

Reviewing Right-touch regulation

Discussion and overview

October 2015

1. Introduction

- 1.1 In 2015, we carried out a formal review of *Right-touch regulation*.¹ The revised version and supporting documents are available at:
<http://www.professionalstandards.org.uk/policy-and-research/right-touch-regulation>.
- 1.2 This paper discusses some of the issues we found, and describes the activities we undertook.
- 1.3 The project consisted of:
 - A call for views
 - Research with patients and service users
 - A seminar on risk in regulation and applications of *Right-touch regulation*
 - A review of the literature on risk in regulation.
- 1.4 We used the findings from each of these pieces of work to bring *Right-touch regulation* up to date, clarify its intended uses, and expand on some of the concepts that are central to the Right-touch approach.

2. Discussion

- 2.1 Through the different elements of this project, we identified a number of areas for discussion which did not have a place in the revised version of *Right-touch regulation*. This section provides an opportunity to explore and explain our thinking in more detail.

Regulating on the basis of risk

- 2.2 The review of the literature on risk presents some robust challenges to risk-based regulation. Further challenges were put to us at the seminar. It is nevertheless our view that risk-based regulation represents the most sustainable and rational organising principle for regulation, and that any obstacles to its implementation need to be overcome. What is also clear, however, is that legitimate challenges should be faced head-on.

¹ *Right-touch regulation* describes our approach to regulation. The ‘right touch’ is the minimum regulatory force required to achieve the desired result. It is a risk-based, outcome-focused approach that challenges the common misconception that more regulation is the best way to reduce harm. Our ultimate aim is to foster a more considered, intelligent approach to regulation, and reduce the prevalence of unnecessary or ineffective regulatory action.

- 2.3 Perhaps the most controversial aspect of risk-regulation is the idea that some risks of harm can be tolerated, and that it is legitimate for a public authority to make a conscious decision to tolerate certain risks – i.e. to accept that some people are likely to be harmed as a result of a policy decision. This may seem particularly unacceptable from an authority that has a duty of care towards members of the public. It is, however, simply a reflection of the fact that it is impossible to eliminate all risks and that some trade-offs must be made. As individuals, we readily take personal risks (e.g. smoking, drinking, extreme sports); as members of a society, we are also prepared to tolerate risks collectively (e.g. deaths as a result of car accidents). We accept these risks either because the benefits are deemed to outweigh the risks, or because eliminating the risks is a practical impossibility.
- 2.4 In our view, clear and honest communication about the rationale underpinning regulatory decisions can make a significant contribution to maintaining public confidence in regulation. It is preferable by far to manage public expectations about what regulators can achieve than to set regulation up to fail through the passive acceptance of the unrealistic outcomes that regulators are sometimes expected to deliver. In addition, perceptions about risks are often skewed – risk-based approaches can introduce some rationality to the conversation.
- 2.5 We should not make light of the methodological challenges for risk-based regulation. The difficulty of obtaining reliable data seems to be a perennial issue in health and social care. For example, most of the regulators we oversee collect diversity monitoring data. It is tempting to analyse fitness to practise data using these categories, and to conclude from a correlation that there is a causal relationship between a group's protected characteristic(s) and the risk it poses. In fact this kind of analysis may tell us little beyond pointing us in the direction of further research.
- 2.6 This type of approach in the regulation of professionals tends to assume that harm arises out of factors relating only to the practitioner in question. The reality is that mistakes, poor practice, and perhaps less obviously deliberate harm are caused by a combination of factors relating both to the practitioners and to the systems and environments in which they operate. Analyses looking for predictors relating to individuals are limited and should be complemented with other analyses that look for predictors in the working environment. An example of this would be to identify the points in a patient's journey where risks are heightened, and the reasons for this heightened risk.²
- 2.7 There would be great benefit therefore in professional regulators and other agencies in our sector working together to identify useful sources of information, and to analyse data intelligently to identify risks of harm and their causes.³

² Van Rensen, E. (June 2015) *Using video reflectivity for engaging health care professionals in practice improvement*. Building the evidence base of professional regulation: an international perspective Health and Care Professions Council conference, Amsterdam

³ Sparrow, M (2008) *The Character of Harms: Operational Challenges in Control*. United States of America, Cambridge University Press

Responding to risk

- 2.8 Once a risk of harm has been identified, regulators need to find ways to change people's behaviour. There was some discussion of this in relation to professional regulation at the seminar we organised. One delegate suggested there may be a gap in the literature on this topic, and our review on risk supports this observation, with the notable exception of Professor Malcolm Sparrow and his work on the sabotage of harms.⁴
- 2.9 Professional regulators of the type that we oversee have both preventative and reactive levers at their disposal, although in practice each regulatory function (standard setting, registration, fitness to practise,⁵ and continuing fitness to practise) often fulfils both. Fitness to practise is primarily a reactive function – action in the form of a sanction is taken against a registrant after an incident has occurred. However, it can also have secondary motivating and deterrent functions, which could be described as preventative: it can deter other registrants from committing misconduct by condemning some actions and motivate them to do the right thing by condoning others.
- 2.10 The work the regulators have done on the duty of candour is an illustration of this. For example, the General Dental Council's fitness to practise panels have been asked to take '*very seriously a finding that a dental professional took deliberate steps to avoid being candid with a patient or to prevent someone else from being so*', while the Health and Care Professions Councils' panels have been asked to view demonstrations of candour positively.⁶ Unfortunately, the impact of this type of motivating/deterrent action is very difficult to measure.
- 2.11 The distinction between preventative and reactive regulation exposes a paradox in professional regulation: we want the focus of regulation to shift more strongly towards preventing harm, but the powers and expertise of those regulators we oversee are currently underdeveloped in this area. Instead the majority of resources are swallowed up by fitness to practise functions. Our review of the cost-effectiveness of the regulators we oversee⁷ found that on average these organisations spent 62% of their budget on fitness to practise, compared with around 5% on quality assuring education and training, and 17% on registration. We know that caseloads have risen since the data was collected for that report, so can reasonably conclude that this proportion is on the rise.
- 2.12 Not only does such a system fall short of reasonable expectations of regulation, it is also unsustainable in the long run. As we concluded in *Rethinking*

⁴ Sparrow, M. (2008) *The Character of Harms: Operational Challenges in Control*. United States of America, Cambridge University Press.

⁵ Among the UK health and care professional regulators, the functions that investigate and handle complaints, are known as 'fitness to practise'.

⁶ See our November 2014 advice to the Secretary of State: *Progress on strengthening professional regulation's approach to candour and error reporting* [Online]. Available at: <http://www.professionalstandards.org.uk/docs/default-source/psa-library/141127-candour-common-approach-progress-advice-final.pdf?sfvrsn=0> (Accessed 6 October 2015)

⁷ Professional Standards Authority (November 2012) *Review of the cost effectiveness and efficiency of the health professional regulators* [Online] Available at: <http://www.professionalstandards.org.uk/docs/default-source/psa-library/november-2012---advice-on-cost-effectiveness-and-efficiency.pdf?sfvrsn=0> (Accessed 1 October 2015)

regulation,⁸ regulation needs to get better at preventing harm. This means developing a better understanding of how to influence the behaviour of professionals, and becoming more sophisticated in how it tackles risks.

- 2.13 The statutory levers of registration, renewal, and fitness to practise will rarely be the most appropriate tool. Changing behaviour through the intelligent use of education and non-regulatory levers may be more effective and proportionate. Influencing other agencies that are closer to the problem may also be a better solution than introducing new forms of regulation at national level.

The role of professionalism, improvement and innovation

- 2.14 We were told throughout this project how important it is that the Right-touch approach should support professionalism, improvement and innovation.
- 2.15 *Right-touch regulation* supports both these things by:
- Discouraging the use of regulation if the risk can be addressed more effectively by agencies closer to the problem, including employers and the professionals themselves, and
 - Encouraging the use of regulatory levers that support positive behaviour change and the exercise of professional judgement rather than seeking to be overly prescriptive.
- 2.16 Professionalism is a term that means different things to different people.⁹ The Royal College of Physicians defined professionalism as ‘a set of values, behaviours and relationships that underpin the trust the public has in doctors’.¹⁰ We believe that it is primarily the professionalism of doctors, social workers, pharmacists, nurses, physiotherapists and the other regulated professions that ensures the delivery of good care. As we say in *Right-touch regulation*, regulation is working in the public interest when it supports professionalism and allows it to flourish.
- 2.17 As for improvement, it remains our view that the *primary* purpose of regulation should be the maintenance of the good enough, which in our sector means good enough to practise. In *Rethinking regulation*, we commented on the difficulties faced by regulators who have tried to do both. We concluded that:
- ‘Once a regulator becomes too intimately involved in putting improvement into effect, it loses its objective and impartial advantage, ends up marking its own homework and being blamed more deeply for continuing problems.’*

⁸ Professional Standards Authority (August 2015) *Rethinking regulation* [Online] Available at: <http://www.professionalstandards.org.uk/library/document-detail?id=f32e5b9e-2ce2-6f4b-9ceb-ff0000b2236b> (Accessed 10 October 2015)

⁹ See the research commissioned by the Health and Care Professions Council on professionalism, *Professionalism in healthcare professionals*, available here: <http://www.hpc-uk.org/assets/documents/10003771Professionalisminhealthcareprofessionals.pdf>

¹⁰ Royal College of Physicians (2005) *Doctors in society – Medical professionalism in a changing world – Report of a Working Party* [Online] Available at: https://www.rcplondon.ac.uk/sites/default/files/documents/doctors_in_society_reportweb.pdf. (Accessed 4 June 2015)

- 2.18 Improvement in front-line practice is of course desirable, but we contest that it is the regulator's responsibility to promote excellence. Regulation should help create the conditions in which quality control is maintained, indeed it is entirely appropriate for regulators to engage in activities that have the effect of improving standards provided their primary purpose is to raise the standard to the 'good enough'.
- 2.19 Finally, there were concerns that the focus on risk in *Right-touch regulation* might prevent innovation in policy-making. Our response to this follows on from what we have said in the preceding paragraphs. *Right-touch regulation* does not stipulate any particular type of response to an identified risk, neither does it define the level or type of risks that warrant a response. There is a huge range of possible solutions to a given problem; some are already commonly used, others have yet to be explored. We hope that *Right-touch regulation* will encourage governments and regulators to develop creative non-regulatory and – where necessary – regulatory solutions, as well as making better use of existing levers.

Applying *Right-touch regulation* in practice

- 2.20 Both the 'Call for views' and the seminar brought to light some important points about barriers to applying *Right-touch regulation*.
- 2.21 Some talked about political pressures and 'top-down' solutions undermining the best efforts to apply the Right-touch principles. Concerns were also raised about pressures from lobby groups and constraints posed by 'existing ways of working'. These are clearly not problems that can be easily resolved. We envisage that in promoting transparent, evidence-based approaches, *Right-touch regulation* can help decision-makers push back against these competing pressures by providing them with a firm evidence base and a well-reasoned rationale.
- 2.22 Others made the point that the current legislative framework could inhibit the development of Right-touch regulatory policy. This is undoubtedly a source of frustration for regulators, as it is very difficult for them to change their governing legislation. But the Right-touch approach promotes making better use of existing mechanisms, and in the absence of legislative reform, regulators can focus on this option, and make effective use of non-statutory levers to help address risks.
- 2.23 As for the bigger picture of health and care regulation, we would argue, as we do in *Rethinking regulation*, that the current framework of professional and system regulation is neither risk-based nor fit for its future purpose, and does need radical reform. This type of reform would of course require major changes to the legislation, so we would agree that at this level the legislation may be inhibiting the development of a regulatory framework in line with our principles.
- 2.24 Concerns were raised about the lack of consistency of application of *Right-touch regulation* across the regulatory framework. We have made a number of changes to *Right-touch regulation* itself which we hope might bring greater consistency to people's interpretations of the guidance. As previously mentioned, we have also used *Rethinking regulation* to explain that some of the

inconsistencies in the current system, which are symptomatic of the piecemeal way in which it has developed over many years, need to be addressed through wholesale reforms.

3. Project overview

Research with patients and the public

⇒ Full report available at <http://www.professionalstandards.org.uk/policy-and-research/right-touch-regulation>.

- 3.1 We commissioned Research Works to carry out research with patients and service users on the following topics:
- What constitutes a potential harm in the eyes of users of health and care services and how various professions and occupations should be overseen to mitigate these potential harms?
 - What kind of oversight service users expect to be in place for certain types of profession and occupations?
 - What evidence service users themselves might contribute to, and how they might be involved in, decision-making on the appropriate type of oversight for the various professions and occupations?
- 3.2 This was a challenging topic to engage members of the public on, because typically participants know very little about regulation and it is a topic that few people think about, particularly in relation to health and social care. For this reason, a deliberative workshop approach was adopted. Deliberative techniques are used when researching topics that target audiences may know little about.
- 3.3 Three qualitative workshop discussions (duration two hours) were conducted. The extended group length ensured that there was sufficient time to introduce different pieces of stimulus and discuss each at length. The sample comprised 24 patients with long-term conditions using a wide range of health and care services. It was segmented into workshop groups (eight participants in each) which were split by age and life stage.
- 3.4 The key recommendations from the research were as follows:
- Governments and regulators should consider the wide range of settings in which health and social care are provided when seeking evidence of harm to patients and service users
 - Any definition of harm needs to encompass mental as well as physical health, direct and indirect harm.¹¹ Policy-makers should also consider the greater vulnerability to harm of certain groups of service users or of people in a vulnerable state
 - Policy-makers should be aware that some types of harm are less visible than others.

¹¹ Direct harm is to the patient or service user's health, indirect harm is through, for example, the negative impact on NHS funding, policies or confidence in a profession or occupation

Seminar on risk in regulation and applications of Right-touch regulation

- 3.5 The purpose of the event was to discuss with a wider group of expert and knowledgeable stakeholders the strengths and weaknesses of *Right-touch regulation* as described at the time.
- 3.6 The event was in two parts:
1. Seminar on risk in regulation
Presentations were given by Dinah Godfree (Professional Standards Authority), Dr Henry Rothstein (King's College London), Juliet Oliver and Tim Livesley (Solicitors Regulation Authority) and Shane Carmichael (General Medical Council). These were followed by a round table discussion on risk in regulation.
 2. Discussion on practical applications of *Right-touch regulation*
Presentations were given by Harry Cayton (Professional Standards Authority), Jane Pierce (General Dental Council) and Tim Walker (General Osteopathic Council). These were followed by break-out sessions on particular topics.
- 3.7 In addition to the speakers listed above, delegates were present from a number of professional regulators from within health and social care and the legal professions, several of the Accredited Registers in our accreditation scheme¹², Manchester Business School, Warwick Business School and the Department of Health (England).
- 3.8 A number of questions emerged across the morning and afternoon sessions representing a variety of perspectives on how regulation works.
- **Evidence:** What should regulators do if there is a paucity of hard data but anecdotal accounts of risk? What is the place of evidence on perceptions of risk? Can risks go unidentified through lack of patient and service user awareness of harm being done or ability / understanding of how to report concerns? Is it right to use the precautionary principle, which gives regulators a licence to intervene as a precautionary measure before a risk has been clearly identified? How can regulators obtain evidence of *why* certain groups of registrants pose risks (not just *that* they pose risks)?
 - **Methodology:** What weight should regulators give to high risks that have a low likelihood of happening and low risks with a high likelihood of happening? How do we decide what is a tolerable level of risk? To what extent should regulators educate the public on the benefits of risk-based regulation? How do we sell the concept of 'acceptable risk' to the public? By focusing on specific risks that may cause unacceptable harm, do we lose sight of the potential impact of a general, lower-level deterioration in standards? Should our understanding of 'risk' include financial, reputational or legal risks to the regulator? If, based on evidence of risk, regulators target certain groups of registrant, could they be at risk of allegations of discrimination? Should regulators mitigate this risk to them

¹² See our website for details: <http://www.professionalstandards.org.uk/accredited-registers>

by promoting the good rather than underlining the bad, or by using secondary levers which don't count as 'less favourable treatment'?

- **Unintended consequences of regulation:** Could the focus on risk lead to a lack of innovation in policy making?
- **Responding to risk:** Can regulators make greater use of secondary levers, more creative approaches to addressing risks within existing legislation, developmental regulatory responses for low-level risks? There is sometimes a lack of clarity about where responsibility for managing a particular risk lies. Risks can be managed by looking closely at the environment in which registrants are working and, where appropriate, building on local mechanisms already in place (the 'granular approach'). Gathering and communicating evidence to challenge the assumption that statutory regulation is necessarily the solution.
- **Limiting factors:** How can regulators respond when a top-down solution is proposed, which is not 'right-touch'? When regulators are asked to manage perceived risks in a particular way (e.g. through statutory regulation of a specific group), they may not think to challenge the approach. There may be longstanding structures and ways of working (some of which may be set out in regulations) which are difficult to change.

Call for views

- 3.9 Our Call for views took the form of a questionnaire and was sent out together with the 2010 *Right-touch regulation* document. We asked questions on the strengths of the guidance and as well as on possible improvements. Overall, we sought to assess the influence of *Right-touch regulation* in the UK and potentially overseas, in a variety of environments and through references to the guidance in literature.
- 3.10 Respondents were generally supportive of the concept of *Right-touch regulation*. Some felt that its effectiveness relied upon the existence of relevant and good quality evidence, which could be difficult to obtain. There was also support for the new principle of 'agility', which is additional to the five defined by the Better Regulation Executive.
- 3.11 The responses suggested the following areas for development:
- How the guidance could better reflect the importance of joined-up regulation and collaborative working, fostering professionalism and the use of evidence in informing regulatory policy
 - The concept of risk (including whether it should be seen in narrow terms of prevention of harm, the calibration of risk and how it is being used in practice)
 - How to adhere to the *Right-touch regulation* approach in practice
 - How to promote consistency of approach in applying *Right-touch regulation* in practice, especially across the regulators

- Clarification of the types of regulatory decision that it is intended to apply to
- The role *Right-touch regulation* has to play in raising standards.

Review of literature on risk in regulation

⇒ Full report available at <http://www.professionalstandards.org.uk/policy-and-research/right-touch-regulation>.

- 3.12 We reviewed the key publications and papers on risk in regulation. The paper looks at the history of risk ideas in public policy and regulation, the generic structure of risk management frameworks, and benefits and limitations of risk-based regulation.

4. Next steps

- 4.1 We will continue to take an interest in how *Right-touch regulation* is interpreted and applied, particularly in other sectors. Please get in touch if you have any feedback, or if you would like to discuss any aspect of this project.

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