## Recognising, supporting and managing risk

## What is the purpose of regulation?

In general, terms the literature states there are three main purposes to regulation. These are to improve performance and quality; provide assurance that minimally acceptable standards are achieved; and provide accountability both for levels of performance and value for money.

In addition, the literature also states that regulation is about: 8 9 12 36

- improving and assuring the professional standards of the majority of practitioners and identifying and addressing poor or bad practice in the case of a minority of practitioners
- putting mechanisms in place that deal with honest mistakes fairly, supportively and sympathetically
- facilitating educational opportunities that prepare practitioners for the complexities of their profession
- strategies that seek to influence behaviour (including both supports and sanctions).

Researchers also state these regulatory purposes are largely achieved through the following means: 33

- the use of standards, rules or targets (both to enter and stay in a profession) and advice and guidance (that may also include performance management interventions) to assist practitioners to act in a competent and ethical manner
- assessment of a practitioner's level of performance or compliance with a regulator's standards, monitoring and analysing data, periodic inspection and informal and formal investigations or enquiries in response to complaints or unsatisfactory levels of performance
- the use of regulatory powers and mechanisms (which can range in severity from an informal warning through to placing limits on scope of practice) to protect the public.

#### Four themes from the literature about responsive regulation

Four themes can be taken from the literature about right-touch risk-based regulation. These themes are that:

- responsive regulation is about identifying risk
- responsive regulation is proportionate to risk
- formal and informal mechanisms are important tools for responsive regulators
- there are some important actions regulators must take in order to be responsive.

These four themes are discussed in further detail below.

### Responsive regulation and identifying risk

Three observations can be made about responsive regulation and the identification of risk.

First, is that a responsive regulator will be collecting and analysing a range of data that informs how it deploys its resources to meet its roles and responsibilities. 67 107 Underpinning this first observation is the assumption that the regulator already has good data collection systems (and therefore data)—although the literature also acknowledges this is not always the case. It also assumes a risk can be described and quantified and that the data relating to a risk is easily extracted and capable of being analysed. 18 108 23 56

Second, is that a responsive regulator is using the analysed data proactively (i.e. from the earliest possible point of engagement) to manage an individual or group of practitioners at risk of not meeting regulatory requirements, including for recertification. 109 38 73 47 26 110

The third observation is that responsive regulation uses both proactive and reactive (e.g. triggered by and acting on complaints or reported incidents) enforcement strategies to protect the public. In some cases, these mechanisms will detect new risks. However, it should be noted that risk-based systems tend to focus on known and familiar risk factors. They are usually retrospective because of the way data is collected and analysed and this often means they fail, or are slow to identify new and/or developing risks. <sup>67</sup>

## Responsive regulation and proportionate risk

Central to responsive regulation is that the regulator will choose the appropriate and proportionate tool (i.e. everything on the spectrum between a light and heavy-handed touch, including possible combinations of carrot and stick approaches where required) for managing a risk. This approach to regulation presupposes that as the level of risk increases (for the public and practitioners) so will the regulatory force required to manage that risk. 25 36 22 67

Examples of factors that influence the degree of regulatory force exerted include the frequency and extent of harm linked to a profession and the type of allegations made about practitioner competence and/or impaired fitness to practise.<sup>22</sup>

Three other messages can be taken from the literature about responsive regulation and proportionate risk. These messages are that:

- engaging in regulatory actions (including over-regulation because there are too many groups or
  excessively onerous regulatory practice) that sit at the heavy-handed end of the spectrum are
  expensive and may generate unnecessary costs that have no additional benefit to the public<sup>22</sup> 40
- regulators should put more of their focus and resources into risks that are likely to cause serious harm<sup>36</sup> 109 22
- although protection of the public is the primary focus, to achieve this goal regulators also need to be responsive to the needs of practitioners.<sup>88</sup> 12

## Formal and informal mechanisms are important tools

Regulators have a range of formal tools and mechanisms that help them to fulfil their roles and responsibilities. Many of these tools fall on the sanction end of the regulatory spectrum and may include disciplinary tribunal hearings; undertaking audits, assessments and competence and fitness to practise reviews; and considering and acting on complaints from other organisations, practitioners and the general public.96 15 7 8 57

It should be noted that researchers have a lot to say about the use and place of complaints as a regulatory tool. 2015 research by Stuart & Cunningham contained the following messages: 111

- complaints are part of a system of checks and balances that hold a profession to account for its practice
- until a practitioner is engaged in a complaints process their awareness and understanding (and often feelings of control) of this regulatory tool are limited
- ideally the complaints process leads to improvement in the standard of health care and includes practitioners and the general public in a way that is positive and constructive for all concerned
- in order for the complaints process to be effective (and some practitioners acknowledge that
  participation in a complaints process has little or no impact on their practise), practitioners must
  engage in careful, structured reflection that allows for learning and change in their behaviours,
  attitudes, knowledge and practise
- practitioners should be encouraged to seek help early so they receive appropriate support and have a level of understanding and awareness that will aid them through the complaints process.

On the issue of the effectiveness of standards and appraisals as good regulatory mechanisms, researchers were sceptical. They specifically cited a lack of evidence to show links between these

mechanisms and positive impacts and/or improvement in practitioner skills, knowledge and behaviours. 22 24

Regulators also use informal mechanisms (e.g. positive feedback on achievements or acknowledgement of a practitioner's strengths) as part of a responsive approach to the maintenance of practitioner competence and fitness to practise. 25 12 8 35 96 88

## Actions regulators must take to be responsive

Research confirms that risk comes in all shapes and sizes that, and that for some regulators, it will fit neatly into existing organisational structures and mechanisms. Baldwin and Black state that

Whether a responsive approach is optimal will depend on a number of other factors such as agency resource levels, the size of the regulated population, the kinds of standards imposed (and how these are received) the observability of non-compliance, the costs of compliance, the financial assistance available for compliance and the penalty structure. 67

However, the literature also confirms that many of these risks do not easily fit standard approaches to regulation. When the latter happens, the literature states a regulator must be flexible and fluid enough to organise itself differently for different types of risk. It must also find ways of doing this that do not cause massive disruption or reorganisation to the regulator. Pegulators must also build relationships with practitioners, which are based on preventing harm and promoting good practice, rather than primarily focusing on punishment and disciplinary actions. 16 11

## Does responsive regulation impact on the decision to retain or incorporate CPD within recertification?

Within the past three years the Dental Council has developed and implemented a new *Strategic Plan* and *Standards Framework*. These documents represent a significant shift in how Council views its roles and responsibilities—specifically that it will be a right-touch risk-based regulator.

# What is right-touch risk-based regulation and what does it have to do with the roles and responsibilities of health regulators?

The traditional role of the regulator—one that in New Zealand is set down in the Act—is that it registers a practitioner at the start of their career; periodically recertifies them; only intervenes when a transgression has been committed; prevents harm; promotes and defends standards of good practice; and seeks assurance of competence and fitness to practise. This traditional role has also been described as the exertion of public authority through a system of rules and laws in which the regulator ensures technical compliance by the regulated.<sup>56</sup>

In the literature, the core purpose and role of regulation (and thus the regulator) is described as:

- the abatement of control of risks to society, while the essence of regulatory craft is to pick important problems and fix them<sup>12</sup>
- identifying and addressing the causes of a risk of harm, rather than responding after the harm has occurred.
- identifying harms, risks, dangers or threats of one kind or another, and then either eliminating them, reducing their frequency, mitigating their effects, preventing them, or suppressing them, and, by so doing, providing citizens higher levels of safety and security 10
- setting standards and checking whether they are met.<sup>22</sup>

The literature confirms that this traditional view of regulation is being challenged, revised and reframed in New Zealand and around the world.

For instance, right-touch and responsive regulation is described as an approach that values trust, transparency and professionalism and aims to transcend the polarised choice between punishment and persuasion.<sup>25</sup> Moreover, the purpose of this approach to regulation is not to eliminate risk.

For the practitioner it means being assisted to obtain compliance. For the regulator it is about using a range of tools to identify and then manage practitioner risk and non-compliance. This includes the important question of when to use persuasion and when to use sanction to encourage or obtain compliance. 109 25

On the issue of regulatory responses, Baldwin & Black suggested compliance was more likely

... when a regulatory agency displays an explicit enforcement pyramid – a range of enforcement sanctions extending from persuasion, at its base, through warning and civil penalties up to criminal penalties, licence suspensions and then licence revocations. Regulatory approaches would begin at the bottom of the pyramid and escalate in response to compliance failures. There would be a presumption that regulation should always start at the base of the pyramid.<sup>67</sup>

On the issue of regulation the Professional Standards Authority said

Professor Sparrow of Harvard University has made compelling arguments that the focus of regulation should move away from the efficient completion of process to a focus on the prevention of specific types of harm. He has also argued, we should think in a more sophisticated way about the nature or character of specific types of risk and therefore what is the best regulatory intervention to prevent risks from materialising into harms.<sup>22</sup>

And on the issue of risk-based regulation. Steve Broker from Consumer Focus said

Put at its simplest terms, all it means is that you allocate your scare resources to where you think the harm is most likely to occur and if that is to be successful that depends on having the right intelligence in place  $\dots$  once you have identified your risk then you decide on the firmness of your touch. On some occasions, a feather light touch is the order of the day but at other times, a vicelike grip is what is needed.  $\frac{107}{}$ 

It should also be noted that the Professional Standards Authority has described the eight elements of right-touch regulation as:88

- identifying the problem before the solution
- quantifying and qualifying the risk
- getting as close to the problem as possible
- · focusing on the outcome
- using regulation only when necessary
- keeping it simple
- checking for unintended consequences
- reviewing and responding to change.

### What is risk and how does it relate to regulation?

As with other aspects of this literature review, there is no common understanding or agreement on the definition of 'risk' or what it means in the context of regulation. The literature contains multiple definitions or descriptions of risk.

These include from: 18

- the Oxford English Dictionary, which defines risk as the possibility that something unpleasant will happen; or a thing causing a risk or regarded in relation to a risk
- the Health and Safety Executive, which defines risk as the chance that something adverse will happen
- Professor Malcolm Sparrow, who talks about the overlap and ambiguity between the meaning of risks and other undesirable commodities like problems and harms, and that in general, 'risk'

- seems prospective and not very likely, while 'problem' seems more current and certain and is therefore risk that has materialised
- The Professional Standards Authority, which says that risk is a term with a number of related meanings—an adverse event, the chances of that event happening and the event itself.

In some respects these definitions raise more questions than answers, about risk and how it relates to regulation. For example, what level of risk is acceptable, especially if the public's confidence in practitioners is maintained? Can regulators collect and analyse enough information to predict the circumstances in which risk or harm will occur and develop a response to reduce the likelihood of recurrence? Can a risk be described, identified or qualified in order that a regulator can better understand, manage and develop workable solutions? The literature tends to suggest the answer to all these questions is yes, even if that yes is qualified.

For example, the research includes discussion on the different approaches to risk assessment. These include risk-based; precaution-based; discourse-based; risk avoidance, reduction; retention and transfer approaches. With regards to these approaches the Professional Standards Authority contends that all of them share the following characteristics in that they: 18 45 43 47 46

- are based on a number of assumptions about regulation and the extent to which risks can be assessed
- tend to follow a standard cycle of risk assessment, design, application and review
- consist of three key elements, information gathering, standard setting and behaviour modification.

## What are the main risk factors for practitioners experiencing competence and fitness to practise issues?

There is a large amount of literature on the risk factors that impact on a practitioner's competence and fitness to practise. For the purposes of this literature review these risk factors are grouped under the following headings:

- conduct risk factors relating to a practitioner's behaviours and attitudes
- competency risk factors relating to a practitioner's skills and knowledge that might affect the risk of departure from standards
- contextual risk factors relating to the environment or structures within which an individual practices.

The Act is driven by public safety, quality assurance and identification of at-risk health practitioners. On the issue of risk, the literature cautions regulators about the need to identify, scope and address the root causes of risk in order to protect the public and support practitioners. 39 86

#### Conduct risk factors

In broad terms, the literature describes conduct risk factors as those relating to a practitioner's behaviours and attitudes. The literature says that attitudes are based on a wide range of external influences as well as a complex set of values and beliefs. The literature also says that attitudes are acquired over a person's lifetime.  $\frac{80}{35}$ 

Specific examples of conduct risk factors referred to in the literature include: 80 47 48 45

- inappropriate behaviour towards patients and/or colleagues
- abusive, aggressive, intimidating, antisocial and disruptive behaviours towards colleagues, patients and subordinates
- failure to attend meetings, lack of punctuality, persistent lateness in responding to work calls or refusal to treat a patient
- inability to use judgment and empathy and effectively manage relationships

- sexual harassment, racial, ethnic or sexist slurs
- threats of retribution and/or litigation and demands for special treatment.

## Competency risk factors

- lack of proper or inadequate communication
- inadequate record keeping, failure to keep up to date records and/or a lack of familiarity with basic clinical/administrative procedures
- poor treatment (e.g. poor prescribing and treatment of conditions, errors during treatment and not treating conditions which should have been treated)
- tendency to use inappropriate or outdated techniques
- basic lack of knowledge and poor clinical/professional judgment.

The evidence suggests that practitioners with poor interpersonal, communication and risk management skills are more likely to receive complaints and experience dissatisfaction both at personal and professional (via the patient and arguably other colleagues) levels. More importantly for the practitioner, this lack of skills and appropriate behaviours can also be the trigger for a competency review. 83 45

Conversely, the literature also tells us that practitioners who are most likely to meet a regulator's competency standards are those who demonstrate the following characteristics: 11

- a tendency to be very well connected and networked professionally
- expresses satisfaction with their career, choices and personal lives.

#### Contextual risk factors

Six groups of contextual risk factors can be drawn from the extensive literature on risk. These groups of risk factors are gender; prevalence of complaints; origin of qualifications when an individual is practicing in another country; professional isolation; age and length of time in practice; and time out of practice.

#### Risk associated with gender

Some researchers have suggested there are a range of factors that influence the performance of a practitioner, including gender.<sup>35</sup>

On the issue of complaints, the evidence shows that:

- an overwhelming majority of medical practitioners represented in complaints procedures were male<sup>28</sup>
- male dentists (as well as other health professionals) in the United Kingdom are more likely to be referred to disciplinary bodies then female dentists<sup>80</sup> 98
- males have a higher risk of recurrence of complaints and/or malpractice claims than their female colleagues<sup>112</sup> 98

Researchers posited that the reasons why gender was a contextual risk factor was because of differences in practicing styles (e.g. levels of risk tolerance, aggressiveness) and interactions primarily with patients (i.e. willingness on patients to file a complaint or express their dissatisfaction on the quality of care from their practitioner), but also presumably with other colleagues 28

#### Risk associated with the prevalence of complaints and practitioner qualifications

The literature confirms that analysis of patient complaints can help identify practitioners with interpersonal problems and predict the likelihood of both the recurrence of complaints and the likelihood of malpractice litigation (where this type of litigation occurs). For example researchers found that: 47 80

- compared with doctors with one prior complaint, doctors with two complaints had nearly double
  the risk of recurrence of a complaint; and doctors with five prior complaints had six times the risk
  of recurrence
- regardless of the number of previous complaints, doctors' risk of further complaints increased sharply in the first six months following a complaint and then declined steadily thereafter
- practitioners' with four or more complaints over a six-year period were found to be 16 times more likely to have two or more risk management files opened than practitioners with no complaints.

Concerning practitioner qualifications, it should be noted that even though the evidence was not as strong, researchers looking at the United Kingdom (UK) found that being a non-UK qualified dental practitioner is a potential risk factor. In addition, international medical graduates also performed less well on postgraduate medical examinations than UK graduates did.<sup>80</sup> <sup>59</sup>

#### Risk associated with professional isolation

Risk associated with professional isolation also received a lot of attention by researchers. Professional isolation is deemed a risk factor because professional networks (both formal and informal) were seen to have a major influence on practitioners. Furthermore, a lack of support mechanisms (including via peer and professional support networks) was seen as potentially compromising a practitioner's performance.<sup>35</sup>

Examples in the literature of where professional isolation might arise included when a practitioner: 45 114

- is practising in a rural area, geographically isolated location or operating in a solo practice
- does not have or does not actively seek out membership or affiliation either to their professional bodies (including associations, colleges and faculties) and/or in their place of employment (such as a hospital or large practice setting).

### Risk associated with age and length of time in practice

There is a significant body of evidence relating to risk associated with age and length of time an individual has been in practice. While the literature has identified length of time in practice as a potential risk factor, it is not a position, which is supported by all researchers.<sup>80</sup> On the issue of length of time in practice, the literature has found that:<sup>43</sup> 73 59

- practitioners who have been in practice for more years (including older physicians) possess less factual knowledge, are less likely to adhere to appropriate standards of care, and may also have poorer patient outcomes
- this risk factor may be associated with complaints, even though it is a common assumption that performance improves with clinical experience
- practitioners may develop mastery in a particular small area of medicine but lose general competencies over time while other practitioners become generalists but lose specialist skills
- individuals who have been in practice longer may be at risk of providing lower quality care than their more recently qualified peers.

Researchers also contend that experience alone does not explain the difference in performance between early and recent graduates and practitioners who have been qualified for a significant period of time. Theories include practitioners qualified longest being less accepting of shifts in theoretical knowledge, best practices and advances in medical techniques and technologies. It is also thought,

that like other poorly performing practitioners, those qualified longest are less likely to keep their knowledge and skills updated (including through regular CPD activities) and are more likely to work in isolation. 73

There is also a significant body of evidence suggesting that age is positively associated with poor performance, erosion of skills and knowledge over time and disciplinary matters. As with the evidence relating to length of time in practice, research suggests that age is symptomatic of diminishing knowledge and/or skills and the challenge practitioners' face in remaining up to date throughout the lifetime of their professional careers. 8 45 73 98 60

#### Risk associated with time out of practice

The General Medical Council has stated there is substantial evidence demonstrating that time out of practice (regardless of the reason) impacts on the skill retention of practitioners. It has also found that:

- although the amount of time between learning and skill loss varies between individuals, skills have been shown to decline over periods ranging from six to eighteen months
- two other factors—length of time out of practice and age of practitioner—also impact on readiness to return to practice
- older practitioners and those who took breaks over three months were at greater risk of competence and fitness to practise issues than their peers and colleagues
- there is agreement that skills fade may be mitigated by practitioners staying in contact with peers and staying aware of developments relevant to their profession and scope of practice.

As with all of the risk factors referred to above, those associated with time out of practice potentially have serious consequences for quality of care and safety of patients.

## Risk profiling as a regulatory tool

Risk profiling tools are used across a range of sectors (including health, social development, law enforcement and finance) for a variety of reasons. In some sectors (i.e. care and protection of children and young people), the use of risk profiling tools is fraught with tension. Notwithstanding these questions, the feasibility of risk profiling as a regulatory tool is worth exploring.

The literature indicates what we already know—there are individuals using good and bad practices within their professions. <sup>56</sup> <sup>31</sup> What regulators need to know is, what are the root causes of both of these types of behaviours? Why—because then the regulator can target an individual practitioner's behaviour rather than an entire group and hopefully use good practices to support and influence positive change in other practitioners. <sup>22</sup>

On the issue of detecting poor practice, 22 8 Allsop & Jones have said

What mechanisms should be used to identify poor practice? What is the threshold below which performance could be said to be poor? Should those whose performance is below a certain level be punished or supported? What is the overlap between assuring competence and detecting poor practice? What are the roles of different regulators in the process and how do they relate to each other?<sup>10</sup>

In addition to Allsop & Jones questions, the literature considers two other questions, which are relevant to this discussion. These are, what are the challenges around the use of risk profiling as a regulatory tool and can risk profiling predict for changes over time? $\frac{10}{10}$ 

As a starting point and for the purposes of this literature review, there is evidence showing it is feasible to identify at risk practitioners based on the number of complaints received about them. This evidence also shows that analysis of data and information can help regulators to identify characteristics that may predict future lapses in practitioner behaviour, competence and fitness to practise. 18 10

Other potential quantitative data sources include information collected during site visits and inspections, results from audits and requests or the sharing of information from other agencies and organisations about a practitioner. Conversely, potential qualitative data sources include reports from previous interactions and visits with practitioners, staff knowledge, information from internal and external stakeholders (e.g. professional associations) and information from other regulated authorities.<sup>109</sup>

Nevertheless, it should be noted that researchers also argue that further research to identify the most reliable and valid indicators is needed before risk profiling is deemed a feasible and credible regulatory tool. 112 108

#### What can we learn from the literature about risk and recertification

The research shows that some regulators have ready-sources of data about risk (although the quality of the data and access is often an issue) while others do not. It also shows that while some regulators collect and analyse this information for risk profiling, others use it for purposes relating to registration and case management. 18 108 109 56

Therefore, the first challenge is to ensure regulators are maximising the collection and use of data in meaningful ways. Data use also presupposes a regulator has developed a long term IT strategy that considers issues around confidentiality, information governance, and ownership of information.<sup>23</sup> 108

If regulators adopt a proactive approach to risk and risk profiling, they should be able to identify areas of risk among practitioners, at different points in their career and depending on their specialty and/or scope of practice/s. Such an approach should be welcomed by practitioners and the public alike because it seeks to prevent harm before it has occurred. Without overstating the issue, the potential associated with regulators understanding the nature of risk and the use of risk profiling could save the lives of patients and practitioners.<sup>56</sup>

On the issue of data, researchers have also: 22 18 108

- expressed concerns that risk profiling may be discriminatory if it targets older and solo
  practitioners on the grounds that they are statistically more at risk of error
- identified the need for regulators to use risk profiling criteria that captures as few false positives as possible
- expressed concerns about reliability and high costs (financial and non-financial) associated with the development of bespoke data collection systems for managing risk
- identified that the person/s who analyse the data will have a significant impact on results because their values and perspectives influence the interpretation of data.

The research on the use and effectiveness of indicators and measures to identify at risk behaviours in practitioners suggests: <sup>23</sup> <sup>108</sup>

- there are relatively few indicators that are universally accepted as unambiguous measures of quality that do not raise further questions or warrant investigation and validation before they are used
- the suitability, usefulness and impact of indicators will depend on clarity about the aims of the measurement
- there are additional problems of interpretation because adverse events and near misses tend to be under-reported
- all datasets have their limitations (including around validity and reliability) because indicators are pointers, rather than markers of performance
- it can be difficult to measure effectiveness when researchers argue gains in knowledge do not necessarily equate to change in practitioner behaviour<sup>63</sup>
- annual random sampling of a proportion of practitioners is highly resource intensive and fails to capture sufficient numbers of members to be a truly effective monitoring process. 90

#### Literature Review (June 2017)

The second challenge for regulators therefore concerns the need to develop scientifically sound and reliable indicators and measures that define risk. Then use those indicators and measures in meaningful ways to improve both the quality of healthcare for patients and practitioner competence and fitness to practise.

The research also notes the difference between measures for improvement (e.g. benchmarking against peers) and measurement for judgment (e.g. for performance assessment and management, or patient choice). The research goes on to say

[In the case of measurement for improvement] the information is used as a tin-opener for internal use, designed to prompt further investigation and action where needed and not as a definitive measure of performance in itself. [In the case of measurement for judgment] the information is used as a dial—an unambiguous measure of performance where there is no doubt about attribution and which may be linked to explicit incentives for good performance ... and sanctions for poor performance (in extreme cases, fines from the regulator or dismissal of senior staff).<sup>23</sup>

This literature review has already highlighted that one of the competency issues relates to the evolving nature and speed at which change (in knowledge, techniques and technology) occurs for many health practitioners.

The third challenge for regulators therefore is to develop indicators and measures that account for this specific risk.

#### **Reference List**

Please note that the majority of the references listed in this discussion document are hosted on external websites and Council cannot guarantee the links will remain current. Please contact us on <a href="mailto:comms@dcnz.org.nz">comms@dcnz.org.nz</a> if you require any of the referenced documentation.

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