability aids, child care, home modifications, and vocational retraining. Most treatment costs are already covered by New Zealand’s universal health care system. (2) Compensation for loss of earnings includes weekly compensation of 80 percent of the claimant’s earnings at the time of injury, up to a set maximum. (High earners can purchase additional first-party income protection insurance.) Weekly compensation was the most important driver of compensation costs during 1992–2003. (3) Lump-sum compensation—a one-time payment of up to US$70,000 to compensate for permanent impairment resulting from...
an injury—is paid in addition to any other ACC entitlements. Support for dependents takes the form of a funeral grant and a survivor's grant paid to surviving spouses and children under age eighteen.

**Affordability.** No-fault systems have the potential to compensate many more patients than malpractice litigation can, but depending on compensation criteria, level of awards, and social context, this need not result in greatly increased costs. Accurately estimating the long-term costs of the New Zealand system is difficult, with uncertainty about future claim rates, changes in life expectancy, and innovations in health care. To date, compensation for medical injuries has cost around US$29 million per year. As in the United States, the most costly claims involve neurological injury to infants: fewer than 7 percent of claims yet more than 16 percent of spending.

The ACC expects that following the 2005 reforms, the number of compensation claims will go up by 50 percent, and many more claims will be successful. However, most of the new claims will involve minor, temporary injuries, which were previously ineligible for compensation. The reforms are expected to cost an additional US$5 million a year.

Four main factors have contributed to the system's affordability. First, New Zealanders benefit from a strong social security system. Injured patients, like everyone else, receive free hospital care and subsidized pharmaceuticals. Yet per capita health spending was only US$1,886 in 2003, compared with US$5,635 in the United States. Thus, New Zealand's public health and welfare systems cover many of the damages that would be at issue in a U.S. medical malpractice claim, leaving the ACC with a much smaller compensation burden.

Second, compensation awards are generally lower and more consistent than under a malpractice equivalent. As described above, economic losses are compensated according to a fixed schedule, and compensation for noneconomic losses is available only for permanent disabilities.

Third, the New Zealand experience suggests that even under such a system (which includes a legal duty of open disclosure), most entitled patients never seek compensation, and many may be unaware that they have even suffered an adverse event. Peter Davis and colleagues have estimated that the ratio of potentially compensable events to successful claims is around thirty to one. Further work is under way to understand the extent of underclaiming and the characteristics of patients who do not claim.

And finally, the New Zealand system does not incur large legal and administrative costs. The system has been very cost-effective, with administrative costs absorbing only 10 percent of the ACC's expenditures compared with 50-60 percent among malpractice systems in other countries.

**Accountability.** Many U.S. commentators have expressed concern that a "no-fault" compensation system equates to a "no-accountability" medico-legal system. For example, Robert Wachter and Kaveh Shojania speculate that "Americans' passion for individual accountability would...torpedo a system that could not assign fault (and with it the duty of compensation) on truly blameworthy errors." Between 1972 and 1994 such criticisms had some legitimate foundation, because the abolition of the right to sue did leave a lacuna in systems of medical accountability. However, in the late 1980s a major inquiry at a leading teaching hospital forced New Zealand to consider this accountability function and recommended the establishment of a Health and Disability Commissioner to restore balance to the system.

The commissioner promotes patients' rights and provides accountability where care has not been provided with reasonable care and skill. As the following case study shows, complaints are resolved using patient advocacy, mediation, or investigation, as appropriate. The actions of organizations and individuals are considered, and the commissioner acts as a gatekeeper to disciplinary proceedings in serious cases. Complaints are used as a "window of opportunity" to improve health services, and lessons learned through complaint investigations are widely disseminated.
A general practitioner referred his patient for mammography of a breast lump and told her he would contact her if there were any problem. Thirteen weeks later (after two phone calls from his patient), the doctor obtained the mammography report and told his patient the results were abnormal. The patient complained to the commissioner, who found that the doctor had failed to provide care of an appropriate standard. The commissioner recommended that the medical center implement a system for follow-up of test results.

In light of this and other cases that involved physicians’ failure to follow up test results adequately, the commissioner drew attention to the topic in a medical journal. This led to debate by general practitioners and the development and implementation of pilot guidelines for improving follow-up of test results.

**Unresolved concerns.** Despite the recent reforms, four major concerns about the ACC system remain unresolved. First, many observers believe that levels of ACC compensation are inadequate, particularly in comparison with tort jurisdictions. This is especially a problem for patients—usually women and the elderly—who are not in paid employment at the time of the injury and thus are unable to claim earnings-related compensation.24

Second, compensating treatment injuries, while excluding most other illnesses from the ACC system, is bound to produce tensions, because ACC assistance is generally higher than that received from the health and welfare systems. This is particularly troubling in the area of birth abnormalities, such as cerebral palsy, in which babies with similar needs could be eligible for very different kinds of support.

Third, the ACC system has been criticized for its duplication of processes following an adverse event.25 In response, the ACC has strengthened interagency relationships with police, coroners, the health and disability commissioner, and other regulatory bodies, to reduce unnecessary overlap.

Finally, although the system is structured to support efforts to improve patient safety, the potential gains are still a long way from being fully realized. After thirty years of the ACC and nine years of independent complaint resolution, New Zealand hospitals appear no safer (or more dangerous) than those in other Western countries. The adverse-event rate of 12.9 percent stands midway between the levels recorded in two countries with shared medical traditions in training and practice: Australia (16.6 percent) and the United Kingdom (10.8 percent).26 Although the recent reforms are expected to bolster efforts to create a culture of learning, the task of making healthcare safer is daunting and will not be achieved through medico-legal reform alone.

**Concluding remarks.** In the 1970s the U.S. Department of Health, Education, and Welfare sponsored a study of New Zealand’s proposed no-fault system. Arthur Bernstein, the study’s author, reported that “the most effective remedies for the ills of our tort system [may] be disclosed by demonstration, in an attractive, usually tranquil, and very civilized little country half a-world away. The developments ‘down under’ thus merit our most careful and continuing observation.”27

Some thirty years later, with the rise of systems thinking about the causes of adverse events, the tort system is looking increasingly anachronistic. Although the New Zealand system has not delivered a perfect solution to the problem of medical injury, it remains popular, and there is no enthusiasm among the public or health care providers for a return to tort law as an alternative. The ACC does not deliver the windfalls of a “forensic lottery,” but it offers injured patients reasonable assistance, quickly, and without rancor. The unfinished business lies in realizing the system’s full potential for enhancing patient safety.

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NOTES


14. Other contributors to compensation cost include the following: social rehabilitation, 34 percent; compensation for noneconomic losses following permanent injury, 8 percent; death benefits, 7 percent; medical costs, 5 percent; and other entitlements, 5 percent. See ACC, A Comprehensive Study of the Cost of Accidental Medical Misadventure Claims (Wellington: ACC, 2003).


16. ACC, A Comprehensive Study.


2.4 Motivations for medico-legal action

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MOTIVATIONS FOR MEDICO-LEGAL ACTION

LESSONS FROM NEW ZEALAND

Marie Bismark, MBChB, LL.B., MBHL *
Edward A. Dauer, LL.B., M.P.H.†

INTRODUCTION

A tangle of motives lies behind a patient or family’s decision to take legal action following medical injury, and money is only one of them.¹ These motives, which all can be considered to represent a demand for some form of “accountability,” generally fit into four themes:² restoration, including financial compensation or some other intervention to “make the patient whole again”; correction, such as a system change or competence review to protect future patients; communication, which may include an explanation, expression of responsibility, or apology; and sanction, including professional discipline or some other form of punitive action.

Previous studies exploring patients’ reasons for filing a malpractice suit have identified a similar spectrum of needs. In the United States, factors that have prompted claims among families of children with severe perinatal injuries have been studied.³ Even though these families presumably faced significant

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² Edward A. Dauer, The Role of Accountability in Legal and Ethical Responses to Medical Error (forthcoming 2006).

³ Hickson et al., supra note 1, at 1359; Frank A. Sloan et al., Suing for Medical Malpractice 65-68 (1993).
economic costs and claimed damages, needing money was mentioned as the reason for a claim by only 24% of the respondents. Among the same group, information and cover-up were mentioned by 20% and 24%, respectively, and the combination of revenge and protecting others scored 19% among all respondents.

Similarly, in the United Kingdom, one study surveyed 227 patients and relatives who were taking legal action through five firms of plaintiff medical negligence solicitors. In open-ended responses to a question asking what the provider could have done after the incident that would have prevented the claim, explanation and apology were mentioned more than twice as often as compensation, and 10 times as often as disciplinary action.

Yet, medical malpractice litigation essentially offers injured patients and their families only one form of redress: financial compensation. Thus, the legal system is used for a variety of reasons, most of which it is not intended to serve. This remedial narrowness may constrain efforts to achieve meaningful malpractice reform and improve patient safety.

New Zealand’s medico-legal system is one of a handful that has attracted American attention as the understanding of medical liability, including its relationship to the avoidance of medical error, has become increasingly well-informed. In New Zealand, injured patients are entitled to government funded, no-fault compensation through the Accident Compensation Corporation (the ACC). The ACC addresses issues of compensation separately from the quality of care: it is not necessary to claim negligence or error as a condition for obtaining compensation, as is the case in the United States.

In conjunction with the compensation system, an independent health ombudsman, the Health and Disability Commissioner (the Commissioner), offers a range of non-monetary remedies. The Commissioner makes an individualized assessment of the best way to resolve patients’ complaints, whether by mediation, referral to another body, or formal investigation. Patients, families, and health professionals all play an active role in the process, from considering the appropriateness of advocacy and mediation, to helping formulate the terms of an investigation, to commenting on the Commissioner’s opinion before it is finalized. The process focuses on promoting patients’ rights, opening lines of communication, and supporting physicians and health care organizations back into safe practice.

New Zealand’s medico-legal system is sensitive to each of the four forms of accountability listed above, and it facilitates creative and context-sensitive

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4 Vincent, supra note 1, at 1609.
5 See Dauer, supra note 2.
responses to the needs of injured patients and their families. While recognizing
the need for caution in applying legislative solutions developed abroad, we
suggest that, in this area, the kiwi may have some lessons for the eagle.

In this article, we use case studies, drawn from New Zealand compensa-
tion claims and complaint files, to illustrate the richness and diversity of injured
patients’ interests. We discuss the varied and flexible mechanisms whereby
the New Zealand system can hear and respond to each of these interests, and
suggest that developing authentic responses to patients’ non-monetary needs
in the United States might offer a key to meaningful tort reform.

I. RESTORATION

A central function of the tort system has traditionally been restoring
the injured person to “wholeness.” This restorative function focuses on the
victim, with at best a secondary concern for the impact on the wrongdoer.
Restoration typically involves monetary compensation, though other forms
of intervention sometimes are more appropriate.

A. Compensation in the United States and New Zealand

The failings of the fault-based American system for compensating medi-
cal malpractice claimants have been well-documented and have led to increas-
ing interest in administrative alternatives. The New Zealand no-fault system,
which compensates injured patients through an independent third party, re-
gardless of physician fault, offers one such alternative. Within the United
States, a number of research projects and pilot programs seek to explore the
promise of such administrative compensation systems.

1. Fault in the United States v. No-Fault in New Zealand

In the United States, compensation is effected principally through the tort
liability process, including litigation and the private claims procedures within
its penumbra. This system is, with rare exceptions, fault-based: the patient
cannot be compensated without at least alleging that the physician defendant
made an error that would not have occurred had the defendant exercised the
appropriate standard of care.

Financial compensation is the form of accountability which civil liability
delivers best, but even as a device for compensation, the American system is
deeply flawed. It is grossly inefficient, and simultaneously over- and under-
inclusive.7 Perhaps even more problematic is that, within a fault-based system,
the patient and health professional are of necessity on opposite sides of the table. The patient’s compensation depends upon the persuasiveness of the allegation that the physician was incompetent.

New Zealand’s no-fault scheme, however, treats compensation and other forms of accountability as separate, though related, functions of a medico-legal system. Patients injured while receiving medical care claim no-fault, government-funded compensation through the ACC, and concern for their financial welfare need not interfere with the continued relationship with their health professional.

New Zealand’s compensation process operates as follows: the patient or bereaved family files a claim, usually without the assistance of an attorney; the ACC obtains information on the alleged injury from the health care provider, seeks expert advice if required, and then makes a decision about whether the injury meets the criteria for compensation. Approximately 40% of claims are accepted, and patients whose claims are declined have a right of appeal. Payments are modest, averaging around $30,000, but are sufficient to meet the costs of treatment, rehabilitation, lost wages, care of dependents, and other expenses. In addition, medical care is provided free of charge through New Zealand’s universal health care system. The scheme is financed through general taxation, and a fixed award schedule means that claimants with similar disabilities receive similar compensation. Full information on entitlements is available to the public through the ACC Web site.

<table>
<thead>
<tr>
<th>Widow seeking compensation for husband’s death following bowel perforation</th>
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<tbody>
<tr>
<td>A 57-year-old man underwent abdominoperineal resection for carcinoma of the rectum. During the surgery, he suffered a bowel perforation, with subsequent sepsis, leading to his death. His widow applied to the ACC for no-fault compensation. An independent expert advised that there was a clear causal link between the surgery and the man’s death, though the surgeon’s actions were not negligent. The man’s widow was awarded a no-fault compensation of around US $120,000.</td>
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</tbody>
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8 See generally Ron Paterson, The Patients’ Complaints System in New Zealand, 21 Health Aff. 70, 74-75 (2002) (discussing the impact of the New Zealand patients’ complaint system and its focus on “resolution of complaints at the lowest appropriate level, acknowledgment of a patient’s concerns, and . . . review and rehabilitation of a substandard practitioner or system”); Marie Bismark & Ron Patterson, No-Fault Compensation in New Zealand, 25 Health Aff. 278 (2006).


10 This case and others throughout the article are taken from the files of New Zealand’s Health and Disability Commissioner, on file with Dr. Bismark. Patient names and other details have been changed to protect anonymity.
The New Zealand compensation system is one of the simplest in the world for patients to navigate, with a statutory requirement for claims decisions to be made within 12 months. Yet, despite few apparent financial or procedural barriers to claiming in New Zealand’s no-fault system, only a small minority of eligible patients actually claim financial compensation. Other available forms of accountability may well be one factor that contributes to these low claim rates.

2. Promise in the United States

Even within the confines of the existing malpractice framework of the United States, some American organizations are finding ways to reimburse injured patients for their out-of-pocket expenses, without the need for a bitter and adversarial legal dispute.

For example, in 2000, COPIC, a physician-owned insurer in Colorado, implemented its highly regarded 3Rs program, a no-fault based risk management program designed to: recognize the depth and breadth of an injured patient’s needs; respond in a timely and effective manner; and resolve the consequences of the event as best as possible. The program focuses on addressing the injured patient’s emotional, physical, and financial needs, and it is underpinned by a commitment to “learning from this first to prevent the second.” Patients can be reimbursed for their out-of-pocket expenses and other costs associated with the medical injury. No payments are made for non-economic damages. Though patients retain the right to sue, not one incident meeting the program’s inclusion criteria has yet proceeded to a malpractice trial. More than 1,700 physicians currently participate in the program. During the 38-month period from the inception of the program to December, 2004, 930 incidents met the criteria for inclusion in the program; exclusion criteria include a written demand for money, death of a patient, or concurrent complaint to the Board of Medical Examiners. Of these 930 incidents, 607 were closed, or were about to close, with good communication alone. Three hundred two were closed with good communication and modest payments. These payments averaged $5,300 per incident, with a range of $95 to $30,000. The remaining 21 incidents went forward to the claims department, where two required settlements and releases. As of June, 2005, not one had proceeded to litigation.

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12 See Davis et al., supra note 6, at 833-34.
The COPIC example demonstrates that, even in the United States, persuading an inexpert jury that some identifiable fault in the course of medical treatment caused an injury need not be an essential element of the plan to deal financially with the consequences of such injury.

B. Intervention in New Zealand

In some cases, the best way to “make the patient whole again” is not through financial compensation, but through another form of action, such as medical care or rehabilitation. New Zealand patients who are struggling to navigate the health care system following an adverse event can seek support from a nationwide network of free, independent patient advocates. These advocates are trained to facilitate face-to-face meetings between patients and health professionals as a means of resolving any issues surrounding the provision of care. Patient advocates play a particularly important role in situations, such as chronic illness, where there is value in preserving the relationship between the patient and health professional following an adverse event.

In other cases, the most appropriate form of “restoration” may involve timely and appropriate care. This scenario is not uncommon in New Zealand, a country where publicly funded health care is rationed and waiting lists for elective surgery are commonplace.

Elderly woman seeking timely access to care
Elderly Mrs. R had a basal cell carcinoma on her right calf. Her oncologist ordered radiotherapy, but there was a delay in providing radiotherapy, as the hospital’s radiotherapy machine had been decommissioned and the hospital was waiting for the new one to arrive. In the interim, Mrs. R’s lesion increased significantly in size. Her general practitioner sought the Commissioner’s assistance to remedy the situation, writing: “I would be grateful for your help expediting treatment for this lady.” The Commissioner referred the matter to the hospital for resolution, and requested a written report on what action had been taken.

II. COMMUNICATION

Following a medical injury, the emotional needs of patients may be as important as their physical ones, and many plaintiffs are motivated by a desire for some form of communication.\textsuperscript{14} They may be seeking to make sense of the

\textsuperscript{14} Hickson et al., supra note 1, at 1362; see Vincent et al., supra note 1, at 1612.
events that led to their injury, or questioning whether there was anything that could have been done to prevent harm. This second patient motive involves disclosure and communication.

A. Explanation

Despite national standards requiring open disclosure of adverse events,15 many patients in the United States are still denied timely and accurate information in the aftermath of injury.16 A valued feature of the litigation system is that patients are allowed to access their medical records and have their case reviewed by an independent expert. This information may help to clarify misunderstandings or confirm their suspicions were well-founded. Unfortunately, claims involving serious injury can take five or more years to resolve, and during this time, patients and families may be continually denied important information about the cause of their injuries.

In New Zealand, such information can be obtained without the financial or emotional costs of litigation. Health professionals have a legal duty of candor following an adverse event,17 and adverse events generally are acknowledged in the medical record.18 Independent patient advocates support patient access to medical records and assure satisfactory answers to questions patients may have. Unfortunately, efforts to obtain an explanation directly from health professionals are not always successful. “I tried to get answers, but the doctor was evasive and downplayed the seriousness of it all,” wrote one woman after she suffered a massive post-operative hemorrhage following a cesarean section. In such cases, the Commissioner may ask an independent mediator to facilitate a meeting between the parties, or may conduct an independent investigation to meet the patient’s need for an explanation of the cause of the adverse event.

Explanations seem to be particularly important to the families of infants and children who have been harmed by medical care.

Mother of child with drug-induced liver failure seeking an explanation
A nine-year-old boy with epilepsy developed carbamazepine-induced liver failure. He was transferred to a children’s hospital in Australia, where he underwent a liver transplant. During the surgery, the boy developed severe cerebral swelling, and he died the next day. In heart-wrenching words, his mother wrote: “His screams and pleas to be helped and saved are my last memories of my son. Nothing can ease my pain over my inability to tell him that I did try to save him. I require answers in order to come to terms with the death of my son.” The boy’s mother had already attempted to communicate directly with the boy’s health care providers, with little success: “I was treated with personal disregard. The lack of communication led to feelings of utter disempowerment.” Given this history of poor communication and the seriousness of the adverse event, the Commissioner conducted an independent investigation, culminating in a written report that provided the boy’s mother with the answers she was seeking.

Many in the United States also have recognized injured patients and their families need to understand what went wrong and why. Recent open disclosure laws may point the way toward more open, honest, and empathic disclosure conversations among physicians, their patients, and patients’ families.\(^{19}\)

One particularly innovative program to facilitate communication between injured patients and physicians was piloted in Massachusetts. The Massachusetts Voluntary Mediation project selected cases in which a complaint against a physician was registered with the Board of Registration in Medicine. After case selection, both patient and physician were contacted and offered voluntary mediation as a way to resolve the complaint. This offered the patient an opportunity for a face-to-face meeting, and the physician a chance to have the complaint removed from the Board’s records. Fifty cases were successfully mediated, and only two cases involved an exchange of money. The vast majority of cases were settled after the patient received an explanation and apology from the physician.

B. Expression of Responsibility/Apology

After a medical injury, a sincere and timely apology can have a powerful impact on the patient or family, and may serve as a critical step in defusing anger and rebuilding trust.\(^{20}\) Some patients seek a formal apology, while others just want to know that someone has accepted responsibility or is willing to stand up and be held accountable for the injury. Typical comments include:

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\(^{20}\) *Id.* at 27.
“Who is responsible?” and “The hospital is not accepting the fact that they could be at fault.”

In a malpractice system, such as the one in the United States, health professionals may have to account for their actions in a court of law. However, this usually only occurs after a long and tortuous process, which often is distressing for both patients and health professionals.

New Zealand health professionals are able to offer apologies unconstrained by fear of litigation. Should a preventable adverse event result in a formal complaint, the actions of a health professional who offered a timely and sincere apology are likely to be viewed more favorably by the Commissioner than the actions of one who attempted to evade responsibility. When an apology is considered appropriate but is not forthcoming, the Commissioner may formally recommend that one be offered.

Paraplegic seeking an apology for inadequate nursing care
A man with paraplegia was admitted to a hospital for rotator cuff surgery. While in the hospital, he developed a large bedsore. After discharge, a district nurse visited him at home, but he was left sitting upright for up to 10 hours a day. His ulcer deteriorated and formed a large cavity. When his general practitioner tried to arrange admission to the hospital, there was a five-day delay before admission. He required extensive surgery, including a skin graft, and suffered depression and loss of quality of life. He wrote: “Apologies are extremely important to people who are hurting and who feel that their hurts have not been taken seriously.”

In this case, the Commissioner arranged for the patient and his daughter to meet with the hospital general manager and a geriatrician. An independent mediator facilitated the meeting, during which the hospital acknowledged that the patient’s treatment was unacceptable and apologized to him and his family. The patient accepted the apology, and the matter was resolved with no further action.

In recent years, several states have adopted “apology laws” designed to protect physicians from having apologies construed as an admission of liability in a court of law. Under most of these apology laws, the protected statements include “gestures expressing sympathy or a general sense of benevolence.” One notable exception, the Colorado apology law, also covers “gestures, or conduct expressing apology, fault, sympathy, commiseration, condolence, compassion, or a general sense of benevolence.” The word “fault” is key, as it means, in Colorado at least, health care providers not only may say “I’m sorry this happened,” but also “I’m sorry I did this to you,” with

statutory assurance that what they say cannot be introduced into evidence if
the patient later brings an action for professional malpractice.22

III. CORRECTION

Although money is the only way the medical malpractice system approxi-
mates the value of a lost life, it does not satisfy a plaintiff’s interest in knowing
what is being done to prevent a recurrence.23 The third form of accountability
reflects the desire for corrective action, frequently expressed by injured pa-
tients and their families.24 Patients and families express sentiments such as,
“I hope this complaint makes a difference for the treatment of others” or “We
certainly wouldn’t want anyone else to go through what we went through.”
The desire to prevent future incidents can be seen both as a genuine desire to
protect others and an attempt to find meaning in the loss that has occurred.

In theory, the tort system may be able to avert harm to future patients by
correcting the present wrongdoer and deterring others in similar positions. In
practice, there is little evidence supporting the deterrence function, and some
credible evidence against it.25 Much of what we know about quality improve-
ment and risk reduction suggests the requisites for improving patient safety
are largely inconsistent with the major features of the civil litigation process.26
In essence, medical malpractice litigation fails to address the question of how
the profession can decrease the probability that disputes will recur.27 The con-
ditions that resulted in the error remain unaddressed, leaving others vulnerable
to the same injury.

A. System Change to Protect Future Patients

Once we accept that unsafe systems, rather than rogue professionals, are
responsible for most medical errors,28 it seems reasonable to enable injured
patients and their families to act as catalysts for system change. Unfortunately,
one inside the courtroom, patients initially motivated by a collective good,
such as a desire for improved patient safety, are required to transform that mo-
tive into a demand for individual enrichment, in the form of monetary damages.

23 Liebman & Hyman, supra note 19, at 30.
24 Hickson et al., supra note 1, at 1362 (including the “desire to prevent injuries to others” among contrib-
utory factors in the decision to file a malpractice claim); Vincent et al., supra note 1, at 1612.
25 See Michelle M. Mello & Troyen A. Brennan, Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform, 80 Tex. L. Rev. 1595 (2002) (critical analysis of studies attempting to establish
the tort system’s deterrence of negligence).
26 Edward A. Dauer & Leonard J. Marcuse, Adapting Mediation to Link Resolution of Medical Malpractice Disputes with Health Care Quality Improvement, 60 Low & Contemp. Probs. 185, 193-95 (1997) (recog-
izing the tort system focuses on “bad apples,” while quality improvement examines “how and why [an] infraction came about”).
27 See Barry C. Dorn, The Evolving Doctor, in RENEGOTIATING HEALTH CARE 237, 252 (1995) (although legal advice “makes perfect legal sense, the perversions and repercussions of malpractice fright make little sense for patient care”).
The message that unsafe systems, rather than rogue professionals, are responsible for most medical errors is gaining acceptance in New Zealand, and many complainants demonstrate insight into what is needed to protect future patients from similar harm. Even among complainants who have suffered the death of a friend or family member through an adverse event, the level of goodwill, forgiveness, and altruism is striking. For example, the daughter of a woman who died of undiagnosed liver cancer wrote: “If lessons can be learn[ed] that would be a good thing. I miss my mum immensely and do this in her memory to help raise the standard of health in our beautiful country.”

As an independent statutory agency separate from the political and policy decision-making process, the Commissioner is well placed to use patients’ desires for safer systems as a positive force for change. Individual complaint investigations frequently result in recommendations for system change. The Commissioner also seeks to contribute to quality improvement by fostering an environment that supports attorneys and protects patients. This “climate control” function is critical in an environment of increased consumer expectations and growing numbers of complaints.

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Bereaved family seeks safer prescribing practices
Mrs. P, an 80-year-old woman, had a long history of adrenal insufficiency for which she took prednisone (a steroid). Mrs. P was admitted to hospital for management of a fracture. Her physician charted the prednisone, but failed to specify the time of administration. The nurses always checked the “time of administration” column to determine which medications needed to be given, so the prednisone was overlooked for four days. Mrs. P suffered an Addisonian crisis and died. Her family’s letter to the Commissioner stated: “We ask you to investigate drug administration practices at [this hospital] and recommend changes to ensure that further deaths do not occur as a result of drug administration errors. We believe the design of the drug chart, and in particular the time column, is the prime cause of this error not being detected. We believe that tangible changes need to take place. We note that [another hospital’s] drug chart is simpler. Could this be safer?” In response to such systems failures, the Commissioner may recommend, for example, that a hospital review its policies or procedures, undertake further staff training, or undergo an external audit.

A very different program, with a similar emphasis on understanding patients’ needs and learning from their experiences, was developed in Washington, D.C. The Carole Houk International (CHI) HealthCare

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29 Paterson, supra note 8, at 74–76 (providing two case studies where changes were implemented to improve patient care in pharmaceutical and hospital practices upon the recommendations of the Commissioner). Furthermore, “[c]omplaints offer a ‘window of opportunity’ to improve health services….” Id. at 75.
Ombudsman/Mediator Program supports the open disclosure of adverse events by physicians and assists the parties in equitably resolving disputes while seeking to learn lessons from what has occurred. This program has been adopted by major health care provider organizations nationwide, including Kaiser Permanente and the National Naval Medical Center. CHI estimates that Health Care Ombudsman Mediators resolve between 90% and 98% of potentially compensable events without legal action. Participant organizations have reportedly reduced their malpractice claims by 20% to 40%. Carole Houk reports: “Lessons learned from cases are analy[z]ed and translated into immediate recommendations to facilitate improvements in patient care delivery and reduce medical errors.”

B. Competence Review

Sometimes the desire for corrective action is focused at the level of the individual, rather than the system. Nevertheless, the focus remains on protecting future patients from harm, rather than punishing the health care professional.

The New Zealand system draws a clear distinction between the concepts of competence review and professional discipline. Professional registration bodies, such as the New Zealand Medical Council and the Nursing Council, are authorized to carry out competence reviews to assure that practitioners have the requisite skills, knowledge, and attitudes to practice safely. Competence reviews have an educative, rehabilitative focus and, while rarely welcomed by practitioners, they are not intended to be a punitive measure. Providers who are impaired by illness or addiction come within the jurisdiction of the Medical Council’s Health Committee and are offered appropriate support and treatment until they are able to resume safe practice.

Parents of a stillborn child seeking a competence review

Ms. L’s pregnancy was at full term. She had been experiencing niggling contractions for four days. Her newly qualified midwife, working without supervision, planned to do a home birth. During a home visit, the midwife was unable to detect the baby’s heartbeat. She arranged for Ms. L to be admitted to the hospital the next day. Labor was induced and a stillborn baby was delivered vaginally. The baby had been dead only a short time and Ms. L’s general practitioner felt she should have had an emergency cesarean the previous day. Ms. L was reluctant to take medico-legal action, but eventually wrote to the Commissioner, saying: “I feel an obligation to mention these matters in case it should be felt that some wider review of the midwife’s competence is advisable.”

In the United States, the concepts of competence review and professional discipline remain closely intertwined, through the mixed function of Boards of Medical Examiners.

IV. SANCTION

The final theme, sanction, involves inflicting harm on a wrongdoer, even when such harm does not benefit the victim. Such punishment serves as vengeance, as expression of personal or social outrage, as moral dessert, and as restoration of the equilibrium between good and evil that was upset by the bad act. Unsurprisingly, the few patients who seek punitive action are often extremely angry, as illustrated by a man whose father had died from a hospital-acquired infection: “Dogs and cats at the SPCA get better treatment than this. I personally will never trust another doctor as long as I live. I don’t know how the bastards sleep at night.”

The New Zealand Commissioner acts as a gatekeeper to disciplinary processes, though these are rarely employed. A successful prosecution before the Medical Practitioners Disciplinary Tribunal can result in conditions being placed on a physician’s practice, or loss of one’s license.

Since the introduction of the Commissioner’s complaint resolution processes and educative competence reviews, there has been a fourfold reduction in the number of disciplinary proceedings against physicians. This suggests that perhaps correction, rather than punishment, had been the true underlying motive in many of these cases.

**Family seeking professional discipline after surgical death**

Thirty-nine-year-old Miss O died following surgery for a kidney angiolympoma. At the time, her surgeon was working under supervision after being found guilty of conduct unbecoming, for removing a healthy kidney from another patient. Miss O’s family members say that, had they been informed of this fact, they would have found another surgeon to perform her surgery. In their minds, professional discipline was the appropriate response to this transgression: “He was supposed to be a specialist in his field, and we put our faith in this man believing she would recover—never again will we make that mistake. What I would like to see come out of this is the doctor being struck off the medical record.”

Disciplinary proceedings are not the only form of punitive action available to patients. The need for sanction also may be satisfied by adverse media publicity or other injury to a health professional’s reputation. When formal processes for sanction are perceived to fail them, some patients may even take matters into their own hands.
Family seeking sanction after father dies of undiagnosed aneurysm

Mr. H, a 62-year-old man, collapsed at home and was brought to the hospital by ambulance. On admission, he was pale and sweaty with a blood pressure of 80/65 and severe abdominal pain. Without taking a history from family members who had witnessed the collapse, a junior emergency department physician diagnosed Mr. H with postural hypotension and suggested that he could be discharged home. Mr. H’s wife of 40 years was very concerned about his condition and insisted that he be admitted overnight for observation. Mr. H died the next day. A post-mortem revealed a ruptured aortic aneurysm. Following his death, the family wrote: “How can this man call himself a doctor? What right did he have to let dad die and not even give him a chance to live? If this means that he has to be severely reprimanded for malpractice then so be it.” In this case, the Commissioner was unable to take further action as the physician left the country without leaving the Medical Council or his former employer with a forwarding address.

V. DISCUSSION

Although New Zealand and the United States have a good deal in common linguistically, culturally, politically, and to a great extent legally and medically, differences caution against applying New Zealand’s experiences to the United States without careful thought. For example, the New Zealand compensation and complaints processes exist simultaneously with a publicly funded health care and accident compensation system that is radically different from the patchwork of coverage policies in the United States. Thus, the economics of claiming and complaining in the two countries are substantially different.

Nevertheless, the New Zealand experience offers important support for the hypothesis that money is not the sole remedy patients seek in the aftermath of an injury. Nor is money the most important thing physicians can offer to injured patients. The financial cost of an injury can be compensated in many ways, including health insurance, disability insurance, and so on. Following an adverse event, physicians are in a unique position. They may offer an explanation and an apology, and they have the ability to implement change. Such remedial measures are intangible goods of enormous value to the injured patient and his or her family.

32 See generally Hickson et al., supra note 1 (discussing several factors, in addition to money, that may contribute to the decision to file a malpractice action).
The optimal approach to medical malpractice reform may depend on how the four motivations are related. However, they may be fully distinct. Within any population, some injured patients may pursue restoration, some punishment, some correction, some communication, some more than one, and some nothing. The hypothesis that patients may pursue a non-monetary remedy might be termed a “weak claim.” This hypothesis picks up the observation that a system offering only compensation fails to effectively and efficiently satisfy some of its participants.

Another view is the “strong claim.” It hypothesizes that some of the injured population considers the four motives partially interchangeable: if one is satisfied, then across that same population the need to satisfy any of the others is reduced. There is considerable empirical support for parts of the strong claim, though the particulars require some working out. It is well established, for example, that apologies, as a form of communication, reduce the perceived need for compensation, and that disclosure of an error, accompanied by expressions of responsibility, using another form of communication, reduces both the demand for compensation and the demand for punishment. Finally, punishment often serves only as a means to correction, such as the prevention of repeated errors.

The strong claim does not say the four forms of accountability are identical or perfect substitutes; there always will be people who need compensation, and others who consider effort to effect system change futile. However, if the strong claim is correct, society’s choice of dispute resolution mechanisms may influence a patient’s objectives. Thus, if money is the only legal remedy available, that is what a patient must demand. If monetary damages beyond compensation for economic losses are unavailable, as in New Zealand, the patient may redirect energy into understanding the causes of the injury and attempting to ensure safer care for others. An approach that responds to patients with effective communication and correction may reduce the need for restoration or sanction.

An important implication of the New Zealand experience is that a shift from fault to no-fault in the United States cannot be undertaken without careful attention to both functions. A compensation system alone, however well-intended, cannot address all patients’ concerns, and any move to an administrative compensation system may require simultaneous reshaping of regulatory processes. The nature of such reform is worthy of more discussion than the brief mention we offer here, but is an area in which the lessons of New Zealand’s approach are worthy of heed.

34 See generally Dauer & Marcus, supra note 26, at 205-12 (examining cases where a pilot mediation program, using face-to-face patient/physician discussion, settled potential negligence claims).
CONCLUSION

People who take medico-legal action after a medical injury display several motivations, all captured by four aspects of accountability: restoration; correction; communication; and sanction.

In a tort-based system, where money is effectively the only remedy available to injured patients, a demand for damages may serve merely as an instrument by which another motivation can be satisfied. Because courts use a limited number of norms to evaluate a more circumscribed universe of relevant facts, the needs of the parties and their wishes for the future become almost irrelevant to the solution.\textsuperscript{35} The voice of patients is not used to improve health services as effectively as it could be, and important opportunities for learning continue to be lost.

In the United States, COPIC’s 3Rs program, the Massachusetts Voluntary Mediation project, and CHI’s Healthcare Ombudsman/Mediator Program demonstrate some of the benefits of innovative dispute resolution processes, even within the American context. By providing compensation where compensation is called for, and addressing other intangible needs appropriately, the interests of patients, physicians, and the public may be better served.

The New Zealand experience with no-fault injury compensation has long been of interest to torts scholars, health care policy analysts, and others in the United States, where a flirtation with no-fault has been persistent if episodic.\textsuperscript{36} By separating financial compensation from other forms of accountability, the New Zealand system is able to distinguish effectively between injured patients’ tangible and intangible needs, and respond effectively to patients’ desire for sanction, restoration, correction, and communication.

\textsuperscript{35} William L.F. Felstiner et al., The Emergence and Transformation of Disputes: Naming, Blaming, Claiming . . . , 15 Law & Soc’y Rev. 631, 647-48 (1980) (stating “[c]ourts . . . may transform the content of disputes because the substantive norms they apply differ from rules of custom or ordinary morality”). Felstiner et al. argues courts transform disputes by individualizing remedies by, for example, awarding money damages when similar plaintiffs may desire increased safety in defective product manufacture. Id. at 648.

\textsuperscript{36} See generally Richard Gaskins, The Fate of “No-Fault” in America, 34 Victoria U. Wellington L. Rev. 213 (2003) (discussing the history of no-fault proposals in the United States, comparing such proposals to the success of New Zealand’s Accident Compensation Commission).
Accountability sought by patients following adverse events from medical care: the New Zealand experience

Marie Bismark, Edward Dauer, Ron Paterson, David Studdert

ABSTRACT

Background: Unlike Canada’s medical malpractice system, patients in New Zealand who are dissatisfied with the quality of their care may choose between 2 well-established medico-legal paths: one leads to monetary compensation and the other to nonmonetary forms of accountability. We compared the forms of accountability sought by patients and families in New Zealand who took different types of legal action following a medical injury. This study offers insights into the forms of accountability sought by injured patients and may help to inform tort-reform initiatives.

Methods: We reviewed compensation claims submitted to the Accident Compensation Corporation (ACC), New Zealand’s national no-fault insurer, following injuries associated with admission to a public hospital in 1998 (n = 582). We also reviewed complaint letters (n = 254) submitted to the national Health and Disability Commissioner (HDC) that same year to determine the forms of accountability sought by injured patients. We used univariable and multivariable analyses to compare sociodemographic and socioeconomic characteristics of patients who sought nonmonetary forms of accountability with those of patients who claimed compensation.

Results: Of 154 injured patients whose complaints were sufficiently detailed to allow coding, 60% sought corrective action to prevent similar harm to future patients (45% system change, 6% review of involved clinician’s competence) and 40% wanted more satisfying communication (54% explanation, 10% apology). The odds that patients would seek compensation were significantly increased if they were in their prime working years (aged between 30 and 64 years) (odds ratio [OR] 1.66, 95% confidence interval [CI] 1.14–2.41) or had a permanent disability as a result of their injury (OR 1.75, 95% CI 1.14–2.70). When injuries resulted in death, the odds of a compensation claim to the ACC were about one-eighth those of a complaint to the HDC (OR 0.13, 95% CI 0.08–0.23).

Interpretation: Injured patients who pursue medicolegal action seek various forms of accountability. Compensation is important to some, especially when economic losses are substantial (e.g., with injury during prime working years or severe nonfatal injuries). However, others have purely nonmonetary goals, and ensuring alternative options for redress would be an efficient and effective response to their needs.

Patients who sue for clinical negligence do so for a variety of reasons. Surveys of plaintiffs in the United Kingdom7 and the United States12 suggest that monetary compensation is frequently not the primary goal. Explanations of what happened and assurances that care will improve appear to be highly valued objectives. A sceptical view of these findings is that, regardless of how litigants may describe their reasons for taking medico-legal action, they have elected to seek money by filing a lawsuit and alleging negligence. The critique is plausible, but it highlights a larger problem: in countries where litigation is the dominant avenue for obtaining redress for perceived problems with care, patients have little choice other than alleging negligence and suing for monetary damages, whatever the specific nature of their concern. These are extremely difficult environments in which to disentangle the different forms of accountability sought by those taking medicolegal action.

In New Zealand, the task is simpler. Patients reveal their preference for monetary or nonmonetary remedies by the choice of legal action they pursue. Those seeking monetary compensation file claims with the Accident Compensation Corporation (ACC), which awards compensation on a no-fault basis.1 Claims data are analyzed and shared with providers in an anonymous form to support improvements in patient safety. Those seeking nonmonetary remedies may complain to an independent Health and Disability Commissioner (HDC), who resolves complaints by advocacy, investigation or mediation; acts as a gatekeeper to disciplinary proceedings; and disseminates findings so that lessons can be learned.7 The processes are separate and designed to meet different patient objectives. They are also highly accessible.

We analyzed ACC claims and HDC complaints from patients who had experienced verifiable injuries due to medical care. Our goals were 2-fold: to determine the forms of accountability sought by injured patients and to test for systematic differences between the characteristics of patients who sought monetary and nonmonetary relief.

Methods

The ACC and the HDC provided us with national data sets of all filed claims and complaints that related to care associated
with admissions to public hospitals in New Zealand in 1998. The filing dates ran through to June 30, 2004. This allowed at least 5.5 years for patients to initiate medicolegal action — a conservative window given that virtually all activity in New Zealand occurs within 2 years.

In 1998 more than 50,000 patients experienced adverse events in New Zealand hospitals (Fig. 1). An adverse event was defined as a prolonged hospital stay or disability after discharge that was due to medical care as opposed to the underlying disease process.\(^2\)\(^7\)

The ACC sample consisted of 1148 claims. ACC adjudicators had determined that 582 (50.7\%) of the claims involved adverse events. A pilot study of compensation decisions established good interrater reliability between ACC adjudicators and New Zealand Quality of Healthcare Study reviewers.\(^2\)\(^3\)\(^4\)

The HDC sample consisted of 398 complaints. We obtained the administrative files on these complaints, which typically included the original letter of complaint, a copy of the patient’s medical record and information obtained through any further investigations by the HDC. Next we determined which of the complaints involved adverse events. We reviewed relevant administrative information using an established implicit review methodology.\(^5\)\(^6\)\(^7\)\(^8\)\(^9\)\(^10\) A total of 254 complaints (63.8\%) were judged to involve adverse events.

To test the reliability of this review, a second lawyer-doctor with extensive experience in adverse event reviews independently assessed a random subsample of 98 complaints, a quarter of the sample. Interrater reliability for determination of adverse events was excellent (estimated kappa value = 0.84).

Ninety-seven (38.1\%) of the letters of complaint contained cursory information that did not permit identification and categorization of the type of accountability sought by the complainants. The rest of the letters (n = 157) were independently reviewed. The type of accountability sought was divided into 4 nonmutually exclusive categories, each with 2 subcategories. The categories, the bases of which have previously been described,\(^11\) are designed to delineate different forms of accountability sought by the patient: communication (explanation or apology, expression of responsibility), correction (competence review or system change to protect future patients), restoration (compensation or intervention) and sanction (punishment or discipline). The coding by the reviewers matched for 132 of the 157 complaints. For the remaining 26 complaints, 1 or more of the selected categories differed. The discrepancies were discussed and consensus on coding was reached for all but 3, which were added to the group that had insufficient information to support accurate coding.

We compared the characteristics of ACC claimants with HDC complainants. Patients who pursued remedies in both arenas (n = 65) were included in the claimant group. We also treated HDC complainants who sought only monetary remedies (n = 15) as claimants. (In other words, these patients were reassigned to the path that better matched their statements, because the HDC does not serve a compensatory func-

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**Fig 1:** Identification of patients who filed claims and complaints that related to care associated with admissions to public hospitals in New Zealand.
tion in the New Zealand system.) These adjustments resulted in a reclassification of 75 complainants as claimants (5 patients were in both groups).

We used Student's t tests to compare continuous age variables and Fisher's exact tests to compare all other characteristics of complainants and claimants. We used logistic regression analysis to explore multivariable differences between the 2 groups. The dependent variable in the model distinguished claimants from complainants. The independent variables were sex, ethnic background (Maori, non-Maori), patient age (newborn, 1–17 years, 18–29 years, 30–64 years, 65–74 years and 75 years or older) and disability (temporary, permanent or death). An additional covariate provided a measure of the patient's socioeconomic status using the New Zealand Index of Deprivation Score. This index, based on small geographic areas, combines 9 census variables reflecting aspects of material and social deprivation. Following previous studies, index scores were separated into quintiles for analysis. The level of significance was set at 5% and no adjustment was made for multiplicity.

This study was approved by the Wellington Ethics Committee and the Harvard Institutional Review Board. All identifying patient details have been changed or removed to protect their anonymity.

**Results**

Table 1 shows the number of HDC complaints by accountability category and subcategory. Table 2 provides examples. About 50% of the complainants articulated a desire to ensure that no one else suffered a similar harm. In general, patients and families demonstrated high levels of goodwill, public interest and altruism. Typical comments included: "I hope that this complaint makes a difference for the treatment of others" and "We certainly wouldn't want anyone else to go through what we went through." Of the 48 complainants who had experienced the death of a friend or family member from an adverse event, 28 (58.3%) stated altruistic motives for complaining, and 4 (8.3%) sought sanctions against the clinician involved. Nearly half of the complainants (49%) sought an explanation of the events that led to their injury. Many of them questioned whether there was anything they themselves could have done to prevent the harm.

Such clarification seemed particularly important to the families of infants and children who had been harmed by medical care: 60.0% (12/20) sought an explanation, compared with 30% of other complainants. This was the only subgroup of patients for whom a desire for communication was mentioned more frequently than a desire for correction. For example, the mother of a child who died of carbamazepine-induced liver failure wrote: "Nothing can ease my pain over my inability to tell him that I did try to save him. I require answers in order to come to terms with the death of my son."

A smaller number of complainants sought other forms of communication. One in 8 patients wanted an apology or assurances that someone had accepted responsibility. Although the HDC's function is not to award monetary damages, 18% of complainants mentioned a desire for compensation. Of these, 54% sought nonmonetary relief as well. Overall, 25.6% of the complainants in the sample (65/254) filed a compensation claim with the ACC before, during or after filing with the HDC.

Although patients in New Zealand who wish to initiate disciplinary proceedings against doctors must do so through the HDC, 12% of complainants sought disciplinary action or punitive measures.

**Characteristics of claimants and complainants**

Analyses identified several significant differences between patients who sought monetary and nonmonetary remedies (Table 3). Those who sought monetary compensation (claimants) were younger than complainants (44 v. 48 years, p = 0.02). Two discrepancies drove this age difference: a comparatively large proportion of claimants in the 30–64 year age group (60% v. 43%) and a comparatively large proportion of complainants in the older age groups.

Claimants were also more likely than complainants to have experienced permanent disability from their adverse event (41% v. 21%, p < 0.001); cases in which the patient died, on the other hand, were more common among complainants (4% v. 33%, p < 0.001). Among patients for whom data on their ethnic background were available, the proportion of Maori patients was lower among complainants than among claimants (9% v. 16%, p = 0.03).

Age and disability differences persisted in the multivariable analysis (Table 4). The odds that patients would seek compensation for their injury were significantly higher if they were aged between 30 and 64 years (odds ratio [OR] 1.66, 95% confidence interval [CI] 1.14–2.41) and had permanent

<p>| Table 1: Forms of accountability sought by complainants following adverse events |
|----------------------------------|------------------|</p>
<table>
<thead>
<tr>
<th>Form of accountability</th>
<th>No. (%) of complainants*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
<td>61 (39.6)</td>
</tr>
<tr>
<td>Explanation</td>
<td>52 (33.8)</td>
</tr>
<tr>
<td>Apology, expression of responsibility</td>
<td>15 (9.7)</td>
</tr>
<tr>
<td>Correction</td>
<td>77 (50.0)</td>
</tr>
<tr>
<td>Lessons learned, system change</td>
<td>70 (45.4)</td>
</tr>
<tr>
<td>Review of provider's competence</td>
<td>10 (6.5)</td>
</tr>
<tr>
<td>Restoration</td>
<td>34 (22.1)</td>
</tr>
<tr>
<td>Compensation for economic losses</td>
<td>28 (18.2)</td>
</tr>
<tr>
<td>Intervention with care or waiting lists</td>
<td>6 (3.9)</td>
</tr>
<tr>
<td>Sanction</td>
<td>19 (12.3)</td>
</tr>
<tr>
<td>Professional discipline</td>
<td>13 (8.4)</td>
</tr>
<tr>
<td>Other punitive measure</td>
<td>8 (5.2)</td>
</tr>
</tbody>
</table>

*Percentages do not add up to 100 because complainants could seek more than 1 outcome.
impairment as a result of their injury (OR 1.75, 95% CI 1.14–2.70). When injuries resulted in death, the odds of a claim were about one-eighth those of a complaint (OR 0.13, 95% CI 0.08–0.23).

**Interpretation**

In this study, we found that patients who pursued legal action in the aftermath of medical injury displayed a range of objectives that fall under 4 categories of accountability: communication, correction, restoration, and sanction. Those who sought nonmonetary relief were primarily interested in better communication and correction. Injury during prime working years and severe nonfatal injuries were associated with higher odds of seeking monetary compensation.

The most commonly sought form of nonmonetary accountability, raised by some 50% of complainants, was the desire for corrective measures to address the causes of harm. This finding underscores the growing recognition that patients can be powerful allies in the quest for safer care if they are given appropriate channels through which to voice their concerns.17,18 Another form of accountability that was frequently sought was the wish to secure information and greater transparency about what had happened. A growing emphasis on the need to disclose adverse outcomes of care may help to head off such concerns.19–21 However, with some notable exceptions, such transparency remains more of an ideal than a reality.12,23 Patients who sought nonmonetary relief also expressed a desire for restoration and sanction, although these were less prevalent factors.

Researchers have already identified severe nonfatal injury as a predictor of litigation claims.24–26 This study included the prime working years of 30–65 as an independent predictor. Access barriers are not a convincing explanation for these differences, since claim filing is free in New Zealand and does not require a lawyer. Rather, we attribute these findings to economic realities. Lost wages and serious injury are hallmarks of higher value of claims. The potential returns on filing a claim to injured patients who fit this profile are relatively large. A related explanation is that the financial needs of injured patients in these subgroups may be considerable, especially if they have dependents. It seems plausible that a threshold exists with respect to bearable monetary

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**Table 2: Examples of accountability sought by patients taking medicolegal action**

<table>
<thead>
<tr>
<th>Form of accountability</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
<td></td>
</tr>
<tr>
<td>Explanation</td>
<td>Family of woman who died of sepsis after delay in instituting appropriate antibiotic therapy following hospital transfer: “We would like this case thoroughly looked into with an explanation and our questions answered”</td>
</tr>
<tr>
<td>Apology, expression of responsibility</td>
<td>62-year-old man with paraplegia in whom extensive bedsores developed while he was in hospital for rotator cuff surgery: “Apologies are extremely important to people who are hurting and who feel that their hurts have not been taken seriously”</td>
</tr>
<tr>
<td>Correction</td>
<td></td>
</tr>
<tr>
<td>Competence review</td>
<td>Parents of baby who was stillborn after inexperienced homebirth midwife delayed hospital admission: “[We] feel an obligation to mention these matters in case it should be felt that some wider review of the midwife’s competence is advisable”</td>
</tr>
<tr>
<td>System change</td>
<td>Young mother who underwent termination of pregnancy at 21 weeks following 4-week delay in being notified that her prenatal scan showed severe congenital abnormalities: “... hope I have raised some areas of health care that need to be addressed to save others suffering”</td>
</tr>
<tr>
<td>Restoration</td>
<td></td>
</tr>
<tr>
<td>Compensation</td>
<td>40-year-old woman in whom multiple abscesses and a gangrenous nipple developed following breast reduction surgery: “I would like to be compensated for the dreadful experience I have undergone”</td>
</tr>
<tr>
<td>Intervention</td>
<td>On behalf of 75-year-old patient whose basal cell carcinoma increased significantly in size during a 9-month wait for radiotherapy services: “I would be grateful for your help expediting treatment for this lady”</td>
</tr>
<tr>
<td>Sanction</td>
<td></td>
</tr>
<tr>
<td>Professional discipline</td>
<td>61-year-old patient in whom biliary peritonitis developed in association with major bile duct injury following laparoscopic cholecystectomy: “I believe there is a case for disciplinary action”</td>
</tr>
<tr>
<td>Other punitive measure</td>
<td>Family of 62-year-old patient who died after ruptured aortic aneurysm was misdiagnosed as postural hypotension: “If this means that someone has to be severely reprimanded for malpractice, then so be it.”</td>
</tr>
</tbody>
</table>
losses due to injury. Beyond the threshold, the need for monetary compensation may become more pressing, whatever other concerns the patient may have. As important as corrective action and improved communication may be, they cannot pay bills.

The economic considerations also help to explain the preponderance of deaths among patients who filed complaints. Compensation in these cases is essentially limited to funeral expenses, unless the deceased was an earner with surviving dependents. Moreover, true restoration is impossible when a family member dies, so it is not surprising that bereaved families gravitate toward other forms of accountability.

New Zealand’s medicolegal system presents a remarkable opportunity to observe injured patients’ motives for legal action. ACC and HDC data are rich enough to help disentangle the different forms of accountability sought by injured patients. A weakness sometimes noted about the studies in the United States and United Kingdom is that they relied on survey responses from patients filing claims within a traditional litigation system.

Our data have several limitations. We ascertained the forms of accountability sought by complainants through letters of complaint, nearly 40% of which did not state one clearly or at all. Some of these complainants may not have been clear in their own minds as to what they were hoping to achieve. The direction and potential magnitude of any bias resulting from the excluded letters are unknown.

Information on ethnic background was missing for a significant number of patients, especially among the HDC complainants, and misclassification is a well-recognized problem with this type of data. The New Zealand Index of Deprivation’s use of measures based on small geographic areas to assign socioeconomic characteristics at the individual level creates the potential for measurement error. However, neither of these data limitations is likely to have led to biases in our main findings.

In pursuing legal action in the wake of an injury, patients in New Zealand vote with their feet, accessing either or both of 2 different medicolegal paths. Their behaviour reveals that injured patients seek manifold forms of accountability, many of which are predominantly or exclusively nonmonetary in nature. This implies that systems that offer litigation as the key or sole mechanism for consumers to bring strong external oversight to bear on clinicians and hospitals may not respond to the wants of many patients. In such systems, a subset of plaintiffs will resort to litigation for lack of more fitting options.

Medicolegal systems based on medical malpractice litigation allow few outlets for achieving nonmonetary goals. Money must serve as a proxy. In contrast, the New Zealand system has the capacity to offer patients different forms of accountability, including, but not limited to, financial compensation for their injuries. The offering of apologies, explanations and assurances of system change, where appropriate, may address many patients’ true concerns without the need for expensive and protracted litigation. However, for some injured patients (e.g., those for whom the financial consequences of injury are particularly devastating) nonmonetary remedies will be inadequate. They should be viewed as supplementing, not supplanting, the need for an effective compensation mechanism.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Sought monetary compensation</th>
<th>Sought nonmonetary compensation</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>365 (61.7)</td>
<td>103 (57.5)</td>
<td>0.29</td>
</tr>
<tr>
<td>Male</td>
<td>227 (38.3)</td>
<td>77 (43.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Age, yr</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>44 (42.46)</td>
<td>48 (45.52)</td>
<td>0.02</td>
</tr>
<tr>
<td>Newborn</td>
<td>28 (4.7)</td>
<td>7 (3.9)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>&lt;18 (except newborn)</td>
<td>33 (5.6)</td>
<td>13 (7.3)</td>
<td></td>
</tr>
<tr>
<td>18-29</td>
<td>76 (12.8)</td>
<td>25 (14.0)</td>
<td></td>
</tr>
<tr>
<td>30-64</td>
<td>353 (59.6)</td>
<td>77 (43.0)</td>
<td></td>
</tr>
<tr>
<td>≥75</td>
<td>72 (12.2)</td>
<td>29 (16.2)</td>
<td></td>
</tr>
<tr>
<td><strong>Ethnic background</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moari</td>
<td>45 (8.7)</td>
<td>20 (15.5)</td>
<td>0.03</td>
</tr>
<tr>
<td>Non-Moari</td>
<td>470 (91.3)</td>
<td>109 (84.5)</td>
<td></td>
</tr>
<tr>
<td><strong>Deprivation quintile (socioeconomic status)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (least deprived)</td>
<td>92 (15.5)</td>
<td>33 (18.4)</td>
<td>0.66</td>
</tr>
<tr>
<td>2</td>
<td>118 (19.9)</td>
<td>39 (21.8)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>185 (31.3)</td>
<td>47 (26.3)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>110 (18.6)</td>
<td>32 (17.9)</td>
<td></td>
</tr>
<tr>
<td>5 (most deprived)</td>
<td>87 (14.7)</td>
<td>29 (16.2)</td>
<td></td>
</tr>
<tr>
<td><strong>Disability</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n = 584</td>
<td>n = 180</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temporary impairment</td>
<td>319 (54.6)</td>
<td>83 (46.1)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Permanent impairment</td>
<td>239 (40.9)</td>
<td>37 (20.6)</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>26 (4.6)</td>
<td>60 (33.3)</td>
<td></td>
</tr>
</tbody>
</table>

*Note: SD = standard deviation.

*Unless stated otherwise.

*Calculations exclude observations with missing values. Information on ethnicity was missing for 128 patients and disability level was missing for 8 patients.
Table 4: Multivariable odds of filing a claim for monetary compensation among injured patients taking legal action*

<table>
<thead>
<tr>
<th>Variable</th>
<th>OR (95% CI) of patient seeking monetary compensation</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1.00†</td>
<td>0.76</td>
</tr>
<tr>
<td>Female</td>
<td>1.06 (0.73–1.55)</td>
<td></td>
</tr>
<tr>
<td>Age, yr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 30 or &gt; 64</td>
<td>1.00†</td>
<td>0.009</td>
</tr>
<tr>
<td>30–64</td>
<td>1.66 (1.14–2.41)</td>
<td></td>
</tr>
<tr>
<td>Ethnic background</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Maori</td>
<td>1.00†</td>
<td>0.12</td>
</tr>
<tr>
<td>Maori</td>
<td>0.60 (0.31–1.14)</td>
<td></td>
</tr>
<tr>
<td>Deprivation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (least deprived)</td>
<td>1.00†</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1.14 (0.63–2.07)</td>
<td>0.66</td>
</tr>
<tr>
<td>3</td>
<td>1.84 (1.04–3.27)</td>
<td>0.04</td>
</tr>
<tr>
<td>4</td>
<td>1.47 (0.79–2.73)</td>
<td>0.23</td>
</tr>
<tr>
<td>5 (most deprived)</td>
<td>1.22 (0.64–2.34)</td>
<td>0.54</td>
</tr>
<tr>
<td>Disability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temporary impairment</td>
<td>1.00†</td>
<td></td>
</tr>
<tr>
<td>Permanent disability</td>
<td>1.75 (1.14–2.70)</td>
<td>0.01</td>
</tr>
<tr>
<td>Death</td>
<td>0.13 (0.08–0.23)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Note: OR = odds ratio, CI = confidence interval. *Dummy variables for missing ethnic information and disability were included in the model in an attempt to retain the patients with missing values for these characteristics. However, all 8 patients with missing disability information claimed compensation, which dropped them from the model and left 794 observations (584 claimants and 180 complainants).

REFERENCES


This article has been peer reviewed.

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2.6 Realising the research power of complaints data

The New Zealand Medical Journal

Realising the research power of complaints data

Marie M Bismark, David M Studdert

...I did not want HDC just to be the ambulance at the bottom of the cliff. I wanted to help build the fence to the top of the cliff, to help make the health and disability system safer. We owe this to the people who are harmed when things go wrong.¹

Medical care is a vital ingredient in population health. However, health services research has repeatedly shown that it is also a hazardous enterprise.²⁻⁶ Fuelled by this realisation, monitoring and improvement of quality and safety has become a health policy priority in many national health systems. But efforts to achieve system-wide improvement face difficult challenges, and the harsh reality is that health care is unlikely to be much safer today than it was a decade ago.⁷⁻⁷

Complaints by aggrieved patients have the potential to be an important window on healthcare quality. Each year the eight health care commissioners in New Zealand and Australia (hereafter, “Commissioners”) receive over 10,000 complaints, many of which highlight preventable adverse events. The complaints have considerable sentinel value: for every adverse event complained of, dozens more lie below the waterline.⁸ To date, however, that value remains largely unrealised.

Research into healthcare complaints

Commissioners have embraced a culture of quality improvement, including the time-honoured mantra that “every defect is a treasure”. They frequently acknowledge that there are valuable lessons to be learnt from their caseloads, and appear committed to using complaint resolution processes as a mechanism to facilitate improvements in the health services. Nonetheless, the fact remains that complaints data is rarely subjected to empirical research.

Commissioners’ annual reports¹⁰⁻¹⁵ typically contain statistics describing general features of the jurisdiction’s overall caseload, and present case studies to illustrate particular themes. But there are few examples of more comprehensive analyses of complaints. Several years ago, we partnered with the New Zealand Health and Disability Commissioner to conduct a pair of studies of complaints: one investigated patients’ motives for lodging them and the other analysed disparities in complaint-lodging behaviour.⁹¹⁷

Several studies in the United States have used complaints data to analyse quality problems arising in long-term care¹⁸ and acute care.¹⁹ In addition, there have been two notable studies of complaints in Australia: a survey of complainants to the New South Wales Health Care Complaints Commission¹⁰ and a retrospective analysis of patient complaints in 67 Victorian hospitals.²¹

Temolokovski and Callaghan’s study joins this small but growing literature. One common thread running through this body of work is that, after observing both the wealth of information available in complaints and the paucity of previous research, investigators are consistently moved to conclude that the data are vastly under-
appreciated and underused as a quality improvement tool. Temolkovski and Callaghan make a similar point. We agree. Why does this situation exist?

**Barriers**

Several logistical and methodological hurdles have traditionally barred progress in using complaints and other types of medicolegal data to study healthcare quality and safety. First, rigorous analysis of complaints demands the application of public health methods, with the right blend of quantitative and qualitative research skills. This means moving beyond analyses of single cases to appropriately aggregated samples that permit statistically reliable identification of patterns and trends.

The technical expertise needed to conduct this work is not ordinarily found in Commissioners’ offices. More importantly, pressing operational commitments and a lack of resources inhibit opportunities to get this type of research off the ground.

The result is a curious situation: Commissioners are swimming in information that could be used to inform improvements in care, and potentially even reduce their caseload in the medium- to long-term, but they lack the means by which to organise and deploy their data toward those ends. Like busy clinicians, Commissioners and their staff are frequently so “immersed in the narrative” of individual patient stories that it becomes difficult to lift their gaze to examine population-level questions.

Second, confidentiality concerns limit researchers’ access to complaints data. As Temolkovski and Callaghan note, fewer than 10% of complaints received by the Health and Disability Commissioner result in an investigation with publicly reported (albeit anonymised) findings, and the basis for selecting those complaints is unclear.

Most of the information compiled and generated during complaints processes is held tight, and appropriately so, because complaints files contain private medical information and sensitive legal documents. A leak of confidential information into the public domain could undermine confidence in the entire system.

Third, as health services researchers are quick to point out, complaints data are unrepresentative of broader quality problems in health care. This is undoubtedly true. Complaints are “biased” in the sense that they are refracted through the lens of patients’ behaviour.

Some patients who experience adverse events will initiate medicolegal action, but most will not. Moreover, some patients complain in the absence of any identifiable decrement in quality, creating a degree of “noise” in complaints data. The direction of some of these biases is predictable. For example certain specialties, such as surgery where adverse outcomes tend to be more severe and readily identifiable, generate disproportionately large numbers of complaints.

Similarly, sources of dissatisfaction with care that are highly visible to patients—communication breakdowns, for example, or breaches of informed consent—are staples in medicolegal caseloads. In addition, there is reasonable evidence to suggest that older patients and those with lower socioeconomic backgrounds are less likely to complain when adverse events occur.\(^9,23\)

While it is important to recognise that complaints data is prone to being skewed in these directions, it does not follow that this feature undoes the value of such data.
Rather, it means that the nature and extent of quality problems identified through complaints should be interpreted carefully, and only ever construed as a partial indicator of the overall standard of health care. Complaints should not, for example, be used as a proxy for the incidence or prevalence of particular adverse events in healthcare systems. But within selected types of adverse events, complaints and other medicolegal events may still offer excellent insights into causal factors.

A final methodological hurdle is that, despite intensive efforts by the World Health Organisation and others to develop taxonomies for adverse events generally, uniform coding methodologies for complaints are lacking. Temelkovski and Callaghan’s suggestion that the “systematic reporting formats” would greatly improve research in this area is on the mark. We believe the benefits could go even further and help stimulate research interest in complaints.

**Benefits**

For researchers able to navigate the barriers to analyses of complaints data, the rewards may be large. In particular, several features of complaints data boost their value in understanding and improving quality.

**A “consumer-initiated” adverse event reporting system**—Complaints are one of the few reliable sources of information on problems in healthcare delivery that worry patients most. Patients often struggle to have their voices heard in debates over quality and safety.

A sustained, public health focus on the content of complaints meets that concern head on. Some of the same biases in complaints data that worry epidemiologists may actually be strengths if they run in the direction of flagging the kinds of systemic failings that matter most to consumers.

**Aggregation**—For events that are infrequent but disastrous, such as wrong site surgery, complaints play a powerful triaging role. Commissioners’ caseloads are able to draw together collections of relatively rare events from across entire healthcare systems, producing concentrated clusters of problems that institution-based adverse event reporting systems or random chart review audits never could.

For some types of events, there may be enough descriptive information about how different types of error occur to guide the design of successful interventions; others may require case-control analyses (using the complaints as cases, and uninjured patients who underwent the same procedure as controls) to illuminate appropriate interventions.

**Concordance with patients’ desire for lessons to be learnt**—Patients with incurable diseases often hope that lessons can be learnt from their suffering to help ease the pain of other patients and families. Hear, for example, the father of a family afflicted by Huntington’s disease speaking of his decision to donate his son’s brain to the New Zealand Brain Bank: “It's not going to help young Chris. It's too late for my boys but it will help someone else”.

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The motivations of many patients and families who seek redress through complaints systems bear striking similarities to this sentiment. They desire that lessons are learnt so that other patients will not have to suffer a similar harm.\footnote{67}

For example, Dale Ann Micalizzi, the mother of an 11-year-old who died during ankle surgery, explains her decision to take medicolegal action following her son Justin’s death: “We weren’t interested in money. We didn’t want to retaliate. We just wanted answers. I don’t want this to happen to somebody else.”\footnote{28}

In such cases, assurances that one’s negative experience will be analysed alongside other similar experiences with the objective of improving quality of care broadly could provide families with a form of satisfaction that even optimal handling of their particular case will not.

**Conclusion**

Systems for receiving and adjudicating healthcare complaints today are built around legal procedure and analysis. There is assiduous attention to due process and consumer rights. It is a culture well-matched to the statutory purpose of complaints resolution and the standard training of Commissioners. However, the enormous potential for well-designed analyses of complaints to improve quality and safety opens up new possibilities for complaints systems.

Commissioners are well-placed to pursue a parallel set of activities focused on drawing lessons for preventing harms from population-level analyses of complaints data. In New Zealand, that role would be consistent with the Commissioner’s statutory purpose of “protect[ing] the rights of health consumers and disability services consumers”,\footnote{29} where a key “right” is the right to have services provided with reasonable care and skill and in a manner that minimises potential harm.\footnote{30}

How to get from here to there? To become more active agents in improving public health, Commissioners require more than ideas. They need the right technical expertise; the right resources, including information technology systems capable of effectively organising complaints data; and the right research questions, prioritised according to considerations like the burden of associated harm and the potential for remediation.

Above all, they need the political will to reimagine the role of Commissioners as guard rail builders in national health systems, not merely paramedics at the base of the cliff.

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References:

2.7 Remedies sought and obtained

Remedies sought and obtained in healthcare complaints

Marie M Bismark, Matthew J Spittal, Andrew J Gogos, Russell L Gruen, David M Studdert

Original viewpoint

ABSTRACT
In the wake of adverse events, injured patients and their families have a complex range of needs and wants. The tort system, even when operating at its best, will inevitably fall far short of addressing them. In Australia and New Zealand, government-run health complaints commissions take a more flexible and expansive approach to providing remedies for patients injured by or disgruntled with care. Unfortunately, survey research has shown that many patients in these systems are dissatisfied with their experience. We hypothesised that an important explanation for this dissatisfaction is an ‘expectations gap’; discordance between what complainants want and what they eventually get out of the process. Analysing a sample of complaints relating to informed consent from the Commission in Victoria (Australia’s second largest state, with 5.2 million residents), we found evidence of such a gap. One-third (59/188) of complainants who sought restoration received it; 1 in 5 complainants (17/101) who sought correction received assurances that changes had been or would be made to reduce the risk of others suffering a similar harm; and fewer than 1 in 10 (3/37) who sought sanctions saw steps taken to achieve this outcome initiated. We argue that bridging the expectations gap would go far toward improving patient satisfaction with complaints systems, and suggest several ways this might be done.

INTRODUCTION
In the wake of adverse events, injured patients and their families have a complex range of needs and wants. These include remedial treatment, information about what went wrong and why, an apology, monetary compensation, assurances that steps have been taken to prevent future harm and, in some cases, disciplinary action against a responsible healthcare provider. The medical negligence system focuses on one class of events (substantial injury due to substandard care) and a single remedy (monetary compensation). It is not designed to address other types of patient dissatisfaction or deliver other remedies. Indeed some of the negligence system’s core features, such as its emphasis on fault finding and the cloak of confidentiality with which it shrouds settlements, actively inhibit opportunities for patients to secure other forms of succour, such as explanations, apologies, prevention and learning.

In the Antipodes, health complaints commissions have emerged as a bold attempt to fill this void. New Zealand and all eight Australian states and territories have established state-based ‘commissions’ over the last 25 years. Commissions have statutory responsibility for receiving, investigating and resolving disputes relating to the provision of healthcare services; collectively, they handle about 10,000 complaints per year. Filing a complaint is free and legal representation is unnecessary. The role of commissions is to act impartially and resolve complaints cheaply, effectively and quickly. To achieve this, commissions deploy an impressive range of procedures (eg, advocacy, mediation and conciliation, formal investigation, referral to other agencies) and remedies (eg, explanations, apologies, monetary payments, corrective action and provider sanctions). The Australian commissions coexist with the civil liability system. In theory, patients have a choice about whether to lodge a complaint, litigate, or do both. In practice, plaintiffs’ lawyers often wait for the outcome of complaints before determining whether to take up the matter as a negligence claim. In New Zealand, medical malpractice litigation is essentially barred. In lieu of this, a system of government funded no-fault compensation operates in parallel with the Commission’s complaints processes.

In summary, commissions fill many of the gaps commentators have long lamented in
the medical negligence system. It thus comes as a surprise to find emerging evidence that commissions often fail short in meeting the expectations of patients and families who turn to them for relief. Studies from Australia,11-13 and similar schemes in other countries,14,15 have all found that a third or more of patients express dissatisfaction with how their complaint was handled.

This article probes this puzzle. We use a case study of complaints from Victoria, Australia’s second largest state with 5.2 million residents, to test the hypothesis that there may be a significant mismatch between what patients want from dispute resolution and what they get. We conclude by considering lessons for Australian commissions, counterpart agencies in other countries and other institutions (eg, hospitals, practitioner registration boards) involved in the resolution of healthcare complaints.

UNDERSTANDING EXPECTATIONS

Studies of what drives consumer satisfaction with complaints resolution processes inside14,16 and outside17-19 healthcare settings point to three dimensions of the experience: the perceived fairness of the procedures used to arrive at the outcomes, the quality of interpersonal interactions during the process and the extent to which the outcomes obtained match those sought. The third dimension, whether consumers get what they want, is a core concern in commerce20,21 but is often poorly understood in human services.

This is certainly the case for healthcare complaints in Australia and New Zealand. Only one study,11 now a decade old, has explored complainants’ expectations and the extent to which they are met. After identifying widespread dissatisfaction with the Health Care Complaints Commission in New South Wales, the authors concluded that ‘understanding what (patients) expect, as well as what they can feasibly and legitimately expect by way of resolution, may obviate some of the difficulties and disappointments revealed by our survey’.

Using data on a sample of complaints lodged with Victoria’s Commission (‘the Commission’), we identified remedies sought by complainants at the outset of their complaint and correlated them with the remedies complainants ultimately obtained.

A CASE STUDY FROM VICTORIA

Data collection and key variables

As part of a larger study of informed consent disputes between patients and doctors, we identified every complaint lodged with the Commission over a 7-year period (1 January 2002–31 December 2008) that alleged problems with the informed consent process and was serious enough to progress to conciliation. Specifically, ‘cases’ were defined as complaints in which a patient (or patient representative) alleged that the quality or quantity of information provided about a treatment prior to the patient’s decision about whether to undertake it, or the process through which the patient was asked to consider such information and make a decision, was deficient.

Details of how the informed consent complaints were identified and reviewed are described elsewhere. In summary, the Commission received 9115 complaints over the study period, 1898 (21%) of which proceeded to conciliation. Two medically-qualified reviewers screened these complaints to determine which met the study definition of a case. For those that did (n=218), the reviewers used an electronic data collection instrument to collect a range of variables about the complaint.

Variables indicating what remedies complainants sought and what remedies they obtained form the focus of this analysis. Information on remedies sought came from the initial complaint letter and responses to the following question on the Commission’s standard complaint form: ‘What do you hope to gain from lodging the complaint? What outcome are you seeking?’ Information on remedies obtained came from the conciliator’s written report on the outcome of each case.

The screening and reviews were conducted onsite at Commission offices in Melbourne between March 2009 and January 2010. The study was approved by the University of Melbourne Human Research Ethics Committee.

Typology of remedies

The instrument directed reviewers to classify remedies sought and obtained into four categories: restoration, communication, correction and sanction. This classification system has been used in previous research2 and aligns well with the range of possible outcomes publicised by the Commission.23,24

Several of the categories warrant further explanation. Although restoration includes monetary compensation, commissions have no legal powers to award monetary damages. Rather, financial settlements occur through the negotiations and dispute resolution processes that commissions oversee; this may involve reimbursement or waiver of out-of-pocket expenses, or more comprehensive forms of financial restitution, such as compensation for lost wages or pain and suffering. Commissions also do not have direct authority to sanction health practitioners and institutions, but they may act as gateways, referring matters to other medico-legal agencies that do, such as health practitioner boards. Finally, the correction remedy refers to action taken by commissions to
leverage improvements in the quality and safety of healthcare in response to particular complaints. The two main ways in which this occurs currently is through the making of formal recommendations and the targeted dissemination of findings.\(^2\)

We counted a remedy as being ‘obtained’ if it was provided in any form. In most cases, it was not possible to make quantitative determinations of the degree to which the remedy’s content matched what the complainant sought. So, for example, a complainant who sought payment and received it was counted as having obtained restoration, even though the amount obtained may have been less than what they desired.

**Reliability of complaint file review**

To test the reliability of the review, a random subsample of around 15% (n=37) of the complaints was re-reviewed by the second reviewer, who was blinded to the first review. The reviewers agreed on the remedies sought in 89% of cases and agreed on the remedies obtained in 92% of cases.

**Remedies sought**

Table 1 shows the frequency with which the four forms of accountability were sought by complainants in the study sample. The vast majority (87%) of conciliated complaints included a request for restoration. Other complaints research has identified this as an important outcome for many patients and their families, particularly those who have suffered serious financial consequences as a result of medical injury.\(^3\)

However, restoration stood alone as a remedy sought in only 25% of the informed consent complaints in our study. This finding resonates with previous research from New Zealand,\(^2\) the UK,\(^1\) the USA,\(^26\) and The Netherlands\(^14\) showing the UK place on non-monetary remedies following adverse outcomes.

Over half (57%) of complainants sought communication in the form of information about what had happened in the care breakdown, an expression of responsibility, or an apology. The desire for information and better communication is well established as a common motive for initiating medico-legal action.\(^1\)\(^2\)\(^7\)

Nearly half (46%) of all claimants sought corrective action to reduce the risk of harm to future patients. As a motivator of medico-legal action, the sentiment that that ‘this should never happen again’ has received much commentary,\(^7\)\(^28\) but only a few empirical studies have quantified its prevalence.\(^1\)\(^2\)\(^14\)

Less than one-fifth (17%) of complainants sought sanctions (in the form of disciplinary action or other punitive measures) against specific individuals or organisations.

**Remedies obtained**

Nearly all patients who sought communication got it (figure 1). This result was somewhat preordained by the fact that, regardless of what patients sought, 94% of all complaints delivered a communication-related remedy. This is because the complaints resolution process is essentially built around facilitating communication between the parties to a complaint. When a complaint is first received, staff will usually encourage the complainant to discuss his or her concerns directly with the health service provider involved. If that is unsuccessful in resolving the matter, written correspondence from the Commissioner’s office may follow, inviting the provider to respond to the complaint. If the complaint is still unresolved, mediation or conciliation may follow, which the main parties typically attend (and all of the complaints in our sample went to conciliation). At any of these points in the process, complainants may receive additional information about what happened to them and why, answers to their questions and perhaps an apology.

By contrast, a large ‘expectation gap’ was evident in relation to the other three types of remedies. A third (59/189) of complainants who sought restoration received it; 1 in 5 complainants (17/101) who sought

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Remedies sought in complaints regarding informed consent in Victoria (n=218)</th>
</tr>
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<tbody>
<tr>
<td>Issue</td>
<td>n (%)</td>
</tr>
<tr>
<td>Restoration</td>
<td>189 (87%)</td>
</tr>
<tr>
<td>Communication</td>
<td>124 (57%)</td>
</tr>
<tr>
<td>Correction</td>
<td>101 (46%)</td>
</tr>
<tr>
<td>Sanction</td>
<td>37 (17%)</td>
</tr>
</tbody>
</table>

*Percentages total >100% because many patients sought multiple remedies.

![Figure 1 Remedies sought and obtained in a sample of informed consent complaints in Victoria (n=218).](image-url)
correction received assurances that changes had been or would be made to reduce the risk of others experiencing a similar harm; and fewer than 1 in 10 (3/37) who sought sanctions saw processes to achieve this outcome initiated.

**IMPLICATIONS OF THE EXPECTATIONS GAP**

Of all dimensions of complainants’ experiences, the outcome may be the strongest determinant of overall satisfaction. Summers and Granbois have described consumer dissatisfaction as “a function of the comparative level of consumers’ expectations and their actual experiences of goods and services”. Our study suggests that, in the field of health care, an expectations gap between the remedies sought and achieved by complainants may contribute to dissatisfaction with dispute resolution processes.

This focus on outcomes must be tempered by recognition that, while complainant satisfaction is important to commissions, it is not their only priority and they are not patient advocates. When the views of complainants are at odds with those of healthcare providers, as commonly occurs, commissions must play the role of honest broker and facilitate an outcome that is fair to all parties.

**LIMITATIONS**

Our data has several limitations. First, the complaints we examined involved conciliated disputes over informed consent in Victoria; the findings may not be generalisable. Because problems in the informed consent involve communication breakdowns, the proportion of cases seeking improved communication may be higher than other types of disputes. However, the generalisability of other aspects of our findings to other types of disputes, or to dispute resolution agencies in other states or countries, is not known.

Second, because the remedies that form the focus of our analysis came from retrospective review of written documentation, they are crude in some respects. For example, complainants may have ‘unspoken’ expectations, and certain outcomes of conciliation may not have been recorded in the conciliator’s final report. Third, we recorded only the presence or absence of various remedies obtained, not qualitative aspects of their nature (eg, the completeness of an explanation, sincerity of an apology, or adequacy of a payment), which undoubtedly affect the extent to which patients’ expectations are met. Finally, the remedies sought by complainants were determined by statements made at the time they first lodged their complaint. Some complainants’ expectations are likely to have changed during the resolution process, as they gained a clearer picture of what happened or of the feasibility of certain remedies.

The likely effect of constraints on our inability to observe these three aspects of complaints (hidden preferences, degrees of preference satisfaction and changing preferences) on the expectations gap identified in our findings is unknown. Nonetheless, it seems implausible that accounting for these factors would eliminate all or even most of the divergence between remedies sought and obtained.

**CONCLUSIONS**

Characterisations of discontented patients as ‘greedy, angry and eager to sue when medical error occurs’ miss the mark; they do not match the complex mix of factors that motivate patients and their families to seek medicolegal redress. In the Australian healthcare system, health complaints commissions offer the broadest range of remedies and, ostensibly, are well placed to meet the heterogeneous expectations of patients who are dissatisfied with their care.

However, this breadth and flexibility is a double-edged sword. Patients’ baseline expectations on entering complaints systems may be high, and sometimes unrealistic, creating ample scope for dissatisfaction when commissions either do not have authority to meet those expectations or determine that doing so in the circumstances at hand would be inappropriate. Such ‘discordant’ outcomes may cause anger and frustration, and may lead to disillusionment with the complaints system. Our findings suggest that many complainants find, despite the range of remedies mentioned on commissioner’s websites, that ‘you can’t always get what you want’.

There are two logical ways in which this expectation gap can be narrowed: by delivering to more complainants the remedies they are seeking and by decreasing unrealistic expectations.

The first tactic requires an improved understanding of what complainants want. Frontline staff who handle complaints should be closely attuned to patients’ and families’ motives for complaint. Without this understanding, satisfaction of preferences will be a fluke. Next, wherever possible, the remedies a complainant prizes should be articulated and carefully considered during the complaint resolution process. In cases where, for example, corrective measures could be taken, the desired outcome should not be denied simply because no-one considered whether lessons could be learnt.

On the other side of the divide, there must be clear-eyed recognition within complaints agencies of the fact that, for many complainants, the complaints resolution process will not—and sometimes cannot—deliver the
remedies patients and their families seek. For example, commissions have no statutory power to sanction errant doctors and few cases are referred on for consideration in disciplinary proceedings. A dose of reality should be administered early in the process to help manage expectations and avoid unnecessary distress and disappointment. (In Victoria, for example, Commission staff strive to identify and discuss unrealistic expectations early on.)

When complaints are poorly handled, there are real risks of worsening relations between patients and providers and extinguishing opportunities for corrective action. Complaint management techniques that identify and take seriously the remedies complainants are seeking, and then coach them from an early stage through the range of feasible outcomes, could go far in bridging the expectations gap and improving satisfaction with healthcare complaints resolution processes.

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Competing interests None.

Ethics approval This study was conducted with the approval of University of Melbourne Human Research Ethics Committee.

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES
2.8 Informed choice: law, medicine and person-centred care

Informed choice: The meeting point of law, medicine, and person-centred care

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Informed choice is the process by which people are educated about a treatment decision and then make an informed and voluntary decision about the healthcare they choose to receive. But behind that simple definition lies a complex history and no shortage of controversy.

This paper is in three parts:

- The past – how did the law of informed choice evolve?
- The present – when does the process go awry in current practice?
- The future – what can doctors and patients do to support informed choice?

Past
The “con” of paternalistic deception

Informed consent is a remarkably recent development in the long history of medicine. From the time of Hippocrates through to the late 19th century, it was an acceptable part of medical practice for doctors to be authoritative, manipulative, silent, and even deceitful as long as they were motivated by “good and noble purposes”. For two thousand years the relationship between doctor and patient was dominated by two duties: first, the doctor’s duty to do what was “best” for the patient; and second, the patient’s duty to trust the doctor without question. Indeed, Hippocrates himself advised “concealing most things from the patient while you are attending to him”.

The reasons for this tradition were threefold. First, most “cures” were effected through the placebo effect and the healing power of nature. As explained by ethicist Daniel Sokol, in the context of therapeutic paucity, hope-instilling deception became an important weapon in a doctor’s remedial arsenal. Second, patients were perceived as childlike dependants who did not have the knowledge, the intellectual capacity, or the moral authority to disagree with a doctor’s decisions. The doctor’s role was to do what was “best” for the patient, and avoid any “ugly prognostications” that “might discourage the patient [or] depress his spirits.” Third, donning a mask of certainty helped doctors to maintain professional power and control over medical decision-making.

In this environment, patients were expected to follow their doctors’ advice with an attitude of respect and gratitude, while doctors refrained from informing patients of any risks or alternatives to the prescribed treatment. Paternalistic deception aimed at eliciting confidence and cooperation was the norm, and patients’ participation in decision-making was alien to the ethos of medicine.

Consent

Gradually, as medicine became more effective and more evidence-based, and the human rights movement took hold, paternalism began to be replaced with concepts of individual autonomy. However, change did not come easily. Behind each of the major legal developments in informed consent stands an ordinary person who had the courage to challenge the status quo and speak up for the right to make decisions affecting his or her own body.

Initially, “consent” involved little more than a person’s acquiescence after having been told what was about to happen. For example, in the 1797 English case of Slater v Baker a doctor initially set a man’s broken femur in accordance with usual practice, but in follow-up, he forcibly re-broke the bone and placed the re-broken bone in a mechanical device with teeth. The judge noted the procedure was out of the ordinary and stated that: “It is reasonable that the patient should be told what is about to be done to him”.

By the early 1900s the idea of unconsented medical touching being an unlawful act was beginning to take hold. In the 1914 case of Schloendoff v. Society of New York Hospital, a woman named Mary Schloendoff had consented to an “ether examination” in order to determine the nature of a lump in her abdomen. However, she expressly stated that there must be “no operation”. Her doctor examined her, found a malignant tumor, and then proceeded to remove it in total disregard of her wishes.

In response to her claim for compensation, Justice Cardozo, of the New York Court of Appeals, wrote, “Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable in damages”.

While this decision clearly established a legal requirement for doctors to obtain a person’s consent, the law did not yet require the disclosure of all relevant information.

Information

The need for consent to be properly informed was not recognised in law until after World War II. The 1947 Nuremberg Code – developed in response to medical atrocities during the
Holocaust - emphasised that research could only be carried out if a participant consented after receiving sufficient information about "the nature, duration, and purpose" of the procedure and "all inconveniences and hazards reasonably to be expected".

The term "informed consent" was coined a decade later in the 1957 case of Salgo v. Leland Stanford Jr. University Board of Trustees. As a result of an investigation for leg cramps, Martin Salgo was left paralysed below his waist. The California Court found that patients are "entitled to the full disclosure of facts necessary to an informed consent", though in a nod back to medicine's more paternalistic roots, the court allowed that "a certain amount of discretion must be employed" in deciding which risks to disclose.

In 1972, a radical development in consent law occurred in the United States. The case of Canterbury v. Spence introduced for the first time a prior considered necessary in an informed consent. Nineteen-year-old Mr Canterbury was a tyro for the FBI. He suffered from back pain, and his surgeon recommended spinal surgery. Postoperatively, he was left incontinent and unable to walk unaided—a devastating outcome for a previously healthy teenager. The judge held that "The patient's right of self decision ... can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The scope of the physician's communications ... must be measured by the patient's need."

This patient-centred approach was subsequently adopted in Australia in the case of Rogers v. Whitney. Manlove Whitney lost sight in her right eye through an eye injury at the age of nine. Prior to surgery on her blind eye, she asked several times if there was anything that could go wrong and was reassured that no serious complications were associated with the surgery. Unfortunately, she developed sympathetic ophthalmia in her good left eye and was left almost totally blind. The High Court judges agreed that the risk of total blindness, no matter how small, was material to her decision and it was negligent not to advise her of that risk. As in the case of Canterbury v. Spence, the test of "materiality" in Rogers v. Whitney was clearly patient-centred: "a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it."

Present

Over the four decades that have passed since Canterbury v. Spence, the requirement for informed consent has become firmly entrenched in law and is now explicitly specified in most codes of good practice for health professionals. (Although in some jurisdictions the tussle between patient-centred and doctor-centred standards of disclosure continues.)

However, despite an outpouring of medical, ethical, and legal writing on informed consent, there remains remarkably little empirical information on how the process actually functions in clinical practice, including the circumstances in which informed consent goes awry.

Not just a signature on a form

We do know that many informed consent procedures have developed to protect the interests of health practitioners, and protect them from medico-legal risk, rather than meet the needs of patients and their families. In many healthcare settings there has been an emphasis on documentation to the detriment of good quality decision-making.

Many informed consent documents are legalistic, vague and uninformative. For a patient or family member who is already feeling frightened and vulnerable, quickly signing and pushing the form away may feel safer than struggling to work through language and concepts that they are ill-equipped to understand. In the United States, research has found that fewer than 20% of patients have the literacy skills required to understand typical informed consent materials. It is therefore unsurprising that within a day of signing an informed consent form nearly half of patients cannot recall the exact nature of the planned operation nor correctly list the major risks.

Indeed, many patients believe that consent forms are meant to "protect the physician's rights." Instead of fostering a dialogue between the doctor and patient, the informed consent process can potentially interfere with the relationship if the focus is placed on completion of forms and decreasing legal liability.

Internationally, there is significant variation in the extent to which people are informed about and involved in decisions regarding their own healthcare. In Japan, for example, some doctors continue to hold the view that patients should not be informed of an incurable cancer diagnosis, or at least not until their family members have been informed and agreed to such a disclosure. In contrast, New Zealand actively promotes and protects patients' rights to effective communication, open and honest information, and an informed choice through a Code of Health and Disability Services Consumers' Rights which is enforced by law by a Health Commissioner. Perhaps it is no coincidence that, in a 2007 international survey by the Commonwealth Fund, New Zealand ranked number one for patient-centred care and patient involvement in treatment decisions.

Medico-legal information

Medico-legal data provide a valuable window into situations where the informed consent process goes awry. A review of nearly 500 litigation and complaint files in Australia, conducted by the Law and Public Health group at the University of Melbourne, found that 1 in 30 malpractice claims and 1 in 9 conciliated complaints alleged problems with informed consent. Full findings from this study will be available through the Medical Journal of Australia [http://www.mja.com.au/].

Over ninety per cent of the informed consent cases involved surgical procedures, with plastic surgeons, orthopaedic surgeons, and vascular surgeons at particularly high risk. Around three-quarters of the cases centred on the allegation that certain complications, which ultimately affected the patient, were not mentioned or properly explained prior to the treatment. These findings clearly indicate that concerns about surgical risks not properly explained are the heartland of contemporary disputes.
over informed consent, at least in Australia. By contrast, other
types of breakdowns in the informed consent process that
have attracted intense scholarly attention (such as failure to
adequately assess patient competence) appear to be infrequent
triggers of formal disputes.

The study also found that disputes over informed consent almost
never involve isolated "dignitary harms". Informed consent
concerns are usually fellow travellers with concerns that the
episode of care was substandard in other ways.

Worryingly, a number of surgeons in the study continued to
justify their failure to disclose risks on the grounds that the
patient clearly needed the operation, the doctor knew best,
and disclosing the risk would simply have worried the patient
or dissuaded him or her from having the surgery. So much for
individual autonomy!

Future

Medicine

Fifty years of informed consent laws have not fully reformed
doctor-patient communications, so it is unlikely that these brief
comments will have much of an impact on medical practice.
But, for what they are worth, our four key recommendations for
doctors are as follows:

1) Get the basics right. For ethical, legal, and clinical reasons it
is important to obtain consent and to be able to show that
such consent was obtained. However, doctors’ medico-legal
anxieties are often directed towards issues which are rarely,
if ever, the substance of a lawsuit or complaint. Our research
suggests that most lawsuits and complaints arise from a
simple failure to “get the basics right”: failure to devote
enough time to important conversations; failure to address
patients’ and families’ fears and concerns; failure to disclose
serious known risks of surgery; and failure to document
discussions. Many doctors would do well to stop worrying so
much about the medico-legal risks of informed choice and
start thinking more about clear and open communication.

2) Aim for dialogue not monologue: An informed choice requires
a two-way conversation about doctors’ hopes, doubts and
expectations and patients’ and families’ wishes and fears.
Moving away from the paternalistic past and toward the
shared responsibilities of participatory medicine requires a
willingness to adopt a wide range of communication methods
— extended discussions, personalised information sheets,
multimedia programs, and feedback techniques — so that
people can more fully understand options and incorporate
their own values and preferences into the decision. Such
approaches may initially seem time-consuming and
expensive, but the time costs are much less than the costs of
unwanted interventions or unanticipated complications.

3) Understand that trust is built on honesty not infallibility.
From the perspective of many patients and families, the
best doctors are often those who have given up the mask of
certainty in order to truthfully acknowledge medical
uncertainties. Such openness is not an admission of
weakness, but rather a sign of strength and trustworthiness.
In the words of Laurence Peter: “Some problems are so
complex that you have to be highly intelligent and well-
informed just to be undecided about them.” Impossible
promises — even implicit ones — leave people with a sense of
distrust that is difficult to reverse.

4) Commit to open disclosure of any risks that do occur. Warning
people of all the significant risks that might arise before
they choose to accept a certain treatment or procedure is
only the first step in an ongoing process. Equally important
is a commitment to openly disclose any risks that actually
do materialise during or after a treatment or procedure. We
would encourage doctors to commit to the timely and truthful
disclosure of any subsequent adverse events as a standard
part of the informed choice process.

“What does this mean for me and my family?”

And finally we turn to the question of most importance to
patients and families as they negotiate complex healthcare
systems: “What does this mean for me (or my family member)?”
We suggest three ways in which consumers can improve the
process of informed choice.

1) Speak up about your concerns, questions, and what’s
important to you. In order to be enabled, empowered and
engaged you need to understand the choices before you.
It is quite reasonable to ask — not just about general risks
— but about those risks might apply in your own personal
situation. How much experience has your doctor had with
this type of procedure? How does your individual risk differ
from the general population? How would you fare with a less
invasive alternative to a given surgical procedure?

2) Seek and use high-quality health information: There is a
wealth of health information available online (some sites
are more accurate and accessible than others) and through
patient and family support groups which can help you
to understand the available options, and how they might
interface with your views, values, and preferences. For
those of you who haven’t seen it yet, we highly recommend
e-patient Dave’s “Let Patients Help” talk (www.ted.com/talks/
dave_debstock_red_meat_n_patient_dave.html) as an example
of the extraordinary impact that personal data and high
quality information can have on a person’s health choices.

3) Recognise that you have a right to partnership in decision-
making: During every healthcare encounter it is worth
remembering that two thousand years of medical tradition
have encouraged doctors to offer certainty and reassurance,
and to withdraw behind a curtain of silence rather than
discuss doubts and concerns. But the reality is that technical
issues are only some of the determinants that impinge on
healthcare choices. How can a doctor act “for your own good”
unless you both understand what your personal “good”
might be? So speak up, speak out, and aspire for not just
informed consent, but informed choice.
Acknowledgements

We acknowledge the contribution of David Studdert and other members of the University Law and Public Health Group. We thank Beth Wilson, the Health Services Commissioner of Victoria, and Avant for supporting research into informed choice in Australia. We are also grateful to Dave de Broukert, Regina Holliday, Helen Haskell, and all of the other patients, families and health practitioners who contributed their ideas towards this paper.
Legal disputes over informed consent for cosmetic procedures: A descriptive study of negligence claims and complaints in Australia

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Summary  Background: Plastic surgeons and other doctors who perform cosmetic procedures face relatively high risks of malpractice claims and complaints. In particular, alleged problems with the consent process abound in this area, but little is known about the clinical circumstances of these cases.

Method: We reviewed 481 malpractice claims and serious health care complaints resolved in Australia between 2002 and 2008 that alleged failures in the informed consent process for cosmetic and other procedures. We identified all “cases” involving cosmetic procedures and reviewed them in-depth. We calculated their frequency, and described the treatments, allegations, and outcomes involved.

Results: A total of 16% (77/481) of the legal disputes over informed consent involved cosmetic procedures. In 70% (54/77) of these cases, patients alleged that the doctor failed to disclose risks of a particular complication, in 39% patients claimed that potential lack of benefit was not explained, and in 26% patients allegations centred on the process by which consent was sought. Five treatment types—liposuction, breast augmentation, face/neck lifts, eye/brow lifts, and rhinoplasty/septoplasty—featured in 70% (54/77) of the cases. Scarring (30/77) and the need for recuperation (18/77) were among the most prevalent adverse health outcomes at issue.

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Introduction

Plastic surgeons and other doctors who perform cosmetic procedures are more likely to experience litigation or formal complaints than most other specialists.1,2 Practitioners have attributed this elevated medico-legal risk to a variety of factors, including unrealistic patient expectations, aggressive plaintiffs' lawyers,3 and inadequate pre-operative assessment4 and bad behaviour by a few substandard providers. Patient advocates and other commentators point to the commoditisation of medicine,5 promotion of suspect aesthetic norms,6 euphemistic portrayal of outcomes,7 and departure from established processes and standards for obtaining informed consent.8

A common thread in these perspectives is that the informed consent process is crucial in the context of cosmetic treatments9,10; it exerts a strong influence on both patients' perceptions of quality and doctors' risks of experiencing legal disputes. However, there is very limited empirical information on the circumstances and nature of medico-legal disputes in this area.

In a recent analysis11 of nearly 10,000 medico-legal disputes, we found that plastic surgeons were sued and complained against over consent issues at more than double the rate of any other specialty or surgical subspecialty. In this study we analyse the cases that involved plastic surgeons and other cosmetic proceduralists. Our aim was to describe the frequency, characteristics, clinical circumstances and outcomes of these cases, and inform efforts to prevent them.

Methods

Study context

Avant Mutual Group Limited (Avant) and the Health Services Commissioner of Victoria participated in the study. Avant is Australia's largest provider of medical indemnity insurance, providing coverage to more than half of the country's registered medical practitioners. The Health Services Commissioner has statutory responsibility for resolving complaints about health care providers in Victoria, Australia's second most populous state with 5.6 million residents. Complaints must be in writing but legal representation is not required. The system is impartial, free and advertised widely in health care facilities.

Case identification and study definitions

By screening 7846 medical malpractice claims and 1891 serious health care complaints resolved between 1 January 2002 and 31 December 2008, we identified 481 informed consent disputes. These disputes included 263 malpractice claims brought against doctors insured by Avant in three states (New South Wales, Victoria and Queensland) and 218 conciliated complaints lodged with the Health Services Commissioner in Victoria during the same period. Our method for determining which claims and complaints met the definition of an informed consent dispute is detailed elsewhere.12 We recap definitions of key terms here.

Following previous studies,13,14 we defined a "claim" as a written demand for compensation. "Conciliated" complaints are those the Health Services Commissioner considered too complex or serious to be resolved through facilitated communication alone, and so refers them to formal conciliation. Approximately 20% of all complaints lodged with the Health Services Commissioner proceed to conciliation.

The study definition of an "informed consent dispute" was broad: a claim or complaint that alleged a deficiency, either in the quality or quantity of information provided to the patient about a treatment prior to a decision about whether to undertake it, or in the process through which the patient was asked to consider such information and make decision. We did not seek to evaluate the merit of patients' allegations. Doing so would have required more information than was available to us, as cases were typically resolved by out-of-court negotiation or conciliation. Moreover, concerns about the consent process often co-existed with other types of allegations which influenced the final outcome.

A "cosmetic procedure" was defined as an operation or other treatment involving a non-pathological body area with the aim of preserving, restoring, or enhancing physical appearance.15 Our study sample consisted of all informed consent disputes identified in the parent study that involved cosmetic procedures (hereafter "cosmetic cases").

Case file review

In the parent study, three doctor reviewers examined the hardcopy claim and complaint files onsite at Avant offices (Melbourne, Sydney and Brisbane) and the HSC (Melbourne) between March 2009 and January 2010. The reviewers were trained on the structure and content of the case files, use of the study instrument, and confidentiality. The instrument guided collection of detailed information on each case, including patient and doctor characteristics, the episode of care at issue, and the patient's allegations.

The instrument also directed reviewers to flag cases that involved cosmetic procedures and that appeared to be cosmetic cases (hereafter "cosmetic cases").
The ethics committee at the University of Melbourne approved the study.

Statistical analysis

Our analyses are descriptive. We calculated counts and percentages for the variables of interest. All analyses were conducted using Stata SE 10.0.

Results

General characteristics

A total of 16% (77/481) of informed consent disputes involved cosmetic procedures. The patients in 88% of these cosmetic cases were female and patients’ median age was 42 years (Table 1). In nearly two thirds of cases (47/77), the practitioner against whom the allegations were made was a plastic surgeon. The vast majority (72/77) of the procedures were performed in privately-owned health care facilities.

Descriptions of the clinical circumstances involved in a selection of cases are provided in Box 1.

Treatments

The disputes arose in relation to a wide array of procedures, ranging from botox injections to major abdominal surgery (Table 2). The most common procedures were liposuction (16 cases), breast augmentation (15), lifts to the face/neck (14) or eye/brow (10), and rhinoplasty or septoplasty (13). One or more of those five types of procedures featured in 70% (54/77) of all cases.

Allegations

In 70% (54/77) of cases, the patient’s allegation was that a complication of treatment materialised that had not been mentioned or fully explained (Figure 1). This allegation was particularly common among patients undergoing abdominoplasty (5/6 cases involving this procedure). For example, one patient who underwent an abdominoplasty claimed that she “was told that the procedure was very basic and so thought everything would be alright”.

The next most common allegation was that the risk that the procedure would confer no benefit (as opposed to harm) had not been mentioned (30/77 cases). This allegation was prominent among patients who underwent rhinoplasty (8/13) and liposuction (9/16). Patients in many of these cases alleged that they had been misled by deceptive advertising and clinicians “overselling” of the procedure.

In a quarter of cases (20/77), patients alleged that the process by which consent was obtained was unsatisfactory. Such process allegations pertained primarily to situations in which patients felt rushed or pressured to proceed during the consent process. For example, one woman was “handed the consent form on the operating table”, while another was “asked to sign forms after receiving sedative medication and didn’t have her reading glasses”. Other allegations about process flaws included failures to provide written information and a refusal to provide an interpreter. Among all 77 cosmetic cases, 21 patients signed their consent forms on the day of surgery and 18 claimed to have received no written information about the procedure prior to giving consent.

In 60% (46/77) of cosmetic cases, the consent allegation was not the only complaint; it stood alongside other allegations about the quality of care rendered.

Health outcomes

Patients’ concerns pertained to a relatively narrow range of adverse outcomes (Table 3). Nearly 70% of patients complained about their appearance following surgery, including concerns about scarring, pigmentation, and asymmetry. In nearly a quarter of cases (18/77), patients were concerned about the need to undergo further surgery to deal with problems arising from their initial procedure. The next most common outcomes were pain (13 cases), nerve damage (10), and infection (9).

In addition to these physical outcomes, patients in nearly 40% (31/77) of cosmetic cases complained of anxiety or depression following their procedure.

Legal outcomes

Of the 34 malpractice claims, 26 were settled out of court (24 with payment and 2 without payment) and 7 were dropped or discontinued. The only claim that proceeded to a court verdict was decided in favour of the defendant.

Consistent with the functions and powers of the Health Services Commissioner of Victoria, a wider range of remedies was sought and obtained in conciliation, including explanations, apologies, and commitments to take

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<th>Table 1</th>
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</tr>
<tr>
<td>Primary care</td>
<td>5</td>
</tr>
<tr>
<td>ENT</td>
<td>3</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
</tr>
<tr>
<td>Facility ownership</td>
<td></td>
</tr>
<tr>
<td>Public</td>
<td>5</td>
</tr>
<tr>
<td>Private</td>
<td>72</td>
</tr>
</tbody>
</table>

a IQR = interquartile range.

b Self-identified as cosmetic surgeon, cosmetic physician, aesthetic surgeon etc.

c General surgery, ophthalmology, urology.
Box 1. Examples of patient complaints on informed consent to cosmetic procedures.

Example 1. A woman who underwent an abdominal lipectomy did not receive any detailed information about potential risks and believed it would be a straightforward procedure. Post-operatively, she suffered from a chronic wound infection, a persistent sinus requiring reoperation, severe scarring and depression.

(Type of allegation: Complication not mentioned)

Example 2. A woman who had bilateral liposuction on her thighs was still unhappy with the appearance of her thighs following the procedure. She felt that her surgeon had been dishonest about the expected outcome.

(Type of allegation: Lack of benefit not mentioned)

Example 3. A woman undergoing bilateral breast augmentation complained that her doctor was "pushy", "arrogant", and urged her to have larger implants than she wanted. Post-operatively she suffered from breast discomfort and hardening around the right implant.

(Type of allegation: Process of obtaining consent was poor)

Example 4. A woman agreed to undergo bilateral canthoplasty and injection of dermal fat into her upper lids. During the surgery, the surgeon also carried out a brow lift which she had not agreed to undergo.

(Type of allegation: Scope of consent exceeded)

corrective action. Monetary payments were made to complainants in 18 (42%) of the 43 complaints.

Discussion

In a sample of informed consent disputes drawn systematically from negligence claims and health care complaints, one in six cases related to cosmetic procedures. Nearly 90% of the patients involved were female, which is broadly in line with the proportion of cosmetic procedures performed on women. Five procedures—liposuction, breast augmentation, face/neck lifts, eye/brow lifts, and rhinoplasty/septoplasty—featured in nearly three-quarters of the cases. The most common allegations were that a particular complication or potential lack of benefit had not been mentioned, and the process by which consent was obtained was unsatisfactory. The adverse outcomes most commonly at issue were poor post-procedure appearance, the need for reoperation, pain, nerve damage and infection.

To the best of our knowledge, this is the first study of its kind. In a recent report, we described general characteristics of a larger general group of consent cases. However, there remains remarkably little empirical information on how the process of obtaining consent to cosmetic procedures actually functions—and malfunctions—at the frontlines of clinical practice. This study profiles "real world" situations in which patients undergoing cosmetic procedures perceived the informed consent component of care to have gone so poorly that they were motivated to seek relief through litigation or conciliation.

Why do cosmetic treatments feature so prominently in disputes over informed consent? Most informed consent disputes are about undisclosed risks. It seems plausible that learning the details of risks tends to matter more for patients undergoing treatments towards the elective end of the care spectrum than for those at the urgent end; and intervening on well patients for the purpose of improving or correcting natural variations is the ultimate form of elective treatment. Additionally, complications of cosmetic procedures are usually visible and out-of-pocket payments are common, further reducing patients' tolerance for risk.

After undisclosed risk, the next most common allegation was that the doctor had not painted a realistic picture of expected benefits. These allegations are likely to reflect a mix of factors: high patient expectations fuelled by the media and other cultural influences; overly optimistic portrayal of likely outcomes by practitioners; and the provision of services to vulnerable or unwell patients who are seeking a "fix" that cosmetic enhancement is unlikely to provide.

Our findings hold several messages for doctors who deliver cosmetic treatments. One message relates to the content of the pre-treatment dialogue. Informed consent is a process, not a signature on a form. Solely providing a laundry list of risks does not adequately discharge the obligation to obtain informed consent. Thus, the tricky question for busy practitioners is which risks should be

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Type of procedure in cosmetic cases.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatments</td>
<td>n</td>
</tr>
<tr>
<td>Augmentation</td>
<td>20</td>
</tr>
<tr>
<td>Breast</td>
<td>15</td>
</tr>
<tr>
<td>Lip</td>
<td>3</td>
</tr>
<tr>
<td>Penis</td>
<td>2</td>
</tr>
<tr>
<td>Cheek</td>
<td>1</td>
</tr>
<tr>
<td>Lift</td>
<td>19</td>
</tr>
<tr>
<td>Face/Neck</td>
<td>14</td>
</tr>
<tr>
<td>Eye/Brow</td>
<td>10</td>
</tr>
<tr>
<td>Buttock</td>
<td>1</td>
</tr>
<tr>
<td>Liposuction</td>
<td>16</td>
</tr>
<tr>
<td>Rhinoplasty/septoplasty</td>
<td>13</td>
</tr>
<tr>
<td>Laser/micordermabrasion/resurfacing</td>
<td>9</td>
</tr>
<tr>
<td>Injection (fillers or botox)</td>
<td>6</td>
</tr>
<tr>
<td>Abdominoplasty</td>
<td>6</td>
</tr>
<tr>
<td>Excision of moles or lesions</td>
<td>4</td>
</tr>
<tr>
<td>Circumcision</td>
<td>2</td>
</tr>
<tr>
<td>Hair transplant</td>
<td>1</td>
</tr>
<tr>
<td>Scar revision</td>
<td>1</td>
</tr>
</tbody>
</table>

a Category totals sum to more than 100% because patients in some cases had multiple procedures.
selected for discussion and emphasis. Our findings highlight several types of risks that matter to patients and which clinicians may routinely undervalue in this selection process—for example, the possibility that the treatment may confer no visible benefit, trigger the need for further surgery, or result in disfigurement, pain, or altered sensation.

Another message from our findings relates to the process through which consent is sought. In one third of cases, patients claimed they felt rushed or pressured, and in a quarter of cases the disputed consent was obtained on the same day as the procedure. The actual content of conversations about risk, however exemplary, may be irrelevant if the dialogue occurs in circumstances in which patients are not given a reasonable opportunity to hear, absorb and consider the information. Allowing some time to pass—ideally several days—between the initial discussion of risks and the procedure itself is generally desirable. The use of written information, audio—visual recordings, and other decision aids, as an adjunct to face-to-face discussions, may also strengthen the patient’s ability to make an informed decision.

Our study has several limitations. First, the line between cosmetic and non-cosmetic treatments is not always clear-cut. We excluded several cases of breast reductions and rhinoplasties/septoplasties where the indications for surgery were largely non-cosmetic. For the rest of our sample the distinction was relatively clear.

Second, we describe perceived problems with the consent process that spark negligence claims and serious complaints, but our sample may be unrepresentative of broader quality problems in this area because they are refracted through the lens of patients’ claiming and complaining behaviour. In particular, some patient allegations may be unfounded (for example, some patients fail to recall risks which were explained pre-operatively) and many instances of poor care do not result in a claim or complaint. Nevertheless, our study does provide an important “window” into those situations where cosmetic patients are sufficiently dissatisfied with the consent process to bring medicolegal action against their doctor.

Third, the generalisability of our findings to claims and complaints in legal systems in other countries is unknown. Many other countries have bodies with similar functions to health service commissions, and the Australian tort system has much in common with its counterparts in other Anglo-American countries. Future research should test
whether similar patterns of informed consent disputes over cosmetic treatments exist elsewhere.

Conclusion

The informed consent process, an integral part of modern health service delivery, takes on special importance in aesthetic medicine. Although cosmetic procedures have lower risks of catastrophic outcomes than many other types of surgery, the informed consent process that surrounds it has "supercharged" elements. High expectations and low tolerance for risk on the patient side meet competitive market pressures on the provider side, and complex social and psychological factors may also be in play.

From a medico-legal perspective, the lesson is that doctors who render cosmetic treatments should take special care to determine and explain the risks, benefits and possible outcomes that matter most to patients. The practical difficulty for busy clinicians, of course, is that such an imperative exists in the context of limited time, where choices must be made about what information to share. Our findings point to the importance of discussing, where relevant, the possibility that treatment may confer no visible benefit, trigger the need for further surgery, or result in disfigurement, pain, or altered sensation. Attention should also be paid to the process by which consent is obtained, with adequate time for reflection and support for informed decision-making. Further research into patients' perspectives on informed consent should help doctors steer an appropriate course in this challenging environment.

Ethics approval

This study was approved by the University of Melbourne Ethics Committee.

Previous communication

This paper is not based on any previous communication to a society or meeting.

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Acknowledgements

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References


2.10 Legal disputes over duties to disclose to disclose treatment risks

Policy Forum

Legal Disputes over Duties to Disclose Treatment Risks to Patients: A Review of Negligence Claims and Complaints in Australia

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Introduction

The 1972 case of Canterbury v. Spence [1] ranks among the best-known court decisions in American and international health law. Mr. Canterbury, a 19-year-old typist for the Federal Bureau of Investigation, became paraplegic and incontinent following spinal surgery. He sued, alleging that the surgeon, Dr. Spence, had failed in his duty to outline the risks of this outcome. Dr. Spence countered that he owed no duty to warn of such an unexpected complication. The enduring significance of the case lies in the decision by the District of Columbia Court of Appeals to reject the traditional customary standard for assessing negligence (what would a reasonable practitioner have done?), and opt instead for a new patient-centered standard (what would a reasonable patient want to know?).

In the 40 years since Canterbury, appellate courts of many U.S. states [2] and many countries—including the United Kingdom [3], Canada [4], Australia [5], Malaysia [6], Ireland [7], and New Zealand [8]—have considered similar cases, disputes in which patients and doctors square off over whether a particular treatment risk ought to have been disclosed. (Descriptions of these cases are provided in Table S1.) Many jurisdictions have moved toward legal standards for risk disclosure that prioritize patient preferences. This general shift compounds an uncertainty that doctors, especially surgeons, regularly face: which types of risks should be emphasized in the consent process?

While the duty to disclose risks has been analysed and critiqued extensively in the health law and bioethics literature [9], this scholarship is largely normative [10]. Remarkably little is known about the clinical circumstances in which doctors and patients disagree about whether a particular risk ought to have been disclosed ("disputed duty cases").

We identified 481 legal disputes over informed consent to medical treatment in Australia. The disputes were drawn systematically from litigation and conciliation files resolved over a seven-year period. In a recent report [11] we described general characteristics of this sample. In this analysis, we describe a subset that involved explicit disagreements between patients and doctors about whether a particular risk ought to have been disclosed. Our aim was to detail the treatments, risks, and adverse outcomes at issue in these cases.

Analysis

Setting

Avant Mutual Group Limited (Avant) and the Office of the Health Services Commissioner of Victoria (HSC) provided data for our analysis. Avant is Australia’s largest provider of medical indemnity insurance, covering approximately 55% of the country’s registered medical practitioners. The HSC, established in 1987, has statutory responsibility for resolving complaints against health care providers in Victoria, Australia’s second most populous state with 5.2 million residents. Patients must initiate complaints in writing but do not require legal representation. The system is free and open to all and is advertised widely in health care facilities.

Data

The sample frame consisted of all malpractice claims (n = 7,846) brought against doctors insured by Avant in three states (New South Wales, Victoria, and Queensland) between 1 January 2002 and 31 December 2008, and all conciliated complaints (n = 1,308) lodged with the HSC in Victoria during the same period. (The HSC data related to all complaints against doctors, regardless of who insured them.) We have previously described our method for screening claims and complaints in this sample frame to determine


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Competing Interests: The authors have declared that no competing interests exist.

Abbreviations: HSC, Health Services Commissioner of Victoria
* E-mail: dstuddert@unimelb.edu.au

Provenance: Not commissioned; externally peer reviewed.
Summary Points

- Doctors, especially surgeons, are often unsure which clinical risks they should disclose and discuss with patients before treatment. Leading medical malpractice cases in many countries have centered on this issue.
- In a sample of nearly 10,000 malpractice claims and conciliated health care complaints from Australia, we identified 481 disputes over informed consent, 45% of which were "disputed duty cases"—disagreements between patients and doctors over whether a particular clinical risk should have been disclosed before treatment.
- Two-thirds of disputed duty cases involved surgical procedures, and the majority (38/45) of cases related to five adverse outcomes: the need for further surgery, poor cosmetic result, impaired vision or hearing, chronic pain, and infertility or sexual dysfunction.
- The most common justifications doctors gave for non-disclosure were that the risk was too rare to warrant discussion or the specific risk was covered by a more general risk that was discussed.
- Although most informed consent disputes appear to involve disagreements about who said what and when, not stand-offs over whether a particular risk ought to have been disclosed, doctors may routinely underestimate the importance of a small set of risks that vex patients.

which ones met the definition of an informed consent dispute [11]. We recap definitions of key terms in Box 1.

Data collection proceeded in two steps. We first undertook an initial review of cases in the parent study [11] and then followed up with an in-depth review reported here. In the follow-up review, one investigator (MBR) returned to Avant and HSC offices between August and November 2010 and re-examined the hardcopy files associated with all cases flagged in the initial review as meeting the study definition of a disputed duty case. We confirmed that the cases met the study definition and collected supplementary information, including details of patients’ allegations and health outcomes, doctors’ responses, and the undisclosed risks in dispute. Probabilities associated with the clinical risks in selected cases were subsequently obtained through a series of Medline searches and literature reviews (one per case).

We did not attempt to judge whether the patient’s or doctor’s position in the disputed duty cases was the correct one. Doing so would have required more information than was available to us in the case files. The case outcomes are not an appropriate proxy for merit. With claims, cases were typically resolved by out-of-court negotiation. Moreover, allegations about deficiencies in the consent process often co-existed with other types of allegations, yet legal outcomes were generally "global", not tethered to specific allegations. With complaints, the HSC runs a dispute resolution process; it generally does not rule on the merit of patients’ allegations or practitioners’ responses.

The ethics committee at the University of Melbourne approved the study.

Findings

Frequency of Disputed Duty Cases

A total of 3.4% (283/7,846) of malpractice claims and 11.5% (218/1,898) of conciliated complaints involved disputes over informed consent. Three-quarters (375/481) of informed consent disputes involved allegations that risks had not been disclosed (Figure 1). However, most of these cases (38%, 330/375) were not disputed duty cases because they did not involve disagreements between patients and clinicians over whether a risk ought to have been disclosed.

Rather, factual disagreements predominated. These were chiefly factual disputes about whether the risk had been disclosed before treatment (e.g., "I would have discussed the risks of thrombosis associated with this contraceptive") or whether the patient’s poor outcome was due to materialisation of the undisclosed risk (e.g., "There was no causal connection between the iodine discogram and her thyroid disease"). In addition, in several cases the doctor conceded that the risk was not disclosed but should have been (e.g., "I didn’t disclose the risk of bile duct injury. I apologise for this and think the case should be settled.").

Nine percent (45/481) of informed consent cases were disputed duty cases. All findings reported hereafter pertain to this special group of cases.

Treatments and Adverse Outcomes

In more than two-thirds of disputed duty cases, the treatment rendered was a surgical procedure (31/45). The rest involved medications (7), anaesthetic procedures (3), obstetric care (3), and a washout of tear ducts performed by a general practitioner.

Table 1 shows the types of adverse outcomes for patients that resulted from materialisation of the undisclosed risks. In a third of cases (15/45), patients complained of not being warned of the risk that further surgery would be needed; in nearly three-quarters of cases (31/45) the complaint centered on not being warned about one of four outcomes: chronic pain, impaired vision or hearing, poor cosmetic result, and infertility or sexual dysfunction.

The dominance of these five outcomes among disputed duty cases is striking: collectively, they featured in 84% of

Box 1. Key Definitions

A claim is a written demand for compensation.

A conciliated complaint is a complaint the HSC considers too complex or serious to be resolved through facilitated communication alone, and so refers it to formal conciliation. (Approximately 20% of all complaints lodged with the HSC proceed to conciliation.)

An informed consent dispute is a claim or complaint that alleges a deficiency, either in the quality or quantity of information provided to the patient about a treatment prior to a decision about whether to undertake it, or in the process through which the patient was asked to consider such information and make a decision.

A disputed duty case is a type of informed consent dispute, one that involves a head-to-head disagreement between a patient and a doctor over the need to explain certain risks. These are situations in which a patient (or the patient’s representative) alleges that a particular risk should have been disclosed before treatment, and a doctor responds that the disclosure was unnecessary or inappropriate.
disputed duty cases. (It is also worth noting that several of the leading court cases, detailed in Table S1, involved this same group of outcomes.) What these outcomes have in common is important quality-of-life implications for patients. Our findings suggest that doctors may underestimate the premium patients place on understanding the risks of their treatment.

The adverse outcomes enumerated in Table 1 are essentially physical in nature. Patients in approximately a third of cases (17/45) also alleged psychological harm, in the form of depression or an anxiety disorder, associated with the adverse outcome.

**Doctors’ Justifications for Non-Disclosure**

Table 2 shows the distribution of cases by type of justification doctors gave for not having disclosed the risk. Examples of selected cases are also shown. The "risk too rare" and "subset of general risk" justifications for non-disclosure were particularly common; collectively, they appeared in nearly two-thirds of the disputed duty cases.

### Risk too rare

The most common justification for non-disclosure (13/45 cases) was that the risk was too rare. These were cases in which doctors argued that the outcome the patient experienced occurred too infrequently in clinical practice to warrant disclosing it during the informed consent process, or the risk was so rare that it was unknown to the doctor.

### General risk was disclosed

The next most common justification (11/45 cases) was that the risk not discussed was encapsulated in a general risk that was discussed. In a quarter of cases, for example, the doctor mentioned generic risks such as bleeding or infection without providing specific information regarding possible consequences for the patient. In another case, a doctor had warned the patient of the risk of an allergic reaction to phenytoin, but had not specifically mentioned the risk of Stevens-Johnson syndrome and blindness. These findings are consistent with research suggesting that clinicians tend to be overly general in their descriptions of some risks, and struggle with discussing serious complications in specific terms [12].

**Other justifications.** Each of the other types of justification applied to relatively few cases. Doctors defended non-disclosure in five cases by arguing that the risk was obvious and a reasonable patient ought to have been aware of it. In four cases, the doctor argued it was sufficient to have advised the patient of the average recovery time for a procedure and been silent on risks of delayed recovery; all of these cases involved cosmetic procedures.

Doctors in a further four cases argued that the need for disclosure was obviated by the fact that the benefits of the treatment clearly outweighed any risks, and disclosing the risk in question would have imposed an unnecessary burden on the patient; all of these cases involved surgical procedures. Arguments that it is unnecessary or inappropriate to "burden" the patient with information about procedures they are about to undergo are paternalistic; they hark back to an earlier era in which there was greater deference to the medical profession, and such exercises of "therapeutic privilege" were common and accepted [13,14].

The final three cases were unusual in that the adverse outcome was patently due to negligent care. The patients in these cases alleged a failure to warn of the risk of the outcome and the doctors argued the risk was not one they needed to disclose. (Technically, the doctors were probably correct, because there is no legal duty to warn of risks arising from negligent care.)

**Rare Risk Cases**

Table 3 provides details of the treatments, adverse outcomes, and risk probabilities for the 18 disputed duty cases in which the doctors’ justification for non-disclosure was that the risk was too rare to warrant it. Our literature review indicated a wide span in these probabilities, ranging from complications described in only a few case reports (e.g., vesicovaginal fistula following varicocele repair) to well-recognised adverse outcomes occurring in over 1% of cases (e.g., fetal laceration during caesarean delivery of a breech baby).

There was no obvious pattern to this wide variability. We had expected an inverse correlation between risk frequency and severity in this group of cases, but...
found no evidence of one. Nor was there evidence of convergence on a standard risk threshold: the probabilities appeared to vary across several orders of magnitude, from less than 0.01% to greater than 1%.

Discussion

Disputed Duty Cases in Context

Landmark court battles [1,3,4,5,6,7,8] over informed consent have centered on what legal standard of care should apply in head-to-head disputes between patients and doctors over whether a treatment risk warrants disclosure. To the best of our knowledge, this is the first study to examine this type of disagreement at the population level. The finding that nine out of ten legal disputes over informed consent cases did not turn on such a disagreement highlights a general point: highly publicized legal cases—which are at the apex of the “dispute pyramid”—can easily distort understanding of the much larger number of “garden variety” disputes and grievances that sit beneath them [15,16].

The finding also has a practical message for practicing clinicians: malpractice claims and complaints over informed consent are not uncommon events, but when they arise they are most likely to centre on mundane factual disagreement over who said what and when, not contests over what should have been disclosed. This underscores that for the informed consent process, like most other areas of clinical practice, regular and careful documentation of interactions with patients is a prudent risk-management strategy. Documentation of the details of consent discussions in the lead-up to surgical procedures is particularly important, as the vast majority of informed consent disputes involve complications following operations [2,11].

Despite their rarity, disputed duty cases are of special interest for several reasons. From a legal standpoint, these are the types of cases that define and test the standard of care to which doctors must adhere in obtaining informed consent. From a medical standpoint, the clinical details of disputed duty cases may point to an important “penumbra” of treatment risks—outcomes about which there is division or uncertainty among doctors as

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>n (%)</th>
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<tbody>
<tr>
<td>Further surgery required</td>
<td>15 (33%)</td>
</tr>
<tr>
<td>Chronic pain</td>
<td>13 (29%)</td>
</tr>
<tr>
<td>Poor cosmetic result or delayed wound healing</td>
<td>9 (20%)</td>
</tr>
<tr>
<td>Impaired vision or hearing</td>
<td>8 (18%)</td>
</tr>
<tr>
<td>Infertility or sexual dysfunction</td>
<td>7 (16%)</td>
</tr>
<tr>
<td>Paralysis</td>
<td>3 (7%)</td>
</tr>
<tr>
<td>Other</td>
<td>12 (27%)</td>
</tr>
</tbody>
</table>

*Total sums to greater than 45 because categories are not mutually exclusive.

Table 2. Doctors’ justifications for non-disclosure of risk in disputed duty cases.

<table>
<thead>
<tr>
<th>Justification Type</th>
<th>n (%)</th>
<th>Case Examples</th>
<th>Treatment and Health Outcome</th>
<th>Excerpts from Doctors’ Justification Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rare risk</td>
<td>18 (40%)</td>
<td>Cyclosporin leading to tinnitus and hearing loss</td>
<td>“It is not our practice to mention all rarely reported side-effects of every medication that is prescribed.”</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rectal prolapse repair leading to inability to ejaculate</td>
<td>“I would not specifically have warned of potential sexual difficulties because the incidence should be relatively low.”</td>
<td></td>
</tr>
<tr>
<td>Subset of general risk</td>
<td>11 (24%)</td>
<td>Migration of gastric reflux collaring leading to cardiac tamponade</td>
<td>“I had mentioned Angelich collars had been known to migrate, I had certainly not mentioned this exceedingly rare complication.”</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Phenylodol leading to Stevens-Johnson syndrome causing blindness</td>
<td>“I did not warn him specifically of Stevens Johnson syndrome though I did discuss allergic reactions in general.”</td>
<td></td>
</tr>
<tr>
<td>Obvious or implied risk</td>
<td>5 (11%)</td>
<td>Cosmetic eyelid surgery leading to post-operative infection</td>
<td>“Although I may not have highlighted problems of infection, most people, particularly if they are married to a doctor, would be aware that any operation can be complicated by infection.”</td>
<td></td>
</tr>
<tr>
<td>Duration of risk</td>
<td>4 (9%)</td>
<td>Cosmetic breast surgery with poor wound healing after one year</td>
<td>“Most would be healed within a couple of months. The maximum time I would have expected would be six months.”</td>
<td></td>
</tr>
<tr>
<td>Risk clearly outweighed by benefits</td>
<td>4 (9%)</td>
<td>Abdominal laparotomy leading to post-operative infection and scarring</td>
<td>“Infection is a solvable problem and the patient would still be in a better position than before the surgery.”</td>
<td></td>
</tr>
<tr>
<td>Risk of negligence</td>
<td>3 (7%)</td>
<td>Gastric lap band leading to perforation of right ventricle by liver retractor</td>
<td>“I did not mention specifically perforation of the heart, but this could be understood as this has never been reported before.”</td>
<td></td>
</tr>
</tbody>
</table>
to the appropriateness of disclosure and warning. From a patient standpoint, disputed duty cases may highlight certain types of risks that patients tend to prioritize more highly than doctors do. What lessons does an analysis of such cases have for how doctors should approach the informed consent process?

What to Disclose: A Balancing Act

The clinical reality is that standardised consent forms are widely used, particularly for common procedures, and they tend to present exhaustive enumerations of risks. Anglo-American courts do not accept that merely handing such forms to patients is a valid way to obtain informed consent. Consequently, clinicians must determine which risks to discuss and emphasise. For busy doctors this necessitates choices because time is limited and effort devoted to consent discussions has opportunity costs [17].

One approach is to focus discussion on risks of outcomes above a certain incidence. The notion of a 1% risk threshold appears to have some currency in clinical practice. However, it has no firm basis in either law or available evidence regarding patients’ attitudes to risk [18,19,20]. Courts regard the probability of a particular adverse outcome as an important element in determining what qualifies as a “material” risk that must be disclosed, but it is one of several elements.

The severity of the outcome associated with a risk also matters. It is reasonable to think of rarity and severity as considerations that operate in tandem, on a sliding scale. Small risks of catastrophic outcomes usually warrant emphasis, as do high risks of relatively minor adverse outcomes, but not low risks of minor outcomes.

Distinctive characteristics of individual patients may also dictate the breadth and depth of discussion about certain risks; the extreme example of a hand operation on a concert pianist helps to illustrate the point. A less obvious consideration is the treatment’s urgency. Details of risks tend to matter more toward the elective end of the treatment spectrum than the urgent or emergent end, which may help to explain the prominence of cosmetic treatments among the disputed duty cases in our sample.

To this recognised set of factors, our analysis draws attention to five outcomes that appear to trigger the majority of disputed duty cases—the need for further surgery, poor cosmetic results, impaired vision or hearing, chronic pain, and infertility or sexual dysfunction. These are outcomes that clinicians may give too little weight and attention in the consent process.

Limitations

Our analysis has several limitations. First, we examined legal disputes over the duty to disclose certain risks; this sample of cases may be unrepresentative of wider disagreements between patients and doctors in this area because they are refracted through the lens of patients’ claiming and complaining behaviour [21]. Second, we were constrained by the information set available in claim and complaint files. Finally, the generalisability of our findings may be influenced by differences in medical-legal systems and, in particular, the prevailing legal standard for informed consent. Since 1992, Australian courts have applied a patient-centred standard [5,22]; the same standard prevails in around half of the states in the US [2] and in a number of other countries [4,6,7,8], where the decision in Canterbury v Spencer has proved to be influential.

Conclusion

The rationale for informed consent springs from the ethical principle of autonomy—the notion that it is patients themselves who should make the final decision about which course of treatment to follow. Increasingly, doctors are expected to advise and empower patients to make rational choices by sharing information that may bear upon the decision, including risks of undesired outcomes. Occasionally, doctors and patients will disagree about whether a particular risk has an important bearing on treatment choices. Improved understanding of these situations helps to spotlight gaps between
what patients want to hear and what doctors perceive patients want (or should want) to hear. It may also be useful information for doctors eager to avoid medico-legal disputes.

Supporting Information

Table S1 Leading court cases on informed consent from 7 countries.

<table>
<thead>
<tr>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Hong Chuan Lay v. Dr. Eddie Seo Foo Koon (1998) 7 MJL.</td>
</tr>
<tr>
<td>8. John Edgar Hurman v. Director of Proceedings (High Court Auckland, CIV 2007-016-000752, 12 March 2005), Wik:</td>
</tr>
</tbody>
</table>

Acknowledgments

This study was made possible by the generous assistance and support of the leadership group and staff of Avant Mutual Group, and the Health Services Commissioner of Victoria, Ms Beth Wilson, and her staff, particularly Ms Lynn Griffin. We thank them. We also thank Dr Paul Nisselle, who helped conceive and launch this project.

Author Contributions

Analysed the data: MB DS. Wrote the first draft of the manuscript: MB DS. Contributed to the writing of the manuscript: AJG RG AG. ICMJE criteria for authorship read and met: MB AJG RC RG AG DS. Agree with manuscript results and conclusions: MB AJG RC RG AG DS. Coordinated the collection of data at Avant: RC.
2.11 Prevalence and characteristics of complaint-prone doctors

Prevalence and characteristics of complaint-prone doctors in private practice in Victoria

Marie M Bismark, Matthew J Spittal and David M Studdert

ABSTRACT

Objective: To identify characteristics of doctors who are repeatedly subjects of complaints by patients.

Design and setting: Case-control study of doctors about whom patients had complained to the Victorian Health Services Commissioner between 1 January 2000 and 31 December 2009.

Participants: 384 doctors in private practice; cases comprised 96 doctors who were the subject of four or more separate complaints; and the control group comprised 288 doctors who were the subject of a single complaint over the study period.

Results: Among doctors in private practice in Victoria, 20.5% (95% CI, 19.7–21.3%) experienced at least one complaint over the decade. Among doctors who were the subject of a complaint, 4.5% (95% CI, 3.6%–5.4%) had four or more complaints, and this group accounted for 17.6% (95% CI, 16.3%–19.0%) of all complaints to the Victorian Health Services Commissioner. Multivariate analyses showed that surgeons (odds ratio [OR], 8.90; 95% CI, 3.69–21.50) and psychiatrists (OR, 4.59; 95% CI, 1.46–14.48) had higher odds of being in the complaint-prone group than general practitioners. Doctors trained overseas had lower odds of being complaint-prone than those trained in Australia (OR, 0.31; 95% CI, 0.13–0.72).

Conclusions: A small group of doctors in private practice in Victoria account for nearly 18% of complaints. Interventions to improve patient satisfaction and public confidence in health services should target complaint-prone subgroups of practitioners.

MJA 2011; 195: 25-28

METHODS

Complaints data

We queried the database of the Health Services Commissioner of Victoria ("the Commissioner") to identify all doctors in Victoria who were the subject of one or more complaints in the decade 1 January 2000 to 31 December 2009. We focused on doctors in private practice because the Commissioner’s complaint resolution processes for public hospital services do not identify individual doctors. In 2004, the midpoint of our study period, 14,981 doctors were registered to practice in Victoria: 72% (10,434) were in private practice, either fully (7052) or partially (3382), and 28% (4147) were in public practice only.

We excluded contacts with the Commissioner that did not proceed beyond the enquiry stage, but did not otherwise attempt to grade complaint severity because no principled criteria exist to allow such grading.

We used the number of complaints per doctor to identify complaint-prone doctors. We defined complaint-prone doctors as those with four or more complaints over the study period. For each complaint-prone doctor, three doctors were randomly selected from among those who were the subject of a single complaint to act as controls.

Demographic data and variables

Using the name and practice address of each complaint-prone and control doctor, we searched the Medical Practitioners Board of Victoria’s register and the Medical Directory of Australia database. From these sources, we obtained information on the doctor’s sex, specialty, training location, practice location, date of graduation, and fellowship status.

For two doctors who had died and three who had ceased practising, some information could not be retrieved. Wherever possible, we retained these doctors in descriptive and univariate analyses, but they were dropped from the multivariate analyses.

We collapsed specialties into five groups: general practitioner, physician, psychiatrist, surgeon, and other. Years in practice were calculated by subtracting the date of graduation from the date of the first complaint, and then coded into tertiles (<21 years, 22–29 years, 30+ years). Training location was classified as Australia or overseas, based on the doctor’s primary medical qualification.

Statistical analysis

Using logistic regression analyses at the doctor level, we regressed a binary variable distinguishing complaint-prone doctors from control doctors on six covariates: sex, practice location (urban or rural), years in practice, training location, specialty, and fellowship of an accredited college (yes or no). All analyses were conducted using Stata 11.1 (StataCorp, College Station, Tex, USA).

Ethics approval

The study was approved by the ethics committee at the University of Melbourne.
1 Derivation of the study population

Doctors in private practice in Victoria: 10,434
Doctors with 1 or more complaints*: 2,142
Doctors with 1 complaint: 1,617
Doctors with 2 or 3 complaints: 428
Doctors with 4 or more complaints: 98 (Casual)
Random selection: 289 (Controls)

*Complaints about them to the Health Services Commissioner of Victoria from 1 January 2000 to 31 December 2009.

RESULTS
Distribution of complaints among doctors
In the decade to 2010, the Commissioner received 31,222 complaints against 21,411 doctors in private practice in Victoria. A total of 20.5% of doctors in private practice were the subject of complaints (95% CI, 19.7%–21.3%), with an average of 1.5 complaints (SD, 1.3 complaints) per doctor who was complained against.

Three-quarters (16,172/21,411) of doctors complained against were the subject of a single complaint during the study period, and 20% (4,281/21,411) were the subject of two or three complaints (Box 1). A total of 96 doctors had four or more complaints (median, 5; interquartile range, 4–6); this is the group we defined as complaint-prone and analysed further.

Box 2 shows the distribution of complaints among doctors. Complaint-prone doctors constituted 4.3% of doctors complained against (95% CI, 3.6%–5.4%) and accounted for 17.6% of all complaints (95% CI, 16.3%–19.0%).

Distinctive characteristics of complaint-prone doctors
Univariate analyses showed that complaint-prone doctors were more likely than control doctors to be male, surgeons or psychiatrists, have trained in Australia, and have been in practice for at least 30 years (Box 3). In multivariate analysis, surgeons had ninefold greater odds of being complaint-prone than GPs (odds ratio [OR], 8.30; 95% CI, 3.69–21.50) and psychiatrists had more than fourfold greater odds of being complaint-prone (OR, 4.59; 95% CI, 1.46–14.43). Doctors trained overseas had lower odds of being complaint-prone than Australian-trained doctors (OR, 0.31; 95% CI, 0.13–0.72). There were no significant differences among the other characteristics examined.

DISCUSSION
This study found that, in the decade to 2010, one in five of Victoria’s approximately 10,000 doctors in private practice had at least one complaint from a patient to the state Health Services Commissioner. There was a heavy concentration of these complaints among a small group of doctors. Specialty was an important factor, with surgeons and psychiatrists significantly overrepresented in the complaint-prone group. Overseas-trained doctors, on the other hand, were significantly underrepresented in this group.

More generally, our findings reinforce the conclusion of previous research that it is incorrect at the population level to construe doctors’ experiences with medicolegal matters as merely the “luck of the draw.”7 Complaints clearly cluster around certain doctors—in Victoria, extrapolations from our findings indicate that less than 100 practitioners, or 1% of the medical workforce in private practice, account for nearly 20% of complaints.

It would be a feasible proposition to mount interventions in a group of this size, and this may help improve patient satisfaction, quality of care, and public confidence in the health care system. Such interventions should be tailored to the concerns identified in complaints and the degree of recidivism. At the low end of the spectrum, they may involve simple guidance (eg, information and feedback), graduating to moderately intrusive measures (eg, specific professional development modules). At the upper end of the spectrum, stronger interventions may be warranted (eg, referral for competence or health assessment), rising to practice restrictions by the appropriate agency where required. In most cases, remediation, re-skilling, or rehabilitation should be enough to help doctors return to safe practice.10

Why surgeons and psychiatrists are disproportionately at risk is not well understood. Previous complaints studies have identified the same phenomenon,6,9,18 as have studies of other medicolegal matters.1,2,5,7-10,12,13,15,19 In surgery, the inherent risks of surgical procedures and the relative visibility of poor outcomes of care are likely to play a role.21 In psychiatry, certain patients may have an increased pro-

2 Distribution among doctors in private practice in Victoria of complaints about them to the Victorian Health Services Commissioner, 2000–2009

<table>
<thead>
<tr>
<th>No. of complaints</th>
<th>Doctors</th>
<th>% (95% CI)</th>
<th>Complaints</th>
<th>Number</th>
<th>% (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 1</td>
<td>2141</td>
<td>—</td>
<td>—</td>
<td>3122</td>
<td>—</td>
</tr>
<tr>
<td>&gt; 2</td>
<td>524</td>
<td>24.5 (22.7–26.4)</td>
<td>1505</td>
<td>48.2 (46.4–50.0)</td>
<td></td>
</tr>
<tr>
<td>&gt; 3</td>
<td>196</td>
<td>9.2 (8.0–10.5)</td>
<td>849</td>
<td>27.2 (25.6–28.8)</td>
<td></td>
</tr>
<tr>
<td>&gt; 4</td>
<td>96</td>
<td>4.5 (3.6–5.4)</td>
<td>549</td>
<td>17.6 (16.3–19.0)</td>
<td></td>
</tr>
<tr>
<td>&gt; 5</td>
<td>50</td>
<td>2.3 (1.7–3.0)</td>
<td>365</td>
<td>11.7 (10.6–12.9)</td>
<td></td>
</tr>
<tr>
<td>&gt; 6</td>
<td>32</td>
<td>1.5 (1.0–2.1)</td>
<td>275</td>
<td>8.8 (7.8–9.9)</td>
<td></td>
</tr>
<tr>
<td>&gt; 7</td>
<td>20</td>
<td>0.9 (0.6–1.4)</td>
<td>203</td>
<td>6.5 (5.7–7.4)</td>
<td></td>
</tr>
</tbody>
</table>
### 3 Unadjusted and adjusted odds of being a complaint-prone doctor

<table>
<thead>
<tr>
<th>Variable</th>
<th>Cases* (n = 96)</th>
<th>Controls* (n = 288)</th>
<th>Unadjusted odds ratio (95% CI)</th>
<th>P</th>
<th>Adjusted odds ratio* (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>8%</td>
<td>22%</td>
<td>1.00 (1.00-1.00)</td>
<td>0.006</td>
<td>1.00 (0.99-1.00)</td>
<td>0.006</td>
</tr>
<tr>
<td>Male</td>
<td>92%</td>
<td>78%</td>
<td>2.98 (1.37-6.48)</td>
<td>1.00</td>
<td>1.00 (0.81-1.44)</td>
<td>1.00</td>
</tr>
<tr>
<td>Trained in Australia*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>90%</td>
<td>76%</td>
<td>1.00 (0.16-2.71)</td>
<td>0.004</td>
<td>1.00 (0.13-0.72)</td>
<td>0.006</td>
</tr>
<tr>
<td>No</td>
<td>10%</td>
<td>24%</td>
<td>0.34 (0.16-0.71)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specialty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General practitioner</td>
<td>23%</td>
<td>43%</td>
<td>1.00 (1.00-1.00)</td>
<td>&lt;0.001</td>
<td>1.00 (0.98-1.00)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Physician</td>
<td>9%</td>
<td>13%</td>
<td>1.40 (0.59-3.30)</td>
<td>0.00</td>
<td>1.39 (1.38-4.03)</td>
<td>0.00</td>
</tr>
<tr>
<td>Psychiatrist</td>
<td>9%</td>
<td>6%</td>
<td>3.14 (1.24-8.00)</td>
<td></td>
<td>4.97 (1.46-14.43)</td>
<td></td>
</tr>
<tr>
<td>Surgeon</td>
<td>45%</td>
<td>10%</td>
<td>5.94 (4.44-15.17)</td>
<td></td>
<td>8.90 (3.69-21.50)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>14%</td>
<td>30%</td>
<td>0.86 (0.41-1.79)</td>
<td></td>
<td>0.98 (0.41-2.34)</td>
<td></td>
</tr>
<tr>
<td>Location</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>7%</td>
<td>14%</td>
<td>1.00 (1.00-1.00)</td>
<td>0.00</td>
<td>1.00 (1.00-1.00)</td>
<td>0.00</td>
</tr>
<tr>
<td>Urban</td>
<td>93%</td>
<td>86%</td>
<td>2.11 (0.91-4.88)</td>
<td>0.023</td>
<td>2.61 (0.88-7.12)</td>
<td>0.356</td>
</tr>
<tr>
<td>Years in practice*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 21 years</td>
<td>23%</td>
<td>36%</td>
<td>1.00 (1.00-1.00)</td>
<td>0.023</td>
<td>1.00 (1.00-1.00)</td>
<td>0.356</td>
</tr>
<tr>
<td>22-29 years</td>
<td>30%</td>
<td>31%</td>
<td>1.59 (0.85-3.00)</td>
<td></td>
<td>1.60 (0.79-3.24)</td>
<td></td>
</tr>
<tr>
<td>30+ years</td>
<td>47%</td>
<td>33%</td>
<td>2.29 (1.27-4.13)</td>
<td></td>
<td>2.52 (0.78-8.27)</td>
<td></td>
</tr>
<tr>
<td>Fellow of an accredited college</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>23%</td>
<td>34%</td>
<td>1.00 (1.00-1.00)</td>
<td></td>
<td>1.00 (1.00-1.00)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>77%</td>
<td>66%</td>
<td>1.73 (1.02-2.94)</td>
<td></td>
<td>0.79 (0.35-1.74)</td>
<td></td>
</tr>
</tbody>
</table>

- *Percentages may not sum to 100 because of rounding error.
- † Missing data on sex (1 doctor), trained in Australia (4 doctors), and years in practice (5 doctors).
- *The multivariate logistic regression model adjusted for all variables shown.

... over a decade, rather than doctors who had experienced none. A comparison of the doctors in our control group to summary statistics for all doctors in Victoria suggests that our controls closely resemble the wider pool in terms of specialty and location, but slightly larger proportions were male and had been in practice for more than 21 years. These differences, although minor, open up the possibility of biases toward the null in our analyses of sex and years in practice. Third, the characteristics we examined were doctor-focused. Patient characteristics, treatment outcomes, and the nature of the patient–doctor relationship are also likely to be important predictors. Finally, our findings are from an analysis of complaints against doctors in private practice in Victoria; the extent to which they can be generalised to practitioners in public hospital settings and in other states is unknown.

The insight that large numbers of complaints are concentrated among a small group of doctors, and that those doctors exhibit distinctive characteristics, has important policy implications. Case-by-case complaint resolution processes overlook the importance of past complaints as a predictor of future complaints, and spread regulators' scarce resources thinly across a wide group of practitioners, most of whom are at minimal risk of future complaints. Aiming interventions at high-risk doctors has the potential to steer outliers back towards safer practice, thereby reducing risks of future harm and patient dissatisfaction. Realising that potential requires two advances: better tools for flagging complaint-prone doctors early in their complaints trajectory; and effective interventions to address problems in a timely fashion. Future research should address both challenges.

**ACKNOWLEDGEMENTS**

This study was funded through an Australian Research Council Federation Fellowship (To David Stucklert). We thank Beth Wilson, Health Services Commissioner of Victoria, and Grant Davies, Deputy Commissioner. Without their support and the assistance of their team in preparing the data, this study would not have been possible.
COMPETING INTERESTS
None identified.

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Correspondence: mariebismark@gmail.com

REFERENCES


Provenance: Not commissioned; externally peer reviewed.
2.12 Identification of doctors at risk of recurrent complaints

Identification of doctors at risk of recurrent complaints: a national study of healthcare complaints in Australia

Marie M Bismark, Matthew J Spittal, Lyle C Gurrin, Michael Ward, David M Studdert

ABSTRACT

Objectives (1) To determine the distribution of formal patient complaints across Australia’s medical workforce and (2) to identify characteristics of doctors at high risk of incurring recurrent complaints.

Methods We assembled a national sample of all 18907 formal patient complaints filed against doctors with health service ombudsmen (“Commissions”) in Australia over an 11-year period. We analysed the distribution of complaints among practicing doctors. We then used recurrent-event survival analysis to identify characteristics of doctors at high risk of recurrent complaints, and to estimate each individual doctor’s risk of incurring future complaints.

Results The distribution of complaints among doctors was highly skewed: 3% of Australia’s medical workforce accounted for 49% of complaints and 1% accounted for a quarter of complaints. Short-term risks of recurrence varied significantly among doctors: there was a strong dose-response relationship with number of previous complaints and significant differences by doctor specialty and sex. At the practitioner level, risks varied widely, from doctors with <10% risk of further complaints within 2 years to doctors with >80% risk.

Conclusions A small group of doctors accounts for half of all patient complaints lodged with Australian Commissions. It is feasible to predict which doctors are at high risk of incurring more complaints in the near future. Widespread use of this approach to identify high-risk doctors and target quality improvement efforts coupled with effective interventions, could help reduce adverse events and patient dissatisfaction in health systems.

INTRODUCTION

To many doctors who are sued or complained against, the event seems random. At the population level, however, there are patterns. Previous studies have compared doctors who experienced multiple malpractice claims,6,7 and disciplinary actions10 with doctors who experienced few or none, and identified differences in the sex, age and specialty profile of the two groups. Such research helps to explain medico-legal risk retrospectively, but does not provide practical guidance for identifying risks prospectively. Clinical leaders, risk managers, liability insurers and regulators all lack reliable methods for systematically determining which doctors should be targeted for assistance and preventive action before they acquire troubling track records. Consequently, the medico-legal enterprise remains reactive, dealing primarily with the aftermath of adverse events and behaviours that lead to costly disputes.

The conventional wisdom is that future medico-legal events cannot be predicted at the doctor level with acceptable levels of accuracy.11,12 Numerous studies have tried,13–23 most with limited success. This body of research has two important shortcomings. First, only a few studies23 report a method for predicting medico-legal risk that is potentially replicable, and these methods are statistically complex. The practical consequence is that regulators and liability insurers today have no clear way of estimating risk at the practitioner level, and doing so is not a standard part of risk management practice.

Second, no study to date has found a way to deal well with temporal aspects of risk, such as the evolving nature of doctors’ medico-legal event histories, which can be crucial information in assembling a risk profile. Previous claims and complaints have been identified as an important predictor of future events, but only in analyses that specify this variable crudely—usually by ‘freezing’ a doctor’s
track record at a specific point to estimate a ‘one-time’ effect. This approach is out of step with how claims and complaints are managed. The frontline challenges are to determine how a practitioner’s risk profile changes over time as new information (including new events) comes to hand; when support or intervention measures to prevent further events are warranted; and how strong those measures should be. A risk prediction method that helped to address these questions would have considerable potential for boosting the contribution of medico-legal institutions to quality improvement.

We assembled a national sample of nearly 19,000 formal healthcare complaints lodged against doctors in Australia between 2000 and 2011. We then used a time-to-event method of analysis to determine characteristics of doctors poised to incur recurrent complaints, and to estimate each practitioner’s risk of recurrence at specific time points. The study had two main goals: to identify predictors of complaint-prone doctors in Australia, and to develop a robust and useful method for forecasting medico-legal risk.

METHODS
Setting
Health service commissions (Commissions) are statutory agencies established in each of Australia’s six states and two territories. Commissions have responsibility for receiving and resolving patient complaints about the quality of healthcare services. Patients or their advocates must initiate complaints in writing, but the process is free and legal representation is optional. Table 1 compares the jurisdiction and functions of Commissions to those of the two other agencies that handle medico-legal matters in Australia—civil courts and the Medical Board of Australia.

Outside of the clinic or hospital in which care is received, Commissions are the primary avenue of redress for patients dissatisfied with the quality of care they have received. Plaintiffs’ lawyers in Australia will rarely take on cases unless they have first proceeded through Commission processes (although the vast majority of complaints do not become negligence claims). At least 10 other Organisation for Economic Co-operation and Development (OECD) countries—including Austria, Finland, Israel, New Zealand and the UK—have similar bodies. In the UK, the closest analogue is the Parliamentary and Health Service Ombudsman. Commissions in all Australian states and territories except South Australia participated in the study. These seven jurisdictions have 21 million residents and 90% of the nation’s 88,000 registered doctors. The study was approved by the ethics committee at the University of Melbourne.

Data
Between May 2011 and February 2012 we collected data on-site at Commission offices in each participating state and territory. Complaints against doctors were identified by querying the Commissions’ administrative data systems. The filing period of interest spanned 12 years and differed slightly by jurisdiction: 2000–2011 for the Australian Capital Territory, the Northern Territory, Queensland, Tasmania and Victoria; 2000–2010 for Western Australia; and 2006–2011 for New South Wales.

All Commissions record the names of persons and institutions that are the subject of complaints, as well as the filing date, the nature of the complaint, the type of health professional named and their practice location. Although all Commissions recorded doctors’ clinical specialty, the quality of this variable was mixed. Doctors’ age and sex were not routinely

| Table 1 | Jurisdiction and functions of key agencies with responsibility for medico-legal matters in Australia |
|---|---|---|
| **Civil courts** | **Health complaints commissions** | **Medical Board of Australia** |
| Cases handled | Negligence claims | Patient complaints |
| Jurisdictional focus | Substandard care causing patient harm | Low-quality care |
| Procedures used | Out-of-court negotiation | Early resolution |
| | Alternative forms of dispute resolution (eg, mediation, arbitration) | Conciliation |
| | Trials before judges | Investigation |
| Remedies | Monetary damages | Communication (eg, facilitate apology or explanation) |
| | | Restoration (eg, facilitate provision of further treatment, fee forgiveness, monetary settlement) |
| | | Correction (eg, recommend system change) |
| | | Correction (eg, requirement that practitioner undergo education, rehabilitation, monitoring etc) |
| | | Sanction (eg, suspension or revocation of practice licence*) |

*Typically, such sanctions are imposed by external administrative tribunals in proceedings initiated by the Medical Board of Australia.
collected. We therefore supplemented the
Commissions’ administrative data with data from
another source.

AMPCo Direct, a subsidiary of the Australian
Medical Association, maintains a comprehensive list
of doctors in Australia, including information on their
sex, date of birth, specialty and subspeciality, and prac-
tice location. We purchased the AMPCo Direct data-
base and matched doctors listed in it to doctors named
in the complaints databases. The matching method is
described in an online supplementary appendix.

Variables
We coded specialty into 13 categories, based on those
promulgated by the Medical Board of Australia.29
Doctors’ principal practice address was classified as
urban or rural, based on the location of its postcode
within a standard geographic classification system.30
The nature of concerns raised in complaints was
sorted into 20 broad ‘issue’ categories. Commissions
run dispute resolution processes; they generally do
not rule on the merit of complaints, nor make find-
ings for or against parties, so it was not possible to
include a variable indicating how meritorious com-
plaints were.

Statistical analysis

Distributional analysis
We plotted the cumulative distribution of complaints
among two populations of doctors: (1) all unique
doctors named in complaints and (2) all practicing
doctors in the seven jurisdictions under study (ie,
regardless of whether they had been named in com-
plaints). The size of this second population was based
on the number of doctors in employment in 2006,31
the median study year. Because certain classes of com-
plaints do not name doctors individually (eg. com-
plaints arising in public hospitals in several of the
study jurisdictions), we adjusted the proportions in
the distributional calculations to ensure the numerators
(number of complaints) matched the denominators
(size of the ‘exposed’ segment of the medical
workforce). Details are provided in the online supple-
mentary appendix.

Multivariable survival analysis
We used multivariable survival analysis to identify pre-
dictors of doctors’ risks of recurrent complaints.
Specifically, we used an Anderson–Gill model32 in
which the time-scale ran from time from first event
(i.e., a doctor’s earliest complaint) and allowed each
doctor in the sample to accrue multiple complaints
over the period of observation. The outcome variable
was the occurrence of a complaint against a doctor,
conditional on the doctor having been named in an
earlier complaint. The covariates were the number of
prior complaints a doctor had experienced,
jurisdiction, and the doctor’s specialty, age, sex and
principal practice location.

The number of prior complaints was specified as a
time-varying covariate. Age was also time-varying in
the sense that we allowed doctors to move into higher
age categories, commensurate with their age at the
time of the complaint. We fit cluster-adjusted robust
SEs to account for doctors who experienced repeated
complaints over time.

Details of model selection and specification are
described in the online supplementary appendix. All
statistical analyses were conducted using Stata 12.1.

Risk predictions
To estimate doctors’ risks of experiencing complaints
over time, we plotted adjusted failure curves.33 34 Details
of the statistical techniques used to create these curves
are provided in the online supplementary appendix. We
also plotted failure curves showing the predicted risk of
recurrent complaints for several individual doctors.
Values for all failure curves were computed using coeffi-
cients from the main multivariable model, and hence,
derived from the survivor function,$\hat{S}(t)$.

Sensitivity analysis
We tested the robustness of estimates from the main
multivariable analysis by rerunning the analysis on a
subsample of complaints ($n=10\ 010$) with issue codes
suggestive of relatively serious concerns (namely, poor
clinical care, breach of conditions, rough or painful
treatment and sexual contact or relationship).

RESULTS
Characteristics of complained-against doctors
and complaints
The study sample consisted of 18 907 complaints against
11 148 doctors. Sixty-one percent of the complaints
addressed clinical aspects of care, most commonly con-
cerns with treatment (41%), diagnosis (16%) and medi-
cations (8%) (table 2). Nearly one quarter of complaints
addressed communication issues, including concerns
with the attitude or manner of doctors (15%), and the
quality or amount of information provided (6%).

Seventy-nine percent of the doctors named in com-
plaints were male, 47% were general practitioners and
14% were surgeons (table 3). Examples of several
complaints are included in the online supplementary
appendix.

Incidence and distribution of complaints
Doctors in the sample were complained against an
average of 1.98 times (SD 2.31). The distribution was
highly skewed, with a small subgroup of doctors accounting for a disproportionate share of complaints.

Figure 1 plots the cumulative distribution of com-
plaints among doctors in six jurisdictions over a
decade. (New South Wales data was not included in
these plots because the complaints window there spanned only 5 years.) The curve on the left side of

the figure shows the distribution of complaints among doctors who experienced one or more complaints in the decade. Fifteen percent of doctors named in complaints accounted for 49% of all complaints, and 4% accounted for a quarter of all complaints. The curve on the right side of the figure shows the distribution of complaints across the full population of practicing doctors, not just those who experienced complaints. Three percent of all doctors accounted for 49% of all complaints, and 1% accounted for a quarter of all complaints.

**Multivariable predictors of recurrent complaints**

In multivariable analyses, the number of prior complaints doctors had experienced was a strong predictor of subsequent complaints, and a dose-response relationship was evident (table 4). Compared with doctors with one prior complaint, doctors with two complaints had nearly double the risk of recurrence (HR 1.93; 95% CI 1.79 to 2.09), and doctors with five prior complaints had six times the risk of recurrence (HR 6.16; 95% CI 5.09 to 7.46). Doctors with 10 or more prior complaints had 30 times the risk of recurrence (HR 29.56; 95% CI 19.24 to 45.41).

Risk of recurrence also varied significantly by specialty. Compared with general practitioners, plastic surgeons had twice the risk (HR 2.04; 95% CI 1.75 to 2.38), and risks were approximately 50% higher among dermatologists (HR 1.56; 95% CI 1.30 to 1.88) and obstetrician-gynaecologists (HR 1.50; 95% CI 1.29 to 1.76). Anaesthetists had significantly lower risks of recurrence (HR 0.65; 95% CI 0.54 to 0.79).

Male doctors had a 40% higher risk of recurrence than their female colleagues (HR 1.36; 95% CI 1.23 to 1.50). Location of practice (urban vs rural) was not significantly associated with recurrence. Compared with doctors 35 years of age or younger, older doctors had 30–40% higher risks of recurrence; this level of heightened risk was similar through the middle-aged and older-aged groups.

**Risks of recurrence over time**

Doctors named in a third complaint had a 38% chance of being the subject of a further complaint within a year, and a 57% probability of being complained against again within 2 years (figure 2A). Doctors named in a fifth complaint had a 59% 1-year
Table 4 Multivariable regression analysis estimating risk of recurrent complaints

<table>
<thead>
<tr>
<th>Number of prior complaints</th>
<th>HR (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (ref)</td>
<td>1.00</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>2</td>
<td>1.93 (1.79 to 2.09)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>3</td>
<td>3.21 (2.87 to 3.59)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>4</td>
<td>4.54 (4.09 to 5.17)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>5</td>
<td>6.16 (5.09 to 7.46)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>6</td>
<td>8.83 (7.05 to 11.05)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>7</td>
<td>9.57 (7.40 to 12.37)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>8</td>
<td>9.49 (7.05 to 12.77)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>9</td>
<td>16.09 (11.72 to 22.10)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>10 or more</td>
<td>29.56 (19.24 to 45.41)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

States and territories

<table>
<thead>
<tr>
<th>Specialty of doctor</th>
<th>HR (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plastic surgery</td>
<td>2.04 (1.75 to 2.38)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Dermatology</td>
<td>1.56 (1.30 to 1.88)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Obstetrics and gynaecology</td>
<td>1.50 (1.29 to 1.76)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>General surgery</td>
<td>1.45 (1.17 to 1.80)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Orthopaedic surgery</td>
<td>1.32 (1.20 to 1.44)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Other surgery</td>
<td>1.30 (1.19 to 1.43)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>1.19 (1.02 to 1.40)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Psychiatry</td>
<td>1.15 (1.02 to 1.30)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>General practice (ref.)</td>
<td>1.00 (ref.)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Internal medicine</td>
<td>0.93 (0.80 to 1.09)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Radiology</td>
<td>0.89 (0.74 to 1.07)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Anaesthesia</td>
<td>0.65 (0.54 to 0.79)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Other</td>
<td>0.65 (0.51 to 0.82)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Age of doctor

| <35 years | 1.00 (ref.) | <0.001  |
| 36–45 years | 1.31 (1.13 to 1.51) | <0.001  |
| 46–55 years | 1.40 (1.22 to 1.62) | <0.001  |
| 56–65 years | 1.43 (1.22 to 1.67) | <0.001  |

Gamma = –0.21 (–0.32 to –0.01)

*Analysis based on 14986 index complaints against 8749 doctors, and 4037 subsequent complaints.

Sensitivity analysis

Re-estimating the main multivariable model using a subset of ‘severe’ complaints produced very similar results to the main model. The online supplementary appendix shows the full set of results.

DISCUSSION

This study of patient complaints made to the chief health-quality regulators in Australia found that the complaints clustered heavily among a small group of doctors. Approximately 3% of practicing doctors accounted for half of all complaints. The number of prior complaints doctors had experienced was a particularly strong predictor of their short-term risk of further complaints. At the practitioner level, short-term risks of recurrence varied widely, from <10% risk among low-risk doctors to >80% risk among high-risk doctors. Overall, recurrent-event survival probability was found to be highly dependent on the number of prior complaints.
analysis showed considerable promise as a statistical approach for flagging complaint-prone doctors early in their complaints trajectory, using only a few simple descriptive characteristics.

Our study used a national sample to examine the distribution and predictors of medico-legal events. Patients treated in healthcare facilities throughout seven states and territories were eligible to file complaints with a Commission about the quality of the care they received. Previous studies of claims and complaints risk have tended to focus on pools of doctors covered by a single liability insurer or a few hospitals. The extent to which complaints were concentrated in a small group of doctors was striking, consistent with other studies of complaints and claims.

This highly skewed distribution of medico-legal events among doctors has several implications. The obvious one is that there is a pressing need for interventions that address the behaviour of doctors who are chronically complained or claimed against. Medical boards in Australia and elsewhere already address conduct, competence and health concerns with certain practitioners, but these efforts may fall short. Our study identifies a target population within which systematic deployment of interventions to improve performance might be manageable: less than 500 doctors accounted for 25% of all complaints that named doctors in the decade under study. Immediate steps to improve, guide or constrain the care being provided by these ‘high-risk’ practitioners could be a very cost-effective way to advance quality and safety, and produce measurable benefits at the system level.

A more sobering implication of the clustering phenomenon is that remediation activities targeted at doctors who have attracted many complaints, while critical, come too late. Complaints are best understood as sentinel events, and complainants as representatives of much larger groups of harmed or dissatisfied patients. By the time multiple complaints have accrued, substantial damage to quality of care is likely to have occurred already. The clustering of medico-legal events highlights the huge gains that would be put in reach by a capability to identify early doctors who are on course to incur multiple complaints.

Our approach is ripe for replication, not only by hospitals and regulators that hold complaints data, but within liability insurers with malpractice claims data, large hospital systems with risk management data, and medical boards and other professional bodies with data on disciplinary matters. Several distinctive aspects of our approach, descriptions of which follow, pave the way for better prediction of medico-legal risk in these settings than has been achieved to date.

Previous efforts to predict malpractice risk in liability insurance pools have included doctors with and without claims in their analyses. This approach suits a core goal in many of these studies: to explore the feasibility of ‘experience rating’ doctors’ liability insurance premiums. By contrast, our study sought to predict risk for purposes of targeting quality-improvement interventions. In this context, it is appropriate to focus on doctors who have been the subject of at least one complaint because this is the group with whom regulators have a natural point of contact and opportunities to intervene. An ancillary benefit of this ‘conditional’ approach to modelling medico-legal risk is that it enhances the ability to identify strong predictors of recurrent risk.
A key technical challenge encountered in previous studies has been how to deal with the recurrent nature of medico-legal events. The approach used by Rolph and others who have emulated his method, fixes the effect of prior events in a single variable at the doctor level. The ‘weighted sum algorithm’ behind the PARS risk score, developed by Hickson and colleagues, comes from analyses regressing a sample of ‘risk management events’ on information obtained from unsolicited patient complaints. A limitation of both approaches is their static consideration of doctors’ event histories. In its application, however, the PARS algorithm adopts dynamic features (doctors risk scores can be recalculated as new complaints appear over time).

An advantage of recurrent-event survival analysis is that it permits dynamic consideration of the effect of time-varying factors in the predictive model itself. In other words, it is not necessary to rely on a snapshot taken of a doctor’s situation at a particular point in time: as risk profiles evolve—and the coefficients on the previous complaints variable in our study illustrate how dramatically this may occur—survival analysis incorporates these changes into the estimation of future risk. A related advantage of survival analysis is that it permits estimation of doctors’ risk levels at different points in time—a year after an index event, 2 years later and so on. Our analysis showed that for some predictors, particularly the number of previous complaints, doctors’ risks of additional complaints were non-linear: the risk tends to rise quickly over the several months after a complaint and then level off by the time the doctor reaches a year without further incidents. For clinical leaders, regulators and liability insurers trying to determine when in a doctor’s trajectory of events to intervene to prevent recurrence, and how aggressively, this kind of temporal information may be very informative.

Our study has several limitations. First, the generalisability of our findings and method—to other types of medico-legal events, to other types of health practitioners, and outside Australia—is unknown, and should be tested. In other medico-legal settings, it may not be possible for practitioners to accrue the large numbers of events that some doctors in our sample did. Lower ceilings on the number of prior events may reduce the predictive value of this variable. Nonetheless, our analyses showed high risks of recurrence within 2 years (>60%) among doctors with as few as four complaints.

Second, the predictors we examined were doctor-focused. Other variables—including, patient characteristics, case-type and outcomes, doctors’ ethnicity and country of training, the practice setting, and aspects of the patient-doctor relationship—may also predict complaint risk. However, because these variables are usually more difficult to measure at the population level, their suitability for large-scale predictive modelling is questionable. Moreover, given the high predictive values obtained with the simple doctor-level variables used in our analysis, the scope to boost predictive values with the addition of other variables is limited. Finally, we used head counts of practitioners, not more sophisticated measures of doctors’ exposure to complaint risk, such as volume of patients treated or procedures conducted.

During the rise of the quality and safety movement over the last 15 years, medico-legal institutions have been largely on the sidelines. They remain essentially reactive enterprises, with workloads that focus on dealing with the fallout from care that has gone wrong. Patient safety experts regard the medico-legal system’s fixation with post-hoc assessments of individual behaviour, rather than prevention and systems, as anachronistic. But as Rolph recognised 30 years ago, methods for accurately and reliably forecasting the medico-legal risk of clinicians have transformative potential because they could focus and drive prevention. Identifying and intervening early with doctors at high risk of attracting recurrent medico-legal events has considerable potential to reduce adverse events and patient dissatisfaction system-wide; it may also help those doctors avoid the vicissitudes of medico-legal processes.

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Contributors MB, MS and DS developed the study idea, collected the data and conducted the analyses; MB and DS wrote the first draft of the manuscript; MW advised on design of the study, contributed expertise in interpretation and analysis of study data, and helped revise the draft manuscript; LG contributed to design and conduct of the statistical analysis and helped revise the draft manuscript; all authors reviewed and agreed on the submitted version of the manuscript. MB, MS and DS are guarantors for the study.

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Competing interests All authors have completed the Unified Competing Interest form and declare that: (1) MB, MS and DS have support from the Australian Research Council (Laureate Fellowship to DS); (2) none of the authors have had a financial
relationships with any organisation that may have an interest in the submitted work in the previous 3 years; (3) none of the authors' spouses, partners or children have any financial relationships that may be relevant to the submitted work and (4) none of the authors have any non-financial interests that may be relevant to the submitted work.

Ethics approval The study was approved by the Human Research Ethics Committee at the University of Melbourne

Provenance and peer review Not commissioned; externally peer reviewed.

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REFERENCES
2.13 Mandatory reporting of concerns

Mandatory reports of concerns about the health, performance and conduct of health practitioners

Abstract

Objective: To describe the frequency and characteristics of mandatory reports about the health, competence and conduct of registered health practitioners in Australia.

Design and setting: Retrospective review and multivariate analysis of allegations of “notifiable conduct” involving health practitioners received by the Australian Health Practitioner Regulation Agency (AHPRA) between 1 November 2011 and 31 December 2012.

Main outcome measures: Statutory grounds for reports, types of behaviour reported, and incidence of notifications by profession, sex, age, jurisdiction and geographic area.

Results: Of 819 mandatory notifications made during the study period, 501 (62%) related to perceived departures from accepted professional standards, mostly standards of clinical care. Nurses and doctors dominated notifications: 89% (727/819) involved a doctor or nurse in the role of notifier and/or respondent. Health professionals other than the respondents’ treating practitioners made 46% of notifications (335/731), and the profession of the notifier and respondent was the same in 80% of cases (557/697). Employers made 46% of notifications (333/731). Psychologists had the highest rate of notifications, followed by medical practitioners, and then nurses and midwives (47, 41 and 40 reports per 10,000 practitioners per year, respectively). Incidence of notifications against men was more than two-and-a-half times that for women (46 vs. 17 reports per 10,000 practitioners per year; P<0.001) and there was fivefold variation in incidence across states and territories.

Conclusions: Although Australia’s mandatory reporting regime is in its infancy, our data suggest that some of the adverse effects and manifold benefits forecast by critics and supporters, respectively, have not materialised. Further research should explore the variation in notification rates observed, evaluate the outcomes of reports, and test the effects of the mandatory reporting law on whistleblowing and help-seeking behaviour.

baseline information on how the regime is working by analysing an early sample of mandatory notifications. Specifically, we aimed to determine how frequently notifications are made, by and against which types of practitioners, and about what types of behaviour.

Methods

We conducted a retrospective review and multivariate analysis of all allegations of notifiable conduct involving health practitioners received by AHPRA between 1 November 2011 and 31 December 2012. The Human Research Ethics Committee at the University of Melbourne approved the study.

Data sources

We obtained data from two AHPRA sources: mandatory notification forms and the national register of health practitioners.

AHPRA receives notifications on a prescribed form. Notifiers may access the form on AHPRA’s website or by calling a notifications officer on a toll-free number. Two of us (MM, DMS) helped AHPRA develop the form in 2011. It includes over 40 data fields; most fields have closed-ended categorical responses, but there is also space for free-text descriptions of concerns. Notifiers may append supporting documentation such as medical records and witness statements.

We obtained PDF copies of all notification forms received in five states and two territories between 1 November 2011 and 31 December 2012. Reports from New South Wales were not included. Although health practitioners in NSW are subject to the same reporting requirements as those in other states, AHPRA has a
Research

1 Elements of mandatory reporting law for health practitioners in Australia

Who can be subject to a report?
All registered health practitioners in Australia (doctors, nurses, dentists and practitioners from 11 allied health professions).*

Who has an obligation to report?
Employers, education providers and health practitioners.

What types of conduct trigger the duty to report?
The practitioner: (a) practised the profession while intoxicated by alcohol or drugs, (b) engaged in sexual misconduct in connection with the practice of the profession, (c) placed the public at risk of substantial harm in the practice of the profession because of an impairment, or (d) placed the public at risk of harm by practising in a way that constitutes a significant departure from accepted professional standards.

What is the threshold for reporting?
Reasonable belief that notified conduct has occurred.

What protections are available to the notifier?
A reporter who makes a notification in good faith is not liable civilly, criminally, in defamation or under an administrative process for giving the information.

What are the penalties for failing to report?
Individuals may be subject to health, conduct or performance action; employers may be subject to a report to the Minister for Health, a health complaints entity, licensing authority and/or other appropriate entity; education providers may be publicly named by the Australian Health Practitioner Regulation Agency (AHPRA).

* Registered students are subject to mandatory reporting if they place the public at risk of substantial harm because of an impairment, or are subject to certain criminal charges or convictions. Health practitioners are exempt from the obligation to report if they reasonably believe that AHPRA has already been notified of the conduct, or if they become aware of the conduct in the course of legal proceedings, professional indemnity insurance advice or approved quality assurance activities. Treating practitioners are exempt from the obligation to report in Western Australia only.

more limited role in relation to notifications made in NSW: when AHPRA receives such notifications, they are referred to the NSW Health Care Complaints Commission to be handled as complaints. AHPRA cannot log and track these notifications in the same way as it can notifications arising in other jurisdictions.

Data collection
We collected data onsite at AHPRA’s headquarters in Melbourne from April 2013 to June 2013. Three reviewers were trained in the layout and content of the notification forms, the variables of interest, methods for searching the health practitioner register, and confidentiality procedures. For each form lodged during the study period, the reviewers extracted variables describing the statutory grounds for notification, types of concern at issue, and characteristics of the practitioner who made the notification (“notifier”) and the reported practitioner (“respondent”). We also coded a variable classifying the relationship of the notifier to the respondent (treating practitioner, fellow practitioner, employer, education provider). Practitioner-level variables extracted from the notification forms were cross-checked with information recorded on the register.

One of AHPRA’s core functions is to maintain a national register of licensed health practitioners. To enable calculations of notification rates, AHPRA provided a de-identified practitioner-level extract of the register as at 1 June 2013. The extract consisted of variables indicating practitioners’ sex, age and profession, and the postcode and state or territory of their registered practice address. Practitioners from NSW and those with student registration were excluded to ensure that the register data matched the sample of notifications. Postcodes were converted to a practice location variable with three categories (major cities, inner and outer regional areas, and remote and very remote areas), based on the Australian Statistical Geography Standard.

Analyses
We calculated counts and proportions for characteristics of notifications, notifiers and respondents. We also calculated frequency of notification according to the professions of the notifiers and respondents, respectively.

We used multivariable negative binomial regression to calculate...
incidence of notifications by five respondent characteristics: profession, sex, age, state or territory, and practice location. Incidence measures reported for each characteristic were adjusted for the size of the underlying population and all other observed characteristics. Details of the calculation method and regression results are provided in Appendix (online at mja.com.au).

All analyses were done using Stata 13.1 (StataCorp).

Results

AHPRA received 850 mandatory notifications during the study period. After excluding notifications relating to nine practitioners from NSW and 22 students, our sample consisted of 819 notifications. The median time between the alleged behaviour and its notification to AHPRA was 38 days (interquartile range, 5 to 58 days).

Grounds and conduct

The distribution of notifications by statutory ground and type of concern, with examples, is shown in Box 2. This information was available for 811 of the 819 notifications. Sixty-two per cent were made on the grounds that the practitioner had placed the public at risk of harm through a significant departure from accepted professional standards; 17% alleged that the practitioner had an impairment that placed the public at risk of substantial harm (more than half of these related to mental health); 13% alleged that the respondent had practised while intoxicated; and 8% related to sexual misconduct (most commonly a sexual relationship between the practitioner and a patient).

Characteristics of notifiers and respondents

The characteristics of notifiers and respondents are shown in Box 3. Nurses and doctors dominated notifications, with 89% of all notifications (727/819) involving a doctor or nurse in the role of notifier and/or respondent. Nurses and midwives accounted for 51% of notifiers and 59% of respondents. Doctors accounted for 29% of notifiers and 26% of respondents.

Men constituted 37% of notifiers and 44% of respondents. Eighty per cent of notifications were about practitioners in three jurisdictions: Queensland (39% [321/819]), South Australia (22% [184/819]), and Victoria (18% [150/819]).

Nexus between notifiers, respondents and conduct

Among the 731 notifications for which it was possible to identify the professional relationship between the notifier and the respondent, 46% were made by fellow health practitioners (ie, health professionals other than the respondents’ treating practitioners) (Box 3). Forty-six per cent of notifications were made by the respondents’ employers; this included cases in which the notifier was also a registered health practitioner (eg, medical director of a hospital) but the notification was made in an employer rather than individual capacity.

Among 766 notifications for which it was possible to tell how the respondent's behaviour came to the attention of the notifier, the conduct was directly observed by the notifier in about a quarter of cases (201/736). In more than half of notifications (376/736), the conduct at issue came to the notifier’s attention through a third party — the patient, a colleague or some other person. For the remainder, the conduct was either identified through an investigatory process such as a record review, clinical audit, or police or coronial investigation (81/736) or self-disclosed by the respondent (78/736).

Intraprofessional and interprofessional notifications

Among 697 notifications for which it was possible to determine the profession of the notifier and the respondent, the profession of the notifier and respondent was the same in 80% of cases (557/697). This concentration of intraprofessional notifications is depicted in Box 4 by the diagonal line of relatively large bubbles running from the bottom left to the top right of the figure. Nurse-on-nurse notifications (those involving nurses and/or midwives) and doctor-on-doctor notifications accounted for 73% (507/697) of notifications.

Interprofessional notifications mostly involved doctors notifying about nurses (7% [51/697]) and nurses notifying about doctors (3% [20/697]). The remainder were widely distributed across other interprofessional dyads.

Incidence of notifications

The unadjusted incidence of mandatory reporting was 18.3 reports per 10,000 practitioners per year (95% CI, 17.0 to 19.6 reports per 10,000)
practitioners per year). Adjusted rates of notification for the five respondent characteristics analysed are shown in Box 5. Psychologists had the highest rate of notifications, followed by medical practitioners, and then nurses and midwives (474, 41.1 and 39.7 reports per 10 000 practitioners per year, respectively).

The incidence of notifications against men was more than two-and-a-half times that for notifications against women (45.5 v 16.8 reports per 10 000 practitioners per year; P < 0.001). Health practitioners working in remote and very remote areas had a much higher incidence of notification than those in major cities and regional areas (60.1 v 17.4 and 25.5 reports per 10 000 practitioners per year). There were also large differences in incidence of notifications across jurisdictions, ranging from 61.6 per 10 000 practitioners per year in South Australia to 13.1 per 10 000 practitioners per year in the Northern Territory.

**Discussion**

We found that perceived departures from accepted professional standards, especially in relation to clinical care, accounted for nearly two-thirds of reports of notifiable conduct received by AHPRA during the study period. Nurses and doctors were involved in 89% of notifications, as notifiers, respondents or both. Interprofessional reports were uncommon. We observed wide variation in reporting rates by jurisdiction, sex and profession — for example, a nearly fivefold difference across states and territories, and a two-and-a-half times higher rate for men than for women.

Our results suggest that some of the harms predicted by critics of mandatory reporting and some of the benefits touted by supporters are, so far, wide of the mark. Concerns that mandatory reporting would be used as a weapon in interprofessional conflict should be eyed with the finding that the notifier and respondent were in the same profession in four out of five cases. Indeed, the low rate of notifications by nurses about doctors (3%) gives rise to the opposite concern. Although nurses are often well placed to observe poorly performing doctors, our data suggest that the new law has not overcome previously identified factors that may make it difficult for nurses to report concerns about doctors.

On the other hand, supporters of mandatory reporting who heralded it as a valuable new surveillance system may be concerned by the low rates of reporting in some jurisdictions. Part of the variation in incidence of notifications across jurisdictions that we observed might reflect true differences in incidence of notifiable events, but it is also likely that differences in awareness of reporting requirements and differences in notification behaviour contribute to the variation. US research suggests that underreporting of concerns about colleagues is widespread, even when mandatory reporting laws are in place. The identified barriers to reporting fall primarily into four categories: uncertainty or unfamiliarity regarding the legal requirement to report; fear of retaliation; lack of confidence that appropriate action would be taken; and loyalty to colleagues that supports a culture of "gaze aversion". Action to be taken to understand and overcome these barriers could be aimed at jurisdictions with the lowest reporting rates.

The higher rate of notification for men that we observed is consistent with previous research showing that male doctors are at higher risk of patient complaints, disciplinary proceedings and malpractice litigation. While systematic differences in specially and the number of patient encounters may explain some of the heightened risk observed for men, other factors, such as sex differences in communication style and risk-taking behaviour, are probably also in play.

The main strength of our study is that we included data from every registered health professional and all one jurisdiction. The ability to access multistate data for research and evaluation purposes is an important benefit of Australia's new national regulation scheme, and could not have been possible 5 years ago. Other federalised countries with siloed regulatory regimes continue to struggle with fragmented workforce data.

Our study has three main limitations. First, because mandatory reporting was implemented in concert with other far-reaching changes to the regulation of health practitioners, it was not possible to compare the incidence of notifications before and after the introduction of the new law. Second, it was not feasible to include information on the outcomes of notifications: too small a proportion of notifications had reached a final determination at the time of our study.
to provide unbiased data. As the scheme matures, it would be useful to explore what proportion of reports were substantiated and resulted in action to prevent patient harm, at an individual or system level. Third, our analysis did not include notifications against practitioners based in NSW.

This study is best understood as a first step in establishing an evidence base for understanding the operations and merits of Australia’s mandatory reporting regime. The scheme is in its infancy and reporting behaviour may change as health practitioners gain greater awareness and understanding of their obligations. Several potential pitfalls and promises of the scheme remain to be investigated — for example, the extent to which mandatory reporting stimulated a willingness to deal with legitimate concerns, as opposed to inducing an unproductive culture of fear, blame and vexatious reporting. Qualitative research, including detailed file reviews and interviews with health practitioners and doctors’ health advisory services, would help address these questions. Further research should also seek to understand the relationship between mandatory reports and other mechanisms for identifying practitioners, such as patient complaints, incident reports, clinical audit, and other quality assurance mechanisms.

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2.14  Mandatory reporting of impaired medical practitioners

Mandatory reporting of impaired medical practitioners: protecting patients, supporting practitioners
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Key words
mandatory reporting, impairment, patient safety, medical regulation.

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Abstract
Taking action to protect patients from impaired colleagues is a long-standing ethical and professional obligation. In 2010, this responsibility was codified in law with the introduction, across Australia, of a new mandatory reporting regimen. While several concerns remain to be addressed, mandatory reporting has the potential not only to reinforce the primacy of patient safety, but also to open internal dialogue about the profession’s response to concerns about practitioner health and well-being. Four years after the introduction of the scheme, key challenges include ensuring the reporting threshold is appropriately defined and clearly understood, improving access to evidence-based health programmes for practitioners, and strengthening upstream protections to prevent and minimise impairment at its roots.
Introduction

One of the most enduring responsibilities of medical practitioners is to act ‘for the good of my patients according to my ability and my judgment and never do harm to anyone’. This includes a longstanding ethical and professional responsibility to protect patients from unsafe colleagues. In 2010, this ethical and professional responsibility was codified in law with the introduction, across Australia, of a new mandatory reporting regime.

Under the new law, registered health practitioners must inform the Australian Health Practitioner Regulation Agency (AHPRA) if another health practitioner has engaged in certain forms of ‘notifiable conduct’ involving intoxication, sexual misconduct, departure from professional standards or impairment. This paper focuses on the last of these grounds: the requirement to notify AHPRA if a practitioner has ‘placed the public at risk of substantial harm in the practitioner’s practice of the profession because the practitioner has an impairment’.

The law defines ‘impairment’ to mean a ‘physical or mental impairment, disability, condition or disorder (including substance abuse or dependence), that detrimentally affects or is likely to affect detrimentally a registered health practitioner’s capacity to practise safely the profession or a student’s capacity to undertake clinical training’. Certain practitioners, including those working for medical indemnity organisations, and treating practitioners in some states, are exempt from the reporting requirement, but still have an ethical duty to make voluntary reports where appropriate.

We discuss the introduction of mandatory reporting as a response to perceived failures in self-regulation, and examine the threshold for notification, the response to notifications and the profession’s wider role in protecting patients and impaired practitioners from harm. In doing so, we hope to address some of the concerns raised by Beran and others, and correct some misconceptions regarding the scheme.

Mandatory reporting as a response to failures in self-regulation

Medical practitioners have long enjoyed the benefits of being a highly regarded and largely self-regulating profession. But those benefits come with a price – the obligation to ensure the competence, good character and trustworthiness of the members of the profession. If a profession fails to meet these fundamental tenets through self-regulation, society can – and will – intervene. Mandatory reporting can be viewed as a response, at least in part, to perceived failures to protect adequately patients from harm caused by impaired practitioners.

Like anyone else, medical practitioners may experience physical and mental illnesses, disabilities and addictions. Indeed, medical practitioners are at higher risk of stress, burnout, mental health concerns, misuse of prescription drugs and suicidal ideation than the general population. For the safety of patients and practitioners, these issues require early identification, and appropriate support and treatment. Unfortunately, medical culture has long resisted such timely intervention – favouring stoicism and self-treatment over the perceived stigma and vulnerability of the patient role. Such attitudes are particularly concerning, coming from a group that have been trained and entrusted to diagnose and treat health problems in others.

Without early identification and appropriate support, illness and disability can evolve into impairment – impacting on the quality and safety of practitioners’ work. Numerous high-profile cases across Australia and New Zealand illustrate the serious harm that patients can suffer under the care of impaired practitioners. Obstetrician and gynaecologist Graeme Reeves violated female patients with sexual assaults and genital mutilation while experiencing depression and a personality disorder. Another obstetrician and gynaecologist, Roman Hasil, moved from hospital to hospital, leaving a trail of complaints and adverse events, while impaired by alcohol dependence and a head injury. In Victoria, anaesthetist James Peters infected 55 women with hepatitis C by reusing needles on patients after injecting himself with fentanyl.

Again and again, cases like these uncovered colleagues and employers who turned a blind eye to warning signs of impairment, did not speak up or failed to act in an appropriate and timely manner. As a result, the public saw a profession that could not adequately regulate itself, and where further action was required to ensure that every registered medical practitioner was ‘good enough’. In response, sweeping changes were implemented to increase scrutiny over health professions and protect patients from harm. One of these was the introduction of mandatory reporting.

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Conflict of interest: M. M. Bismark is the recipient of a Fellows Career Development Fellowship from the Royal Australasian College of Physicians (RACP) to research mandatory reporting of health practitioners in Australia. J. M. Morris is a community member of the Australian Health Practitioner Regulation Agency (AHPRA) Community Reference Group. C. Clarke is the former Chair of the Medico-legal Expert Advisory Group of the RACP.

The views presented here are the personal views of the authors and do not represent the opinion of AHPRA or the RACP.
Purpose of reporting

The purpose of mandatory reporting is to protect patients from being harmed by health practitioners whose capacity to practise safely is impaired. Few would dispute this as a laudable aim. Arguably, it might have been achieved through a well-functioning system of voluntary self-regulation. But in reality, health ministers and officials, acting on behalf of the public, lost confidence in the profession’s capacity to achieve this, and some professional freedoms were curtailed. In the face of these changes, we must take stock of the reasons mandatory reporting was deemed necessary, and practitioners’ ethical and professional obligations under the new law.

The impact of a mandatory reporting regimen depends on three key factors. First, whether the reporting threshold is appropriate and clearly understood. Second, whether reports result in a timely and appropriate response. And third, whether reporting requirements are embedded in a broader system that prevents and mitigates risks before they reach the reporting threshold.

Threshold for reporting

The first factor influencing the success of mandatory reporting is whether an appropriate reporting threshold is applied and understood. The threshold for mandatory reporting, as expressed in both legislation and guidelines, is high. This is appropriate. Importantly, health conditions or disabilities do not equate, on their own, to ‘impairments’, unless their impact on practitioner performance compromises safety. Many practitioners practise safely with illness and disability, through suitable career choices, voluntary practice adjustments and appropriate treatment. In these cases, patients are protected from harm, and the mandatory reporting threshold is not met. But where these measures are refused, resisted or insufficient, the health condition may present a risk to patients, becoming an impairment of potential regulatory interest.

The first and most significant concern about the threshold for reporting relates to the obligations of practitioners providing treatment to practitioner-patients. Treating practitioners have long had an ethical obligation to take appropriate action to avert danger to others. In the words of Justice Tolérine in the Tarasoff case: ‘The protective privilege ends where the public peril begins’. At the same time, we must guard against the risk that fear of reporting may compound existing barriers to help-seeking by unwell practitioners. A review of the new regulatory scheme is considering whether the law should be clarified to reflect the intent that notification is not required where a practitioner is receiving treatment and does not present a risk of substantial harm.

The second concern is that many practitioners remain unsure about the nature and scope of their obligations. Recent research identified a greater than fourfold variation in reporting rates across different states and territories. This suggests a need for a clearer articulation of the risk threshold (including an appropriate distinction between past and future risk), and further education and advice for practitioners.

The final concern about the threshold for reporting is that, in a small number of cases, practitioners appear to have made trivial or vexatious reports for personal or anti-competitive reasons. In response, we note that such behaviour, undesirable as it is, can occur under any regulatory system that permits reports or notifications – voluntary or mandatory. As long as practitioners have a right to raise concerns about colleagues – a right few would dispute – there is the potential for misuse. AHPIRA has made it clear that notifications that are frivolous, vexatious or not in good faith may be subject to conduct action. But the profession must also take responsibility for its role in preventing misuse of mandatory reporting.

Regulatory response

The second factor influencing the success of a mandatory reporting regimen is the appropriateness of the regulatory response. Reporting requirements alone achieve little unless both practitioners and the public have well-placed confidence that reports will be managed in a fair, timely and appropriate manner.

Appropriate regulatory responses are proportional and responsive to circumstances. In line with international best practice, Australian regulators support alternative-discipline health programmes as a first option for impaired practitioners. The Medical Board may impose conditions that support a safe return to practice, or require a practitioner to limit the scope of his or her practice to avert certain risks. In cases where appropriate protections are already in place, the Board will commonly take no further action. In rare cases, a practitioner’s registration may be suspended to protect patients from harm. Some practitioners – particularly those who lack insight into their illness – will, understandably, perceive restrictions on their practice as punitive. However, the intent of mandatory reporting of impairment is not to punish practitioners, but to ensure public safety within a framework that supports their return to safe practice where possible. Perhaps this has not been effectively communicated, and more publicity and education could assist understanding.
The fairness and timeliness of regulatory processes also matter. It is critical that notifications are managed effectively and efficiently to protect the public. Concerns expressed during the review of the national scheme include a lack of information provided to notifyers, delays in investigation and poor communication of outcomes. Addressing these concerns may help increase the trustworthiness of the scheme.

Sound outcomes data would also assist the profession to evaluate the impact of mandatory reporting. Such evaluations are difficult because the law is relatively new, and the causality between mandatory reporting and patient protection is not always clear and direct. It is manifestly difficult to prove efficacy where the measure of success is preventing an unpredictable outcome (i.e. patient harm). Nevertheless, it is important that AHPRA support efforts to examine the outcomes of mandatory reports, and their impact on patient safety.

One element in a system

The third element to consider is the broader context in which mandatory reporting operates. Mandatory reporting is a safety net intended to catch cases of dangerous practitioner impairment that reach a late and serious stage. The more we can identify and support practitioners at an early stage of their illness or disability, the less often mandatory reporting will come into play. Strengthening ‘upstream’ elements of our system is the best way for the profession to establish its ability – and trustworthiness – to prevent and address impairment through self-regulation, rather than legislation.

To care well for our patients, we must also care for ourselves and our colleagues. Yet many medical practitioners do not have a regular general practitioner; professional stigma around mental illness remains high, and cultures of stoicism and denial persist. Effective intervention by colleagues or employers can – and should – occur before the mandatory reporting threshold is met. But significant cultural barriers, which predate the introduction of mandatory reporting, can make it difficult for concerned colleagues to speak up. These include rigid hierarchies and fear of career repercussions.

There are hopeful signs that these attitudes are slowly changing. Educators are paying more attention to self-care in the medical curriculum; employers are recognising the importance of safe working hours, effective supervision and bullying prevention; researchers are developing tools to help identify high-risk practitioners early in their career trajectory; and insurers and colleges are developing programmes to assist practitioners in difficulty.

Once identified, it is essential that practitioners with health concerns are able to access timely, effective and evidence-based treatment and support. Internationally, service models for impaired medical practitioners range from phone support lines to intensive case management. Within Australia, a number of states offer doctors’ health services, tailored to the needs of medical practitioners, based on the success of physicians health programmes in the United States. The Medical Board has recently committed to funding a nationally consistent set of health services to medical practitioners and students in all states and territories, to be run at arms’ length from the Board.

Conclusions

Taking action to protect patients from impaired colleagues is a long-standing professional and ethical obligation. Yet there were worrying signs that the profession was not living up to this responsibility, including some high profile cases where failures to identify or address impairment in time resulted in serious patient harm. The resulting damage to the public’s trust saw the introduction of a mandatory duty to report situations where a practitioner’s impairment presents a risk of ‘substantial harm’ to the public.

While some practitioners will continue to dispute the need for regulatory intervention, mandatory reporting is now embedded in law and is unlikely to be repealed (though its application to treating practitioners is under review). Currently, we consider the profession’s energy best spent in three areas: ensuring the reporting threshold is appropriately defined and clearly understood, advocating for improved access to evidence-based health programmes for practitioners, and strengthening upstream protections to prevent and minimise impairment at its roots. While a number of concerns remain to be addressed, mandatory reporting has the potential not only to reinforce the primacy of patient safety, but also to open internal dialogue about the profession’s poor record on practitioner health, promoting new approaches to wellness.

Indeed, the transformative power of mandatory reporting may lie less in the regulatory response to individual cases, and more in the profession’s response to its message.
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2.15 The legacy of the Cartwright Report

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CRITICAL PERSPECTIVES

The Legacy of the Cartwright Report: “Lest It Happen Again”

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Abstract The 1987 Cartwright Report into events at New Zealand’s National Women’s Hospital catalysed sweeping changes to promote and protect patients’ rights. A generation on, it is comfortable to believe that such sustained and deliberate violations of patient rights “couldn’t happen here” and “couldn’t happen now.” And yet, contemporary examples beg a different truth. Three of Cartwright’s messages hold an enduring relevance for health practitioners and patients: the need for patients to be respected as people; to be supported to make informed choices; and to have their voices heard, even when they whisper. These challenges cannot be met in isolation from broader determinants of patients’ rights and will require social, technological, and cultural change in order to prevent another “unfortunate experiment.”

Keywords Cartwright Inquiry · Patients’ rights · Medical regulation · Informed choice

The Cartwright Report

In 1987, an article entitled “An ‘unfortunate experiment’ at National Women’s” appeared in New Zealand’s Metro magazine (Coney and Bunkle 1987). The article exposed unethical conduct at New Zealand’s leading women’s hospital. Beginning in 1966, obstetrician and gynaecologist Dr. Herbert Green deliberately under-treated women with cervical abnormalities to observe whether they subsequently developed cancer. The women were not told of the study, nor was consent obtained for their “participation.” Many developed invasive cancers that may have been prevented with conventional treatment (McCredie et al. 2008).

The revelations sparked public outrage and a judicial inquiry, led by Judge Silvia Cartwright. The resulting Cartwright Report (Cartwright 1988) led to sweeping changes. A Health and Disability Commissioner was established, and the world’s first legislated code of patients’ rights was enshrined in law (Paterson 2002). A network of patient advocates was established, and patients’ rights are now taught in medical schools and displayed on waiting room walls. Similar reforms followed in several other countries (Bismark et al. 2013).

A generation on from the Cartwright Report, comfortable in congratulating ourselves for these wide-reaching reforms, it is tempting to believe that Dr. Green’s conduct was a one-off aberration, made possible by the patriarchal medical culture of the time—an aberration that happened a long time ago, in an era less enlightened than our own. “Couldn’t happen here,” we say, “couldn’t happen now.”

The Cost of Complacency

Such complacency would be both harmful and misplaced, because serious and sustained patient rights violations do happen “here.” “To the question of whether events such as
those investigated by Judge Cartwright still occur today, the answer is quite simply ‘Yes’” (Campbell, Chuan, and Chin 2009, 182).

In 2012, an Australian oral surgeon was disqualified from practice following convictions for indecent assault and other offences relating to a bogus university “study.” Claiming to be investigating “the blood pressure effects of masturbation,” he convinced adolescent men to masturbate in front of him and rewarded them with money or discounted surgery. His behaviour went unchecked for years (ICC v Bosanguit [2012] NSWDT 2).

In 2013, a New Zealand clinic was found to have coerced and exploited patients seeking assistance with erectile dysfunction. Doctors failed to provide sufficient information about treatment options, pressured patients into treatment contracts, and failed to adequately respond to concerns. The Health and Disability Commissioner found that the clinic’s conduct showed a disregard for patients’ rights and for its responsibilities as a provider of health services (Health and Disability Commissioner 2013).

In 2014, a Canadian anaesthesiologist was sentenced to 10 years in prison for sexually assaulting 21 female patients over a span of four years. He chose his victims for their vulnerability and forced sexual acts onto them while they were under conscious sedation during surgery. His offending was concealed from colleagues by a surgical screen, his “forensic” understanding of operating room behaviours, and the blinkered view of colleagues who dismissed initial complaints as implausible (Mandel 2013).

These cases are anything but isolated. Hardly a month goes by without a court, disciplinary tribunal, or journalist reporting a serious, sustained breach of patients’ rights. And those are only the ones we know about.

Reading these cases, three things stand out. First, these practitioners approached patients as a means to an end, rather than people worthy of respect. They violated core ethical responsibilities—disregarding patients’ interests in favour of their own, flouting informed consent, and trampling on professional boundaries.

Second, these patients were denied informed choice through coercion, force, or fraud. The barriers faced by patients varied: limited literacy, poverty, sedation, shame, and/or isolation from other patients’ experiences. Yet all had the same effect of rendering the patients vulnerable to trusted professionals.

Third, after their ordeals, these patients’ voices were muffled by youth, gender, social status, or the fear (and reality) of not being believed. One teenager’s father refused to pursue justice because of the surgeon’s reputation. Another woman was told she hallucinated her sexual assault. Their credibility was crushed; their voices silenced.

**Respect, Choice, and Voice**

For anyone familiar with the Cartwright Report, these issues around respect, voice, and choice carry a saddening sense of déjà vu. A generation ago, that ground-breaking report set the same three alarm bells ringing.

The first alarm bell was about respecting patients as people. Some women were recalled to Dr. Green’s clinic more than 40 times for tests and biopsies, unaware of the true nature of their condition (Cartwright 1988). Dr. Green seemed unmoved that these “participants” were real women with children, jobs, and financial stresses, who had more pressing things to do than undergo invasive investigations, only to not receive necessary treatment.

The second alarm concerned choice. The Cartwright Report noted that “It is not difficult to imagine a situation where a patient has too little medical knowledge to ask the right questions” (Cartwright 1988, 134). Cartwright highlighted that, when a person does not know the treatment options or what questions to ask, theirs is not a truly informed choice. And doctors are obliged to ensure that “yes” means “yes” and does not merely arise from fear of compromising future care.

The third alarm related to patient voice. Cartwright came back to the concept of voice over and over, from patients who were afraid to rock the boat by asking too many questions to futile attempts by Dr. Green’s colleagues to raise concerns (Paul 2000). In thinking about these muffled voices, we would do well to remember the words of Arundhati Roy: “There’s really no such thing as the ‘voiceless.’ There are only the deliberately silenced, or the preferably unheard” (Roy 2004, 4).

There are important differences between the recent examples of misconduct above and Dr. Green’s “unfortunate experiment.” And yet, the same issues live on—lack of respect, compromised choice, and silenced voice. Far from being confined to a “moment in time,” the Cartwright alarms are still ringing. But too often, we do not even hear them, much less heed them.
Has Anything Changed?

Before turning to consider what more needs to be done to better protect patients’ rights, it is helpful to reflect on what has been achieved so far, because, ongoing difficulties acknowledged, a lot has changed. Recommendations from Cartwright that were once challenging and controversial are now well-established.

In relation to choice, the Cartwright Report recommended:

The patient is entitled to all relevant information concerning her treatment, the options for treatment, and all information concerning her possible inclusion in a research trial. The focus should be centred on the patient and not on the doctor. It is a principle designed to protect and preserve the patient’s rights, not to protect the doctor from liability (Cartwright 1988, 136).

Across New Zealand and Australia, codes and charters of patients’ rights now enshrine the right to effective communication, sufficient information, and informed choice. The prevailing legal standard is a patient-centred one: “What would a reasonable patient want to know?” rather than “What would a reasonable doctor disclose?” (Rogers v Whitaker [1992] HCA 58; 175 CLR 479; 23 NSWLR 600; 109 ALR 625).

In relation to patient voice, the Cartwright Report recommended that legislation provide for a statement of patients’ rights and the appointment of a Health Commissioner to protect and promote those rights. It is testament to the Cartwright Report’s impact that these recommendations came to fruition, with independent complaints commissioners now operating across New Zealand and Australia. There is little doubt that patients’ rights are more widely recognised now, and more strongly protected, than 25 years ago.

And yet there remains the third major concern: respect. The very first sentence of the New Zealand Code of Rights states that: “Every consumer has the right to be treated with respect” (Health and Disability Commissioner 1996, Right 1). Yet, respect for patients—hard to define, intangible to measure, and intensely personal—remains the least convincing domain of change. On paper, “respectful, patient-centred care” may be the new normal, but the lived reality of many patients and their families often reveals otherwise.

Three Future Challenges

We suggest that the most pressing unfinished business of the Cartwright Inquiry lies not in further regulation of patients’ rights—those foundations have been laid—but in buttressing this still fragile structure with social, technological, and cultural support.

Social Determinants: Patients’ Rights as Human Rights

First, to borrow from Hilary Clinton’s comments on women’s rights, we need to acknowledge that patients’ rights are human rights and human rights are patients’ rights (Clinton 1995). It is naïve to think that health practitioners will treat all patients with respect and dignity always, while society continues to tolerate profound inequality and injustice.

All too often, the harm caused by health care is simply the final spill in a cascade of disparities. Patients from less privileged socioeconomic backgrounds are more likely to be exposed to risk factors such as smoking, alcohol, and poor nutrition, more likely to become unwell, less likely to access necessary health services, less likely to receive timely and appropriate care, more likely to be harmed by health care, and less likely to receive compensation for that harm.

In a way, hospitals are an echo chamber of broader social inequalities and norms. We cannot begin to meaningfully address a family’s complaint that their child’s diagnosis was delayed, when they live in a community without adequate housing, good nutrition, and affordable access to medical care. We cannot begin to meaningfully address a woman’s complaint that the benefits of cosmetic procedures were oversold (Bismark et al. 2012), while we tolerate a society where body dissatisfaction, age-based discrimination, and gender inequities are the norm.

As long as women, people with disabilities, indigenous minorities, and others are oppressed by unequal status and daily discrimination, our hospitals will never be an oasis of dignity and equality. Anyone who sincerely cares about patient rights must also care about broader human rights.

Technology: Plugging the Information Gaps

Second, we must rethink how patients are supported to make choices about care. The Cartwright Report noted that patients have a right to understand their options and
relevant risks and benefits. But we are fooling ourselves if we believe that traditional medical consultations always facilitate such true informed choice.

We must reach beyond the confines of the consult. Technology can help patients access support when and where they need it most (Burns et al. 2013), breaking free of the restrictions of 9 a.m. to 5 p.m. face-to-face appointments.

Technology can assist patients to understand treatment options. There is good evidence that patients who use interactive educational tools, followed by a discussion with a health practitioner, better understand the risks and benefits of proposed treatments than those who have the discussion alone (Schenker et al. 2011).

Technology can also help patients and their families to monitor their progress—a privilege that was not extended to Green’s patients. For one family, it took 10 years after their mother’s death from cervical cancer to receive records that revealed the significance of Green’s “wait and see” policy of non-treatment (Matheson 2009). How differently would her story have ended had she and her family been able to see those records in real time?

And finally, technology can allow patients to hear the voices of others, ending the veil of secrecy that has long surrounded poorly performing practitioners. Clare Matheson writes: “I had no inkling that my case was just the tip of the iceberg” (Matheson 2009, 58). Current regulatory practice renders patients heavily reliant on health practitioner boards to filter concerns and act on their behalf. This paternalistic approach strips patients of the choice to hear others’ voices and to decide what counts as “good enough.” In a world where we can readily access information from other consumers on the responsiveness of a hotel or the safety of an airline, the days of doctors and regulators saying “just trust me” must surely be numbered.

Culture: Learning to Listen and Listening to Learn

And finally, we need a cultural shift in the way that we hear the concerned voices of patients and colleagues. Charlotte Paul writes: “Despite the huge changes to the regulatory environment—the external morality of medicine—over the last twenty years, dealing with colleagues who err remains difficult” (Paul 2000, 94). Rather than fearing, resenting, or dismissing complaints and notifications of concern, we need a paradigm shift that allows health practitioners to see them as an invitation to learn; a light illuminating the path to improvement (Jha 2013).

Most people who lodge a complaint or notify an employer or registration board of a concern are not “troublemakers” or “out to get” a practitioner. They recognize that the harm that has occurred can never be undone. They simply want to know what went wrong and why and to make sure nobody else suffers the same preventable harm (Bismark and Dauer 2006). We have very good reason to listen to those concerns. A national study of patient complaints in Australia found that fewer than 5 percent of doctors accounted for nearly 50 percent of complaints (Bismark et al. 2013). The voices of patients and other health practitioners matter—not just for the resolution of individual concerns, but for the protection of future patients.

We also must find creative ways to hear the voices of patients who don’t complain. For every patient who complains about a serious, preventable injury, dozens more never lodge a complaint with a health commissioner, particularly those who are elderly, socioeconomically disadvantaged, and in an ethnic minority (Bismark et al. 2006). Once again, issues of social equity underpin missed opportunities for improvement. The recent Berwick Report argues that for health care to become safer, we must “hear the patient voice, at every level, even when that voice is a whisper” (Berwick 2013, 18).

Rising to meet the challenges outlined above won’t be easy, but doing so will be worth the effort. A kinder and more equitable society, a technologically literate and informed patient community, and a health profession that listens with openness and humility: Only when these supports are in place will the Cartwright bells stop ringing their alarm and instead become the background accompaniment to an ever-vigilant collective conscience in health care.

In the words of Clare Matheson, the courageous woman whose story catalysed the Cartwright Inquiry: “We must never forget, lest it happen again” (Matheson 2009, 58).

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Disclosure  Marie Bismark is a director of the Young and Well Cooperative Research Centre, which aims to better understand the influence of technology on young people’s health and well-being.

References


Chapter Three: Discussion

“I believe that academia has much to offer regulatory agencies—a risk control orientation demands substantial analytic sophistication, and problem-solving methods require attention to measurement and methodological rigor rare in government.”

- Malcolm Sparrow

3.1 Summary

The New Zealand and Australian medico-legal systems are often held up as being at the forefront of medical regulation internationally. And indeed, they do offer many advantages over a traditional tort-based system. The process of lodging a complaint or making a notification is simpler and less costly than filing a law suit. Complaints commissioners can offer a range of non-monetary remedies as part of their complaint resolution processes. Mandatory reporting requirements oblige practitioners and employers to report concerns about impaired colleagues to regulators. And, in New Zealand, no-fault compensation is available to injured patients without the requirement to demonstrate negligence. Together these features fill many of the gaps long lamented in the medical negligence system.

And yet, even these medico-legal systems fall short in meeting the expectations of patients, practitioners, and the public. The collection of works set out above probes this puzzle, using tools from the field of epidemiology, rather than traditional methods of medico-legal analysis. We collected tens of thousands of claims, complaints, and notifications and analysed them for patterns that might help those agencies better meet the needs of those they serve.

3.1.1 Findings

Papers 2.1 to 2.5 explored patients’ motives for medico-legal action and the ‘gap’ between what they desire and receive. We found that, following an adverse event, only a small proportion of patients will bring a claim or complaint. Among serious, preventable adverse events identified by the New Zealand Quality of Health Study, only 4% resulted in complaints. Among those patients who were eligible for no-fault compensation, fewer than 5% claimed it.
At a population level, there are significant differences between those who take medico-legal action and those who do not. As expected, the propensity of injured patients to complain increased with the severity of injury. Odds of complaint were more than ten times greater for serious permanent injuries than temporary injuries. Of more concern was our finding that the odds of complaining were significantly lower for patients who were elderly, of Māori ethnicity, or lived in the most deprived areas. Previous studies in the United States had similar findings. However, we were surprised to find that such profound under-claiming and access disparities persist in New Zealand, where no-fault compensation and complaints processes were intended to be accessible to all.

Our analysis of claims and complaints showed that patients who pursue medico-legal action in the aftermath of medical injury seek four forms of accountability:

- Communication (explanation or apology, expression of responsibility)
- Correction (competence review or system change)
- Restoration (compensation or intervention)
- Sanction (punishment or discipline).

Among patients in New Zealand who took medico-legal action, 50% sought corrective action to prevent similar harm to future patients. Typical comments included: “I hope that this complaint makes a difference for the treatment of others” and “We certainly wouldn’t want anyone else to go through what we went through.” Forty percent wanted better communication.

Injured patients and their families involved in medico-legal action have many objectives besides money. However, for some patients, apologies and explanations do not suffice as a substitute for financial compensation. The odds that patients would seek compensation were significantly increased if they were in their prime working years, or had a permanent disability as a result of their injury.

Unfortunately, there is evidence of a significant ‘expectation gap’ between what patients seek and what they eventually get out of the complaints process. Analysing a sample of complaints relating to informed consent in Victoria, Australia, we found that just one third of complainants who sought restoration received it, and only one in five complainants who sought correction received assurances that changes had been made to prevent future harm. There are two logical ways in which the expectation gap can be narrowed. Either by
decreasing unrealistic expectations, or providing more complainants with the remedies they seek.\textsuperscript{68}

Papers 2.8 to 2.10 offered a deeper dive into a common area of medico-legal concern: informed consent. Just as certain practitioners appear to be at higher risk of complaint, so too are certain types of procedures and complications. Among 481 malpractice claims and serious healthcare complaints involving informed consent, we found that a disproportionate share (16%) related to cosmetic procedures. Based on a detailed review of these cases, it seems that certain factors ‘supercharge’ a healthcare interaction for a medico-legal complaint: an elective procedure, a rushed and pressured consultation, an unrealistic portrayal of benefits, and highly visible complications.\textsuperscript{72} In a separate analysis, we identified a small group of adverse outcomes that seem to matter a lot to patients, yet may not be routinely disclosed during the informed consent process: poor cosmetic result, the need for further surgery, impaired vision or hearing, chronic pain, and infertility or sexual dysfunction.\textsuperscript{95}

Papers 2.11 to 2.14 focused on understanding the characteristics of high-risk practitioners in order to help prevent harm. While medical practitioners feel that they all practice under a medico-legal cloud, our research confirmed that it “doesn't rain on everybody equally and that some physicians have a malpractice dark cloud.”\textsuperscript{96} While we expected to find some clustering, based on previous studies of malpractice claims, complaints and disciplinary actions, we were surprised by the extent to which some doctors were over-represented in complaints data. Among our national sample of 19,000 complaints to health complaints commissioners, just three percent of all doctors accounted for nearly half of all complaints.\textsuperscript{62}

The number of prior complaints doctors had experienced was a strong predictor of subsequent events, and a dose-response relationship was evident.\textsuperscript{62} Male doctors had a 40% higher risk of recurrence than their female colleagues, and older doctors had a 30 to 40% heightened risk of recurrence.\textsuperscript{62} Doctors named in a third complaint had a nearly 60% probability of being named in a further complaint within two years.\textsuperscript{62}

Mandatory reporting offers another potential way for regulators to identify high-risk practitioners. However, early data from Australia’s new mandatory reporting regime suggest that many practitioners remain unsure about the nature and scope of their obligations, with wide variations in reporting behaviours between different groups.\textsuperscript{71} Key challenges include ensuring the threshold for reporting is appropriately defined and clearly understood,
improving access to evidence-based health programmes, and strengthening upstream protections to prevent impairment at its roots.\textsuperscript{70}

3.1.2 Themes

During a decade of research in this field, three powerful themes emerged.

First, patients and other practitioners serve an important surveillance role and can be powerful allies in the quest for safer care. Their eyes and ears are effective in identifying problems, but only if medico-legal agencies are committed to listening, and making it safe and worthwhile for them to speak up. Hearing the voices of patients is also crucial for providing them with the remedies that they want and need. In practice, the voices of many injured patients go unheard, either because they never file a claim or complaint, or because there is a mismatch between what they seek, and what an entity is equipped to deliver. In particular, the relatively low propensity to complain among patients who are elderly, socio-economically deprived, or of Māori ethnicity suggests troubling disparities in access to, and utilisation of, claims and complaints procedures.\textsuperscript{65} In thinking about these muffled voices, we would do well to remember the words of Arundhati Roy: “There’s really no such thing as the ‘voiceless’. There are only the deliberately silenced or the preferably unheard.”\textsuperscript{97}

Second, important patterns have been overlooked because agencies have lacked the time, resources, and analytical skills to make sense of population-level data. The claims and complaints we reviewed are a rich and nuanced source of data on risks to patient safety and sources of patient dissatisfaction. But once an individual file has been closed, it is usually archived without further analyses of how it contributes to broader patterns of concern. Agencies will commonly undertake some descriptive analyses for their annual reports, but these tend to focus on numbers of cases resolved and days to closure rather than contributing to an improved understanding of risks and causal factors. A better understanding of ‘hot spots’ of medico-legal concern has real potential to inform the way we train medical practitioners, communicate with patients, and design regulatory systems. In the words of Geoffrey Moore: “Without big data analytics, companies are blind and deaf, wandering out onto the web like deer on a freeway.”\textsuperscript{98}

And third, serious adverse events rarely happen without warning. Our research shows a significant concentration of risk among a relatively small number of health practitioners. Much as detection dogs are used to sniff out security risks from among the thousands of passengers who pass through an airport each day, powerful statistical methods have potential
to help medico-legal agencies identify those few practitioners who are at significantly increased risk of future complaints compared with their peers.\(^7\) Having identified the concentration of risk, the next challenge for regulators is to develop and evaluate programs to try and reduce that risk.

Collectively, our findings suggest that a reactive and process-driven approach to resolving individual cases has ‘dulled the senses’ of medico-legal agencies. It is not that they do not want to hear patients’ and practitioners’ voices at the population level or see patterns of concern. Rather, they do not have the right organisational skills and experiences to do so. As discussed in our recommendations below, an effective approach to regulation requires, at its core, substantially enhanced analytic capabilities. Perhaps it is time for the medical and legal professions to recognise that epidemiology is as indispensable to medical regulators as it is to public health.

### 3.1.3 Limitations

In undertaking our research we encountered some recurring limitations related to data quality, coding taxonomies, and availability of denominator data.

**Data quality and completeness**

Medico-legal data in Australia and New Zealand remains widely dispersed across different agencies.\(^9\) The establishment of the Australian Health Practitioner Regulation Agency has helped to address this problem by bringing together over seventy health practitioner regulation boards under one umbrella. However, each of the nine health complaints commissioners across Australia and New Zealand still operates independently, and data relating to claims is held by multiple insurers. We were partially able to overcome this limitation through a labour-intensive process of collecting data on-site from each agency. However, privacy considerations and data quality issues limited our ability to identify practitioners who moved across state boundaries or who came to the attention of multiple medico-legal agencies.

The completeness and accuracy of data varies widely, though this is slowly improving. Some key variables such as ethnicity are not collected, or are only collected by some agencies. Overcoming this limitation will be particularly important for understanding access to medico-legal agencies by indigenous Australians: a group who already experience a cascade of disparities within the Australian healthcare system.

**Coding taxonomies**
Our ability to analyse some crucial questions was also hampered by the lack of principled and consistent taxonomies for coding variables such as complaint issue or the seriousness of harm. We were also unable to code the merit of patients’ complaints, because commissioners focus on resolving complaints, rather than issuing a decision as to whether they were upheld. As a result we had to rely on complaint issue type as a crude proxy measure of severity. The need for international standardised terminology, common methods of measurement and evaluation, and compatible reporting of adverse events, has been recognised for at least a decade. However, within the international patient safety community these goals remain elusive.

**Denominators**

Two crucial denominators frequently missing from analysis of medico-legal events are workforce composition and adverse event rates. For our analyses, we obtained workforce composition data from the medical register, and adverse event rates from the New Zealand Quality of Healthcare Study. While this was a significant advance on much other research in this field, the denominator problem is far from solved. In particular, robust adverse event data remains hard to come by due to the enormous time and cost associated with undertaking the large-scale file reviews required to identify all adverse events within a patient population. Obtaining workforce denominators is easier, although the medical register only provides head counts of practitioners. For future studies we hope to develop more sophisticated measures of doctors’ exposure to complaint risk, such as full-time equivalents or patient/case volumes.

### 3.2 Contribution

#### 3.2.1 Development of knowledge

The first contribution of our research was to provide new evidence on the nature of patient harms, and the characteristics of high-risk practitioners, as seen through the eyes of medico-legal agencies. For example, this research was the first to match epidemiological data on medical injuries to claims for compensation in a no-fault environment. This enabled us to show that, even in a no-fault compensation system, rates of compensation claiming remain low. We were also the first to describe the characteristics of notifiers and respondents under Australia’s new mandatory reporting regime. And our analyses of 19,000 patient complaints helped to identify the characteristics of complaint-prone practitioners.
We also developed a number of new taxonomies to assist with the classification and understanding of medico-legal cases. Our taxonomy for classifying patient motives for medico-legal action has been adopted by other researchers. Furthermore, a taxonomy that we helped to develop for coding patients’ complaints is used by the regulatory boards of fourteen health professions across all states and territories of Australia.

3.2.2 Development of methods

The second way in which we advanced medical scholarship was by demonstrating the potential for methods drawn from epidemiology to be applied to medico-legal data in Australia and New Zealand. Traditionally, medico-legal agencies have focused on the resolution of individual cases. When they did apply analytical tools, they were often drawn from legal scholarship with a focus on legal principles and precedent. While such tools have their place, they offer a narrow visual field, constraining the ability of agencies to see the patterns that are writ large across hundreds or thousands of cases.

Recent decades have seen the growth of the patient safety movement and empirical legal studies. At their intersection lies the field of empirical health law research, where scientific methods rather than legal analysis are applied to medico-legal data. Building on the work of Brennan, Studdert and Mello, we demonstrated the ability for medico-legal researchers to use standard tools from epidemiology and biostatistics (including case-control studies, regression analyses, and survival analyses) to specify risk concentrations, identify problem areas, and patterns of non-reporting. We have demonstrated the power of these tools in addressing problems that previously seemed intractable. For example, previous researchers had attempted to estimate medico-legal risk at the practitioner level, but were unable to adequately account for temporal aspects of risk, such as the evolving nature of claim and complaint histories. We have taken an important step towards solving this problem, by using methods more commonly used to predict survival among different groups of patients.

Thus, one useful contribution of this collection of works lies in helping to transfer some of the expertise developed through 350 years of epidemiology into the domain of medico-legal regulation. By aggregating information and comparing groups, as epidemiologists do, medico-legal agencies are more likely to be able to see the patterns that will support evidence-based decisions.
3.2.3 Impact on policy and practice

The ultimate goal of public health research is an impact on policy and practice. To date, the most definitive impacts of our work on policy and practice have occurred in five areas:

- Initiatives to improve access to medico-legal agencies by vulnerable patients in New Zealand
- Consideration of no-fault compensation as an option in jurisdictions considering tort reform
- A greater appreciation of the importance of non-monetary remedies in a balanced medico-legal system
- A strengthened approach by medico-legal agencies to practitioners with multiple previous claims or complaints
- Stimulation of in-house epidemiological research by medico-legal agencies.

First, our findings brought medico-legal agencies in New Zealand face-to-face with the reality that focusing solely on caseloads excluded from their attention other problems not well-represented in claims and complaints. Our finding that Māori patients are less likely to claim or complain than their non-Māori counterparts prompted both the Health and Disability Commissioner and the Accident Compensation Corporation in New Zealand to ask themselves why patients might be reluctant to use their processes. Following my return to New Zealand from my Harkness Fellowship, I was appointed as a non-executive director of ACC, where I helped to oversee the implementation of a new Māori strategy. This strategy involved Māori working with Māori to understand and overcome barriers to claiming compensation following a treatment injury.

Second, the research undertaken into New Zealand’s no-fault compensation scheme has been closely considered by a number of countries contemplating tort reform. I have presented my findings at a number of tort reform symposia, including invited presentations to the Health Select Committee of the Irish Parliament, and the Health Council of Canada. Our findings also remain relevant to the United States where tort reform is still a contentious political issue. I have presented to symposia in Colorado and Washington DC and hosted scholars and policymakers on visits to New Zealand and Australia as they seek to understand the comparative advantages of our systems.

Third, by offering insights into the forms of accountability sought by injured patients, our research helped to move policy discussion around remedies beyond crude characterisations of
‘greedy litigants’ or ‘apologies as a panacea’ for medical harm. Instead we provided a more nuanced understanding of the types of remedies that matter most to different groups of patients. By highlighting discrepancies between remedies sought and achieved, we also supported efforts to bridge that gap through improved understanding of patient needs, reform of resolution processes, and clearer articulation of what different agencies are able to provide at the outset of the process. In 2014, I served on the Expert Reference Group of a review looking at ways in which the consumer experience of AHPRA processes could be improved. The recommendations of that review, including significant changes to the way AHPRA communicates with patients and practitioners, are in the process of being implemented.

Fourth, the insight that large numbers of complaints are concentrated among a small group of doctors, and that those doctors exhibit distinctive characteristics, has important policy implications. Detecting problems early opens up the possibility for interventions that act at the earliest feasible opportunity to prevent or minimise harm. We offer regulators a robust and useful method for forecasting medico-legal risk. An applied tool for translating our method into practice is still under development. However, a number of agencies, including the Medical Board of Australia, have already implemented new processes designed to identify and more closely scrutinise cases involving practitioners with multiple previous complaints. International interest is evidenced by the fact that our paper in BMJ Quality and Safety was published with three accompanying editorials, and was awarded best BMJ paper of 2013.

Finally, our research has stimulated further in-house research by at least four of the medico-legal agencies who provided data for this study. The organisations we have worked with have been quick to appreciate that a clearer view of risk allows one to more effectively and efficiently address it. Regulators are constantly faced with choices about how to allocate scarce resources. The evidence-base presented here, along with the epidemiological tools we adapted, offer one way for medical-legal agencies to make these choices more rationally and analytically. These agencies also see the benefits of attending to underlying problems, rather than treating each incident in isolation. Population thinking is a skill that has to be acquired. It does not emerge naturally from common life experience. Yet, many regulators are short on the requisite people, skills, and analytical versatility to undertake the kinds of analyses needed to make sense of the data they collect at a population level. Having seen the benefits of epidemiological research, a number of agencies have appointed new staff with skills in this area, and identified further research questions that they wish to see explored.
We do not suggest that all medico-legal decisions should be evidence-based. Just as evidence-based medicine integrates an individual’s skills and assessment with the best available evidence from medical research, so too should evidence-based policy. As expressed by Shojania et al., insistence on evidence should not “prevent implementation of practical, low-risk, but understudied interventions that seem likely to work.” For some regulatory decisions, there are no objective criteria with which one can locate the optimal balance between competing interests. These decisions can be informed, but not resolved, by epidemiology. Our hope is that the epidemiological approach we describe will complement and enhance medico-legal agencies existing efforts to protect patients and support practitioners.

### 3.3 Recommendations

Building on the research presented in this collection of works, I offer the following recommendations to legislators, regulators, practitioners, educators, patients, and consumer advocates. Though they are derived from our research findings, it is worth noting that these recommendations exemplify many of the core tenets of the World Alliance for Patient Safety. Namely, producing a culture of safety, promoting education, proactively identifying risk, encouraging teamwork, basing practice on evidence, and above all, realising the benefits of knowledge-sharing and collaboration.

#### 3.3.1 For legislators and regulators

I recommend that legislators and regulators:

- Attend to and amplify the voices of vulnerable groups of patients. This will require going beyond daily caseloads to understand the perspectives of patients (and potential whistleblowers) who may not have the cultural capital and confidence to confide in a medico-legal agency.
- Acquire the skills, technology, and analytical capabilities needed to move nimbly from our readily perceptible world—dominated by individuals and chance—to the world of ‘populations’ where patterns can be seen and risks can be visualised. Look for patterns of concern, and think of ways to resolve a cluster of similar, related or recurring incidents, rather than single incidents.
- Invest in developing, implementing, and evaluating systems for identifying and intervening with high-risk practitioners early in their career trajectories. Support the availability of early interventions for practitioners at risk of impairment, such as those
offered by doctors’ health advisory services. The knowledge and skills needed to do this are unlikely to exist within any one agency, so data-sharing and strengthened inter-agency relationships will be vital.

### 3.3.2 Practitioners and educators

I recommend that practitioners and educators:

- Maintain a critical perspective toward the beliefs and norms of the medical profession. Sometimes the risks that matter most to patients are not those that doctors are used to disclosing.\(^{95}\)
- Rather than fearing, resenting, or dismissing claims, complaints, and notifications of concern, try to see them as an invitation to learn.\(^{109}\) External regulation is of little use without a “functioning internal morality”.\(^{46}\) Ultimately, both patients and practitioners benefit when patterns of concern are identified and addressed sooner rather than later.
- Accept that being part of a profession carries a responsibility to help ensure that professional peers are “good enough”.\(^{40}\) Ideally, the profession should be able to identify and provide support to colleagues at risk—from medical school\(^{110}\) through to retirement—long before medico-legal action is required.

### 3.3.3 Patients, families and consumer advocates

And finally, a few words for patients, families, and consumer advocates:

- Please, do not give up on your efforts to have your voices heard by the healthcare system. Medico-legal agencies offer one forum, but there are others that may better meet your needs, and bring about the changes you wish to see.\(^{77}\) The impact of the women who gave evidence before the Cartwright Inquiry should give you confidence in Margaret Mead’s advice that we should “Never doubt that a small group of thoughtful, committed citizens can change the world; indeed, it’s the only thing that ever has.”
- You know what risks and outcomes matter most to you, and that information should matter to your doctor too. Use technologies and the power of the crowd to inform your choices. Keep encouraging health practitioners and medico-legal agencies to ‘lift their gaze’ from traditional ways of thinking and to a new approach in which your choices and knowledge are valued and respected.
- Continue to push for transparency of information about high-risk practitioners. In a world where we can readily access information on the service provided by a hotel or
the safety of an airline, the days of medico-legal agencies saying “just trust me” must surely be numbered. Indeed, it is not unforeseeable that patient-directed websites will one day leapfrog over the role of regulators in providing meaningful information about which doctors are ‘good enough’.

3.4 Further research
After ten years of research in this field, we have achieved much but, in other ways, our work has just begun. Promising future research opportunities for researchers with an interest in this field can be found by progressing in any one of four dimensions:

- Dive deeper into current research questions
- Move forward from identifying risks to designing interventions
- Look outward to understand how medico-legal agencies fit in the broader landscape
- Rise up to higher level problems of risk prediction

**Deeper into current research questions**

Many of the empirical research papers presented in this collection of works invite a deeper dive into causation, using more qualitative research techniques. Detailed file reviews and semi-structured interviews would be useful in understanding, for example, why many Māori patients choose not to complain, why older male practitioners are at heightened risk of medico-legal action, or why certain treatment risks matter more to patients than to practitioners.

**Forward into interventions**

Identifying patterns and risks is just the first step. For each of the risks identified in this collection of works we still need to understand the causes and consequences, design and implement solutions, and assess the effectiveness of interventions. Such a program of work could usefully connect with existing academic thinking on “right touch regulation”. When are light touch interventions effective? When is a more heavy-handed approach required? How can we make better use of mediation and other alternative dispute resolution mechanisms to reach outcomes that are for both the patient and practitioner?

**Out into the broader health sector**

A third area of promising research relates to improving medico-legal agencies’ understanding of where they are positioned in relation to the broader health system. Regulation is just one
very small piece of the patient safety puzzle, and regulators are more likely to succeed if they use strategies that are responsive to the culture of those being regulated. For example, it would be useful for complaints commissioners and medical boards to understand where professional colleges are moving on issues such as revalidation. This would help achieve coordinated progress towards a system in which “no patient should suffer preventable harm”.

**Up into higher level concepts regarding risk prediction and regulation**

Many of the problems faced by medico-legal agencies are not unique to the health sector. Through our research in this area, we have already established connections with academics working in fields as diverse as suicide-prevention, road traffic accidents, financial services disputes, and mandatory reporting of child abuse. Across seemingly diverse fields, there are shared interests in identifying ‘high-risk’ individuals, understanding why certain groups are unlikely to raise concerns, and narrowing the gap in expectations between regulators and those they serve. An articulation of high-level findings and risk-prediction strategies from multiple fields would help to weave the different strands of interdisciplinary work in this area together.

### 3.5 Conclusions

Twenty-five years on from the Cartwright Inquiry, medico-legal agencies find themselves at the confluence of several growing ideas: patient safety, responsive regulation, empirical legal studies, and ‘big data’ analyses of consumer information. The medico-legal systems of Australia and New Zealand are widely regarded as a promising alternative to the pitfalls of medical malpractice litigation. Yet, despite their advantages over a court-based system, concerns remain: regulatory systems can be daunting to access, slow to act, and sometimes seem to ‘miss the point’ with their reactive and process-driven approach.

At the most basic level, medical regulators exist to protect patients from harms of one type or another. But clarity on the best way to achieve this remains elusive. This collection of works has offered an empirical approach to several pressing questions in medical regulation. Our analyses drew on a decade of epidemiological research using data collected from insurers, complaints commissioners, and regulatory boards across Australia and New Zealand.

Our findings provide valuable insights into patterns of under-claiming, the remedies that patients seek, tension points that lead to medico-legal action, and the characteristics of complaint-prone practitioners. At a broader level, our research illustrates the promise of
epidemiological methods as a way of sharpening the senses of regulators: helping them to better hear patients’ voices and see patterns of concern.

As medical practice and community expectations evolve, so too must medical regulation. Our research suggests that a clear focus on purpose, an agility of response, a proactive approach to preventing harm, and the curious mind of a scientist are all qualities that will stand medico-legal agencies of the future in good stead.\textsuperscript{18}
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