What is Evidence in Medical Regulation?

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Introduction
The theme of our conference is "Medical Regulation in the Real World: Bringing Evidence to Bear". It's a challenging theme – it hints that academics, policymakers, politicians and media and public commentators hold forth about medical regulation from a theoretical perspective but lack a 'real world' view of the messy and complicated day-to-day work of medical boards. Our conference theme also challenges us to look beyond our own practices to evidence from other systems that may have better ways of regulating doctors.

Personal background
If beauty lies in the eyes of the beholder, equally our view of evidence varies depending on the personal lens through which we see the world. What you see as a red herring, I may see as a red flag. So, let me briefly give you some personal background, since it will help you understand the perspective that I bring to this discussion of evidence in medical regulation.

I am trained in law, not medicine. But I have long been interested in how people get cared for when they become patients, and fascinated by doctors and what makes them tick. I find the patient-doctor relationship intriguing. For many years, I have been interested in how society supports that relationship, ensures good quality care for patients, and protects the public as consumers of health care.

My first contact with the world of medicine came in the 1980s, when my youngest brother studied medicine and commenced work as a house surgeon in a hospital in a provincial city in New Zealand. I was surprised when he told me occasional stories of consultants widely known within the hospital community to be substandard. My young doctor friends told me similar stories. I found it a surprising state of affairs, but it did not occupy me greatly at the time. I was busy with my own studies and career.

Fast forward to the year 2000. I had just been appointed as New Zealand's Health and Disability Commissioner (HDC), a national health ombudsman responsible for handling complaints about health care and disability services. I now had a "public watchdog" role, charged with promoting and protecting patients' rights in New

Zealand. Complaints about doctors whose care or communication was alleged to be substandard featured prominently in our work.

Over the intervening two decades, I had spent a brief period in legal practice, before working as a legal academic in Canada and New Zealand. I had started a new course in medical law at Auckland University, studied biomedical ethics and health policy in the United States, and worked in health policy and regulation in the New Zealand Ministry of Health.

I was consulted on the drafting of the first modern health practitioner statute in New Zealand (the Medical Practitioners Act 1995) and helped draft New Zealand's Code of Patients' Rights 1996. The Code was enacted in response to a public inquiry revealing major failures in the treatment of women with cervical carcinoma in situ at National Women's Hospital in Auckland in the 1960s and 1970s. The new law gave patients (and other consumers of health and disability services) legally enforceable rights. This was the Code that I was responsible for upholding as Health and Disability Commissioner.

Co-regulation

The legal enforceability of patients' rights is not the only novel feature of the New Zealand system for handling patient complaints. The other key point is that power has been taken away from the traditional health professional regulators – medical, nursing, dental and other professional boards – and placed in the hands of an independent statutory Commissioner. Instead of the traditional system of self-regulation, New Zealand has a system of *shared or co-regulation*.

Although the professional boards retain sole responsibility for registration or licensure, and for quality assurance of a physician's practice, the independent Commissioner is responsible for handling all patient complaints about doctors (and other health professionals and healthcare organisations). The Commissioner, alongside the boards, plays a key role in setting professional standards. When problems in a doctor's practice come to light, the evidence is often considered both by the Commissioner (in assessing the patient complaint) and the medical board (in subsequent performance review processes). Bifocal review of the evidence often brings different factors to light.

I recall appearing before Dame Janet Smith at the Shipman Inquiry in Manchester, England, along with Andre Jacques from the College des Medicins du Quebec and Rocco Gerace from the College of Physicians and Surgeons of Ontario. Our participation was a curious mix of formal legal process and academic seminar. I remember Rocco telling the judge, after I had explained that a lawyer adjudicates

complaints about doctors in New Zealand, that Ontario doctors would *never* accept being regulated by someone who is not medically qualified!

Medical regulatory tightrope
My role as Commissioner gave me a lot of insights into the views of patients and families when they experience inadequate care and communication at the hands of a poorly performing doctor. I also had a lot of contact with medical boards in New Zealand and abroad, and gained some insight into the unique pressures of your world and the tightrope you walk.

Boards have to balance public and professional concerns. The balancing act is well described by Carl Ameringer in his definitive 1999 study of US boards, *State Medical Boards and the Politics of Public Protection.* Given their traditional composition of predominantly medical members, boards have tended to err on the side of remediation and rehabilitation of physicians rather than formal discipline and public disclosure. Ameringer argues that boards have embraced quality improvement ideas and became "guide dogs", not "watchdogs".

I have watched the Medical Council of New Zealand face criticism from all quarters: interrogation by politicians at the Parliamentary Select Committee about why overseas-trained doctors from Asia and the Middle East were driving taxis when they could be using their medical skills to treat patients; hostile media questions about why Dr X had been allowed to continue in practice when the latest scandal revealed a woeful lack of skills; attack by the New Zealand Medical Association and local doctors whenever any stricter standards were proposed; censure from the courts at the hands of litigious doctors, sometimes on debatable points of statutory interpretation; and vigorous questioning from Ministers of Health seeking assurance that medical regulation is inexpensive (since the State pays the registration fees for doctors working in the public system in New Zealand), facilitates workforce development and innovation, *and* protects the public. And as if all this wasn't enough, the Medical Council has to put up with occasional criticism from the Health and Disability Commissioner. Quelle horreur!

Roadmap
So, after that introduction to my background and my perspective on your world, let me give you a roadmap for my talk. What do I mean by evidence? What is the context in which a medical board operates? What is evidence-based regulation? What does evidence mean in the three specific contexts of registration or licensure, complaints and their resolution, and quality assurance of a physician's practice?

Evidence

First, what do I mean by evidence? My Oxford English dictionary tells me that the word comes via Old French from the Latin *evidentia,* meaning 'obvious to the eye or mind' – from *videre*, to see. This is revealing, since one of the most common criticisms of medical regulators when a licensed doctor has harmed patients, is that the board turned a 'blind eye' to the available evidence.

Some of you will have read this book by James Stewart, *Blind Eye: How the Medical Establishment let a Doctor get away with Murder*. Between 1984 and 1997 Michael Swango fatally poisoned up to 60 patients during a medical career that took him from Illinois to South Dakota, New York and Zimbabwe before the FBI tracked him down and he was found guilty of three murders and sentenced to life imprisonment. Even as a medical student he had been nicknamed "Double-0 Swango—licensed to kill", after five of his patients died mysteriously at Southern Illinois University. There were numerous warning signs throughout his career, notably his conviction in 1985 of aggravated battery for poisoning co-workers, leading to a lengthy prison sentence. Yet Swango managed to start afresh, finding medical work in new locations using forged documents to trick medical boards.

Having held a prominent public office with a public protective function, I know that nothing is more calculated to cause sleepless nights than the thought that, on your own watch, you might have failed to act on the available evidence and, *as a result, harm ensued that could have been prevented*. This is resignation material!

Fellow workers may also be accused of turning a blind eye to the evidence – which is why some countries, like Australia, have legislated to mandate reporting by health practitioners of concerns about the health or competence of another practitioner. This was one of the underlying concerns in the Shipman Inquiry. As most in this audience will know, between 1975 and 1998, general practitioner Harold Shipman killed at least 215 patients, possibly as many as 260. His technique was to administer fatal overdoses of morphine to his victims (mainly middle-aged or elderly female patients), sign their death certificate, and forge their medical records to indicate that they had been in poor health. Should neighbouring health practitioners have detected that something was amiss and taken action sooner?

Medical bodies are not the only ones to stand accused of ignoring the evidence. Politicians are highly prone to the same tendency. As I was leaving New Zealand last week, a cartoon appeared in the press. It showed our Prime Minister purporting to investigate allegations that a political ally had taken unlawful donations, ignoring the evidence at his feet and suffering a self-inflicted burn wound when his own actions came under the spotlight. We ignore evidence at our peril.

So, evidence has a general meaning of that which is obvious to the eye or mind of any reasonably observant bystander. Evidence also has a *legal meaning*, when it is used to describe information provided by a party or witness or expert, or drawn from a document, tending to establish facts in an investigation or during court proceedings. The law of evidence is a highly specialised subject – one that I had the privilege of studying at Oxford from the eminent Sir Rupert Cross, a brilliant scholar and teacher who was blind. At its heart, the law of evidence involves determining whether information that a party wants to rely on in court is *relevant*, is *probative* of the facts in dispute without being unduly *prejudicial*, is reliable (for example, not a confession obtained by duress) and is not otherwise inadmissible (such as the so-called 'fruit of the poisoned tree', evidence obtained during an unlawful search and seizure).

Medical tribunals are free from the strict rules of evidence that traditionally bind courts – but they are subject to an over-riding duty to act fairly, which means that many of the same objections to evidence (as being unreliable or unsafe) may be invoked by counsel for the doctor. A great English judge, Lord Diplock, put the matter thus in the *Moore* case in 1965 (it actually concerned evidence before an industrial tribunal):

"The requirement that a person exercising quasi-judicial functions must based his decision on evidence means no more than that it must be based on material which tends logically to show the existence or non-existence of facts relevant to the issue to be determined, or to show the likelihood … of the occurrence of some future event … It means that he must not spin a coin or consult an astrologer, but he may take unto account any material which, as a matter of reason, has some probative value …"

Finally, because this is a conference of medical boards, it is worth referring to the context in which the term 'evidence' is most often used in relation to contemporary medicine: 'evidence-based medicine' or EBM. This means practising medicine in a way that is empirically sound, in other words consistently with guidelines (preferably from randomized controlled trials, and better still from meta-studies of such trials, such as those produced by Cochrane collaborations), rather than in accordance with 'traditional' practice. Critics of evidence-based medicine argue that it leads to 'cookbook medicine' and that it underestimates the importance of clinical judgement in the context of the individual patient. Interestingly, given my earlier discussion of evidence as that which is obvious to the eye or mind, the mantra of EBM sometimes seems to keep what is obvious to the mind and senses obscured. As Mangin notes, "We need to trust the evidence of our own eyes as our patients beta test treatments for the

first time in the real world of multi-morbidity, unknown adverse effects and individual preferences." (Mangin D. Adherence to evidence-based guidelines is the key to improved health outcomes for general practice patients – the 'no' case. *Journal of Primary Health Care.* 2012;4(2):158-160 at 160.)

Context
Turning to the context of medical regulation, I want to make two important preliminary points.

1) First, any discussion of what evidence might mean for a medical board should begin with consideration of the functions and objectives of the particular board. I assume, but stand to be corrected, that most if not all of the 32 countries represented by medical boards at this conference have passed legislation that specifies the role of the medical board – for example, whether its functions include oversight of medical education or professional discipline. In the case of federal jurisdictions such as Australia, the United States and Canada, state or provincial legislation prescribes the role of medical boards.

In the United Kingdom, the Medical Act states that "the main objective of the General [Medical] Council in exercising their functions is to protect, promote and maintain the health and safety of the public" (s (1A)). This is a very powerful signal about the primarily public protective function of the regulator – and will shape how the Council sets its strategic directions and what evidence it takes into account when doing its business.

Even if a regulator simply acquires legal status from local laws, but is otherwise a true self-regulatory body that sets its own course, it will still have a charter or constitution that, like the statute that creates most regulators, will specify its functions and objectives. It is always important to use these founding documents as the starting point.

2) Secondly, the composition of the body that governs the medical board is key, because the background and competencies of the people who oversee the enterprise and assess material before a board for decision inevitably colours how a board approaches its task and what is seen to count as evidence. Are members of boards appointed for their skills and competence, with reference to specific criteria? Or are they members elected by the profession (who may see their role as a representative one) or political appointments?

What is the balance of medical professional and lay members? The Medical Council of Ireland has 13 lay and 12 medical members – the first board in the world to have a lay majority. However, many boards still have a preponderance of medical members, with a small minority of lay members. In a medical regulatory

context, changes to traditional ways of looking at evidence seem more likely if there is at least an equal number of lay members, who may then be emboldened to challenge the status quo.

Evidence-based regulation
Let's assume we know the role and composition of a medical board. What do I mean by evidence-based regulation? In my view, no matter how broad or narrow the scope of a board's role, *an effective regulator brings evidence to bear in the way that it goes about its business*. The decision to regulate a profession will usually follow a risk-based assessment by government – is regulation necessary to protect the public? But there is still a lot of discretion for individual boards in *how* they exercise their powers.

Many of you will be familiar with the concept of *right-touch regulation* developed by Harry Cayton and the Centre for Healthcare Regulatory Excellence in London (soon to be reborn as the Professional Standards Authority). It builds on the idea of 'smart' regulation and on the following principles:

- *Proportionality*, intervening only when necessary, after a proper assessment of risks and costs
- *Consistency* in application of rules and standards
- *Targeted* interventions, focusing on the problem and minimizing side effects
- *Transparency*, regulators are open and their information is accessible
- *Accountability* by public reporting and giving reasons for decisions
- *Agility*, being forward looking and proactive rather than reactive.

Cayton describes this approach to regulation as using "an evidence-based assessment of issues" and allowing for "an inclusive debate, not dominated by expertise about process, but informed by experience and evidence relevant to the outcome [with] more insight, less oversight" (para 5.1).

This is an enlightened way of thinking about how medical boards can function more effectively. What might it mean in practice?

A progressive board will recognize the fundamental values and principles that underpin healthcare regulation (such as the primacy of the public interest and the importance of consumer voice) as *self-evident*. A responsive regulator will solicit evidence from consumer and public interest groups, and from the regulated profession, to clarify the expectations of these key groups. It will look for evidence of emerging 'hot spots' and areas of risk in current medical practice, where it needs to focus attention. It will undertake regular surveys of public and professional opinion, asking for feedback on how well it is performing and areas

for improvement. It will seek consultation feedback to inform the development of guidance for the profession, in discrete areas such as professional boundaries and for broad fields such as 'Good Medical Practice'.

I know that many medical boards already do this. Not all boards will have the financial resources to undertake survey research. Other means, such as having a consumer advisory council, may be more practical and cost-effective. What matters is that a board is outward-looking in the way it does its job, and looks for evidence of community and professional opinion.

Some boards, like the New Zealand Medical Council, commission qualitative research with consumers, medical organisations, colleges, government officials and journalists about the board's role and performance, and whether its communications are effective and understood. For example, the Council's 2010 survey of 503 randomly selected members of the public shows that respondents rated trust in their own doctor as significantly higher than trust in doctors in general.

The results of this sort of research may sometimes be perplexing and even a little confronting, but I salute regulators who take their heads out of the sand and look for evidence of what people think about the regulated profession and the regulator itself.

Surveys of users of a Council's services are also important. Did a complainant find the Council's processes easy to understand, timely and fair? Similarly, did a doctor seeking to be registered, facing a complaint investigation, or undergoing a performance assessment, find the process comprehensible, constructive, timely and fair? One of my current roles is to chair the Banking Ombudsman scheme in New Zealand. I know from my work in financial and health service complaints that some consumers and providers, when surveyed after involvement with an official agency, do not differentiate between unhappiness with the outcome and the process. But it is only by asking that we can learn how to improve our services.

Of course boards receive plenty of unsolicited feedback. Some of it is very revealing. I like the example of a mock letter based on feedback received by the UK Pensions Ombudsman. The writer berates the agency for writing "incomprehensible nonsense", and says: "My doctor tells me about complicated medical stuff in ways that I can understand. Why don't you try harder to avoid complicated words and official sounding language?"

We don't need expensive surveys to find evidence of how users find our services.

Often the evidence is right before our eyes – but we are quick to dismiss it and characterize the person complaining as "difficult". Medical boards, like hospitals, could significantly improve the quality of their services just by taking feedback seriously and acting to fix problems.

To conclude my comments on evidence-based regulation, I wish to make a plug for medical boards to gather and publish data about the effectiveness of their interventions – and to compare their performance with other boards. Surgeon Bruce Keogh, Medical Director of the UK National Health Service, says that "surgeons have a moral and professional duty to know what they are doing, how well they are doing it and to use that information to help them improve – otherwise they have no right to be doing it at all." (S. Boseley, G. Zorlu, et al, 'Huge disparity in NHS death rates revealed', *The Guardian*, 13 June 2010.) The same can be said of medical boards. You need to continually evaluate how you are doing.

Currently, a board's annual report will usually report a lot of data about the demographics of practising doctors, and the number of doctors subject to health, competence or conduct processes. Even for a motivated journalist or well-informed member of the public, it's hard to make much sense of this.

Take a sensitive area such as a board's oversight of drug or alcohol addicted doctors. If a board takes a rehabilitative 'monitoring' approach, can that board demonstrate that its approach is successful in returning addicted doctors to safe practice without jeopardising patient safety? Alternatively, can a board that adopts a "two strikes and you're out" approach to addicted doctors show that this more punitive approach offers equal or greater protection, when it risks making such doctors less likely to seek help for their addiction?

Every day boards, like governments, face policy choices. Sadly, we have come to expect politicians to adopt policies (particularly in relation to criminal justice, penal policy, immigration and social welfare) that appease vocal sections of the community – often with scant regard to evidence of long-term outcomes when these sorts of interventions have been adopted in other countries. Medical boards also face public and political pressure and may be tempted to make knee-jerk responses. By gathering data on effectiveness of interventions, sharing information with counterparts internationally (something IAMRA facilitates), and making information publicly available, boards can practise evidence-based regulation that will better serve their communities.

Registration

Let me turn now to the three core areas of a medical board's work, where it needs

to assess evidence. First, registration.

I want to focus on the fraught area of registration of international medical graduates or IMGs. This is an area where boards face conflicting pressures – from governments and employers who want to ensure access to health services for communities; from hospitals and health services, who want to be assured that an IMG will be safe to practise, with an appropriate level of support and supervision; from IMGs themselves, who have immigrated to a new country and want to put their hard-won skills to work, but often find themselves "lost in the labyrinth" of registration processes; and from patients, who expect to be treated by competent doctors who can communicate effectively in the local language and are well oriented to local culture – which may include sensitivity to indigenous people and to the role of women in the new society.

What does evidence mean in the context of registration of IMGs? This is a complex area, and I have no wish to preach to the choir. I will briefly discuss two infamous IMGs who caused a lot of problems for patients, fellow workers, hospital managers and medical boards in Queensland and New Zealand. The first is Dr Jayant Patel.

Dr Patel was Indian-qualified, US-trained surgeon employed as Director of Surgery at Bundaberg Base Hospital, a public hospital in a provincial city in Queensland, from 2003 to 2005. After numerous complaints from staff were brushed aside, it took the efforts of a determined "whistleblowing" nurse, a local journalist and a member of Parliament, to bring concerns about the standard of Patel's surgery to public attention. A disproportionate number of his patients had died or suffered major surgical complications. Patel was vilified in the media as "Dr Death". His surgical performance at Bundaberg Hospital and the circumstances of his registration and employment were scrutinised in a Commission of Inquiry undertaken by a retired judge Geoffrey Davies QC.

The Inquiry highlighted numerous systemic and individual failures. I want to discuss two evidence-related points from the saga of Dr Patel.

First, his conviction of the manslaughter of three patients at Bundaberg Hospital, and of causing grievous bodily harm to another patient, was recently overturned by the High Court of Australia, on a point of evidence. At trial, a lot of evidence had been produced about Dr Patel's personal and professional failings. Eventually, the trial judge intervened and said, "This trial is not about botched surgery. It is about surgery performed competently enough". The reformulated prosecution case was that no competent surgeon would have undertaken surgery of the type performed on these patients. The High Court found that a miscarriage of justice had occurred

and sent the case back for retrial. Justice Heydon quoted this statement from George Savile in 1750:

"The angry buzz of a multitude is one of the bloodiest noises in the world."

This is a salutary reminder to medical boards, tribunals and courts of the need to focus on evidence that is directly relevant – and not be swayed by prejudicial evidence that is not probative of the issue at hand.

The second point is that the Medical Board of Queensland failed to properly assess the available evidence before registering Dr Patel. It did not undertake the basic inquiries that would have revealed his troubled disciplinary history and practice limitations in the United States – matters that eventually came to light when a journalist did a google search. Dr Patel was registered as a doctor in Queensland because of what the inquiry judge called a "negligent omission" by the board in failing to notice a 'notation' on Dr Patel's certificate of licensure from Oregon. Had the missing notation been followed up, it would have revealed that Dr Patel was subject to disciplinary restrictions from performing certain types of surgery. Proper inquiries would also have revealed earlier disciplinary proceedings in New York. Finally, the board did verify Dr Patel's qualifications, nor reference check his work experience. The Commission of Inquiry stated that a medical board is not excused from performing its statutory role because it lacks resources.

The second case is my own 2008 inquiry into Slovakian trained gynaecologist Roman Hasil. The inquiry was prompted by the high failure rate in tubal ligations Dr Hasil performed at Wanganui Hospital (a public hospital in a small city in New Zealand). During my inquiry, Dr Hasil's earlier imprisonment in Singapore for assault, his drinking problem, and allegations of callous behaviour towards female patients in the past, all came to light. Subsequently, Australian medical authorities re-opened investigations into allegations of such behaviour during Dr Hasil's previous employment in a New South Wales Hospital. The warning signs had been there all along, but no one had looked at the evidence closely enough.

The New Zealand Medical Council had checked the references Dr Hasil provided and sought more current references prior to registering him, but it did not contact the Australian state medical boards where he had worked and his previous employer. I noted in my inquiry report:

"[T]here were sufficient flags regarding the documentation in this case to have made such enquiries prudent … reasonable enquiries at the time would likely have revealed Dr Hasil's difficult past and triggered further scrutiny."

While I was investigating Dr Hasil, it emerged that he was been registered by the Medical Board of Queensland and was working there. As an editorial in the Queensland *Courier Mail* (29 February 2008) commented, "It is almost inconceivable that the state's health authorities allowed a previously jailed, overseas-trained doctor with a drinking problem" to work without checking his past.

There are other complex issues related to evidence and IMGs, which I do not have time to cover – citing original degree certificates, to detect forged documents; criminal history checks; the vexed issue of assessment of language skills; and general assessment of competence. But one key lesson from Patel and Hasil is *the importance of doing basic, common sense checks well*, and being alert to gaps in the evidence and missing documentation.

Complaints

I am a firm believer in the value of complaints. I like this statement from John Milton: "When complaints are freely heard, deeply considered, and speedily reformed, then this is the utmost bound of civil liberty that wise men look for."

Unfortunately, in my observation, it is all too common for agencies to handle complaints behind a veil of secrecy (so they are not "freely heard"), to give complaints a "once-over-lightly" rather than deep consideration, and to take far too long to reach a conclusion, let alone take any decisive action – the opposite of "speedy reform".

So, what to say about evidence in the context of complaints?

As I explained earlier, in New Zealand the Health and Disability Commissioner, rather than the health professional boards, handle patient complaints. The Commission, like medical boards, is effectively free to regulate its own procedure, and is not constrained by the traditional rules of evidence that bind courts – but is subject to an overriding duty to act fairly, in accordance with the rules of natural justice.

I have three points to make about evidence in relation to complaints.

First, *it is all too easy to dismiss a patient complaint as unproven*, when it relates to an issue of communication and turns into a *"he said", "she said"* dispute. If there are no witnesses to a consultation, and the issue is not one where a doctor would be expected to keep a file note, it will usually be impossible to reach a conclusion – but it may still be warranted to tell the doctor that whatever was said, clearly the patient left the consultation unhappy and they might want to reflect on how

things could have been done differently.

However, if the disputed matter involves whether the doctor undertook an investigation or asked a diagnostic question, when the patient denies that this occurred, the following words of Lord Mansfield, in the 1774 case of *Blatch v Archer*, are apposite:

"It is certainly a maxim that all evidence is to be weighed according to the proof which it was in the power of one side to have produced..."

In other words, if a doctor fails to document doing something he claims to have done, the fact-finder may decide that it did not happen, since the doctor could and should have kept a record that would have put the matter beyond dispute.

My second point about evidence in the context of complaints is the *tricky issue of similar fact evidence*. It is difficult enough to establish that substandard care was provided on a single occasion. But it is even more difficult to prove a pattern of substandard practice establishing incompetence or poor performance by a doctor. Requirements of fairness to the individual practitioner whose work is under scrutiny mean that each case is looked at in isolation.

This blinkered legal approach makes it very difficult for a medical board or tribunal to see the overall pattern of a doctor's practice. In handling an individual complaint, the focus is usually confined to the care of a single patient. It is rare for a review body to consider concurrently cases involving one doctor and several patients, and when it does so, it must be careful not to allow evidence from one case to taint consideration of another. Contrast this with the medical approach of seeking a full history and considering any similar episodes, before making a diagnosis.

The Australian Health Practitioner Regulation National Law Act 2009 has a helpful provision that enables a national board to take into account notifications about a health professional that *"suggest a pattern of conduct"* (s 149(2)(b)) – but if none of the prior matters have been properly investigated, the board may still find itself hamstrung.

There may be significant "grey" material, such an incident reports and previous complaints or concerns suggesting that a doctor's performance was subpar. However, a board can usually consider only evidence of *proven* problems from the doctor's past that are directly relevant to the matter now at issue. This may make it hard to uncover the full picture of a doctor's practice.

My third point about evidence and complaints relates to what I call "frequent flier" doctors. Important new research from Marie Bismark and colleagues at the University of Melbourne (currently still under peer review) suggests that less than 5% of practising doctors account for around half of all complaints to healthcare complaint commissioners in Australia. An earlier pilot study indicated the maldistribution of complaints against doctors in private practice in Victoria. Obviously, interventions targeted at the frequent fliers could prevent a lot of problems – for patients and medical boards.

During my time as Commissioner, we erred on the side of sharing information with the regulator, in the face of vigorous opposition from the aptly named Medical Protection Society. We signed an information-sharing memorandum of understanding with the Medical Council, agreeing to notify the Council "of three or more similar 'low level' matters relating to a registered medical practitioner within the past five years, which may indicate a pattern of conduct indicative of wider competence concerns". The purpose was to ensure that "frequent fliers" did not fly under the radar.

If a doctor is an outlier by attracting several complaints, that is likely to be a pointer to problems in their practice that warrant closer scrutiny by the regulator. Having a low threshold for indepth investigation is especially important when many complaint commissioners and medical boards favour "low level resolution" by informal means, without formally investigating most complaints.

Quality assurance
Finally, let me briefly discuss evidence in the context of quality assurance of a physician's practice.

[In 1885, Canadian William Osler was in his mid 30s and had recently moved from McGill University to the University of Pennsylvania. He was beginning to make waves in a medical career that would establish him, by the early 20th century, as the leading physician and medical educator on both sides of the Atlantic. Osler wrote in the *Canadian Journal of Medicine and Surgery* of 1885: "In a well-arranged community, a citizen should feel that he can at any time command the services of a man who has received a fair training in the science and art of medicine, into whose hands he may commit with safety the lives of those near and dear to him." Osler's goal remains aspirational 127 year later.

The topic of quality assurance of a doctor's practice brings into play several different types of evidence. First, there is the evidence from surveys in many countries that *patients assume that medical boards already check that a doctor remains competent* and fit to practise, before issuing an annual practising

certificate. In a survey undertaken for the New Zealand Medical Council in 2010, 75% of respondents said that their confidence in doctors would be increased if doctors' performance was subject to regular review.

Secondly, there is the *evidence of effectiveness* that medical associations and individual doctors demand from boards proposing to introduce new ways of assessment competence, as the General Medical Council has found ever since revalidation was first proposed in 1999 – and as the New Zealand Medical Council is now finding in introducing more rigorous recertification for general registrants. This is work in progress. Doctors understandably seek evidence that new ways of checking competence will detect problems and improve practice, to justify the time and expense involved. But patients and the public deserve better assurance of competence than current board processes give them.

Thirdly, there is evidence in the sense of the *portfolio of evidence* on which an individual doctor's practice will be assessed. This might include the doctor's CPD records, multisource feedback from patients and colleagues, and annual appraisal reports from a local 'responsible officer'. The content of the evidence portfolio will vary from country to country, but it is safe to say that in the next decade many countries will be implementing more rigorous and sophisticated ways of assuring a doctor's practice. Evaluation of the utility of the new forms of evidence will be important.

Conclusion

Let me draw my talk to a close. Why does it matter whether medical boards bring evidence to bear in the way they regulate? It matters because the public relies on you to do your job properly. Boards do not exist simply to guide the profession and remediate problem doctors. You have a critical role of protecting the public from the harm of poor medical practice. You need to be a public watchdog. And to remember that good watchdogs bark when they see evidence of harm!

Following the release of my Hasil inquiry report, the Queensland *Courier Mail* gave the following advice to the state medical board:

"Simply sticking to the letter of the law is not enough. … This is more than a matter of system and processes. It is also a question of attitude. Those who are responsible for ensuring medical standards need to be proactive and always ready to challenge, test and investigate further …"

What counts as evidence in medical regulation will not always be black and white. As we all know, there are few certainties in life, medical practice or regulation. I

like this poem from New Zealand doctor poet Glenn Colquhoun, which highlights some of the complexities. It comes from his *Playing God* collection, and is entitled:

'A brief format to be used when consulting with patients'

The patient will talk.
The doctor will talk.

The doctor will listen while
the patient is talking.

The patient will listen while
the doctor is talking.

The patient will think that the doctor
knows what the doctor is talking about.

The doctor will think that the patient
knows what the patient is talking about.

The patient will think that the doctor
knows what the patient is talking about.

The doctor will think that the patient
knows what the doctor is talking about.

The doctor will be sure.
The patient will be sure.

The patient will be sure.
The doctor will be sure.

Shouldn't hurt a bit, should it?

Patients and the public rely on medical boards to use to gather and use evidence effectively. I look forward to the day when we can all rely on the public medical register and a current licence to practise medicine as assurance that any licensed doctor is competent. We do not want to take "pot luck". We want to know that every doctor is "good enough", a professional in whom we can be sure.