About the Professional Standards Authority

The Professional Standards Authority for Health and Social Care promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and registration of people working in health and care. We are an independent body, accountable to the UK Parliament.

We oversee the work of nine statutory bodies that regulate health professionals in the UK and social workers in England. We review the regulators’ performance and audit and scrutinise their decisions about whether people on their registers are fit to practise.

We also set standards for organisations holding voluntary registers for people in unregulated health and care occupations and accredit those organisations that meet our standards.

To encourage improvement we share good practice and knowledge, conduct research and introduce new ideas including our concept of right-touch regulation. We monitor policy developments in the UK and internationally and provide advice to governments and others on matters relating to people working in health and care. We also undertake some international commissions to extend our understanding of regulation and to promote safety in the mobility of the health and care workforce.

We are committed to being independent, impartial, fair, accessible and consistent. More information about our work and the approach we take is available at www.professionalstandards.org.uk
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Introduction
This revised paper sets out the Professional Standards Authority’s refreshed thinking as we explore the role and value of regulation in controlling the risk of harm to the public. Common themes have emerged through our oversight of the health and care professional regulators, in our advice to Governments on areas of regulatory policy and in our development of accredited registers. Our original paper was published in 2010. Since then, we and others have applied it to a variety of problems in regulation both in the UK and internationally.

Right-touch regulation describes the approach we adopt in the work we do. It is the approach that we encourage regulators to work towards, and it frames the contributions we make to wider debates about the quality and safety of health and social care and the development of regulation. It also provides a framework for thinking about wholesale reform of existing regulatory arrangements.

This paper reaffirms that this approach is the right one to take. It explains Right-touch regulation in practice and outlines the benefits it offers for professional regulation and to wider health and care delivery, as our area of expertise and experience.

In 2010, we hoped that other areas of regulation might find this approach useful too; in 2015, we know that others have tried it and found it so. We have drawn on these collective experiences, clarified some areas, expanded on the concept of risk, discussed responsibility, and defined Right-touch regulation more clearly. We have also provided some practical examples to illustrate the approach. The core principles, however, remain unchanged.

We continue to see this as a work in progress, and an approach to be debated and improved over time.

What is Right-touch regulation?
The concept of Right-touch regulation emerges from the application of the principles of good regulation identified by the Better Regulation Executive in 2000, to which the Professional Standards Authority has added agility as a sixth principle.

With this addition, the principles state that regulation should aim to be:

- **Proportionate**: regulators should only intervene when necessary. Remedies should be appropriate to the risk posed, and costs identified and minimised
- **Consistent**: rules and standards must be joined up and implemented fairly
- **Targeted**: regulation should be focused on the problem, and minimise side effects
- **Transparent**: regulators should be open, and keep regulations simple and user friendly
- **Accountable**: regulators must be able to justify decisions, and be subject to public scrutiny
- **Agile**: regulation must look forward and be able to adapt to anticipate change.

These principles provide the foundation for thinking on regulatory policy in all sectors.

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1In our paper *Rethinking regulation* we argue that the current regulatory arrangements are outdated, inefficient and ineffective. We suggest that the principles of Right-touch regulation should be used to help design a better, more coherent regulatory system.

2In their 2009 report on *Themes and Trends in Regulatory Reform*, The House of Commons Regulatory Reform Committee agreed with us that ‘agility’ is an important objective for the regulatory agenda.

3Agility in regulation means looking forward to anticipate change rather than looking back to prevent the last crisis from happening again. We consider that an agile regulator would foresee changes that are going to occur in its field, anticipate the risks that will arise as a result of those changes, and take timely action to mitigate those risks. At the same time, an agile regulator would not react to everything as changes may occur which do not need a regulatory response.
of society.\textsuperscript{4} We see the concept of Right-touch regulation emerging naturally from the application of these six principles: bringing together commonly agreed principles of good regulation with understanding of a sector, and a quantified and qualified assessment of risk of harm. It is intended for those making decisions about the design of an assurance framework.

In practice this means we work to identify the regulatory force needed to achieve a desired effect. Our analogy is finding the right balance on a set of scales (Figure 1). When weighing something on balancing scales, nothing happens until you reach the desired weight, at which point the scales tip over. Once they have tipped any further weight added to the other side is ineffectual. So the right amount of regulation is exactly that which is needed for the desired effect. Too little is ineffective; too much is a waste of effort.

Our thinking is in line with what others have called better regulation,\textsuperscript{5} or common sense or rational approaches to regulation, but it is categorically not ‘light-touch’. For us, Right-touch neatly describes the role that regulation should play. It builds on an accurate and informed assessment and analysis of the sector and the risks in it; it is common sense in that it describes the role regulation should play, building on its strengths, staying true to its objectives, and working with the tools it has at its disposal. It recognises that there is no such thing as ‘zero risk’, and that all decisions about what and how to regulate will involve a trade-off between different risks and competing benefits.

Right-touch regulation recognises that there is usually more than one way to solve a problem and regulation is not always the best answer. It may be more proportionate and effective, for instance, to strengthen employment practices or to foster professionalism. New regulations should be introduced only as a last resort. The regulator is usually furthest removed from the harms it is trying to prevent and as such regulation is a blunt instrument for promoting behaviour change. Today, more than ever given economic circumstances, the challenge is to find the most efficient, common sense solutions that are close to the problem.

Right-touch regulation is the minimum regulatory force required to achieve the desired result.

**Right-touch regulation in practice**

Through our work we have identified eight elements that sit at the heart of using the concept of Right-touch regulation in practice. Built into these elements are commitments to use evidence to identify and understand problems, and to draw on the roles and responsibilities of different parts of the system to deliver the best solution. The consequences of adopting this approach may be less regulation or more regulation, but should certainly mean better regulation.

\textsuperscript{4}The idea that governments should have an over-arching policy for decisions about regulation was supported by the OECD in their 2012 report Recommendation of the Council on Regulatory Policy Governance.

\textsuperscript{5}Our thinking is in line with what others have called better regulation, or common sense or rational approaches to regulation.
Three: get as close to the problem as possible
Once we have identified the problem and fully understood the risks, we must look for a solution that is as close to the problem as possible. Regulation is distant and removed from the point of care and problems are best solved near to where they occur. Targeted regulation needs to understand, both the range of hazards and the factors that increase or decrease the risk of them resulting in harm. In healthcare this means understanding the context in which the problem arises and the different tools that may be available to tackle the issues. We may need to work with organisations and individuals that are closer to the problem to bring about change. Some problems may be best tackled by regulatory measures applying to a whole profession, while others may require more targeted regulation or a non-regulatory approach. See case studies 2 and 3 in the appendix for a practical example.

Four: focus on the outcome
Adopting a Right-touch approach means staying focused on the outcome that we are looking to achieve, rather than being concerned about process, or prioritising interests other than public safety. The outcome should be both tangible and measurable, and it must be directed towards the reduction of harm. Staying focused on the outcome helps identify the most appropriate solution. Having a clearly defined and measurable outcome also makes it easier to measure effectiveness. See case studies 1 and 3 in the appendix for a practical example.

Five: use regulation only when necessary
Once the problem has been considered, we may begin to examine whether a regulatory change is the right proposal, evaluating this
against the options of doing nothing and the risks and benefits of intervening. Making changes to regulation, especially statutory regulation, can be a slow process, so regulation should only be used as a solution when other actions are unable to deliver the desired results. A Right-touch regulatory solution must keep to the six principles of good regulation and should build on existing approaches where possible. This will often involve looking for solutions other than regulation and may require regulators to work with other organisations and people to bring about change. See case studies 1 and 3 in the appendix for a practical example.

**Six: keep it simple**
For regulation to work, it must be clear to those who are regulated, clear to the public, clear to employers, and clear to the regulator. If each cannot explain to the other what the purpose of a regulation is and why it will work, it is not simple. This is as true in health and social care, with such a wide variety of agencies and individuals involved, as it is in other sectors. Avoiding complexity will lead to a greater impact. A regulatory response should be as simple as it can be while achieving the desired outcome. See case study 1 in the appendix for a practical example.

**Seven: check for unintended consequences**
Assessing the probable impact of a particular solution is an essential step to help us avoid unintended consequences. In a system as interconnected and complex as health and social care, it is inevitable that proposing a change in policy and practice will have consequences for other parts of the system. If regulations are not workable, people will work around them and in doing so create new risks. Regulating to remove one risk without a proper analysis of the consequences may create new risks or merely move the risk to a different place. See case studies 3 and 4 in the appendix for a practical example.

**Eight: review and respond to change**
We should build flexibility into regulatory strategy to enable regulation to respond to change. All sectors evolve over time, as a result of a range of different influences. Regulators must not be left managing the crises of the past, whilst ignoring or being unable to react to new evidence that calls for change. This is what we mean by agility. A programme of regular reviews, post-implementation evaluation and sunset clauses can all help here. See case study 1 in the appendix for a practical example.

The decision tree (Figure 2) shows how these eight steps translate into a decision-making process.

**Right-touch regulation and responsibility in health and social care**
In our work with regulators, accredited registers and others we formally define Right-touch regulation as follows:

‘Right-touch regulation is based on a proper evaluation of risk, is proportionate and outcome focused; it creates a framework in which professionalism can flourish and organisations can be excellent’

The interests of patients and service users are at the heart of all our work, and this is clearly set out in our legislation. Many health and care organisations share this aim, either explicitly or implicitly. They have a role to play to achieve this wider benefit.
Figure 2. The Right-touch regulation decision tree.
The quality of care received by individual patients and service users is the end result of a wide range of decisions made by a number of different agents. For example:

- **People**: self-management decisions taken or not taken by people
- **Professionals**: education, training and continuing professional development
- **Providers**: their policies and guidance, and local clinical governance arrangements
- **Commissioners**: through contracting arrangements
- **Regulators**: setting and maintaining standards, controlling entry to the profession, and taking action in response to concerns
- **Other bodies**: any organisations who have an impact on standards of practice, such as accredited registers, professional organisations, royal colleges, arm’s-length bodies, and government departments.
- **Legislation**: for example, human rights, equality, data protection, consumer protection, health and safety.

Regulation is part of a set of possible solutions to risks in a sector. This is recognised in our development of the accredited registers programme under the Health and Social Care Act 2012, which offers a new model of assured registration to manage risks associated with unregulated occupations. All regulatory policy development should be seen in this context, and regulation will only be effective if this wider perspective is taken. It may be necessary for regulators to look for ways in which they can influence registrant behaviour through other organisations or people.

Right-touch regulation is about sharing the responsibility for mitigating the risk of harm between the different organisations and people involved in its management. We believe that it is primarily the professionalism of individuals that keeps the public safe, and in the case of health and social care also ensures the delivery of good care.

Professional regulation is working in the public interest when it supports professionalism and allows it to flourish. It does this through promotion of standards of competence and conduct, by taking action where these standards are breached, and through quality assuring education. It does not seek to address all aspects of risk. It cannot prevent every possible thing that could go wrong. Indeed over-regulation can give a false level of assurance and lead to increased risk.

Right-touch regulation supports professionalism by:

- Discouraging the use of regulation if the risk can be addressed more effectively by the professionals themselves; and
- Encouraging the use of regulatory measures that support positive behaviour change and the exercise of professional judgement, rather than seeking to be overly prescriptive.

Patients and the public also have responsibility for managing risks, becoming involved in discussions about their treatment options, the different levels of risk involved, and the possible consequences for their health. For vulnerable people this responsibility is shared and extended to family, carers and advocates. People have a fundamental and essential contribution to make to high-quality healthcare. The concept of Right-touch regulation recognises the value and importance of the involvement of patients and service users in assessing risks for themselves and making appropriate choices. Right-touch regulation requires the active participation of patients and service user.

There is an inherent risk in all interventions in health and social care and
Figure 3. Indicative illustration of how different agents might share the responsibility for mitigating the risk of harm for two occupations in healthcare.

Paramedics practise in the relatively controlled environment of the NHS. Practitioners still bear a large share of the responsibility, but employers, commissioners, and regulators (both service and professional) between them play an important part in preventing harm. As paramedics work in emergency care, people do not have any significant control over the care a paramedic provides them.

Acupuncturists The vast majority of acupuncturists work in private practices, and they are usually self-employed. Both practitioners and patients can therefore be expected to bear a larger share of the responsibility for preventing harm than in the previous example. Their premises are nevertheless inspected by local authorities and the products they use are subject to controls. Some are on registers accredited by the Authority, which are also responsible for preventing harm.
nothing can be said to be completely safe. For example, there is no such thing as an absolutely safe medicine, since someone will suffer an adverse reaction or side effect. Given the wide range of influences on care outcomes, it is neither proportionate nor targeted to expect regulation to act on every safety or quality concern (potential or actual) that may arise. Ultimately, the responsibility for managing risks in healthcare is shared between all parties.

Figure 3 illustrates how the share of responsibility for preventing harm might vary depending on the occupation. Each of these bears a greater or lesser share of the responsibility for mitigating risks. These examples indicate how the proportions might vary according to the respective contribution of each agent. In both examples, practitioners hold a large share of the responsibility. The share of people, employers, and regulators varies greatly. Commissioners also play a role.

**Right-touch regulation and risk**

When we talk about risk, we mean the risk of harm to the public that the regulator is there to reduce.

In the first version of Right-touch regulation we said that risks must be quantified. In reviewing how the approach has worked we now suggest that to understand a problem fully we must both quantify and qualify risks to enable us to see how frequently harm occurs, what impact it has, and what causes it. We recognise that risk quantification is complex and challenging, but it is essential if we are to make informed decisions about which harms to address. Risk qualification is equally important because it allows us to understand what causes the harm and how it could be prevented. Regulation should focus on identifying and addressing the causes of a risk of harm, rather than responding after the harm has occurred.9,10

This two-fold evaluation is essential if we want to describe regulation as ‘risk-based’. The term ‘risk-based regulation’ should only be used when such an evaluation has taken place. Describing regulation as risk-based in the absence of a proper evaluation of risk is, in our view, misleading and can undermine wider confidence and trust in regulation.

Once a risk has been evaluated, a decision needs to be made about its tolerability. This is a difficult moral decision that will require clear justification. If the risk cannot be tolerated, action will need to be taken – although a further decision will need to be made about whether it can indeed be effectively addressed through regulatory means.

There is no justification for regulation when a risk has merely been identified but not quantified or qualified. In particular we should be cautious of justifying regulation on the basis of theoretical harm without a proper assessment of risk. In this way, Right-touch regulation runs counter to the ‘precautionary principle’, which is used as a licence to intervene before a risk has been evaluated and identified as meeting the threshold for action. The only exception to this is where the severity of the theoretical harm is very high, and it is not possible to quantify the risks robustly. The precautionary principle is distinct from the exercise of foresight, which we see as part of the agility principle – the ability to anticipate risks is essential to good regulation.

We find it helpful to separate hazards, risks and harms (Figure 4).11 Hazards are the conditions or events that can lead to or contribute to harm. Risk is the likelihood of a harm materialising. In health and social care, harm is physical injury or psychological distress experienced by people through interaction with health or social care practitioners and services. In other sectors
Broadly speaking, these hazards can be categorised as follows:

- **Intervention**: the complexity and inherent dangers of the activity
- **Context**: the environment in which the intervention takes place
- **Agency**: service user vulnerability or autonomy.

In looking for categories of people who are statistically more likely to cause harm, caution must be exercised, particularly when using data about diversity characteristics. Taking regulatory action based on an apparent statistical correlation between harmful behaviour and a group defined by, say its age or ethnicity, is likely to be discriminatory. It may also be ineffective and wasteful, because a correlation does not necessarily signify a causal link. Any correlation should therefore be examined

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Figure 4. How hazards create the risk of harm – an example from healthcare.

harm may be defined differently.

Any regulatory response should be proportionate to the risks identified. We find it helpful to think of the range of possible responses on a risk-based continuum of assurance, with those providing the greatest regulatory force (e.g. for the highest-risk professions) at one end of the continuum, and decreasing amounts of regulatory force as the risk decreases. Regulation should only be used where the risk of harm is sufficient to warrant it and it is the most effective means of control.

Regulators need to understand the range of possible physical and psychological harms to patients and service users. In our sector, this focus is on harms that are caused by the actions of professionals.

They also need to understand the range of possible hazards and what increases and decreases risk. In health and care this means understanding the range of hazards created by problems with practitioners’ conduct and competence – as well as those created by the working environment.

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*Some regulators collect diversity data about their registrants and may use this to look for links between such characteristics and likelihood of harm.
more closely to discard the spurious' links and identify the circumstantial hazards that create an increased risk of harm.

One of the key strengths of risk-based regulation is that when used well, it provides a clear, transparent and rational basis for determining what and how to regulate. It can therefore be an effective means of pushing back against other pressures and justifying decisions about resource allocation. For risk-based regulation to be effective, regulators must communicate their approach clearly to the public, their registrants, and other stakeholders.

**Conclusion**
Right-touch regulation is an approach to regulatory decision-making. It means always asking what risk we are trying to address, being proportionate and targeted in regulating that risk or finding ways other than regulation to promote good practice and manage risks of harm. It allows the development of the appropriate contribution of the regulatory regime to the delivery of wider aims.

It promotes the creative use of existing mechanisms for the reduction of harm and supports professionalism and a joined-up approach to regulation. It is agile and responsive to the ever-changing circumstances and risks in which it operates.

In practical terms, the benefits of Right-touch are seen in a number of ways:

- Outcomes are described in terms of the beneficiaries of regulation rather than the needs of others involved in delivery of health and social care, and policy development is devoted to achieving this aim.
- It builds in the need for regular reviews to ensure that regulatory approaches and frameworks remain up to date and fit for purpose.
- It provides a coherent framework for tackling a range of regulatory issues, such as managing new areas of practice and extending regulation to new groups.
- Policy making is well informed, reflecting realities and the wider context, building on evidence and risk assessment.

We believe that this approach also yields broader benefits. The analogy (Figure 1) with weighing scales demonstrates the impact we want regulation to have. At the balancing point, regulation is having its most efficient impact on the problem being tackled. This will continue to be of vital importance as the costs of health and social care increase over time. Right-touch regulation forces us to be certain that the costs of regulation are worth the benefits they also bring. While patients and the public have the right to expect safe care, the cost of regulation is ultimately passed onto the public. Adopting the Right-touch approach will help regulation maximise the benefits.

The Right-touch approach can enhance trust and confidence. Recent, well-publicised ‘failures of regulation' emphasise the value of public confidence in regulation. We need to make sure regulation remains relevant to the needs of today’s society, and that it reacts appropriately to issues as they arise. We should also not exaggerate claims for regulation, implying that everything can be safe and nothing will go wrong. Adopting Right-touch regulation will allow people to feel confident that regulation is acting in the best way it can.

The Professional Standards Authority will continue to promote this approach, which we believe has already led to improvements in regulation in the UK and elsewhere. It provides a valuable set of guiding principles.
to help regulation work efficiently and to enhance confidence in the contribution of regulatory systems to society.

**Appendix: Case studies**

On page 6, we described eight elements that were key to putting Right-touch regulation into practice. The importance of each of these steps will depend on the regulatory question being asked. The following case studies show how particular elements of Right-touch regulation have been applied to individual pieces of work.

**Case study 1: Transition to independent practice for dentists**

The General Dental Council (GDC) had been considering whether or not there should be a period of provisional registration for dentists between their initial qualification and entry to the full dentists register. However, it was important to identify the problem before the solution first. So the dental regulator changed the policy question from ‘Should we have a period of provisional registration?’ to ‘Is the problem about risk to patients and the public?’ This meant the GDC could focus on the outcome of patient and public safety.

To inform the work, the regulator committed to use evidence and data to quantify and qualify the risks. This included a call for information and workshops with key stakeholders, a literature review and an analysis of fitness to practise and registration data. Although a substantial amount of information was collected, it was difficult to draw definite conclusions about risks posed specifically by new entrants to the dentists register. Since we should use regulation only when necessary, the GDC decided the evidence was simply not strong enough to support major regulatory change at that stage. Instead, its approach was to build on structures already in place, as outlined below.

Despite the inconclusive evidence, the regulator could not rule out that some risks might exist, since informed professional stakeholders had raised anecdotal concerns. In addition, a common theme across the various information-gathering exercises was that newly qualified healthcare professionals needed additional support or supervision in order to make the transition to independent practice. So, the GDC fostered a collaborative approach across the dental sector to ensure that all those involved in the early stages of a dentist’s career worked together to deliver the common outcome of protecting patients and the public.

In practice and to keep things simple, this meant clearly setting out the roles of the various bodies who support dental students and new registrants and defining the linkages between them. The postgraduate dental deans developed their foundation training programmes, which were available to dentists after they qualify and join the register, in order to promote consistency and quality across training and assessment. The two bodies that represented undergraduate education and postgraduate training worked together on a ‘clinical passport’ for new UK graduates to take from their dental school into foundation training.

The GDC also worked collaboratively to facilitate information-gathering on any risks to patient and public safety. This, together with other initiatives to improve the quality of data and evidence available, provided the GDC with a robust mechanism to review the policy and respond to change, if necessary.

**Case study 2: Handling complaints against doctors**

In order to manage certain complaints, the General Medical Council (GMC) decided to get as close to the problem as possible.

The GMC has changed the way it deals with certain complaints that do not meet
In this case study, the problem, risks and context were considered and professional regulation was not the answer. Other solutions — closer to the point of care — were proposed in order to help achieve patient and service user safety (get as close to the problem as possible, focus on the outcome, use regulation only when necessary).

This approach may also have prevented an unintended consequence: if professional regulation had been adopted, the role of healthcare assistants and support workers may have become more tightly defined; the scope of their roles might then have become less flexible and less able to meet the needs of local populations.

Case study 3: The Cavendish Review

The Francis Report and other reports highlighted poor care in health and social care. One possible response to these reports would have been to regulate healthcare assistants and support workers. However, the outcome of a review led by Camilla Cavendish showed how this vitally important part of the healthcare workforce could be developed through ways other than professional regulation.

The quality of care for patients and service users depends upon the skills, knowledge, experience and compassion of those on the front line. In the case of healthcare assistants and support workers, this can be achieved through effective local management processes, such as recruitment and training, delegation, appraisal and supervision. Therefore, the Review recommended that:

• Training and education be developed for healthcare assistants and support workers (for example, through a Certificate of Fundamental Care)
• Employers be supported to test values, attitudes and aptitude for caring at recruitment stage
• Caring be made a career (for example, through bridging programmes into pre-registration nursing and other health degrees)
• Healthcare assistants and support workers be developed through leadership, supervision and support in the workplace
• Healthcare assistants and support workers have the time to care (for example, local authorities should commission for outcomes and not by the minute).

Case study 4: Continuing fitness to practise of osteopaths

On piloting its revalidation scheme, the General Osteopathic Council (GOsC) undertook to check for unintended consequences.

While we support this approach in principle, its effectiveness has yet to be determined.
The initial scheme required a multi-layered self-assessment followed by the submission of a portfolio for review by GOsC appointed assessors. Throughout the pilot phase, nearly three quarters of participants reported that the completion of revalidation tools helped them to reflect on their current clinical practice. However, if the scheme were to be presented and administered in the way initially proposed, osteopaths would see it as a test that needed to be passed, rather than an opportunity for reflecting honestly on their practice. There was a risk that osteopaths would be cautious about admitting – especially to GOsC appointed assessors – that there were areas of practice in which they needed to improve. Ironically, the unintended consequence of a policy designed to support professionalism and protect patients and the public could be to discourage osteopaths from developing professionally through self-reflective learning.

The GOsC took on board this risk and proposed a new scheme based on peer review of CPD activity and sign-off by another healthcare professional. The aim was to support professionalism by enabling honest self-reflection and feedback amongst peers. In addition, it would reduce the isolation of osteopaths working on their own and so improve quality of practice in this way too.
References
7 National Health Service Reform and Health Care Professions Act 2002. [Online] Available at: http://www.legislation.gov.uk/ukpga/2002/17/contents (Accessed 3 September 2015) [Note that at the time of publication, there were a number of outstanding amendments still to be made to the online version available at legislation.gov.uk.]