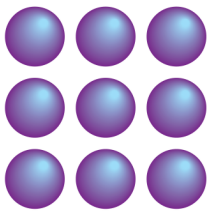
Right-touch regulation

August 2010



council for healthcare regulatory excellence

About CHRE

The Council for Healthcare Regulatory Excellence promotes the health and well-being of patients and the public in the regulation of health professionals. We scrutinise and oversee the work of the nine regulatory bodies[1] that set standards for training and conduct of health professionals.

We share good practice and knowledge with the regulatory bodies, conduct research and introduce new ideas about regulation to the sector. We monitor policy in the UK and Europe and advise the four UK government health departments on issues relating to the regulation of health professionals. We are an independent body accountable to the UK Parliament.

Our aims

CHRE aims to promote the health, safety and well-being of patients and other members of the public and to be a strong, independent voice for patients in the regulation of health professionals throughout the UK.

Our values and principles

Our values and principles act as a framework for our decision making. They are at the heart of who we are and how we would like to be seen by our stakeholders.

Our values are:

- Patient and public centred
- Independent
- Fair
- Transparent
- Proportionate
- Outcome focused

Our principles are:

- Proportionality
- Accountability
- Consistency
- Targeting
- Transparency
- Agility

1 General Chiropractic Council (GCC), General Dental Council (GDC), General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC), Health Professions Council (HPC), Nursing and Midwifery Council (NMC), Pharmaceutical Society of Northern Ireland (PSNI), Royal Pharmaceutical Society of Great Britain (RPSGB)

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Foreword

Regulation touches the point between the public and the personal. Over regulation is seen as an interference in personal conduct; under regulation is seen as an abdication of public responsibility. When harm happens we blame ineffective regulation but when we are stopped from doing something risky we say regulation is excessive. The public, media and politicians often face both ways, wanting more or less regulation depending on the moment and the mood. The rhetoric says 'cut red tape' but the practice is usually more regulation, whether it be for dangerous dogs, for bankers, for people who work with children or for medical research. We want to be free and we want to be safe. Nothing is wrong with either.

Here, in *Right-touch regulation*, we seek the balance between these extremes. We think regulation has an important public role but that it exists to protect people, not to control unduly how they chose to live their lives. We think that as individual citizens we should expect to look after ourselves and those we care about and those we have responsibility for. We should be helped to do so by laws, regulations and standards that restrain those who intend ill, those who are careless of the well-being of others and those whose greed or incompetence causes harm.

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

This paper sets out eight elements of right-touch regulation and five agencies that act to deliver high-quality healthcare. It shows how these can be applied in a step-by-step process to test out whether regulation is necessary and how it can be right-touch.

We have been implicitly developing this approach to regulation in our performance reviews, audit and policy work over the last two years. Now we want to make our model explicit and to invite discussion and debate. Right-touch regulation is a concept against which our work as a public body can be tested and challenged. We publish it as a contribution to a wider debate about how to ensure regulation is effective, appropriate and proportionate, whether in health and social care or in other sectors of the economy. Getting the balance right will help all of us to have trust and confidence in regulation. We invite you to engage in the debate.

Harry Cayton
Chief Executive
August 2010

1. Introduction

1.1 This paper outlines CHRE's thinking as we explore the role and value of regulation. Common themes have emerged through our oversight of the health professional regulators and in our advice and recommendations to Government on areas of regulatory policy. In this paper we explain these in greater detail and define more clearly our concept of right-touch regulation.

1.2 Right-touch regulation describes the approach we adopt in the work we do. It is the approach that we encourage our regulators to work towards, and it frames the contributions we make to wider debates about the quality and safety of healthcare and the development of regulation.

1.3 This paper argues 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 healthcare delivery, as our area of expertise and experience. However, we believe that the application of this approach would be valuable in other sectors and to other areas of regulation and we would welcome responses and debate in this respect.

2. What is right-touch regulation?

2.1 The concept of right-touch regulation emerges from the application of the principles of good regulation identified by the Better Regulation Executive in 2000[2]:

- 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.

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

2.2 To these five CHRE has added agility as a sixth principle. This was first proposed in our advice to the Department of Health and the Pharmacy Regulation and Leadership and Oversight Group on aspects of the establishment of the General Pharmaceutical Council.[3] Our advice reflected on the context of rapid change expected over the next ten years in pharmacy practice and the appropriate regulatory response to this.

2.3 Agility 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. In 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.[4]

2.4 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 an accurate and quantified assessment of risk. In practice this means we work to identify the right level of regulation that is needed to achieve a desired effect. Our analogy is a set of scales. You put the weight on one side and start to pour flour into the bowl. Nothing happens until you reach the desired weight at which point the scales tip over. If you continue to pour flour into the bowl nothing more happens as the scale has already

2 Better Regulation Executive, 2000. Five principles of good regulation
3 CHRE, 2008. Advice to the Department of Health and the Pharmacy Regulation and Leadership Oversight Group on aspects of the establishment of the General Pharmaceutical Council
4 House of Commons Regulatory Reform Committee. 2009. Themes and Trends in Regulatory Reform. Available at: http://www.publications.parliament.uk/pa/cm200809/cmselect/cmdereg/329/329i.pdf [accessed 29 June 2010]

tipped. 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.

2.5 Our thinking is in line with what others have called smart regulation[5], or common sense or rational approaches to regulation. For us, right-touch neatly describes the role that regulation should play. It is smart in that 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 is the role regulation should be playing, building on its strengths, staying true to its objectives, given the tools and levers it has at its disposal.

2.6 Right-touch regulation recognises that there is usually more than one way to solve a problem and that regulation is not always the best answer. It may be more proportionate, for instance, to promote greater cooperation and sharing of good practice. Today, more than ever given the economic circumstances, the challenge is to find the most efficient, common sense solutions to problems. Right-touch regulation is the minimum regulatory force required to achieve the desired result.

5 European Commission. April 2010. Stakeholder Consultation on Smart Regulation. Available at: http://ec.europa.eu/governance/better_regulation/smart_regulation/docs/smart_regulation_consultation_en.pdf [accessed 28 June 2010]

3. Right-touch regulation in healthcare

3.1 In our work with the health professional regulators we formally define right-touch regulation as follows:

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

3.2 For CHRE the outcome is clearly articulated in our legislation: 'the health, safety and wellbeing of patients and other members of the public'. Many healthcare organisations share this aim in the work they do, either explicitly or implicitly. They have a role to play and a contribution to make to achieve this wider benefit.

3.3 The quality of healthcare received by individual patients and members of the public is the end result of a wide range of different decisions. For example:

- Self-management decisions taken or not taken by people
- Health professionals' education, training and continuing professional development
- Employers' policies and guidance, and local clinical governance arrangements
- Commissioners' contracting arrangements
- Good practice identified by advisory groups, such as professional organisations, royal colleges, arm's-length bodies
- National legislation, for example, human rights, equality, data protection, consumer protection, health and safety.

3.4 Regulation is part of a set of possible solutions to risks in the healthcare sector. This is captured for example in the GMC's four layer model of regulation which highlights the roles and responsibilities of regulators, employers, teams and individuals in public protection. All policy development should be seen in this context, and regulation will only be effective if this wider perspective is taken. Right-touch regulation provides a means of tackling an issue in such a way that an appropriate balance of the responsibilities of individuals, employers and regulators can achieved.

3.5 We believe that it is primarily the professionalism of doctors, osteopaths, pharmacists, nurses, physiotherapists and the other 25 regulated professions that deliver quality care. Regulation is working in the public interest when it supports professionalism and allows it to flourish. It can do this through promotion of standards of competence and conduct, by taking action where these standards are breached, and through quality assuring the education of professionals. It does not seek to address all aspects of risk, and regulation (of health professionals or in its other forms) is not the solution to prevent every possible thing that could go wrong. Indeed over-regulation could give a false level of assurance and lead to increased risk.

3.6 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 the public in assessing risks for themselves and making appropriate choices. Right-touch regulation requires the active participation of citizens.

3.7 There is an inherent risk in all interventions in healthcare and nothing can be said to be completely safe. For example there is no such thing as an absolutely safe medicine, since there will always be someone who will suffer an adverse reaction or side effect. Given the wide range of influences on healthcare, 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 are shared between all parties.

3.8 Figure 1 provides an illustration of these shared responsibilities for high-quality healthcare. 'People' refers to patients, service users, carers and families, advocates and representative organisations. 'Professionals' refers to individual health professionals, peer groups, teams, and professional organisations and representative bodies. 'Law' refers to case law, common law and legislation. Lord Darzi, in *High Quality Care for All*,[6] defined quality as care that is 'clinically effective, personal and safe'. Each of these exerts a greater or lesser force in the delivery of high-quality care. In this example the sectors are not to scale. They would vary in size if we wished to illustrate the respective contributions of each group of agencies to managing different problems. An example of this can be seen in Annex 2.

Figure 1: *Agencies which contribute to delivering high-quality healthcare*

6 Darzi, A. 2008. High quality care for all: NHS Next Stage Review final report. DH: London

4. Right-touch regulation in practice

4.1 Through our work we have identified the following eight elements that sit at the heart of using the concept of right-touch regulation in practice. Built into these elements are commitments to using evidence and data 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 may be more regulation, but will certainly mean better regulation.

Identify the problem before the solution

4.2 We need to identify the problem before we can determine whether any particular policy solution is the right one. Often in policy development the need for regulatory change, as a solution, is identified before the problem is properly described and understood. This can lead to inefficiencies as resources are spent developing a regulatory solution when the problem itself may be better dealt with in other ways.

Quantify the risks

4.3 Once the problem has been identified we need to understand it fully and quantify the risks associated with it. Without this evaluation it is impossible to judge whether regulatory action is necessary or whether other means of managing issues are better used. Regulation should only be an option when it clearly provides the best solution. Simply identifying a real or potential risk is not sufficient. We have to understand whether the problem will create new risks to patient safety and public protection.

4.4 A proper evaluation and understanding of risk 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 proper evaluation of the risk is, in our view, misleading and can undermine wider confidence and trust in regulation. There is no justification for regulation when a risk has merely been identified but not quantified. In particular we should be cautious of justifying regulation on the basis of potential rather then real risks.

Get as close to the problem as possible

4.5 Once the problem has been described and we have quantified the risks, it is necessary to consider where and how the problem occurs. In healthcare this means understanding the impact on patient care and the different levers and tools that may be available to tackle the issues. Targeted regulation needs to understand the cause of risk. Regulatory action is distant and removed from the point of care and problems are best solved near to where they occur. This means we consider options that are the responsibility of organisations and individuals rather than regulators. It may be appropriate for a change to be made that affects the whole profession, regardless of the environment they work in. In this case it may be right to consider a regulatory solution.

Focus on the outcome

4.6 Adopting a right-touch approach means it is essential to stay focused on the outcome that we are looking to achieve rather than being concerned about process, or prioritising interests other than public safety. Health professional regulation provides a useful illustration of the need to identify and focus on an outcome. Recent reforms have put public protection and patent safety at the heart of health professional regulation. This was in response to concerns that a self-regulatory approach put the needs and interests of the profession ahead of patients and the public. We may still see evidence of this today in some of the debates around extending regulation to 'aspirant groups' or calling on regulators to recognise elements of professional career enhancement that do not pose extra risks to patient safety and public protection. Staying focused on the outcome helps to identify the most appropriate solution.

Use regulation only when necessary

4.7 Once the problem, the risks and the context have 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 problem solver 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.

Keep it simple

4.8 Patients and the public – the intended beneficiaries of this regulatory activity – have told us they find the current system of regulation confusing and difficult to navigate. We also know that it is important for health professionals to have clear boundaries and to be confident that they know where they are. In healthcare, with such a wide variety of agencies and individuals involved, avoiding additional complexity will lead to a better functioning system. That being so, it is essential that nothing is done that leads to a more complex approach, and where possible steps should be taken to simplify how the outcome is currently achieved. This also means using existing tools more effectively rather than inventing entirely new approaches. Where there is a choice between simple and complex solutions, the simplest is likely to be best.

Check for unintended consequences

4.9 Assessing the impact of a particular solution is an essential step to help us avoid unintended consequences.[7] In a system as interconnected and complex as healthcare, it is inevitable that proposing a change in policy and practice will have consequences for other parts of the system. It is likely that regulatory solutions will have consequences and these should be considered in assessing the overall benefit of any change in regulatory (or other) approaches. 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, creating a new problem.

7 NAO. 2010. Assessing the impact of proposed new policies. London: National Audit Office

Review and respond to change

4.10 We should be building flexibility into regulatory strategy to allow regulation to respond to change in healthcare. All sectors evolve over time, as a result of a range of different influences. Regulators must not be seen to be managing past crises while being ignorant of new evidence that should call for change. This is what we mean by agility. A programme of regular reviews, post-implementation evaluation and sunset clauses can all help here.

4.11 A framework of questions that captures these essential elements of the right-touch approach is shown in Annex 1. Annex 2 describes an example from our recent policy work, demonstrating how this concept and the question framework influence our approach and guide our analysis and recommendations.

5. The benefits of right-touch regulation

5.1 Right-touch regulation focuses on the problem, the outcome and the roles and responsibilities assumed by different agencies. It uses an evidence-based assessment of issues. It allows for an inclusive debate, not dominated by expertise about process, but informed by experience and evidence relevant to the outcome. The right-touch approach can be summed up as 'more insight, less oversight.'

5.2 In practical terms, the benefits 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 healthcare, 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, extending regulation to new groups
- Policy making is well informed, reflecting realities and the wider context, building on evidence and risk assessment.

5.3 We believe that this approach would also yield broader benefits. The analogy we drew above 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. Right-touch regulation forces us to be certain that the costs of regulation are worth the benefits they also bring. We recognise that over regulation is ineffective, and professional regulation must always be aware of its duty to be cost effective. While patients and the public have the right to expect high-quality healthcare, the cost of regulation is ultimately passed onto the public. Adopting the right-touch approach will help regulation maximise the benefits.

5.4 If regulation is to add real value, it needs to be ready to cooperate and collaborate for the health, safety and well-being of patients and the public. Allowing all parts of the system to play their full part can provide a more appropriate response to a problem. Alongside the regulators, employers, educators, individual professionals and their peer group, and patients themselves have particular roles and responsibilities to fulfil, as Figure 1 demonstrates.

5.5 Right-touch regulation is agile. Regulation works well when it is in touch with and up to date with experiences and real world practice. Regulatory approaches need to remain focused on delivering their objective in the light of change and in this respect wide-ranging strategic reviews are as essential as regular updates of standards of conduct and training. This position is inherent in our view that agility is a principle of good regulation and the need for review is built into our right-touch approach.

5.6 The right-touch approach can enhance trust and confidence. The impact of 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.

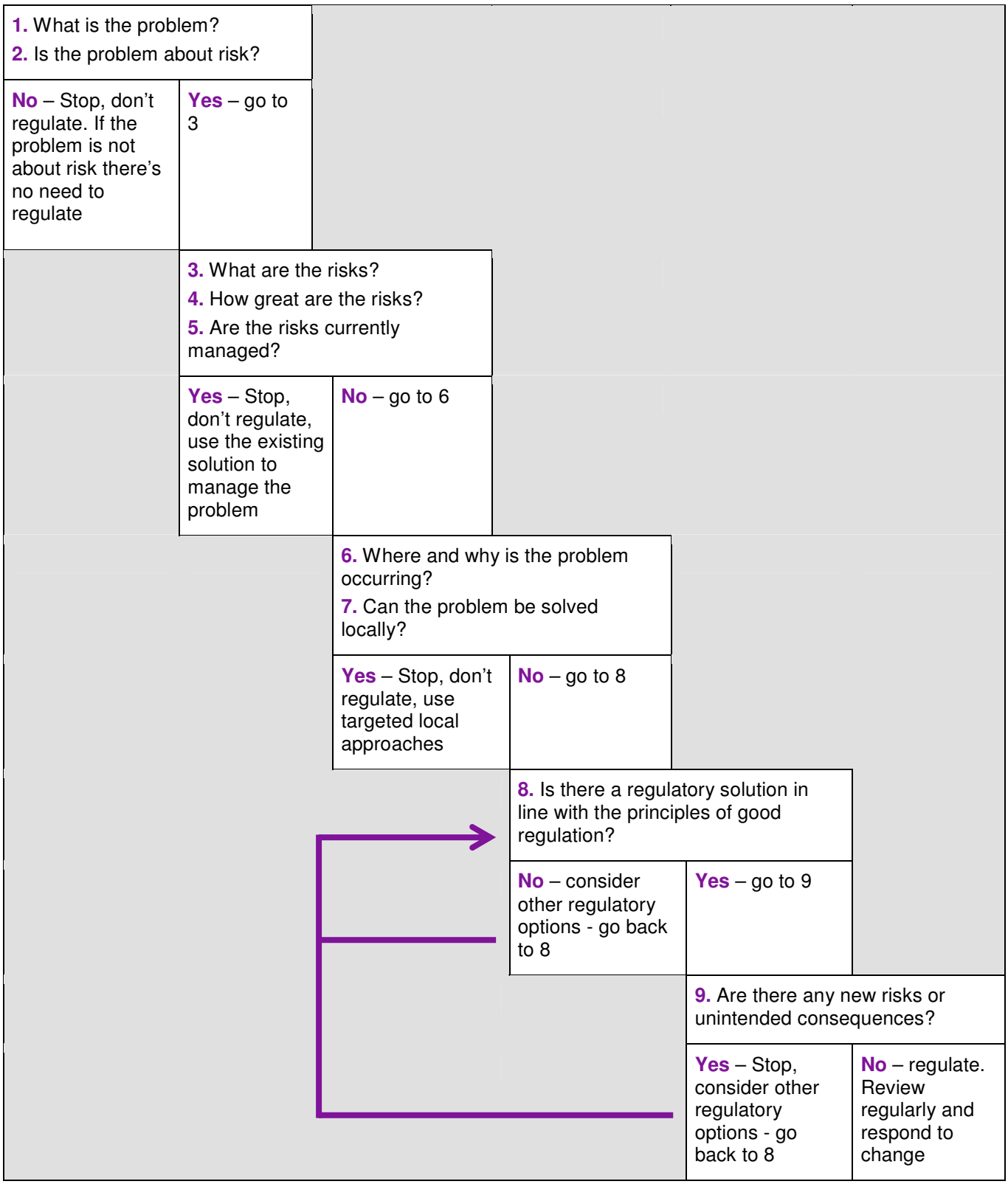
6. Conclusion

6.1 Right-touch regulation means always asking what risk we are trying to regulate, being proportionate and targeted in regulating that risk or finding ways other than regulation to promote good practice and high-quality healthcare. It allows the development of the appropriate contribution of the regulatory regime to the delivery of wider aims.

6.2 For CHRE, this aim is described in terms of the health, safety and well-being of patients and other members of the public, and through the work we do, the role we fulfil and the debates we engage in, we seek to promote right-touch regulation as a means of achieving regulatory excellence.[8] We believe this approach provides a valuable set of guiding principles to help regulation work efficiently and to enhance confidence in the contribution of regulatory systems to society.

8 We define excellence as the consistent performance of good practice combined with continuous improvement.

Annex 1: Right-touch regulation decision tree



Annex 2: Case study on managing extended practice

1. What is the problem?

There are occasions when registered health professionals extend their practice. This may be into areas overseen by other regulators, such as podiatrists undertaking surgery, or into currently unregulated areas, such as nurses performing acupuncture. A model of 'distributed regulation' was proposed to us to provide oversight of professionals in these circumstances. Under this approach professionals who extend their practice would be subject to a set of standards agreed by all the regulators.

The premise behind this proposal was that current methods of oversight for professionals who extend their practice are inadequate; and the distributed model could provide a form of assurance as an alternative to statutory regulation.

2. Is the problem about risk?

The model of 'distributed regulation' could appear to be shaped around the convenience of health professionals – as a means of avoiding costly dual registration – rather than about risk. We concluded that when a professional is operating in two distinct fields (for example, a nurse/physiotherapist, or a doctor/dentist), dual registration remains necessary. The remaining potential risks are outlined below.

3. What are the risks?

We identified two main areas of risk that might be associated with registered professionals extending their practice:

- Professionals might be unclear about the standards of practice that they should be working to
- Regulators might not be equipped to manage fitness to practise issues in areas of extended practice.

4. How great are the risks?

It is difficult to quantify these risks as they were not reported to us and we had no evidence to support them. Interrogation of CHRE's fitness to practise data did not reveal any specific issues, or a disproportionately high number of cases, for professionals in extended roles. We were provided with evidence of how regulators currently manage the risks as they arise. These are outlined below.

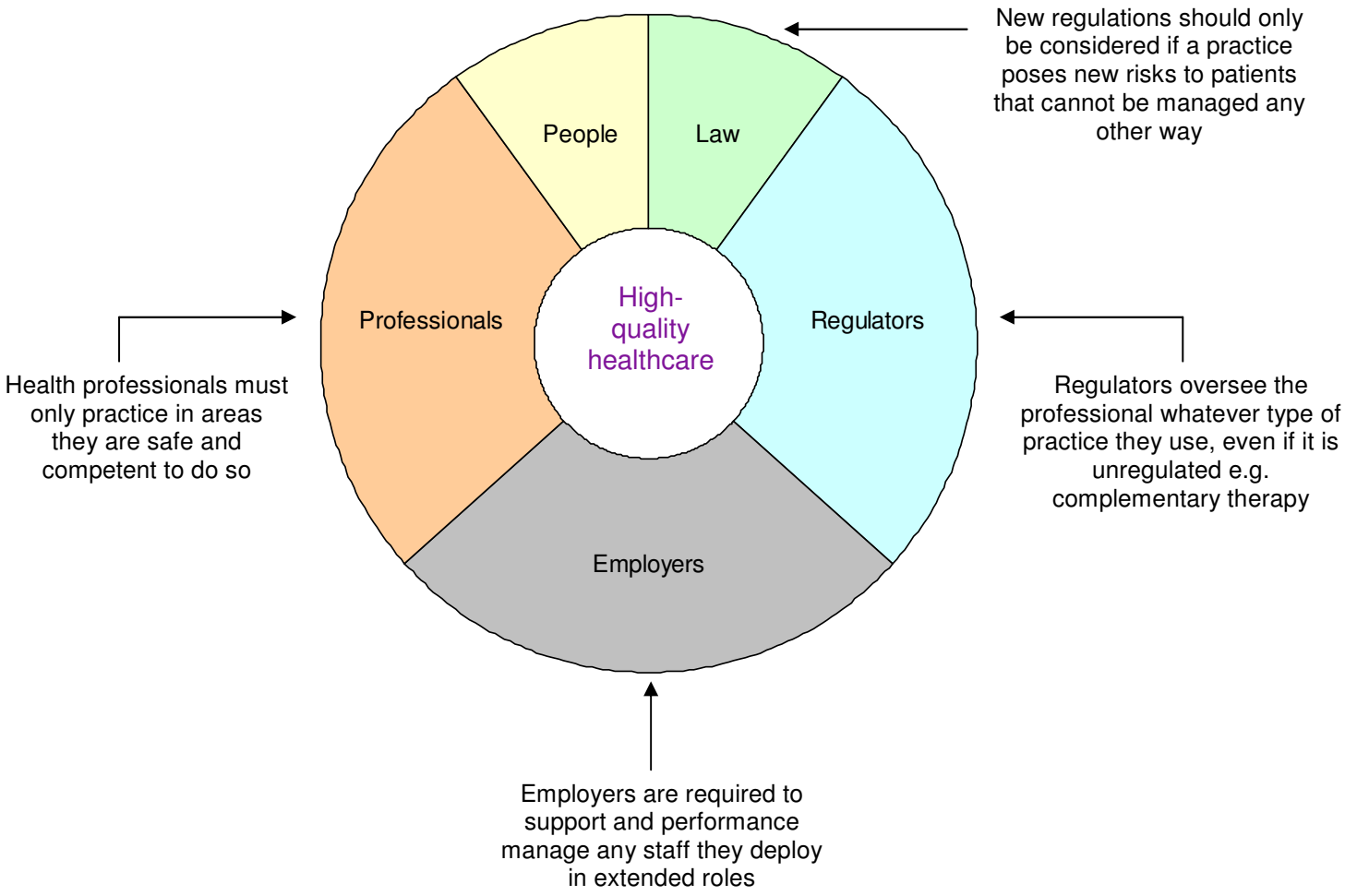
5. Are the risks currently managed?

We concluded that the broad areas of risk identified above can be managed with the tools already at the regulators' disposal, and there is no need to introduce additional regulation:

- Regulators currently seek expert advice in fitness to practise cases that involve areas of extended practice
- Regulators' codes stress that professionals must only practice where they are competent to do so. The codes still apply, even when professionals are using treatments in an unregulated area of practice.
- Regulators may create specialist lists or annotations to the register if there are extra risks to patient safety.

These mechanisms are complemented by the role of employers to support and performance manage staff in extended roles, and importantly by professionals who should only practice in areas they are competent to do so. Therefore we concluded that there was no need to introduce additional regulation.

Figure 2: ***Relative contributions of agencies to provide high-quality healthcare when professionals extend their practice***



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