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Building Public Confidence in Medical Registration Revalidation: Reform of Medical Registration Law in Australia, a New Risk-Based Approach

Abstract

This article examines the reform of the Australian Health Practitioner National Law to introduce medical registration revalidation. Revalidation is a regulatory performance management practice designed to regularly and proactively confirm the competence of medical practitioners. The reform is of major importance to the future of this area of law and the operation of the health sector. Its implementation will be the most significant reform yet undertaken. It will significantly shift the law’s current contribution to constraining dangerous practice from a largely reactive stance onto a more proactive footing. Finally, it will represent the largest single quality improvement and patient safety program in Australia. In aid of advancing the case for registration regulation, we describe the recent history of the National Law, provide analysis of the proposed revalidation reforms and then apply a novel empirical method of a discrete choice experiment to determine the Australian general public’s acceptance of and preferred approach to medical registration revalidation regulation. We argue that the reform represents a potentially effective and, importantly, acceptable reform to existing regulatory performance management and disciplinary systems, but also that revalidation will bring with it wide-ranging changes to the nature of existing approaches to regulation of medical practice in this jurisdiction.

# Introduction

How to best protect the public from healthcare-related or ‘iatrogenic’[[1]](#footnote-2) harm has been a permanent feature of debate in Australia.[[2]](#footnote-3) Research undertaken over the past thirty years has revealed a scale of harm in the contemporary healthcare system of significant proportions.[[3]](#footnote-4) Based on the best work available, at least ten per cent of admissions to acute care hospitals in Australia are associated with iatrogenic harm. These rates of iatrogenic harm have not measurably improved at a system level for fifty years,[[4]](#footnote-5) and studies find that between 50 and 80 per cent of all adverse events are potentially preventable.[[5]](#footnote-6) Public and professional attention to iatrogenic harm has increased in parallel with the growing understanding of iatrogenic harm and its impacts. A significant part of that increased attention has been focused on the role of legal and regulatory frameworks and practices which are designed to protect the public from iatrogenic harm by constraining dangerous healthcare practice.

In the Australian context, this question of a regulatory response to iatrogenic harm has focused in large part upon the national system of health practitioner regulation and its operation and impacts.[[6]](#footnote-7) The Health Practitioner National Law (‘*National Law*’), introduced in 2010, established the national registration and accreditation scheme for the regulation of health practitioners and students.[[7]](#footnote-8) The system that it creates is a protective jurisdiction. ‘Protection of the public’[[8]](#footnote-9) or alternatively, protecting the ‘health and safety of the public’ [[9]](#footnote-10) remains its primary role, justifying its exercise of powers with relation to practitioners ‘who may be putting the public at risk as a result of their conduct, professional performance or health.’[[10]](#footnote-11) The National Law utilises control of health practitioner registration as the central mechanism to both prevent and manage issues of performance or competency that threaten the health and safety of the public.[[11]](#footnote-12) Once registered, health practitioners and relevant students are made subject to codes of conduct and other statements that define acceptable professional practice,[[12]](#footnote-13) must comply with obligations expressed in various Registration Standards as to continuing professional development, indemnity and other matters,[[13]](#footnote-14) and are bound by regulatory health, performance, conduct and disciplinary systems.

A perennial feature of scholarly and professional discussion of the regulation of healthcare practitioners is the largely reactive nature of laws constraining practice that threatens the health and safety of the public. On the one hand, the National Law facilitates proactive measures, such as the setting of professional standards, accrediting educational offerings and requiring continuous professional development by registered health practitioners. Yet, in the face of developing or actual failures of professional skills and knowledge, the National Law only engages with practitioners who come before disciplinary bodies – a reactive model. At present, this arrangement may fail to identify a practitioner who may be placing the public at risk by failing, or being at risk of failing, to perform to an acceptable standard. Unless a matter comes before an appropriate regulatory actor by way of a complaint or other notification, regulatory performance management systems are limited in both formal powers and practical systems to identify, investigate, assess or compel improvements in a practitioner’s competency. In essence, having achieved initial or specialist registration as a health practitioner,[[14]](#footnote-15) there is no structure or opportunity for the fitness of practitioners to be re-assessed within a regulatory performance management context save for occasions where a practitioner is involved in disciplinary process. This creates a series of gaps and ‘blind spots’ for the regulator. Moreover, it limits the available mechanisms through which a practitioner might seek to either confirm, or improve their fitness to practice outside of formal disciplinary processes.

In response to this challenge, the Medical Board of Australia (‘MBA’), Australia’s principal regulator of medical practice, has considered introducing a form of medical registration revalidation, similar to that which exists in the United Kingdom.[[15]](#footnote-16) Revalidation is a more proactive regulatory approach, designed to ‘affirm or establish the continuing competence of physicians’[[16]](#footnote-17) whilst strengthening and facilitating ethical and professional ‘commitment to reducing errors, adhering to best practice and improving quality of care’[[17]](#footnote-18) by the medical profession. The aims of the MBA’s proposed regulatory reform have been clear, in that it aims for revalidation to be both a quality improvement intervention and to drive potentially transformative improvements in patient safety.[[18]](#footnote-19) Once implemented, it will be amongst the largest quality improvement and patient safety programmes in Australia and one of the most significant reforms to medical registration and regulatory performance management systems ever undertaken. Its implementation will be the most significant reforms to the system established by the National Law, and it promises to significantly shift the balance between law’s current contribution to constraining dangerous practice from a largely reactive stance onto a more proactive footing, including an important change in the role of existing medico-legal practices, such as formal patient complaint systems. To justify the significant investment revalidation will require, and to drive the potential benefits it aims for, the regulatory and practical structures must be both well-accepted by practitioners and patients, as well as fit-for-purpose.

A range of potential revalidation models have been considered,[[19]](#footnote-20) with the MBA recently proposing its preferred approach.[[20]](#footnote-21) It now plans to commission clinical advice and research towards a trial and implementation of what it has termed its ‘Professional Performance Framework’ (Medical Board of Australia, 2018), preferring not to use the term ‘revalidation’ for reasons which are not made entirely clear, except that the proposed performance framework embeds ‘revalidation’ activities into a broader set of existing and new performance management activities (Medical Board of Australia, 2018; The Medical Board of Australia, Expert Advisory Group on Revalidation, 2017). Regardless of the nomenclature, revalidation activities are part of this broader performance framework. They are referred to one a ‘pillar’ of the framework, and are named ‘Active Assurance of Safe Practice’. The MBA proposes that these revalidation aspects or ‘pillar’ of the framework operate based on a formal method for proactive identification of potential practitioner competency risk. Earlier, the MBA’s expert advisory group had proposed to achieve this by bifurcating revalidation into two separate, but related, stages. The first stage was to consist of universally compulsory continuing professional development activities. These would be “nested” within a second stage that consists of more vigorous activities that would only apply to select medical practitioners. These more active measures involve external or independent input or oversight and were to take on a more summative character testing that the practitioner is not only “up-to-date” but assessing if they are “fit to practise. Much of this structure is reflected in the, currently high-level performance framework, where those medical practitioners subject to the more active appraisal and review activities (referred to as “peer review” and managing the risk of poor performance) will be selected based on a risk profile in which age, isolation, and potentially specialty and patient complaints will be considered as potential markers of risk, or in response to an identified issue of competence.

On the face of the proposed regulatory reform, proactive identification of practitioners whose competency may be ‘at risk’, is a potential advance in aid of improving the quality and safety of Australian health care. Moreover, the proposal presents a potentially efficient way of driving that aim through its proposed utilisation of a risk-based regulatory approach; a method that finds support in recent research using existing Australian complaints and investigation data that revealed that a small group of Australian doctors (3%) attract half of all complaints, and an even smaller group (1%) a quarter of all complaints.[[21]](#footnote-22) Most notable, however, is that the proposed model places the ‘voice’ of the public and existing, but underutilised, medico-legal practices and data sources such as patient complaints, at the heart of medical registration regulation in a way not seen in Australia before. Existing patient-initiated medico-legal complaints data has directly shaped the proposed risk-stratification model.[[22]](#footnote-23) Patient complaints, compliments and input into ‘multi-source’ feedback will be directly and compulsorily integrated into the universally mandated component of revalidation. So too will patient-sourced and other related data then drive the availability or application of the second more intensive revalidation stage, and thus any remediation activity prescribed for an Australian medical practitioner. If the reform proceeds in this way, this will differentiate the Australian system in a material way from the otherwise ‘notable absence’[[23]](#footnote-24) of the patient in this health regulation and policy context noted by others, where in the UK for example, one recent reflection noted approvingly that ‘[i]mportantly, the public’s direct input [into a decision as to whether a GP may be revalidated] is restricted to patient satisfaction questionnaires…’[[24]](#footnote-25)

This article examines the regulatory context of revalidation. So too does it determine the Australian general public’s acceptance of and preferred model for the reform of medical registration regulation. Inspired by this interest in revalidation approaches that emphasise the ‘voice’ of the public, we do so by application of a novel empirical legal method, namely a discrete choice experiment (‘DCE’) and qualitative methods to support instrument development.We understand this to be the first application of the DCE method to this question. So too, does the application of this method develop our understanding of the use of discrete choice as a way of eliciting information regarding the general public’s preference in relation to a legal and regulatory reform.

We proceed by first engaging with the existing regulatory performance management context in Australia. We provide a review of available options and processes for the management of unprofessional conduct and professional misconduct, as well as the ‘health pathway’ for responding to impairment in Part II. In Part III, we consider the methodological aspects of Discrete Choice Experiments in the regulatory and policy field, and present our designed experiment. In Part IV we present the results of the experiment, followed by discussion and analysis of its implications in Part V by way of conclusion.

# Background: Healthcare Quality and Safety, Medical Practitioner Registration & Revalidation

The introduction of revalidation processes as a way of assuring adequate clinical standards seems to have gained traction in Australia after the Patel affair.[[25]](#footnote-26) Dr Jayant Patel – who had been dubbed ‘Dr Death’[[26]](#footnote-27) by his own medical colleagues – was accused of causing widespread, serious harm and death,[[27]](#footnote-28) during his tenure as Director of Surgery at Bundaberg Base Hospital in Queensland. In subsequent reviews and inquiries, it became clear that patterns of harm had been disregarded and inadequately managed by practitioners, medical and other managers and the regulatory system itself.[[28]](#footnote-29) Whilst Patel went on to face multiple manslaughter charges for his role at Bundaberg,[[29]](#footnote-30) he was first found guilty, and then, upon retrial following a miscarriage of justice,[[30]](#footnote-31) not guilty.[[31]](#footnote-32) He ended the almost decade-long legal process with a guilty plea in relation to four counts of fraud.[[32]](#footnote-33) He immediately flew back to the United States, where he had earlier been de-registered or restricted in his practise of medicine, some years before taking up the role at Bundaberg. The associated media and political process was significant, with a series of public inquiries, and an intensified focus on the quality and safety of healthcare.[[33]](#footnote-34)

Patel is, of course, not the only Australian medical practitioner to have demonstrated practice below acceptable competency standard.[[34]](#footnote-35) Nor is he the only one to have challenged the effective working of our regulatory schemes. Helen Kiel notes in recent work on regulating impaired doctors that there is a significant body of research and opinion about so-called ‘problem doctors’[[35]](#footnote-36) and regulatory performance management. Some of what marks that scholarly and professional literature is both significant gaps or silences and claims that both informal and formal regulatory performance management systems have failed either the public, the health system, doctors themselves, or all three. For this reason, recent consideration of the ‘optimal function of regulators’[[36]](#footnote-37) has focused on both the regulator’s willingness, and ability, to move beyond complaint or notification investigation after poor conduct has been discovered, towards a more active stance, directing their energies towards proactive identification of poor performance.[[37]](#footnote-38) This move has been described by Kiel as ‘changing hindsight into foresight’.[[38]](#footnote-39)

## The Regulation of Medical Practitioner Registration: The National Law

In the Australian context, the question of a more forward-looking regulatory response to medical practitioner competency must focus upon the national system of regulation, its operation and its impact.[[39]](#footnote-40) A variety of actors contribute to professional registration and disciplinary regulation in Australia.[[40]](#footnote-41) The powers to grant and administer health practitioner registration exists, like all of health law and regulation, in a complex and overlapping ‘institutional constellation’[[41]](#footnote-42) within which government, professions, market, and civil society actors operate to regulate at the health service entity, state or territory, national, inter-governmental and supra-national levels.[[42]](#footnote-43) That being said, the registration of Australian medical practitioners is principally governed in a formal sense by a national registration and accreditation scheme that came into effect in 2010,[[43]](#footnote-44) and it is by using this control of registration, that proposals for revalidation plan to operate.

The Health Practitioner National Law (‘National Law’), introduced in 2010, established the national registration and accreditation scheme for the regulation of health practitioners and students. Whilst the National Law was designed to create a national, and nationally consistent registration and performance system, it falls within the jurisdiction of each State and Territory to establish the enabling legislation.[[44]](#footnote-45) As such, the national scheme of relatively uniform legislation was achieved by adoption of the National Law first by Queensland,[[45]](#footnote-46) followed by other States and Territories enacting their own law in a cascading fashion.[[46]](#footnote-47) There is some significant variation between State and Territory implementations of the National Law. Most notable perhaps in New South Wales and Queensland, that retained various elements or institutional arrangements from the earlier regulatory system, enacting a co-regulatory approach. That the national scheme has thus become in many important respects, a ‘national’ law in name only[[47]](#footnote-48) is not universally problematic, with variation between jurisdictions providing for continuity of regulatory cultures, systems and practices long-embedded in those jurisdictions, as well as the potential for developing regulatory responses more suited to local conditions.

Like all other health professions regulated by the national scheme,[[48]](#footnote-49) the National Law establishes a National Board for medical practitioners, the Medical Board of Australia (‘MBA’).[[49]](#footnote-50) The MBA includes the functions of registering medical practitioners,[[50]](#footnote-51) investigating and managing concerns (notifications) about the performance, conduct and health of medical practitioners,[[51]](#footnote-52) to establish panels to conduct hearings in relation to health and professional performance, as well as develop relevant standards, codes or guidelines.[[52]](#footnote-53) The National Board is supported in this work by the Australian Health Practitioner Regulation Agency (AHPRA), to whom a range of its functions are delegated.

The MBA is a protective jurisdiction. ‘Protection of the public’[[53]](#footnote-54) or alternatively, protecting the ‘health and safety of the public’ [[54]](#footnote-55) remains its primary role, justifying its exercise of powers with relation to ‘medical practitioners who may be putting the public at risk as a result of their conduct, professional performance or health.’[[55]](#footnote-56) Much of the MBA’s power to do so relies upon its ability to control registration. And it is through this control of registration that the MBA and other actors in New South Wales and Queensland’s co-regulatory jurisdiction manage issues of performance or competency. Once registered, practitioners become subject to the jurisdiction of the MBA and others regulatory actors in relation to their professional performance.

Issues of practitioner performance or competency can arise in a range of ways. ‘Notification’ is the primary concept used in the National Law. Notifications are either concerns or complaints made to AHPRA, except in the co-regulatory jurisdictions of NSW or Queensland, where the Health Professional Councils Authority (HPCA) – on behalf of the NSW health professional councils – or the Health Care Complaints Commission (HCCC) in NSW or the Office of the Health Ombudsman in Queensland are the regulatory actors that receive notifications within the National Law. Notifications may be either be voluntary or mandatory. Voluntary notifications may be made by members of the public or a registered health practitioner. The more controversial mandatory notification system concerns notification made by other registered health practitioners or managers of health services and systems.[[56]](#footnote-57)

Once received, a notification may give rise to the exercise of a range of powers. These include the MBA or other actors taking immediate action, investigation of the notification, undertaking a performance or health assessment that may lead to a disciplinary panel or tribunal hearing. At this point, it may be found that a practitioner has engaged in unprofessional conduct or professional misconduct,[[57]](#footnote-58) have been found to have engaged in unsatisfactory professional performance,[[58]](#footnote-59) or that their health is impaired and their practice may place the public at risk.[[59]](#footnote-60) Potential outcomes of such findings include the ability to impose various limits or restrictions upon an individual practitioner’s registration. So too can the practitioner receive a caution or reprimand, suspension or cancellation of their registration should the need arise.

Whilst there is a now well-established and active disciplinary process available under the National Law, until and unless a matter comes before an appropriate regulatory actor by way of a notification, the MBA or other parts of the regulatory performance management system are limited in both formal powers and practical systems to investigate, assess or compel improvements in a practitioner’s competency. A practical example assists in demonstrating the current state of affairs.[[60]](#footnote-61) Identification of a competency issue may arise in the course of participating in clinical practice, brought to the notice of hospital or health services, managers, clinical or medical leadership, or colleagues, by virtue of formal or informal means. These concerns may be resolved at the health service or local level, resulting in either a return to satisfactory performance, or termination of employment/redeployment without the regulator being made aware of the issue having occurred. [[61]](#footnote-62) In some cases the concern might relate to very specific and particular factors present in the local work environment. Local resolution or termination/resignation might then be suitable, with performance in a new or different work environment resolving the matter and presenting no further risk of harm. However, if the matter relates to a competency or performance related issue that are independent of local factors, ending a local performance management process by either termination or resignation of employment with the practitioner finding work elsewhere leaves the new employer or the relevant regulator none-the-wiser as to the existence of this competency or performance issue and its failed remediation. This more complex scenario stands alongside the alternative option where a practitioners’ competency declines over time, with no one, including perhaps the practitioner themselves, noticing.

In relation to deteriorating or sub-standard physician competency this leaves much of the regulatory performance management system and resources available only after a notification is made, and with significant ‘gaps’ in its coverage where local performance concerns or remediation exist in silos. For these reasons, responding to competence issues in medical practice is currently piecemeal.

## Medical Registration Revalidation

Despite the existence of regulatory performance management systems, at present, there is no way to systematically identify doctors at risk of, or currently exhibiting, sub-standard competency. Revalidation processes have been proposed to address this issue. From a regulatory perspective, it seems likely that this reform will be achieved by embedding a revalidation process and its requirements or standards into a ‘Registration Standard’. Each national board, including the MBA, are required to develop Registration Standards on continuing professional development, indemnity insurance requirements, English language skills and matters regarding any criminal history of applicants and registered health practitioners.[[62]](#footnote-63) A National Board is also able to develop and recommend Registration Standards relating to the physical and mental health of applicants, registered health practitioners and students, scope of practice and any other issue relevant to the eligibility, suitability or competency of individuals.[[63]](#footnote-64) These Registration Standards are approved by the Ministerial Council,[[64]](#footnote-65) are used during registration and re-registration processes, and are admissible in disciplinary proceedings in all jurisdictions as evidence of what constitutes appropriate professional conduct or practice for the relevant health profession.[[65]](#footnote-66)

Whilst the legal implementation of revalidation by use of registration standards is quite straightforward, the content of that reform represents an area of significant debate. Other jurisdictions have trialled or implemented revalidation,[[66]](#footnote-67) and their experience has been influential on debate in Australia. Central to the discussions in Australia has been the regulatory model and experience of revalidation in the United Kingdom. In that jurisdiction, revalidation is administered by the General Medical Council (GMC), that jurisdictions’ equivalent of the MBA.[[67]](#footnote-68) Implemented in 2012, registered medical practitioners engage in revalidation cycles lasting five years. Compulsory activities include completion of five annual appraisals, continuing professional development activities, and compilation of a portfolio, that includes a flexible set of information, including review of significant events and multi-source feedback.[[68]](#footnote-69) Based on that process, a recommendation to the GMC supporting or not supporting revalidation is made by a ‘responsible officer’. The ‘responsible officer’ is a formal office, held by a variety of nominated senior and experienced medical practitioners who are either regionally, college or employer-based. In the first period of its use, 63 doctors left practice as a result of the revalidation scheme.[[69]](#footnote-70)

The success or otherwise of revalidation in the UK has been applied to evaluation of revalidation proposals in Australia. Perhaps the most memorable claim in this genre, has been the view that notorious serial killer and doctor, Harold Shipman, who killed an estimated 250 people, ‘would probably have been able to revalidate if he sorted out the correct paperwork.’[[70]](#footnote-71) In a more sober tone, President of the Australian Society of Anaesthetists, Guy Christie-Taylor, notes that ‘healthcare delivery by medical practitioners in Australia is organisationally quite different from the UK,’ [[71]](#footnote-72) and that ‘despite some local failures of medical regulation and hospital governance, there has been no widespread loss of faith of the community in either its doctors or the current regulatory system.’[[72]](#footnote-73) Kerry Breen, former President of the Australian Medical Council and past Chair of the Australian Health Ethics Committee of the NHMRC, similarly argues that the UK’s introduction of revalidation was premised on a ‘need to regain the trust of the community and to promote participation in continuing professional development’[[73]](#footnote-74) both being trends that do not apply to the Australian context, nor ‘justifiable grounds for introducing a similar process in Australia.’[[74]](#footnote-75)

Given the unique regulatory environment in Australia, the ‘gaps’ in the principal regulator’s ability to successfully intervene prior to harm arising from a competence issues, and the mixed experience of revalidation in overseas jurisdictions, there are, at present, significant gaps in the evidence or theory to support a particular model or characteristics of a revalidation system.[[75]](#footnote-76) These complexities, contests and unsettled evidence in relation to revalidation means, at present, that ‘the precise purpose and preferred approach to revalidation remains unclear’.[[76]](#footnote-77) However, this means that there is scope for transparent debate and evidence development to better ensure that benefits of revalidation are delivered to ‘patients, the health systems and profession as a whole.’ [[77]](#footnote-78) This is urgent, especially as there seems to be an inevitability to the introduction of revalidation.[[78]](#footnote-79)

# Understanding Public Preferences: Discrete Choice Experiment

In aid of advancing the evidence base in relation to revalidation, we conducted a discrete choice experiment to determine the Australian general public’s acceptance of and preferred model for medical registration revalidation. This experiment was undertaken during the MBA’s Expert Advisory Group on Revalidation’s deliberation. Discrete choice experiments present respondents with a short scenario or vignette, after which they are shown, sequentially, several pairs of potential responses and forced to choose their preferred response from each pair. The underlying premise is that respondents choose what they value in the context in which they are asked to make the choice.[[79]](#footnote-80)

Discrete choice methods have been applied successfully in a variety of health and health system-related contexts.[[80]](#footnote-81) For instance, de Bekker-Grob et al identified 69 published choice-based studies in health care in 2012,[[81]](#footnote-82) whilst the ISPOR task force has developed methodological guidance for such studies.[[82]](#footnote-83) Within the health context, discrete choice has been used in aid of developing and design of risk and side-effect profiles of medication,[[83]](#footnote-84) and to revise quality of life indicators.[[84]](#footnote-85) Whilst less frequent, discrete choice has also been applied in policy-related research in healthcare contexts. Practitioner preferences for the design of a healthcare-associated infection surveillance system,[[85]](#footnote-86) patient and community member preferences in relation to health service delivery models,[[86]](#footnote-87) and policy responses to rural and remote medical workforce shortages,[[87]](#footnote-88) are all examples of areas where discrete choice has been successfully used to influence policy formulation. It has been applied in a limited manner as an empirical legal method, with contentious regulatory issues having been subject to discrete choice experiments. This includes recent work on the design of legal and regulatory responses to cannabis use,[[88]](#footnote-89) on ‘reverse-engineering’ the selection of areas of a city for committing robbery,[[89]](#footnote-90) on the regulatory language displayed on complementary medicines,[[90]](#footnote-91) and on the pre-market approval of medical devices.[[91]](#footnote-92)

The common motivation expressed for the application of discrete choice to regulatory and policy questions has been its potential to direct regulatory decision making in a more patient or community-centred approach.[[92]](#footnote-93) Ho et al, in their work on pre-market regulatory approval of devices to treat overweight and obesity, are emblematic in this regard. They argue that patients’ have a unique role in influencing what treatment should be made available. Patient perspectives regarding benefits and values flow from their unique, lived experience, with a condition and the consequences of choices they make for their own care. These patient perspectives ‘can be different from those of regulators and care providers’,[[93]](#footnote-94) and in so far as they are, the voice of patients should be privileged.

In common with the justification for discrete choice, patients and their experiences have also been at the centre of calls for revalidation.[[94]](#footnote-95) For a regulatory body like the MBA whose primary purpose is protective, there is an absolute necessity to genuinely engage and prioritise the voice of the public when designing regulatory and policy interventions in their name. Due to the intersection of discrete choice’s own ability to elicit the voice of the public, its existing application in the health policy and regulatory setting, and the need to contribute to the revalidation debate in a manner that prioritises the perspectives of the public on this important question of regulatory design, we believe that a discrete choice experiment was a suitable way of contributing to the development of legal and regulatory responses to physician competency issues and as suitable method to advance the empirical study of law.

## Discrete Choice Experiment Design

In a discrete choice experiment choices are made between possible pairs constructed by varying the ‘levels’ of different ‘attributes’. For example, a discrete choice experiment relating to delivered pizzas might construct different pairs of options based on the ‘type of pizza’ (either gourmet or traditional), the ‘price’ ($13 or $17) and the ‘manners shown by the delivery driver’ (polite and friendly or simply friendly).[[95]](#footnote-96) Given these possible levels (type of pizza, price and manners) and possible attributes (either gourmet or traditional etc.), respondents are asked to make a series of choices between varying combinations of levels. One such ‘choice set’ presented to a respondent might be as follows:

|  |
| --- |
| Figure 1: Fictional Choice Set - ‘Delivered Pizza’ |
|  | Option A | Option B |
| 1 Type of Pizza | Gourmet | Traditional |
| 2 Price | $17 | $13 |
| 3 Manners shown by the delivery driver | Polite | Polite and Friendly |
| Choose which option you prefer: | Option A☐ | Option B☐ |

The respondent will need to choose between Option A and Option B. Having chosen, they will be presented with another set of options. This and subsequent choices will consist of differently constructed options, mathematically calculated to efficiently test the various valuations and driving forces of a respondent’s choice. By making such repeated choices, each time with differently constructed options, respondents’ preferences in relation to the relative importance of different aspects of a pizza delivery offering become clear.

In our study, we described an adverse event scenario to respondents and then presented them with several pairs of possible recommendations about what should happen to the health professionals involved in the adverse event. In our DCE the hypothetical recommendations were constructed by presenting differing combinations of the levels for each of the of six attributes (see Table 1):

|  |
| --- |
| **Table 1:** Discrete Choice Experiment, Attributes & Levels |
| **ATTRIBUTE** | **LEVELS** |
| 1 Government-issued fine for the doctor | * No fine for the doctor.
* A fine equivalent to one day of the doctor's salary
* A fine equivalent to one month of the doctor's salary
* A fine equivalent to one year of the doctor's salary
 |
| 2 Restriction on future medical practice for the doctor by the Medical Registration Board | * No restriction on practice or disciplinary proceedings for the doctor
* Noting of the incident on the doctor’s permanent medical registration record
* Temporary suspension of the doctor’s registration as a medical practitioner and right to work as a doctor
* Permanent cancellation of their registration as a medical practitioner
 |
| 3 Criminal trial for manslaughter for the doctor | * No criminal trial for the doctor
* Criminal trial of the doctor for manslaughter with a finding of Not Guilty
* Criminal trial of the doctor for manslaughter with a finding of Guilty but with no imprisonment
* Criminal trial of the doctor for manslaughter with a finding of Guilty and imprisonment
 |
| 4 Restriction on future nursing practice for the nurse by the Nursing and Midwifery Board | * No restriction on practice or disciplinary proceedings against the nurse
* Noting of the failure to prevent this breach on the permanent record of the nurse
* Temporary suspension of the nurse’s registration and right to work as a nurse
* Cancellation of their registration as a nurse
 |
| 5 Publicity and public reporting of the Incident | * No publicity or public reporting of the incident
* A comment on an internet article about the doctor appears, describing the incident
* A public Facebook status appears condemning the doctor for their actions
* A Facebook group of patients harmed by the doctor is started
 |
| 6 Verification of the doctor’s skills | * No verification processes for the doctor
* A mentoring program and review of the doctor’s skills by a colleague from the same hospital
* Formal re-training by the doctor in relevant skills and topic areas
* Formal review and check of the doctor’s skills by independent senior doctor
 |

This results in 46 = 4096 possible recommendations and therefore a total of 4096x4095/2 = 8,386,560 possible pairs of recommendations. A sample choice set constructed using our attributes and levels is shown in Table 2:

|  |
| --- |
| Figure 2: Discrete Choice Experiment, Sample Choice Set |
| At the end of the investigation, health authorities are left with a choice about what to recommend should happen to the ICU doctor and assisting nurse. If these were the only options, which alternative would you choose? |
|  | **Option A** | **Option B** |
| 1 Government-issued fine for the doctor | **No fine for the doctor** | **A fine equivalent to one month of the doctor’s salary** |
| 2 Restriction on future medical practice for the doctor by the Medical Registration Board | **Noting the incident on the doctor’s permanent medical registration record** | **Permanent cancellation of their registration as a medical practitioner** |
| 3 Criminal trial for manslaughter for the doctor | **Criminal trial of the doctor for manslaughter with a finding of Guilty but with no imprisonment**  | **Criminal trial of the doctor for manslaughter with a finding of Guilty but with no imprisonment**  |
| 4 Restriction on future nursing practice for the nurse by the Nursing and Midwifery Board | **Temporary suspension of the nurse’s registration and right to work as a nurse** | **No restriction on practice or disciplinary proceedings against the nurse** |
| 5 Publicity and public reporting of the incident | **No publicity or reporting of the incident.** | **A public Facebook status appears condemning the doctor for their actions.** |
| 6 Verification of the doctor’s skills | **A mentoring program and review of the doctor’s skills by a colleague from the same hospital.** | **Formal review and check of the doctor’s skills by an independent senior doctor** |
| Choose which option you prefer: | **Option A**☐ | **Option B**☐ |

On each occasion respondents were forced to choose the recommendation they felt was more appropriate. In total, each respondent was shown 16 different pairs of recommendations. Attributes and their attendant levels were constructed by literature review and regulatory knowledge. We discuss that process below.

## Attributes & Levels: Translating Regulatory Options

For exploring responses to different models of revalidation, we constructed an attribute named ‘Verification of the doctor’s skills’ (Attribute 6, Table 1). Four levels were chosen to convey, in significantly truncated form, the current regulatory setting of ‘no revalidation’ (Level 0) alongside revalidation approaches proposed by Archer et al in commissioned research for the Medical Board of Australia.[[96]](#footnote-97)

In their major review of international revalidation models, Archer et al identified a set of common elements used in revalidation models. Continuing professional development activities were found to have been the most frequently utilised method of medical regulation, operating at varying degrees of intensity and duration. Peer review and/or practice review was used by the majority of reference jurisdictions, whilst few jurisdictions integrated systematic review of patient complaints.[[97]](#footnote-98) Based on this review, Archer et al were able to propose a set of three potential models, labelled by them as Model A, B and C.

Archer et al’s ‘Model A’ represented a basic approach to revalidation. Operating entirely online, medical practitioners would be required to produce an annual online portfolio of evidence to demonstrate participation in mandatory but self-directed CME as well as participation in a multi-source feedback process. Archer et al’s ‘Model B’ similarly required construction of an online portfolio. However, in Model B, continuing professional development activities were directed, with a number of mandatory activities. So too did Model B include an online learning component, bi-annual appraisals for targeted groups (based on factors such as age) as well as participation in a multi-source feedback process with a mandated number of patients and peers. In this model, revalidation appraisal would be undertaken for all doctors every fifth year as is the case in the UK. Finally, Archer et al’s ‘Model C’ built upon Model A and Model B by requiring development of an online portfolio evidencing continuing professional development, but added requirements to engage in blended (online and face-to-face) learning. Annual appraisals and multi-source feedback with accompanying facilitated feedback and a mandatory review of patient complaints were also added to the approach.

A key differentiator between these and all potential revalidation models is whether revalidation is achieved by applying a formative (to support individual learning), summative (minimum standards of performance) or mixed approach.[[98]](#footnote-99) For example, Archer’s Model C comprised of both formative and summative components. To this end, we constructed Levels for use in our discrete choice experiment by distinguishing between formative and/or summative methods as their key differentiating factor. Recalling the Levels relating to revalidation shown above (Table 1), Level 1 was constructed to convey the *essence* of a formative revalidation (being ‘up to date’), Level 2 a mixed-method model combining elements of Level 1 and Level 3 (being both ‘up to date’ and ‘fit to practise’) and Level 3 a summative approach (being ‘fit to practise’).[[99]](#footnote-100) In this way, levels were constructed on a spectrum running between the poles of formative and summative approaches, there being no clear ‘hierarchy’ in relation to the phenomenon of revalidation models, simply advantages and disadvantages attached to each of the dominant conceptual poles:



Figure 3: Revalidation Options Spectrum

A potential weakness of this study is that all revalidation models are complex and none are as yet employed in the Australian healthcare system. Even in their proposed form, they describe a highly textured social practice in a setting, and with meanings, largely unfamiliar to the general public. This presents challenges when constructing a DCE both because of the need for brevity, and its application to non-specialists. As such, we constructed a series of ‘proxies’ to express the fundamental or essential differentiators between potential revalidation models:

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| Table 2: Comparison Between Archer’s Proposed Revalidation Models and the DCE’s Constructed Proxies |
| **DCE Attribute Level** |  | **Revalidation Model ( Proposed by Archer et al)**[[100]](#footnote-101) | **DCE’s Attribute Level Description (‘Proxies’)** |
| Level 0 |  | **Status Quo:** |  | No verification processes for the doctor. |
| Level 1 |  | **Model A:** | ‘up to date’(Formative) | A mentoring program and review of the doctor’s skills by a colleague from the same hospital. |
| Level 2 |  | **Model C:** | ‘up to date’ + ‘ fit to practise’(Formative & Summative) | Formal re-training by the doctor in relevant skills and topic areas. |
| Level 3 |  | **Model B:** | ‘fit to practise’(Summative) | Formal review and check of the doctor’s skills by independent senior doctor. |

 varying levels of oversight (‘by a colleague’ and ‘independent senior doctor’), formative support of individual learning (‘mentoring program…doctor’s skills…same hospital’), summative appraisal processes (‘formal review…by an independent senior doctor’) or mixed approaches of summative appraisal (‘formal re-training’) with formative elements (‘in relevant skills and topic areas’). This was necessary as the fine detail of models remains unsettled, and successfully conveying complex structures — such as the office of the UK’s Responsible Officer as proposed by Archer et al (in their Model ‘C’)[[101]](#footnote-102) — is impossible in this setting. The novel integration of remediation activities directly into the structure of the MBA’s revalidation model further complicated construction. Level 2, that explicitly includes ‘formal re-training’, is thought to adequately represent this integration of remediation activities, that are a mixture of formative and summative activities undertaken to rectify and confirm rectification of competency concerns. Level 3 is thought to represent the confirmatory aspects of a remediation process alone, without the more supportive formative elements that are present in most remediation efforts. Initially the vignette and attribute and level descriptions were reviewed by two legal academics and two health services/nursing academics outside of the research team. The second phase involved three non-specialists who attempted to complete choice sets manually, providing feedback to researchers. This was supplemented by a panel member pilot of approximately 50 respondents, who undertook the electronic version of the DCE instrument with opportunity to seek guidance or provide feedback. Despite potential inability to differentiate between levels given the subtle differences in wording, both specialists and non-specialists were able to detect and describe differences between the levels proposed. The use of ‘the independent senior doctor’ compared with a ‘colleague from the same hospital’ was a clear differentiator.

Although the order of levels within each attribute reflects an underlying synthesis of the literature, regulatory knowledge and our own model construction, respondents were not presented with them in that order. An example of one pair that was presented in a choice-set is shown in Table 2. We used the design construction techniques described in Street and Burgess to construct a set of 160 pairs like the example in Table 2 that allowed for the estimation of the effect of each attribute on the recommendation selected.[[102]](#footnote-103) Our design ensures that a respondent is unable to make all their decisions based on a single attribute — for example, by persistently selecting the recommendation that has the greatest or least impact on the nurse or doctor.

## Vignette Development

The vignette was a fictionalised representation of a routine central line insertion in a NSW ICU, where the proceduralist (an intensive care physician) neglected to don a surgical cap after being reminded to do so by a nurse. This vignette was loosely based on a scenario described by Burrell et al. in their work on reducing mortality and morbidity associated with insertion and management of central lines in the NSW ICU setting.[[103]](#footnote-104) We fictionalised and extended that scenario, describing a particular Central Venous Line (CVL) insertion that results in iatrogenic death. This was to reinforce the ‘violation’[[104]](#footnote-105) at the heart of this fictionalised adverse event, whilst reducing the potential for responsibility attribution (that is unmeasured) to impact on the DCE.

This vignette represents, in one sense, a ‘limit case’ scenario in relation to healthcare provision, iatrogenic harm and revalidation. Iatrogenic death is not a ‘typical’ outcome of physician incompetence. However, we know that between 10 and 16 per cent of all hospital admissions in Australia result in some form of iatrogenic harm.[[105]](#footnote-106) Initially a highly controversial claim, it is now well-accepted that at least 10 per cent of admissions to acute care hospitals are associated with an adverse event, including 0.3 per cent associated with iatrogenic death and 1.7 per cent with a major iatrogenic disability.[[106]](#footnote-107) Scholars agree that the rate of adverse events has not measurably improved for fifty years, despite significant efforts to do so.[[107]](#footnote-108) Though not yet wholly settled, landmark studies in the area find that between 50 and 80 per cent of all adverse events are potentially preventable.[[108]](#footnote-109) Up to 27,000 people die from iatrogenic harm per annum in Australian hospitals.[[109]](#footnote-110)

So too do we know that central line-associated blood-stream infections, the cause of the fictionalised death in our vignette, are strongly associated with mortality,[[110]](#footnote-111) but can also be almost wholly prevented.[[111]](#footnote-112) Prevention, importantly, is not a matter of applying innovative medical science, new surgical techniques, or other truly novel, extraordinary, or unusual activities. Instead, success in reducing central line-associated infections like that used in our vignette, is predicated on success factors that are inexpensive, and are fundamentally about reaching and sustaining compliance with social, technical and clinical/procedural approaches that are well-known.[[112]](#footnote-113) In the study from which we sourced the scenario, patients who had CVLs inserted by clinicians who did not comply with maximal sterile barrier precautions had a relative risk of central line-associated bacteraemia 1.62 times greater than those whose clinicians were compliant.[[113]](#footnote-114) In that study, like our vignette, ‘hat wearing was identified as the contentious component’[[114]](#footnote-115) of the clinician’s barrier precautions. At a practical level, then, the vignette reflects scenarios where revalidation might be used and useful, as the vignette represents a correctable failure in competency.

The vignette’s focus upon an identified issue with competency, aligns with the MBA’s proposed model. Following the work by Archer et al and Bismark et al[[115]](#footnote-116) the MBA’s proposal is to target doctors who are either ‘at risk’ or who are performing poorly for summative, appraisal-like testing and remediation activities. This brings ‘forward’ remediation, out of the realm of formal disciplinary proceedings.[[116]](#footnote-117) It is thus aimed at ensuring the ‘continuing competence of physicians’[[117]](#footnote-118) rather than a broadly applied preventive measure for all medical practitioners. In practice, this proposal means that the revalidation process will, in very large part, be no different to activities and requirements already operating as a part of the regulatory performance management system. Continuing professional development is already universally compulsory for medical practitioners in Australia. Running a discrete choice experiment that focuses on that situation (of standard, competent performance met with the usual CPD requirements) will likely reveal very little of significant interest. Instead, the ‘new’, contentious and currently unclear element of the MBA’s proposed revalidation model are plans to engage beyond universally compulsory CPD for doctors specifically at risk of in need of remediation. Recalling the discussion above, these activities will be available or applied in response to (a) an identified issue in competence or (b) a material risk of a competency issue. Our vignette is designed to reflect the type of scenario where this more involved and active revalidation/remediation activity will likely apply.

A practical constraint in this study is that only single vignette design was available, driven resource limitations and by our broader aim to study responses to events of clear failure in physician competence, as part of a broader study on quality and safety in healthcare.

Our study utilised a commercially sourced, double opt-in panel of Australian residents maintained by [Redacted]. We stipulated recruitment targets (rather than quotas) based on key demographic variables (age, gender, rural/metro) as is common in the application of DCEs. Whilst acknowledging limitations in the method,[[118]](#footnote-119) the advantages of online panel approaches been documented by a range of authors.[[119]](#footnote-120) The panel method was felt to be well suited to the aims and scope of this research project, and is widely used in DCE designs.

We used a mixed logit (MIXL) model to quantify the characteristics that describe popular approaches to medical revalidation.[[120]](#footnote-121) Using the MIXL model, we can allow for preference heterogeneity (variability of individual tastes and preferences for different characteristics) amongst respondents. More details about the MIXL model can be found in Train.[[121]](#footnote-122) The analysis was performed using Stata. Ethics approval was granted by [Redacted] ([Redacted]) and funding for the study was made available by [Redacted].

# Results

Driven by the use of recruitment targets on age, gender and self-reported rural/metro location, results compare favourably with known distributions in the NSW population (Table 3):

|  |  |  |
| --- | --- | --- |
| Table 3: Respondent Characteristics |  |  |
| **Characteristic** | **Percent (n=1000)** | **Comparator (NSW)** |
| **How likely would you be to recommend your last healthcare service to friends and family if they needed similar care or treatment?** |
| Extremely Likely | 19.1% | - |
| Likely | 42.2% | - |
| Neither likely or unlikely | 25.7% | - |
| Unlikely | 6.0% | - |
| Extremely Unlikely | 4.0% | - |
| Don’t Know | 3.0% | - |
| **Age:** |  |  |
| 18-29 | 17.8% | 17.9% |
| 30-39 | 19.1% | 18.6% |
| 40-49 | 19.1% | 18.8% |
| 50-59 | 17.6% | 17.3% |
| Over 59 | 26.4% | 27.4% |
| **Gender:** |  |  |
| Male | 48.5% | 49.3% |
| Female | 49.9% | 50.7% |
| Intersex | 1.0% | - |
| Indeterminate | 0.6% | - |
| **Level of Highest Educational Attainment:** |  |  |
| Secondary Education | 21.0% | 34.5% |
| Certificate Level | 21.2% | 17.5% |
| Advanced Diploma and Diploma | 16.3% | 9.2% |
| Bachelor Degree | 26.8% | 17.6% |
| Graduate Diploma and Graduate Certificate Level | 4.7% | 2.6% |
| Postgraduate Degree Level(Comparator Source: Australian Bureau of Statistics: Education and Work, Australia, May 2015, 62270DO001\_201505) | 10.0% | 6.3% |
| **Ever Worked in the Healthcare Industry:** |  |  |
| Yes | 14.9% | - |
| No | 85.1% | - |
| **Visits to a General Practitioner in the past twelve months for your own healthcare:** |
| I haven’t been in the past twelve months | 9.7% | - |
| Once | 16.9% | 18.6% |
| 2-3 times | 35.7% | 42.0% |
| More than 3 times(Comparator Source: Australian Bureau of Statistics, Health Services: Patient Experiences in Australia, 2009, 4839.0.55.001) | 37.7% | 39.4% |
| **Place of Usual Residence:** |  |  |
| Greater Sydney | 64.9% | 60.4% |
| Rest of NSW(Comparator Source: 2011 ABS Census, 2016 New South Wales State and Local Government Area Population Projections classification of Sydney Metropolitan and Regional LGAs.) | 35.1% | 39.6% |

Results of the MIXL analysis are shown in Table 4 for all attributes and levels of the DCE related to revalidation:

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| --- |
| **Table 4:** Results of DCE (MIXL Model) |
| **Attribute** | **Level** |  |
| **Verification of the doctor’s skills** | No verification processes for the doctor | 15% |
| A mentoring program and review of the doctor’s skills by a colleague from the same hospital | 26% |
| Formal re-training by the doctor in relevant skills and topic areas | 31% |
| Formal review and check of the doctor’s skills by independent senior doctor. | 28% |
| **N:** | 1,000 |  |
| **Observations:** | 16,000 |

The model predicts that when presented with options that only vary on the revalidation attribute, approximately 15% of choices would be for no revalidation process, whilst approximately 85% would be for one of the three models of revalidation. This indicates strong support for revalidation in response to a scenario like the one presented in our vignette. If the aggregate volume of choices made by respondents is understood to represent preferences for particular revalidation approaches, this reveals that respondents preferred the following revalidation models (in descending order of preference):

* formal re-training of the doctor in relevant skills and topic areas (Level 2);
* formal review and check of the doctor’s skills by an independent senior doctor (Level 3); and
* a mentoring program and review of the doctor’s skills by a colleague from the same hospital (Level 1).

As levels were constructed as proxies for the options proposed by Archer et al, this order represents a preference in descending rank order of their models for revalidation: ‘Model C’, ‘up to date’ + ‘ fit to practise’, a mixed formative and summative approach; followed by ‘Model B’, ‘fit to practise’, a summative approach; and, lastly, ‘Model A’, ‘up to date’ a formative approach.[[122]](#footnote-123) Each of these three options was preferred to the ‘status quo option’ of no revalidation activity.

In relation to other attributes, such as a criminal trial for the doctor, a fine for the doctor, or for registration-based disciplinary processes for the nurse of doctor, respondents always reported a preference that was significantly different from the reference level (that no form of action be taken in relation to the particular attribute, e.g. no fine, no criminal trial). In all cases except one, that preference was positive; that is, respondents indicated that they wanted some form of response/action, rather than none. The single exception was when presented with the option of deregistering the nurse in the vignette relative to the reference level of no registration restrictions.[[123]](#footnote-124)

In summary, the results do not display a stark preference for one particular form of revalidation. However, they do indicate a strong preference for revalidation of some type. The implication is that, subject to the DCE's own contextual factors and influences, if presented in revalidation models resembling Level 2 (‘up to date’ &‘ fit to practise’, a mixed formative and summative approach) or Level 3 (‘fit to practise’, a summative approach), approximately 59% of choices made by respondents would flow to that option, whilst approximately 85% would be for one of the three models of revalidation.

# Protection of the Public

Patients have been identified as the ‘discursive glue’[[124]](#footnote-125) at the centre of prevailing frames surrounding revalidation. Yet, there has been a lack of patient perspective-driven policy in revalidation literature. This is an especially problematic state of affairs given the nature of the MBA and its practice of registration as primarily to give effect to their responsibility to protect the public. Moreover, if revalidation is to be truly focused on ensuring, amongst other things, that ‘patients remain at the heart of medical care’,[[125]](#footnote-126) then the desires of patients and the general public should be both elicited and provided with significant weight in debates about law reform in these areas. This research contributes to placing the perspectives of the public at the heart of medical care that concerns them, and the design and function of a key protective jurisdiction which is bound to protect them and their interests. What is absolutely clear from the results of the DCE is that the public indicate a clear preference for revalidation processes in response to a failure in physician competence. Moreover, they prefer a model that expresses a mixture of both formative and summative elements.

Reading the aggregate flow of choices elicited by this DCE the purely formative option - mentoring and skill review by a colleague – achieved the weakest allocation of preferences. This options expressed by use of a proxy the ‘weakest’ of revalidation models canvassed by Archer et al:[[126]](#footnote-127) internet-based revalidation, with participation in multi-source feedback, alongside mandatory, but wholly self-directed, CPD. That model lacks really any summative character or independent external review. That model, if implemented would be able to broadly demonstrate that medical practitioners were generally ‘up to date’ but not necessarily ‘fit to practise’.[[127]](#footnote-128) By contrast, the strongest flow of choices in the DCE flowed to the option that encapsulated Archer et al’s preferred model (Model C in the report); a revalidation model involving a mixture of both formative and summative elements. This model was expressed by the proxy language of ‘formal re-training by the doctor in relevant skills and topic areas’ in our DCE. If this form of revalidation was implemented in the proposed regulatory reform, this model of revalidation would broadly ensure that a doctor would be up-to-date (as indicated by the re-training aspect of the proxy) as well as ‘fit to practise’ (as indicted by the formality of that re-training). By reading the DCE results in line with the proposals made by Archer et al, we conclude that a combination of summative and formative revalidation is likely to be more acceptable form of law reform to the general public than doing nothing.

Subject to further detail, trial and successful implementation, it seems likely that the combination of formative and summative assessment proposed by the Medical Board of Australia’s Expert Advisory Group on Revalidation will be an acceptable response to the broader public. At present, the MBA’s Expert Advisory Group on Revalidation proposes an integrated approach to revalidation regulatory reform. It would consist of two components: a strengthened form of CPD, and proactive identification and assessment of ‘at-risk’ and poorly performing practitioners.[[128]](#footnote-129) This proposal represents a mixed-model of revalidation, integrating largely formative CPD activities to support individual learning (‘up to date’) and summative appraisal to ensure minimum standards of performance (‘fit to practise’) in select cases. In practice, this proposed model would seem to arrange CPD to ‘nest’ within the secondary summative component, using CPD to assist in identifying ‘at risk’ medical practitioners by use of compulsory performance review and outcome measurement alongside validated education activities. So too, does it seem possible that practitioners will be referred or required to complete the more intensive, summative, aspects of the second part of the model should they meet particular risk profiles, based on practice type and other factors such as age and gender. Perhaps, there is also scope for referral of practitioners into this second stage of revalidation based on the existence of particular complaint or notification activity. However, the line between regulatory performance management and disciplinary processes on the one hand, and the revalidation process on the other will require some work to establish, particularly if they overlap in some way. All of this goes to say that according to the preferred model, a form of summative appraisal revalidation activity would be compulsory for all medical practitioners (to satisfy their CPD requirement). This selection of a mixed formative and summative approach is supported by the findings presented here.

Not only will the proposed regulatory reform be acceptable to the public, its implementation will significantly advance the law’s contribution to constraining dangerous medical practice from a largely reactive stance onto a more proactive footing. This represents a potentially effective and, importantly, acceptable reform to existing regulatory performance management and disciplinary systems. However, the proposal will also provide the opportunity for reassessment of the role of existing medico-legal practices, like complaints, in support of other forms of proactive regulatory action in support of the quality and safety of healthcare. Existing medico-legal processes and practices have been subject to almost consistent critique and discomfort in Australia. The long and often complex reception of tortious negligence,[[129]](#footnote-130) indemnity insurance systems, and (currently) mandatory reporting requirements are all part of the tensions and debates surrounding the practice of medicine. Perhaps this tension surrounding regulatory system design and administration is not a bad thing. However, through this process, medico-legal mechanisms and practice have very often come to be cast as an unwelcome interloper in the field of patient safety and regulation of the profession—threatening unjust, inaccurate and otherwise unhelpful punitive action.[[130]](#footnote-131) One outcome of the suspicion or tension surrounding existing medico-legal practices has been the establishment of silos around particular regulatory mechanisms and their outputs. For example, formal complaints mechanisms might collect and manage complaints at a local hospital or health service level, whilst statutory health complaints or ombudsman bodies that are best positioned to monitor and evaluate broader patterns of complaint or concern are left without access to the complaints data unless a complaint is made directly to them. These silos must be broken down. These significant resources, experience, expertise and data should be mobilised in aid of advancing healthcare quality and safety,[[131]](#footnote-132) and to do so means bringing whatever information we have to bear on the task of protecting of the public. Thankfully, the current revalidation regulatory reform proposals promise to do just that. Various silos of information will be tapped, drawing directly upon existing medico-legal processes like complaints systems to design and administer various facets of the proposed revalidation model. In particular, the use of existing complaints data held by various actors to formulate and justify the risk-based targeting of revalidation’s more rigorous processes represent just such an integration of otherwise separate medico-legal practices and their outputs in a productive way. In so far as it will do so, this represents a potentiation of the patient’s and general public’s contribution to revalidation efforts and the regulation of healthcare quality and safety by harnessing their existing contribution made through those channels.

Finally, the implementation of revalidation will work to greatly assist achieving the fundamental purpose of a medical registration system: the protection of the public. Whilst protection of the public requires that particular practitioners be stopped from continuing to risk the safety and health of their patients, this is not its only feature. The concept is broader than this and the features of the protective jurisdiction are multiple:

It includes protecting the public from the similar misconduct or incompetence of other practitioners and upholding public confidence by setting and maintaining those standards and, where appropriate, by cancelling the registration of practitioners who are not competent or otherwise not fit to practise, including those who have been guilty of serious misconduct. Denouncing such misconduct operates both as a deterrent to the individual concerned, as well as to the general body of practitioners. It also maintains public confidence by signalling that those whose conduct does not meet the required standards will not be permitted to practise.[[132]](#footnote-133)

Ian Freckelton echoes this sentiment, writing that ‘protection’ is a ‘subtle and complex concept’, one which ‘includes addressing public disillusionment after phenomena such as Shipman, Bristol, Bailey and Patel. It also requires maintenance within the general community of trust and well-founded confidence in the integrity and competence of health practitioners.’[[133]](#footnote-134) Even amidst such multiple and subtle features of ‘protection’, establishing a revalidation system seems to represent a potentially significant advance on all fronts. As a regulatory performance management method, it will support the identification and response to ‘similar misconduct or incompetence’[[134]](#footnote-135) of practitioners by drawing records of complaint and misconduct directly into its design and proactive risk-based targeting. It will assist in identifying those ‘practitioners who are not competent or otherwise not fit to practise’[[135]](#footnote-136) before harm has occurred, rather than in the reactive manner available today. All the while, it will be able to build and maintain public confidence and trust in the protective jurisdiction and its processes by reflecting the public’s sentiments and desires in the task of protecting that very same public.

1. Iatrogenic harm is harm to the person, including death, which arises in the course of medical or health care treatment caused by the application of treatment itself, rather than the underlying disease or injury. Bill Runciman, Alan Merry and Merrilyn Walton, *Safety and Ethics in Healthcare: A Guide to Getting It Right* (Ashgate Publishing, Ltd., 2007) Chapter One; William Runciman and J Moller, *Iatrogenic Injury in Australia* (Australian Patient Safety Foundation, 2001) 8. [↑](#footnote-ref-2)
2. The question of medical registration and protection of the public was front of mind even in 1868, where a medical practitioner (who signed his letter ’Scalpel’) wrote to the Editor of the Sydney Morning Herald in support of the publication of the ‘Medical Register’ as a ‘step in the right direction’. The register contained the qualifications of practitioners and the letter writer declared that they had ‘long looked forward to the publication of the various qualifications of “doctors”, as it is the only means by which the properly educated practitioner can be distinguished from the imposter or the imperfectly qualified.’ ‘The Medical Register.’ *The Sydney Morning Herald* (NSW), 10 March 1868 5. [↑](#footnote-ref-3)
3. See Runciman and Moller, above n 1; Robert L Wears, Kathleen M Sutcliffe and Eric Van Rite, ‘Patient Safety: A Brief But Spirited History’ in Lorri Zipperer (ed), *Patient Safety: Perspectives on Evidence, Information and Knowledge Transfer* (Ashgate Publishing, Ltd., 2014) 3; however compare the early account by Illich of iatrogenesis, see Ivan Illich, *Limits to Medicine: Medical Nemesis : The Expropriation of Health* (M. Boyars, 1995). [↑](#footnote-ref-4)
4. Jeffrey Braithwaite, Robert L Wears and Erik Hollnagel, ‘Resilient Health Care: Turning Patient Safety on Its Head’ (2015) 27(5) *International Journal for Quality in Health Care* 418, 419; Wears, Sutcliffe and Van Rite, above n 3. [↑](#footnote-ref-5)
5. The 1994-95 Australian QAHCS study reported Preventability was not strongly associated with age, sex or insurance status, nor was it associated with the level of disability, except for death (in which 70% of Adverse Events showed high preventability). Only 1.2% of AEs in the “no preventability” category resulted in death, compared with 4.1% in the “low preventability” category and 6.5% in the “high preventability” category. Some of this association between preventability and death could be ascribed to outcome bias Ross M Wilson et al, ‘The Quality in Australian Health Care Study’ (1995) 163(9) *Medical Journal of Australia* 458; the QAHCS study reported 51% preventability across all adverse events, see Runciman and Moller, above n 1, 22; see also the QAHCS results reinterpreted where all adverse events were re-classified as to whether they fell into one of two categories, “potentially preventable”, or “not preventable with current medical knowledge” rather than using the six-point scale in the QAHCS, it was found that 80% of adverse events fell into potentially preventable categories William Runciman, MJ Edmonds and M Pradhan, ‘Setting Priorities for Patient Safety’ (2002) 11(3) *Quality and Safety in Health Care* 224. [↑](#footnote-ref-6)
6. Helen Kiel, ‘Regulating Impaired Doctors: A Snapshot from New South Wales’ (2013) 21(2) *Journal of Law and Medicine* 429, 430. [↑](#footnote-ref-7)
7. *Health Practitioner Regulation National Law Act* *2009* (QLD); *Health Practitioner Regulation National Law* (NSW) No 86a (‘*Health Practitioner Regulation National Law (NSW)*’) (known also as the Health Practitioner Regulation National Law [NSW]); *Health Practitioner Regulation National Law (ACT) Act* *2010* (ACT); *Health Practitioner Regulation (National Uniform Legislation) Act* *2010* (NT); *Health Practitioner Regulation National Law (Victoria) Act* *2009* (Vic); *Health Practitioner Regulation National Law (South Australia) Act* *2010* (SA); *Health Practitioner Regulation National Law (Tasmania) Act* *2010* (TAS); *Health Practitioner Regulation National Law (WA) Act* *2010* (WA). [↑](#footnote-ref-8)
8. *Health Practitioner Regulation National Law Act* *2009* (QLD) s 3(2)(a). [↑](#footnote-ref-9)
9. See in the NSW enactment of the National Law, that an additional New South Wales provision provides that ‘In the exercise of functions under a NSW provision, the protection of the health and safety of the public must be the paramount consideration’, *Health Practitioner Regulation National Law (NSW)* (NSW) No 86a, s 3A. [↑](#footnote-ref-10)
10. The Medical Board of Australia, Expert Advisory Group on Revalidation, ‘Expert Advisory Group on Revalidation Interim Report’ (August 2016) 43. [↑](#footnote-ref-11)
11. This includes their ability to set educational, character and other standards for student and initial registration, alongside the more obvious use of registration within the context of disciplinary processes, where registration conditions, restrictions or de-registering a person are all ways in which the regulator uses their control of registration. [↑](#footnote-ref-12)
12. Medical Board of Australia, ‘Good Medical Practice: A Code of Conduct for Doctors in Australia’. [↑](#footnote-ref-13)
13. These registration standards are provided for within the National Law, see for example *Health Practitioner Regulation National Law (NSW)* (NSW) No 86a, ss 38-41; as to registration standards themselves, see for example, Medical Board of Australia, *Registration Standard: Continuing Professional Development* (1 October 2016) <http://www.medicalboard.gov.au/Registration-Standards.aspx>. [↑](#footnote-ref-14)
14. For those regulated health professions who have a form of specialist registration. For others, such as Nursing and Midwifery, the equivalent is an ‘endorsement’ of registration, that identifies registered nurses and midwives who meet the relevant registration standard for either specific forms of advanced practice (such as rural or isolate practitioners who may supply scheduled medicines), or as a Nurse Practitioner. [↑](#footnote-ref-15)
15. Julian Archer et al, ‘The Evidence and Options for Medical Revalidation in the Australian Context: Final Report’ (7 October 2015). [↑](#footnote-ref-16)
16. Tanya Horsley et al, ‘National Programmes for Validating Physician Competence and Fitness for Practice: A Scoping Review’ (2016) 6(4) *BMJ Open* e010368. [↑](#footnote-ref-17)
17. Stephen N Bolsin, Elizabeth Cawson and Mark E Colson, ‘Revalidation Is Not to Be Feared and Can Be Achieved by Continuous Objective Assessment’ (2015) 203(3) *The Medical Journal of Australia* 142. [↑](#footnote-ref-18)
18. The Medical Board of Australia, ‘Options for Revalidation in Australia: Discussion Paper’ (August 2016) 6. [↑](#footnote-ref-19)
19. Archer et al, above n 15. [↑](#footnote-ref-20)
20. Medical Board of Australia, ‘Building a Professional Performance Framework’ <http://www.medicalboard.gov.au/Registration/Professional-Performance-Framework.aspx>; The Medical Board of Australia, above n 18, 2; see especially The Medical Board of Australia, Expert Advisory Group on Revalidation, ‘Expert Advisory Group on Revalidation Final Report’ (August 2017) <http://www.medicalboard.gov.au/Registration/Revalidation.aspx>. [↑](#footnote-ref-21)
21. MM Bismark et al, ‘Relationship between Complaints and Quality of Care in New Zealand: A Descriptive Analysis of Complainants and Non‐complainants Following Adverse Events’ (2006) 15(1) *Quality & Safety in Health Care* 17; Marie M Bismark et al, ‘Remedies Sought and Obtained in Healthcare Complaints’ (2011) 20(9) *BMJ Quality & Safety* 806; Marie M Bismark et al, ‘Identification of Doctors at Risk of Recurrent Complaints: A National Study of Healthcare Complaints in Australia’ (2013) 22(7) *BMJ Quality & Safety* 532. [↑](#footnote-ref-22)
22. Based on the empirical work of Bismark and Studdert, see Bismark et al, ‘Identification of Doctors at Risk of Recurrent Complaints’, above n 25. [↑](#footnote-ref-23)
23. Marilys Guillemin et al, ‘Revalidation: Patients or Process? Analysis Using Visual Data’ (2014) 114(2–3) *Health Policy* 128. [↑](#footnote-ref-24)
24. Jill Thistlethwaite, Rodger Charlton and Jane Coomber, ‘Revalidation for Relicensing: Reflections on the Proposed British Model’ (2012) 41(1/2) *Australian family physician* 70, 71. [↑](#footnote-ref-25)
25. M Parker, ‘Monitoring Doctors’ Clinical Competence: A Queensland Focus’ (2001) 9(1) *Journal of Law and Medicine* 105, 105; see also Margaret Cunneen, ‘The Patel Case – Implications for the Medical Profession’ (2010); this was amongst other calls for regulatory responses, see in relation to the vexed example of criminal prosecution, David J Carter, ‘Correcting the Record: Australian Prosecutions for Manslaughter in the Medical Context’ (2015) 22(3) *Journal of Law and Medicine* 588. [↑](#footnote-ref-26)
26. Reported by Radio National’s Background Briefing, the Morris Inquiry heard from a key witness, Toni Hoffman, a nurse in the Bundaberg ICU, that 'the hospital’s chief anaesthetist dubbed Dr Patel ‘Dr Death’. And that his incompetence was so well known among hospital staff they’d say, "If I have an accident on the weekend, fly me out to Brisbane, don’t let Dr Patel touch me."’ Radio National, Australian Broadcasting Corporation, ‘Bundaberg’s Dr Death’, *Radio National*, 7 June 1000 <http://www.abc.net.au/radionational/programs/backgroundbriefing/bundabergs-dr-death/3451382>. [↑](#footnote-ref-27)
27. Commissioner Davies reported in his final report evidence that 'there were 13 deaths in which an unacceptable level of care on the part of Dr Patel contributed to the adverse outcome; and there were a further 4 deaths in which an unacceptable level of care by Dr Patel may have contributed to the outcome. He found, in addition, 31 surviving patients where Dr Patel’s poor level of care contributed to or may have contributed to an adverse outcome’, see Hon Geoffrey Davies, ‘Queensland Public Hospitals Commission of Inquiry (“The Davies Commission”)’ (30 November 2005) 4 <http://www.parliament.qld.gov.au/documents/tableOffice/TabledPapers/2005/5105T5305.pdf>. [↑](#footnote-ref-28)
28. See, Nikita Tuckett, ‘Balancing Public Health and Practitioner Accountability in Cases of Medical Manslaughter: Reconsidering the Tests for Criminal Negligence-Related Offences in Australia after R v Patel’ (2011) 19(2) *Journal of Law and Medicine* 377; Ian Dobinson, ‘Doctors Who Kill or Harm Their Patients: The Australian Experience’ in Danielle Griffiths and Andrew Sanders (eds), *Bioethics, Medicine and the Criminal Law: Medicine, Crime and Society* (Cambridge University Press, 2013); Owen Bradfield, ‘Serving Two Masters? Recent Legal Developments Regarding the Professional Obligations of Medical Administrators in Australia’ (2011) 18(3) *Journal of Law and Medicine* 545. [↑](#footnote-ref-29)
29. *R v Patel* [2010] QSC 233; *R v Patel; ex parte A-G (Qld)* [2011] QCA 81 (21 April 2011) (‘*Patel 3*’); *Patel v The Queen* (2012) 247 CLR 531 (‘*Patel*’); *R v Patel* [2013] District Court of Queensland Indictment No 1701 of 2013 (21 November 2013); see for an overview of the prosecutions of Patel, Carter, above n 29. [↑](#footnote-ref-30)
30. *Patel* (2012) 247 CLR 531. [↑](#footnote-ref-31)
31. *R v Patel* [2013] District Court of Queensland Indictment No 1701 of 2013 (21 November 2013). [↑](#footnote-ref-32)
32. Ibid [4] (‘...you are the author of all of the misfortune that has resulted from your totally undeserved employment in Queensland.’ ). [↑](#footnote-ref-33)
33. See especially the work of Thomas, who provides a detailed account of much of the saga surrounding Patel, a process in which his journalistic contribution was key, Hedley Thomas, *Sick to Death: A Manipulative Surgeon and a Health System in Crisis-- a Disaster Waiting to Happen* (Allen & Unwin, 2007). [↑](#footnote-ref-34)
34. Carter, above n 29; Kiel, ‘Regulating Impaired Doctors’, above n 6. [↑](#footnote-ref-35)
35. Kiel, ‘Regulating Impaired Doctors’, above n 6; see also Helen Kiel, *Problem Doctors in Disciplinary Tribunals: Who Do Protective Orders Protect? An Analysis of Australian Tribunal Decisions from 2010 – 2013* (2016). [↑](#footnote-ref-36)
36. Ian Freckelton, ‘The Emergence and Evolution of Health Law’ (2013) 29 *Law in Context: A Socio-Legal Journal* 74, 84. [↑](#footnote-ref-37)
37. Ibid. [↑](#footnote-ref-38)
38. Helen Kiel, *Problem Doctors in Disciplinary Tribunals: Who Do Protective Orders Protect? An Analysis of Australian Tribunal Decisions from 2010 – 2013* (PhD Thesis, University of Technology Sydney, 2016) 266. [↑](#footnote-ref-39)
39. Kiel, ‘Regulating Impaired Doctors’, above n 6, 430. [↑](#footnote-ref-40)
40. For example, State and Territory Departments of Health, quality and safety accreditation agencies and providers, Medical Advisory Committees of Private Hospitals, internal mortality and morbidity committees and processes through to specialist medical colleges and education providers. [↑](#footnote-ref-41)
41. Judith Healy, *Improving Health Care Safety and Quality: Reluctant Regulators* (Ashgate Publishing, Ltd., 2013). [↑](#footnote-ref-42)
42. For an overview of the shared/overlapping responsibilities at different levels of government, see the report of the now-defunct Commonwealth Federation reform project, Commonwealth of Australia, Department of the Prime Minister and Cabinet, ‘Reform of the Federation White Paper. Issues Paper 3—Roles and Responsibilities in Health’ (11 December 2014). [↑](#footnote-ref-43)
43. The national scheme came into effect on the very same day that Jayant Patel was first sentenced to seven years imprisonment for manslaughter. [↑](#footnote-ref-44)
44. Although, as discussed below at Part #, the National Law as force in each jurisdiction is designed to have extraterritorial application. [↑](#footnote-ref-45)
45. *Health Practitioner Regulation National Law Act* *2009* (QLD). [↑](#footnote-ref-46)
46. Ibid; *Health Practitioner Regulation National Law (NSW)* (NSW) No 86a (known also as the Health Practitioner Regulation National Law [NSW]); *Health Practitioner Regulation National Law (ACT) Act* *2010* (ACT); *Health Practitioner Regulation (National Uniform Legislation) Act* *2010* (NT); *Health Practitioner Regulation National Law (Victoria) Act* *2009* (Vic); *Health Practitioner Regulation National Law (South Australia) Act* *2010* (SA); *Health Practitioner Regulation National Law (Tasmania) Act* *2010* (TAS); *Health Practitioner Regulation National Law (WA) Act* *2010* (WA). [↑](#footnote-ref-47)
47. See Kiel, above n 39. [↑](#footnote-ref-48)
48. Currently, health practitioners regulated by the NRAS through the National Law include: Aboriginal and Torres Strait Islander health practitioners; chiropractors; Chinese medicine practitioners; dental practitioners (including dentists, dental specialists, dental hygienists, dental prosthetists and dental therapists); medical practitioners; medical radiation practitioners; nurses and midwives; optometrists; osteopaths; pharmacists; physiotherapists; podiatrists; and psychologists. See in relation to practitioners outside of the NRAS, J Wardle, ‘Holding Unregistered Health Practitioners to Account: An Analysis of Current Regulatory and Legislative Approaches.’ (2014) 22(2) *Journal of law and medicine* 350. [↑](#footnote-ref-49)
49. See for example in NSW, *Health Practitioner Regulation National Law (NSW)* (NSW) No 86a, ss 38-41. [↑](#footnote-ref-50)
50. The registration of medical practitioners themselves occurs in a consistent manner across all jurisdictions, it is, rather, from that point ‘onwards’ where divergences occurs. Most especially this is in relation to the management and process of complaints and notifications, as well as the process for adjudicating upon them. In NSW specifically, the forms of practitioner professional liability differ in form and substance as well. [↑](#footnote-ref-51)
51. See in relation to so-called ‘impaired’ doctors, Kiel, ‘Regulating Impaired Doctors’, above n 6. [↑](#footnote-ref-52)
52. See for example *Health Practitioner Regulation National Law (NSW)* (NSW) No 86a, ss 31-41 (as to the establishment, powers, functions and relationship of national boards to State and Territory Boards in the co-regulatory jurisdiction of NSW). [↑](#footnote-ref-53)
53. *Health Practitioner Regulation National Law Act* *2009* (QLD) s 3(2)(a). [↑](#footnote-ref-54)
54. See in the NSW enactment of the National Law, that an additional New South Wales provision provides that ‘In the exercise of functions under a NSW provision, the protection of the health and safety of the public must be the paramount consideration’, *Health Practitioner Regulation National Law (NSW)* (NSW) No 86a, s 3A. [↑](#footnote-ref-55)
55. The Medical Board of Australia, Expert Advisory Group on Revalidation, above n 10, 43. [↑](#footnote-ref-56)
56. This aspect of the National Law remains very contentious in some quarters, see Hon Nick Goiran et al, ‘Mandatory Reporting of Health Professionals: The Case for a Western Australian Style Exemption for All Australian Practitioners’ (2014) 22 *Journal of Law and Medicine* 209. [↑](#footnote-ref-57)
57. Unprofessional Conduct is conduct of a registered health practitioner that ‘is of a lesser standard than that which might reasonably be expected of the health practitioner by the public or the practitioner’s professional peers’. In New South Wales the definition of ‘unsatisfactory professional conduct’ is provided at s 139B and includes (inter alia): (a) Conduct that demonstrates the knowledge, skill or judgment possessed, or care exercised, by the practitioner in the practice of the practitioner’s profession is significantly below the standard reasonably expected of a practitioner of an equivalent level of training or experience…(l) Any other improper or unethical conduct relating to the practice or purported practice of the practitioner’s profession. The test for unsatisfactory professional conduct in New South Wales is therefore more stringent than the test for unprofessional conduct under the National Law. [↑](#footnote-ref-58)
58. Despite the use of the same nomenclature, the definition of the more serious matter of Professional Misconduct again differs in relation to NSW alone. Defined under s 5 of the National Law, Professional Misconduct includes: ‘(a) unprofessional conduct by the practitioner that amounts to conduct that is substantially below the standard reasonably expected of a registered health practitioner of an equivalent level of training or experience; and (b) more than one instance of unprofessional conduct that, when considered together, amounts to conduct that is substantially below the standard reasonably expected of a registered health practitioner of an equivalent level of training or experience; and (c) conduct of the practitioner, whether occurring in connection with the practice of the health practitioner’s profession or not, that is inconsistent with the practitioner being a fit and proper person to hold registration in the profession.’ The equivalent provision operating in NSW defines professional misconduct as meaning: ‘(a) unsatisfactory professional conduct of a sufficiently serious nature to justify suspension or cancellation of the practitioner’s registration; or (b) more than one instance of unsatisfactory professional conduct that, when the instances are considered together, amount to conduct of a sufficiently serious nature to justify suspension or cancellation of the practitioner’s registration.’ The NSW provision is more stringent in this regard, requiring that the conduct be (in one instance or an aggregate of instances) sufficiently serious nature to justify suspension or cancellation of the practitioner’s registration. The National Law as in force in other jurisdictions more simply refers to ‘conduct substantially below the standard…’ or, more broadly, conduct that is ‘inconsistent with the practitioner being a fit and proper person to hold registration in the profession.’ [↑](#footnote-ref-59)
59. The existing disciplinary process constructs a division between what is understood to be ‘conduct related’ matters, and those which relate to the health (‘impairment’) of a practitioner. [↑](#footnote-ref-60)
60. See for a more complete accounting of scenarios like this, The Medical Board of Australia, Expert Advisory Group on Revalidation, above n 10, 43. [↑](#footnote-ref-61)
61. The Medical Board of Australia, Expert Advisory Group on Revalidation, above n 10. [↑](#footnote-ref-62)
62. See for example, *Health Practitioner Regulation National Law (NSW)* (NSW) No 86a, s 38(1). [↑](#footnote-ref-63)
63. See for example, ibid s 38(2)(c). [↑](#footnote-ref-64)
64. Currently defined as the Australian Health Workforce Ministerial Council comprising Ministers of the governments of the participating jurisdictions and the Commonwealth with portfolio responsibility for health. Following reforms to the Council of Australian Governments (‘COAG’) in 2013, the Ministerial Council/Australian Health Workforce Ministerial Council continues to meet under the auspices of the newly reformed COAG Health Council (which comprises a slightly expanded membership of Commonwealth, State, Territory and New Zealand Ministers with responsibility for health matters, and the Commonwealth Minister for Veterans’ Affairs). The 2014 Terms of Reference for the COAG Health Council contemplates a future reform to the National Law such that reference to the Australian Health Workforce Ministerial Council will be changed. See ‘Scope of Council responsibility’, Council of Australian Governments Health Council, ‘COAG Health Council 2014 Terms of Reference’ 3 <http://www.coaghealthcouncil.gov.au/Portals/0/Final\_COAG%20Health%20Council%20Terms%20of%20Reference\_2014.pdf>. [↑](#footnote-ref-65)
65. See for example, *Health Practitioner Regulation National Law (NSW)* (NSW) No 86a, s 41. [↑](#footnote-ref-66)
66. See Archer et al, above n 15. [↑](#footnote-ref-67)
67. For an up-to-date and critical account of the operation of the model, see the recent work of Chamberlain, John Martyn Chamberlain, ‘Malpractice, Criminality, and Medical Regulation: Reforming the Role of the GMC in Fitness to Practise Panels’ (2017) 25(1) *Medical Law Review* 1; John Martyn Chamberlain, ‘Risk-Based Regulation and Reforms to Fitness to Practise Tribunals in the United Kingdom: Serving the Public Interest?’ (2016) 18(5–6) *Health, Risk & Society* 318; see generally John Martyn Chamberlain, *Medical Regulation and Revalidation: A Critical Introduction* (Policy Press, 2015). [↑](#footnote-ref-68)
68. Guidelines dictate that feedback must be sought from multiple health professional colleagues (of whom only half should be doctors) and from multiple patients. [↑](#footnote-ref-69)
69. Between January 2013 and July 2013, Kerry J Breen, ‘Revalidation — What Is the Problem and What Are the Possible Solutions?’ (2014) 200(3) *Medical Journal of Australia* 153 <https://www.mja.com.au/journal/2014/200/3/revalidation-what-problem-and-what-are-possible-solutions>. [↑](#footnote-ref-70)
70. Thistlethwaite, Charlton and Coomber, above n 28, 71. [↑](#footnote-ref-71)
71. G Christie-Taylor, ‘Revalidation for Anaesthetists: Will It Be Effective, Evidence-Based and Practical?’ (2015) 43(5) *Anaesthesia and Intensive Care* 563, 564. [↑](#footnote-ref-72)
72. Ibid. [↑](#footnote-ref-73)
73. Breen, above n 73. [↑](#footnote-ref-74)
74. Ibid. [↑](#footnote-ref-75)
75. Christie-Taylor, above n 75, 563 ('The strongest criticisms of revalidation have been of its sparse evidence base’). [↑](#footnote-ref-76)
76. Marie Bismark, *Marie Bismark: Gauging Revalidation* (5 October 2015) MJA InSight <https://www.mja.com.au/insight/2015/38/marie-bismark-gauging-revalidation>. [↑](#footnote-ref-77)
77. Ibid. [↑](#footnote-ref-78)
78. Ian Freckelton, ‘Regulating Health Practitioner Professionalism Regulating Health Practitioners’ (2005) 23 *Law in Context: A Socio-Legal Journal* 1, 17 (‘The move from disciplinary regulation toward the broader notion of fitness to practice revalidation is inevitable. The real question is how it can be most effectively and practically implemented.’). [↑](#footnote-ref-79)
79. Mabel Amaya-Amaya, Karen Gerard and Mandy Ryan, ‘Discrete Choice Experiments in a Nutshell’ in Mandy Ryan, Karen Gerard and Mabel Amaya-Amaya (eds), *Using Discrete Choice Experiments to Value Health and Health Care* (Springer Netherlands, 2008) 13 <http://link.springer.com.ezproxy.lib.uts.edu.au/chapter/10.1007/978-1-4020-5753-3\_1>. [↑](#footnote-ref-80)
80. Deborah J Street and Leonie Burgess, *The Construction of Optimal Stated Choice Experiments: Theory and Methods* (John Wiley & Sons, 2007); Mandy Ryan, Karen Gerard and Mabel Amaya-Amaya, *Using Discrete Choice Experiments to Value Health and Health Care* (Springer Science & Business Media, 2007); Philip L Russo et al, ‘Novel Application of a Discrete Choice Experiment to Identify Preferences for a National Healthcare-Associated Infection Surveillance Programme: A Cross-Sectional Study’ (2016) 6(5) *BMJ Open* e011397; Esther W de Bekker-Grob, Mandy Ryan and Karen Gerard, ‘Discrete Choice Experiments in Health Economics: A Review of the Literature’ (2012) 21(2) *Health Economics* 145; M Ryan et al, ‘Use of Discrete Choice Experiments to Elicit Preferences’ (2001) 10(suppl 1) *Quality and Safety in Health Care* i55. [↑](#footnote-ref-81)
81. Esther W de Bekker-Grob et al, ‘Sample Size Requirements for Discrete-Choice Experiments in Healthcare: A Practical Guide’ (2015) 8(5) *The Patient-Patient-Centered Outcomes Research* 373. [↑](#footnote-ref-82)
82. F Reed Johnson et al, ‘Constructing Experimental Designs for Discrete-Choice Experiments: Report of the ISPOR Conjoint Analysis Experimental Design Good Research Practices Task Force’ (2013) 16(1) *Value in Health* 3. [↑](#footnote-ref-83)
83. Denzil G Fiebig et al, ‘Preferences for New and Existing Contraceptive Products’ (2011) 20(S1) *Health Economics* 35. [↑](#footnote-ref-84)
84. Rosalie Viney et al, ‘An Australian Discrete Choice Experiment to Value Eq-5d Health States’ (2014) 23(6) *Health Economics* 729. [↑](#footnote-ref-85)
85. Russo et al, above n 84. [↑](#footnote-ref-86)
86. V Watson et al, ‘Involving the Public in Priority Setting: A Case Study Using Discrete Choice Experiments’ (2012) 34(2) *Journal of Public Health* 253; Simon Dixon et al, ‘Assessing Patient Preferences for the Delivery of Different Community-Based Models of Care Using a Discrete Choice Experiment’ (2015) 18(5) *Health Expectations* 1204. [↑](#footnote-ref-87)
87. Anthony Scott et al, ‘Getting Doctors into the Bush: General Practitioners’ Preference for Rural Location’ (Working Paper No 13/12, 2012). [↑](#footnote-ref-88)
88. Marian Shanahan, Karen Gerard and Alison Ritter, ‘Preferences for Policy Options for Cannabis in an Australian General Population: A Discrete Choice Experiment’ (2014) 25(4) *International Journal of Drug Policy* 682. [↑](#footnote-ref-89)
89. Wim Bernasco and Richard Block, ‘Where Offenders Choose to Attack: A Discrete Choice Model of Robberies in Chicago’ (2009) 47(1) *Criminology* 93. [↑](#footnote-ref-90)
90. Jean Spinks and Duncan Mortimer, ‘The Effect of Traffic Lights and Regulatory Statements on the Choice between Complementary and Conventional Medicines in Australia: Results from a Discrete Choice Experiment’ (2015) 124 *Social Science & Medicine* 257. [↑](#footnote-ref-91)
91. Martin P Ho et al, ‘Incorporating Patient-Preference Evidence into Regulatory Decision Making’ (2015) 29(10) *Surgical Endoscopy* 2984. [↑](#footnote-ref-92)
92. See for example, ibid; Ryan et al, above n 84; Dixon et al, above n 90. [↑](#footnote-ref-93)
93. Ho et al, above n 95. [↑](#footnote-ref-94)
94. Guillemin et al, above n 27, 128. [↑](#footnote-ref-95)
95. A scenario we modify from the work of Louviere et al, Jordan J Louviere et al, ‘Designing Discrete Choice Experiments: Do Optimal Designs Come at a Price?’ (2008) 35(2) *Journal of Consumer Research* 360. [↑](#footnote-ref-96)
96. Archer et al, above n 15. [↑](#footnote-ref-97)
97. Ibid 30–31. [↑](#footnote-ref-98)
98. Archer et al, above n 15. [↑](#footnote-ref-99)
99. Ibid. [↑](#footnote-ref-100)
100. Ibid. [↑](#footnote-ref-101)
101. Ibid. [↑](#footnote-ref-102)
102. Street and Burgess, above n 84. [↑](#footnote-ref-103)
103. Anthony R Burrell et al, ‘Aseptic Insertion of Central Venous Lines to Reduce Bacteraemia’ (2011) 194(11) *The Medical journal of Australia* 583. [↑](#footnote-ref-104)
104. Alan Merry and Alexander McCall Smith, *Errors, Medicine and the Law* (Cambridge University Press, 2001); see also, Alan Merry and Warren Brookbanks, *Merry and McCall Smith’s Errors, Medicine and the Law* (Cambridge University Press, Kindle Edition, 2017). [↑](#footnote-ref-105)
105. See in the specifically Australian and New Zealand context, Wilson et al, above n 5; PB Davis et al, ‘Adverse Events in New Zealand Public Hospitals: Principal Findings from a National Survey’ (Number 3, December 2001) <https://www.health.govt.nz/system/files/documents/publications/adverseevents.pdf>; Peter Davis et al, ‘Adverse Events in New Zealand Public Hospitals I: Occurrence and Impact’ (2002) 115(1167) *New Zealand Medical Journal* <http://www.nzma.org.nz/journal/115-1167/271/>; Runciman and Moller, above n 1; Peter Davis et al, ‘Adverse Events in New Zealand Public Hospitals Ii: Preventability and Clinical Context’ (2003) 116(1183) *New Zealand Medical Journal* U624. [↑](#footnote-ref-106)
106. Runciman and Moller, above n 1, 17; these rates are now regarded as consistent across both advanced and developing healthcare systems, see Angus Corbett, Jo Travaglia and Jeffrey Braithwaite, ‘The Role of Individual Diligence in Improving Safety’ (2011) 25(3) *Journal of Health Organization and Management* 247, 248; John D Hamilton, Robert W Gibberd and Bernadette T Harrison, ‘After the Quality in Australian Health Care Study, What Happened?’ (2014) 201(1) *The Medical Journal of Australia* 23; RM Wilson et al, ‘Patient Safety in Developing Countries: Retrospective Estimation of Scale and Nature of Harm to Patients in Hospital’ (2012) 344 *BMJ* e832. [↑](#footnote-ref-107)
107. See for example, Braithwaite, Wears and Hollnagel, above n 4, 419; Wears, Sutcliffe and Van Rite, above n 3. [↑](#footnote-ref-108)
108. The 1994-95 Australian QAHCS study reported Preventability was not strongly associated with age, sex or insurance status, nor was it associated with the level of disability, except for death (in which 70% of Adverse Events showed high preventability). Only 1.2% of AEs in the “no preventability” category resulted in death, compared with 4.1% in the “low preventability” category and 6.5% in the “high preventability” category. Some of this association between preventability and death could be ascribed to outcome bias Wilson et al, above n 5; the QAHCS study reported 51% preventability across all adverse events, see Runciman and Moller, above n 1, 22; see also the QAHCS results reinterpreted where all adverse events were re-classified as to whether they fell into one of two categories, “potentially preventable”, or “not preventable with current medical knowledge” rather than using the six-point scale in the QAHCS, it was found that 80% of adverse events fell into potentially preventable categories Runciman, Edmonds and Pradhan, above n 5. [↑](#footnote-ref-109)
109. Runciman and Moller report a figure of 10,000 deaths in Australia per annum on 1992 figures, however, it is unclear from this report the exact source of this figure Runciman and Moller, above n 1, xv; The earlier QAHCS findings in Australia found 230,000 preventable iatrogenic injuries in 1992, of which 13,000 were associated with death Eric J Thomas et al, ‘A Comparison of Iatrogenic Injury Studies in Australia and the USA I: Context, Methods, Casemix, Population, Patient and Hospital Characteristics’ (2000) 12(5) *International Journal for Quality in Health Care* 371, 372; although hospital activity reporting is almost uniformly reported as separations (which includes discharges, transfer or statistical type changes) it seems the analysis of the incidence of iatrogenic in the landmark studies during the 1990’s was based upon ‘discharge’ (home). As such, the estimate of 27,000 iatrogenic deaths per annum is based on an extrapolation of the widely agreed 0.3% incidence of iatrogenic death applies to discharge (home or to place of usual residency including residential aged care) which in 2013-14 accounted for 8,969,032 of 9,702,304 total separations (26,907 per annum) Australian Institute of Health and Welfare, ‘Admitted Patient Care 2013–14, Australian Hospital Statistics’ (No 60 Cat. HSE 156, 2015) (Table 5.37) 134 <http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129550480>; this assumes, per Braithwaite et al, that these rates have not materially shifted since their accounting in the early 1990’s and 2000’s, see Braithwaite, Wears and Hollnagel, above n 4, 419. [↑](#footnote-ref-110)
110. Matthew J Ziegler, Daniela C Pellegrini and Nasia Safdar, ‘Attributable Mortality of Central Line Associated Bloodstream Infection: Systematic Review and Meta-Analysis.’ (2015) 43(1) *Infection* 29, 29 (‘CLABSI is associated with a significantly increased risk of death’. This systematic review and meta-analysis reported significantly increased odds of death, reporting a calculated odds ratio of 2.75 [CI 1.86–4.07]). [↑](#footnote-ref-111)
111. Burrell et al, above n 107. [↑](#footnote-ref-112)
112. See in particular the excellent post-hoc theoretical evaluation work of Dixon-Woods et al, which outlines key success factors in the Michigan Keystone programme, Mary Dixon-Woods et al, ‘Explaining Michigan: Developing an Ex Post Theory of a Quality Improvement Program’ (2011) 89(2) *The Milbank Quarterly* 167, 176 (Namely, [1] isomorphic pressures, [2] networked community effects, [3] reframing CVC-BSIs as a social problem, [4] changing practice and culture at the sharp end by using interventions with different effects, [5] using data as a disciplinary force, and [6] skillfully using “hard edges"). [↑](#footnote-ref-113)
113. Burrell et al, above n 107. [↑](#footnote-ref-114)
114. Ibid. [↑](#footnote-ref-115)
115. Archer et al, above n 15; Bismark et al, ‘Relationship between Complaints and Quality of Care in New Zealand’, above n 25; Bismark et al, ‘Remedies Sought and Obtained in Healthcare Complaints’, above n 25; Bismark et al, ‘Identification of Doctors at Risk of Recurrent Complaints’, above n 25. [↑](#footnote-ref-116)
116. The Medical Board of Australia, Expert Advisory Group on Revalidation, above n 10. [↑](#footnote-ref-117)
117. Horsley et al, above n 16. [↑](#footnote-ref-118)
118. Mario Callegaro et al, ‘Online Panel Research’ in rio Callegaro et al (eds), *Online Panel Research* (John Wiley & Sons, Ltd, 2014) 1 <http://onlinelibrary.wiley.com/doi/10.1002/9781118763520.ch1/summary>. [↑](#footnote-ref-119)
119. Hilary Bambrick, Josh Fear and Richard Denniss, ‘What Does $50,000 Buy in a Population Survey? Characteristics of Internet Survey Participants Compared with a Random Telephone Sample’ (Technical Brief No.4, October 2009) <http://www.tai.org.au/sites/defualt/files/TB4%20%20Phone%20and%20internet%20survey%20comparison%20final\_7.pdf>. [↑](#footnote-ref-120)
120. Daniel McFadden and Kenneth Train, ‘Mixed MNL Models for Discrete Response’ (2000) 15(5) *Journal of Applied Econometrics* 447; Leonie Burgess, Deborah J Street and Nada Wasi, ‘Comparing Designs for Choice Experiments: A Case Study’ (2011) 5(1) *Journal of Statistical Theory and Practice* 25. [↑](#footnote-ref-121)
121. Kenneth Train, *Discrete Choice Methods with Simulation* (Cambridge University Press, 2009). [↑](#footnote-ref-122)
122. Archer et al, above n 15. [↑](#footnote-ref-123)
123. These results are the subject of ongoing research. [↑](#footnote-ref-124)
124. Julian Archer et al, ‘“No One Has Yet Properly Articulated What We Are Trying to Achieve”: A Discourse Analysis of Interviews With Revalidation Policy Leaders in the United Kingdom’ (2015) 90(1) *Academic Medicine* 88. [↑](#footnote-ref-125)
125. Archer et al, above n 15. [↑](#footnote-ref-126)
126. Ibid. [↑](#footnote-ref-127)
127. Ibid. [↑](#footnote-ref-128)
128. The Medical Board of Australia, Expert Advisory Group on Revalidation, above n 10. [↑](#footnote-ref-129)
129. Rahmati and colleagues are one voice amongst a growing group who question the received orthodoxy of the tort crisis. Following analysis of approximately thirty years of medical malpractice claims data from Illinois, they write that: Tort reform may be a good idea or a bad idea. However, tort reform is aimed at a problem that has little to do with the malpractice crises that prompted Illinois to take action in the first instance. In other work, we find that damage caps have limited, if any, potential to reduce health-care spending and attract physicians. Those looking for a magic bullet for the ills that beset the health-care system would be well advised to look elsewhere, Mohammad Rahmati et al, ‘Insurance Crisis or Liability Crisis? Medical Malpractice Claiming in Illinois, 1980-2010: Insurance Crisis or Liability Crisis?’ (2016) 13(2) *Journal of Empirical Legal Studies* 183; Rahmati and colleagues join others including Black, Zabinski, Frakes and Jena who have come to look with fresh eyes at the data in recent years, see Bernard S Black, Wagner and Zenon Zabinski, ‘The Association between Medical Malpractice Risk and Healthcare Quality: Evidence from Texas’ [2011] (No. 11-20) *Northwestern Law and Economics Research Paper*; Michael D Frakes, ‘The Surprising Relevance of Medical Malpractice Law’ [2015] *The University of Chicago Law Review* 317; Michael Frakes and Anupam Jena, ‘Does Medical Malpractice Law Improve Health Care Quality?’ [2016] *Journal of Public Economics* <DOI: 10.1016/j.jpubeco.2016.09.002>. [↑](#footnote-ref-130)
130. In relation to civil litigation, see for example, C Wood, ‘The Misplace of Litigation in Medical Practice’ (1998) 38(4) *The Australian & New Zealand Journal of Obstetrics & Gynaecology* 365; Corbett, Travaglia and Braithwaite, above n 110; Angus Corbett, ‘Regulating Compensation for Injuries Associated with Medical Error’ (2006) 28(2) *Sydney Law Review* 259; Angus Corbett, ‘Australia: An Integrated Scheme for Regulating Liability for Medical Malpractice and Indemnity Insurance Markets That Does Not Include the Goal of Improving the Safety and Quality of Health Care’ (2011) 4 *Drexel Law Review* 199; David M Studdert et al, ‘Negligent Care and Malpractice Claiming Behavior in Utah and Colorado’ [2000] *Medical Care* 250; Studdert DM et al, ‘Defensive Medicine among High-Risk Specialist Physicians in a Volatile Malpractice Environment’ (2005) 293(21) *JAMA* 2609; Eric J Thomas et al, ‘Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado’ [2000] *Medical Care* 261; compare for example more recent work by Frakes and colleagues, Frakes, above n 133; Frakes and Jena, above n 133; See for example in relation to criminal law specifically, (#pages needed from lit review), Alan Merry, ‘When Are Errors a Crime?—Lessons from New Zealand’ in Charles A Erin and Suzanne Ost (eds), *The Criminal Justice System and Health Care* (Oxford University Press, 2007); AF Merry, ‘How Does the Law Recognize and Deal with Medical Errors?’ (2009) 102(7) *Journal of the Royal Society of Medicine* 265; Sidney Dekker, *Just Culture: Balancing Safety and Accountability* (Ashgate, 2nd Edition, Kindle Version, 2012); Sidney WA Dekker, ‘Eve and the Serpent: A Rational Choice to Err’ (2007) 46(4) *Journal of Religion & Health* 571; Sidney Dekker, ‘The Criminalization of Human Error in Aviation and Healthcare: A Review’ (2011) 49(2) *Safety Science* 121; Sidney WA Dekker, ‘Criminalization of Medical Error: Who Draws the Line?’ (2007) 77(10) *ANZ Journal of Surgery* 831; O Quick, ‘Medicine, Mistakes and Manslaughter: A Criminal Combination?’ (2010) 69(1) *Cambridge Law Journal* 186; Oliver Quick, ‘Prosecuting “Gross” Medical Negligence: Manslaughter, Discretion, and the Crown Prosecution Service’ (2006) 33(3) *Journal of Law and Society* 421. [↑](#footnote-ref-131)
131. The work of Black and Frakes in particular offers a much needed and much more detailed engagement with law’s instrumental effects on the micro-practices and quality and safety outcomes of medical care. The point here is rather more foundational, but nonetheless important, that the relationship has been productive in a range of ways (which deregulation and law reform in fact effaces and threatens), see for example Karl Y Bilimoria et al, ‘Association Between State Medical Malpractice Environment and Surgical Quality and Cost in the United States’: (2016) 263(6) *Annals of Surgery* 1126; Myungho Paik, Bernard Black and David A Hyman, ‘The Receding Tide of Medical Malpractice Litigation: Part 1-National Trends’ (2013) 10(4) *Journal of Empirical Legal Studies* 612; Myungho Paik, Bernard Black and David Hyman, ‘The Receding Tide of Medical Malpractice Litigation: Part 2-Effect of Damage Caps’ (2013) 10(4) *Journal of Empirical Legal Studies* 639; Daniel P Kessler, ‘Evaluating the Medical Malpractice System and Options for Reform’ (2011) 25(2) *The Journal of Economic Perspectives: A Journal of the American Economic Association* 93; Frakes, above n 133; Steven A Farmer, Bernard Black and Robert O Bonow, ‘Tension Between Quality Measurement, Public Quality Reporting, and Pay for Performance’ (2013) 309(4) *JAMA* 349; Myungho Paik, Bernard Black and David A Hyman, ‘Do Doctors Practice Defensive Medicine, Revisited’ <https://www.scholars.northwestern.edu/en/publications/do-doctors-practice-defensive-medicine-revisited>; Myungho Paik, Bernard S Black and David A Hyman, ‘The Direct and Indirect Effects of Medical Malpractice Reforms: Evidence from the Third Reform Wave’ [2012] (No 13-20) *Northwestern Law and Economics Research Paper* <http://www.ssrn.com/abstract=2110656>; Zenon Zabinski and Bernard S Black, ‘The Deterrent Effect of Tort Law: Evidence from Medical Malpractice Reform’ [2013] *SSRN Electronic Journal* <http://www.ssrn.com/abstract=2161362>; Frakes and Jena, above n 133. [↑](#footnote-ref-132)
132. *Health Care Complaints Commission v Do* [2014] NSWCA 307 (4 September 2014) [45]. [↑](#footnote-ref-133)
133. Ian Freckelton, ‘The Margins of Professional Regulation: Disjunctions, Dilemmas and Deterrence’ (2006) 23(2) *Law in Context* 148, 167; Helen Kiel echoes Freckleton’s words in support of them, Kiel, above n 42, 7. [↑](#footnote-ref-134)
134. *Health Care Complaints Commission v Do* [2014] NSWCA 307 (4 September 2014) [45]. [↑](#footnote-ref-135)
135. Ibid. [↑](#footnote-ref-136)