Rethinking regulation

In this paper, we argue that regulation needs a radical overhaul if it is to support rather than stand in the way of the serious changes being proposed for our health and care services. We will not be able to change health and care unless we also change the way it is regulated. We need to apply right-touch regulation principles, to understand better what regulation can and can't do to control the risk of harms, to deregulate in some areas and focus regulation more effectively in others. We need to remove barriers between professions and create new roles. Health and care regulation is incoherent and expensive and there is little evidence for its effectiveness; if it was going to improve care it would have done so by now. It's time to rethink regulation.

August 2015

professional standards authority

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

Introduction

The regulatory framework for health and care is rapidly becoming unfit for purpose. The people who run regulation struggle to provide coordinated or coherent oversight of the delivery of care, despite their valiant efforts, because its parts are not designed to work together well.

The reforms of the past decade have seen considerable improvements made, in particular in governance, transparency and public involvement. Yet still regulation is asked to do too much, to do things it should not do, things it cannot do and things that don't need doing. It is expensive to operate but there is little evidence of its effectiveness and impact. It has grown out of the problems of the past, but needs to face the challenges of the future.

a more radical approach to regulatory reform is needed to meet the demands of health and social care in the future

Ahead are the massive challenges of a healthcare system creaking under the strain of an aging population, long-term conditions, comorbidities, the rising cost of health technologies and a global shortage of health and care workers. If health and care services are to be reformed in the way envisaged in many a forward thinking plan for service delivery across the UK, be it the *Five Year Forward View*[1] or *A Route Map to the 2020 Vision for Health and Social Care*[2], then UK health and care regulation must also be reformed.

The arrangements for the delivery of health and social care are changing and developing rapidly, but the regulatory arrangements do not have the agility to move with them. In the Health Foundation paper *Asymmetry of Influence*,[3] Douglas Bilton and Harry Cayton described the current arrangements in place for statutory regulation of health and care professionals:

'Nine organisations regulate health professionals in the UK and social workers in England. Some of these regulate single professions, while others regulate several occupations; some have enormous registers, such as the Nursing and Midwifery Council at nearly 700,000 and some are relatively tiny. The General Chiropractic Council for example, has 2,846 registrants. Some have been in existence for a long time – more than 150 years in the case of the General Medical Council (GMC) – while others are more recent creations. Most are UK wide bodies except for the General Pharmaceutical Council (Great Britain) and the Pharmaceutical Society of Northern Ireland. The Health and Care Professions Council (HCPC) regulates 15 health professions on a UK basis, and social workers in England only – Scotland, Wales and Northern Ireland each have their own separate social work regulators. The General Optical Council is the only body to regulate students, although social work students are regulated in Scotland, Wales and Northern Ireland. All of the bodies have a common set of functions yet there are differences in legislation, standards, approach, efficiency, amongst others.'

It is harder still to keep track of the total number of organisations involved in the regulation, inspection, audit and scrutiny of different aspects of health and social care services, from medical devices to health and safety in residential homes. This structure makes it almost impossible for members of the public to navigate their way through. The organisations themselves must divert their resources into attempting to manage numerous jurisdictional boundaries and attempts to work collaboratively become cumbersome and bureaucratic.

A proliferation of regulatory organisations inevitably impedes the pace of change and improvement across the sector. It also embeds operational inefficiency and unnecessary expense, as we have shown in our work on cost-effectiveness and efficiency, both in the UK[4] and Australia.[5]

There is no overarching design for these arrangements, nor any sense in which they have been fashioned to make them coherent or efficient. While the Law Commissions' 2014 draft bill[6] was a serious effort to simplify the regulators' underpinning legislative framework, it set out only to tidy up what already existed. It was not the Law Commissions' remit to challenge whether what exists is really fit for purpose. We have overseen professional regulation for the past 12 years, observed and engaged with system regulators in the UK, studied regulatory systems in other countries, and reviewed relevant research. We have noted the changes to health and care delivery, workforce demands and economic realities. We are now convinced that a more radical approach to regulatory reform is needed to meet the demands of health and social care in the future.

We believe that what is needed is a reassessment of the role of regulation in promoting safety and quality, followed by a deliberate and considered redesign of the institutions and processes of regulation. It should be focused on achievable outcomes, based on a sensible set of shared values and principles, and with a reasonable way of evaluating effects and impact. Regulation must be designed around the people it affects and in a way that protects patients and supports professionals, employers and other staff delivering care to achieve the standards required of them. This means that professional regulation cannot be reengineered in isolation; its reform will have ramifications for system regulators, product regulators and the organisations that deliver care, amongst many others. To attempt to redesign one element in isolation would only serve to perpetuate the unhelpful complexity. A coherent design needs to be drawn up with a rational implementation plan. The arrangements for regulation need to be made efficient, effective and adaptable for the years to come.

This paper sets out our thoughts on why this is the right approach to the reform of both professional regulation and system regulation in the health and care sector. We draw on a range of academic research and other evidence to argue for a greater focus on what works and on the reduction of harm. We set out why we think regulatory change is needed in the light of changes in the health and care workforce, including the breaking down of professional boundaries, wider societal change, and changes in the organisations that deliver care. We argue for a better understanding of risk and a consistent method for the assessment of risk to ensure that we are using the correct regulatory approach, including a wider adoption of our right-touch principles[7] for regulatory design.

We propose that there should be shared objectives between professional and system regulators, and as far as possible shared data and intelligence. We argue for a renewed focus on how regulators can support registrants' professionalism, and prevent them from being overburdened with rules and guidance to the detriment of performance.[a] We ask whether we need the large number of regulators that we have. We propose that regulators should shift the allocation of their resources to a greater focus on preventing breaches of standards. We set out our belief in the importance of clear governance,

[a] In Asymmetry of Influence: the role of regulators in patient safety, Health Foundation Thought Paper October 2013, Cayton and Bilton draw attention to the existence of 152 sources of published guidelines in NHS Library; 21 sources of guidelines for anaesthetists alone. At the time of writing DH had published over 3000 guidelines, NICE 1,000. p.5

purpose and objectives for a reformed sector. Finally, we set out what will need to be achieved to create a regulatory framework fit for future health and care services run by a flexible and diverse workforce.

What is the problem we are trying to solve?

As we have begun to describe, regulation as we know it today has evolved in a piecemeal fashion over the past 150 and more years. Economic regulation is as old as trade itself. We can trace the regulation of occupations back to mediaeval guilds, focused as much on the self-interest of the trade as they were on the quality of the service. System regulation perhaps has its origin in the various Factory Acts and Education Acts of the early nineteenth century, but the proliferation of regulatory agencies is a late twentieth century phenomenon. In 1945, Aneurin Bevan was clear it was the role of government to provide the infrastructure and resources and then make way for the health and care professionals to provide care.

Today, we have more than 20 different regulatory agencies overseeing health and care. Each new organisation, and each new regulatory intervention, has been created in response to specific stimuli without the benefit of an overarching design, a controlling intelligence, or a coherent set of principles. Regulation, which under the current system is an instrument of law and dependent on detailed primary legislation and therefore parliamentary timetables and legislative resources. It is slow and generally behind the trend, neither keeping pace with current changes nor anticipating future needs. It has led to a vastly complicated and incoherent regulatory system where the costs and benefits are unquantified and unclear. The different regulatory organisations, as we suggested above, have differences in legislation, standards, approach, and efficiency, amongst others.

Over the years that the Authority has been reviewing the professional regulators' final fitness to practise decisions, their caseloads have risen year on year. The Authority reviewed 590 decisions in 2004/2005 and 4,043 in 2014/2015;[8] this of course is in the context of a huge increase in complaints more widely in the health and care system. Investigating and hearing allegations that registrants are not fit to practise is the most expensive by far of the four main regulatory functions.[b] This is despite the fact that the percentage of registrants who are subject to fitness to practise proceedings is tiny.

We do not know, of course, whether all that would be of concern to regulators is being brought to their attention, and in this regard we are conscious of the report published by Healthwatch England in October 2014, which claimed that 'fewer than half of those who experience poor care actually report it'.[9]

Despite the fact that fitness to practise allegations are made against a small percentage of the total number of registrants, the continuing instances of harm to patients and the public resulting from unprofessional conduct is of great concern. The professional codes set out clearly the standards of behaviour that are expected and the guidance produced by regulators assists registrants in understanding how they apply to different situations. While our understanding of the circumstances in which care fails is improving, it is far from complete. To make it so, amongst other factors, we need a fuller understanding of the behavioural influence of regulators. The Authority has amassed a substantial body of

[b]The four functions are setting standards, keeping a register, quality assurance of higher education courses, and investigating and hearing allegations of unfitness to practise.

research on different aspects of regulation. Yet as Dr Oliver Quick of Bristol University wrote in his literature review in 2011 on the behavioural effects of regulatory activity and interventions on those regulated,[10] 'the most notable finding to emerge from this review is the shortage of systematic knowledge on the main research question. Few studies have directly addressed the question under review: how does professional regulation affect the behaviour of those subject to regulation?' We also need to understand more fully, of course, the circumstances that support the ongoing resilience of the vast majority of professionals.

As health and social care has changed, so have the expectations of the public of the institutions and people who deliver care. Yet, the current structures of professional regulation are based largely on a model of self-regulation by doctors created 150 years ago. They are based on the notion of a professional having mastery of a body of knowledge at a time when the corpus of medical knowledge needed was relatively small – and upon professional autonomy based on that knowledge. Professional autonomy was a privilege won through the mechanism of self-regulation.

However, no doctor today could master the entire body of medical knowledge, and nor are doctors any longer the masters in terms of commanding the delivery of care. This concept of professionalism – the autonomous self-managing expert – that underpins the self-regulatory model was rejected by the Royal College of Physicians in its report in 2005,[11] preferring instead a definition of professionalism expressed 'as a set of values, behaviours and relationships that underpin the trust the public has in doctors'. But still the older version of professionalism remains preserved in the way regulatory law is framed.

At a global level, the demands being placed on the health and care workforce are also unprecedented. In a 2013 report, the World Health Organisation (WHO)[12] described 'an ageing workforce with staff retiring or leaving for better paid jobs without being replaced, while inversely, not enough young people are entering the professions or being adequately trained. Increasing demands are also being placed on the sector from a growing world population with risks of noncommunicable diseases (e.g. cancer, heart disease, stroke etc) increasing. Internal and international migration of health workers is also exacerbating regional imbalances'.

The report predicted a global shortage of healthcare workers of 12.9 million by 2035. Dr Marie-Paule Kieny, WHO Assistant Director General for Health Systems and Innovation, said in the report that 'the foundations for a strong and effective health workforce for the future are being corroded in front of our very eyes by failing to match today's supply of professionals with the demands of tomorrow's populations'. In future, we can expect increasing mobility, both of patients in pursuit of care and professionals in pursuit of work.

The flow of health and care workers around the globe is mostly from low-income to high-income countries. A 2010 policy briefing for the Organisation for Economic Co-operation and Development[13] cited figures from the WHO and stated that of 57 countries with a critical shortage of healthcare workers, 36 were sub-Saharan African countries. As the briefing states, 'in less developed countries that have particularly high emigration rates, emigration contributes to exacerbate the acuteness of health workforce problems and further weaken already fragile health systems'. As the Ebola outbreak in Liberia, Guinea and Sierra Leone demonstrated, depleted health

systems faced with a crisis of this scale are then dependent on emergency intervention from the west and the heroic efforts of individual healthcare workers.

Within the UK, the continuing challenges facing the NHS were summarised soberingly by the NHS Institute for Innovation and Improvement (as was):

- 'The persistent gap between demand for healthcare and the resources available to meet these
- The need to move from a 'sickness' to a 'health' service
- Disparities in health profiles and outcomes for different geographical and social groups
- The co-existence of 'collaboration' and 'competition' in policy prescriptions and institutional arrangements
- The increasing demands placed on services by patterns of health and ill health, notably resulting from an ageing society
- The need to increase accountability to the public
- A workforce that are 'battle weary' following successive structural reforms.'[14]

Recently, Lord Rose in his review of leadership in the NHS[15] has written that 'the level and pace of change in the NHS remains unsustainably high: this places significant, often competing demands on all levels of its leadership and management. The administrative, bureaucratic and regulatory burden is fast becoming insupportable'. He observed that 'regulators appear to be in overdrive and whilst some of this is understandable there needs to be a renewed focus on the sharing of information between regulators and for their perspective to change to consider outcomes rather than inputs'. He found three areas of particular concern: first, the lack of a single vision and ethos; second, insufficient management and leadership capability to deal with the scale of change; and third, 'a need for proper overall direction of careers in management'. His findings are consistent with those of the King's Fund report[16] in 2011 which found that the NHS is over-administered and under-managed.

Care is delivered by teams of people, teams whose members constantly change, varying by shift, by procedure and place. Integrated care expands those teams still further. The volume of care needed and delivered has also expanded. We have few small, individual hospitals providing a relatively small range of procedures; instead, the delivery of care is a large scale, complex management operation, requiring expert managers. We need to ensure that we have the right balance of clinical and non-clinical management expertise, such that we do not deflect specialist clinical resources away from the direct provision of care unnecessarily.

In future, we can expect further changes in professional roles and boundaries, the introduction of new technologies and innovative treatments, a shift to more care being delivered in the community and at home, and increasingly shared responsibility for the delivery of care from individuals to teams. We can expect the delivery of health and social care to become more integrated. Within the UK, the changed political landscape may result in further divergence of the arrangements for the management and delivery of care. The *Five Year Forward View* explicitly promotes variety, while the continuing drive to cut costs will demand ever greater evidence of productivity and efficiency.

Added to this is the changing future pattern of demands on services. Some scientists claim that the knowledge that

will allow ageing prevention already exists, enabling a potentially massive extended human life span.[17] Yet, at the same time we are also told that by 2030 74% of men and 64% of women in the UK will be obese or overweight.[18] With predictions such as these, it seems inevitable that more, and more skilled, self-care and self-management will be the only way to meet the inevitable and inexorable increase in demand for health and care.

regulators should redefine the outcomes they are seeking to achieve and rethink how they will do so

We have outlined above in very general terms some of the factors that will affect the delivery, purpose and governance of regulation in the future. In the face of such change and uncertainty, it seems to us that regulation must first clarify and focus on its role. Too often we have seen examples of regulatory mission creep, where regulators have sought to expand the boundaries of their activity in ways that have resulted in confusion for the public and internal conflict of interest. As we wrote recently in our submission on a new merged Public Services Ombudsman, 'multiple roles within the same organisation can result in a loss of focus on core issues, internal competition for resources, and a diffusion of purpose and responsibility'.[19] We expand more on the issue of governance and purpose later in this paper.

With a renewed focus on its purpose, it seems clear to us that regulators (including inspectorates) should redefine the outcomes that they are seeking to achieve, and rethink how they will do so, based on evidence of what works, and drawing on a wide range of research and data.

A further area of work is the need for a fuller and more refined understanding of risk; the sector needs to develop a shared understanding of the risks that it is seeking to manage and the harms it is seeking to prevent. A coherent way of assessing the risks that arise from different kinds of professional practice, and a shared methodology for managing different kinds of risk, will be a crucial component of more rational regulatory design in future. This is the focus of the next section of this paper.

Risk and the regulation of people

The issue of risk in health and care is complex, possibly uniquely so. In the September 2014 paper *A continuum of safety models*,[20] Professor Charles Vincent of Oxford University and Professor René Amalberti set out three models of safety: first, the 'ultra-resilient model' that 'involves occupations in which seeking exposure to risk is inherent in the economic model of that occupation'; second, the 'high reliability organisations' model that typically applies 'to occupations in which risk management is a daily affair; though the primary aim is to manage risk and avoid unnecessary exposure to it'; and third, the 'ultra-safe systems' model that is 'completely procedural', and 'requires operators to be identical and interchangeable within their respective roles'.

The authors observe that 'some working environments have even more complex problems to solve since their activities cross the three models'. This is typically the case of hospitals and that 'healthcare is a fantastic model for studying safety, probably much better than any other setting, because all the complexity is to be found in the same place'.

We wrote in *Right-touch regulation* that 'Right-touch regulation is based on

a proper evaluation of risk'.[7] It should follow that the way in which our health and care professionals are regulated, the organisational and other arrangements, should accordingly be constructed on a proper assessment of the risks that arise from the practice of the different professions. In addition, the structures of regulation should provide different approaches for different levels of risk as they arise in the practice of different professions and occupations.

Calls for statutory regulation are often made by those referred to as 'aspirant groups', reflecting an out-of-date view that regulation is a badge of professional status and something to be achieved, rather than a system to be applied where risks justify its intervention. Whether and how a group is regulated should not be based on how successfully or how determinedly that group aspires to it. The decision should be based on what form of assurance is the right one for the nature of the risk of harm that the practice in question presents to the public. Statutory regulation should be preserved for those professions for whose practice it is the most effective risk management approach.

We should also be careful not to perpetuate the idea that the business of regulation is the elimination of risk as opposed to the reduction of harms. All health and care interventions have an element of risk which cannot be totally eliminated, without disproportionate input of time, money and effort. To eliminate all risk would probably also eliminate the possibility of any benefit for the patient. The total elimination of risk would also prevent beneficial innovation and the development and uptake of innovative practice and working. In rethinking their purpose, we believe that regulators should reopen a dialogue with their registrants and the public about the nature of risk in practice, and the regulator's attitude to risk.

Regulators should address the perception that regulation is an 'iron cage',[21] inhibiting professional judgement and standing in the way of innovation. It should set out clearly its role that of registrants and that of others in managing the hazards that inevitably arise from innovative practice.

The idea that risk of harm can be totally eliminated also threatens to corrode the trust that the public has in health professionals, organisations that deliver care, and regulators. As well as seeking to address the way they engage on risk with their registrants, regulators should also seek to renew their engagement about risk and uncertainty with the public, and seek to build relationships of trust with all of their stakeholders. In the face of disasters in health or elsewhere, media coverage and political responses can confirm the public's shaken faith in how safe services really are.

Yet, work in recent years on the public understanding of risk has brought science and statistics to bear to demonstrate new ways to understand and interpret uncertainty. For example, in an article in July 2014, Professor David Spiegelhalter of Cambridge University demonstrated how neither a cluster of aviation tragedies nor a cluster of cyclist deaths in London should of itself change our understanding of the risks involved in either flying or cycling.[22] Despite our emotional reaction to these awful tragedies, over the long term it would be unusual if we did not occasionally experience such clusters, and the fact is that in aviation at least there is 'a clear decline in the rate of accidents over the last 40 years'.

The last government's command paper *Enabling Excellence; autonomy and accountability for health and social care staff*[23] was one of the few attempts to

create an overarching and coherent policy for risk management in health and care occupations. In the paper, the government proposed a new approach to managing risks using accreditation of occupational registers, in addition to statutory regulation. Two years ago following the implementation of the Health and Social Care Act 2012, we began to accredit registers of those practitioners in health and occupations whose registration is voluntary – that is, where groups have self-organised to establish a register, identify standards for access, standards of conduct and competence for registrants, and complaints procedures. We have found accredited registers are an appropriate method to manage risk arising from those professions whose work results in less extreme risk of harm for patients and service users. As Bilton and Cayton wrote in *Finding the Right Touch: extending the right-touch regulation approach to the accreditation of voluntary registers*,[24] 'the scheme provides a proportionate method to provide the public with assurance that voluntary register holders are upholding standards of practice for groups of workers for whom statutory regulation would be unnecessarily burdensome and expensive'.

to regulate occupations that do not need it is inefficient and wasteful

Now that the system of accreditation is well established, there is a framework of assurance options available for different groups within the health and care workforce and a new flexibility and range of occupations to employ in the delivery of care. As the Authority has written recently in a report on the programme, 'accredited registers are a new approach to regulation – a solution designed for today's problems not yesterday's. It is less costly than statutory regulation, proportionate to risk, agile, swift and able to flex as needed to meet changing healthcare demands and delivery models.'[25]

Since establishing accredited registers, we have continued to develop our thinking on the idea of a range of approaches that are suitable to the level of risk that needs to be managed. In our paper titled *An approach to assuring continuing fitness to practise based on right-touch regulation principles*[26] we stated that 'we find it helpful to think of the range of possible continuing fitness to practise frameworks on a risk-based continuum, with those providing the highest level of assurance (for the highest-risk professions) at the top of the scale, and decreasing levels of assurance as the risk decreases.' More recently, we have developed the idea of a continuum of assurance, which demonstrates that as the level of risk increases, the 'regulatory force' required to manage that risk also increases (Figure 1).

We developed the idea of 'regulatory force' in our work on cost efficiency and effectiveness of regulators,[4] as a way to describe the increased quantum of regulatory intervention required as the risk and complexity of the regulatory task increases. The regulatory force required turns on such factors as the frequency and extent of harm linked to a profession and the type of allegations made about impaired fitness to practise and the maturity of the profession. As regulatory force increases, the cost of regulating will also increase. The regulatory task is also influenced by operational complexity, such as the number of education providers whose courses the regulator quality assures, the number of professions regulated by a single regulator and so forth. It follows from the concept of regulatory force that to regulate occupations that do not need it is inefficient and wasteful.

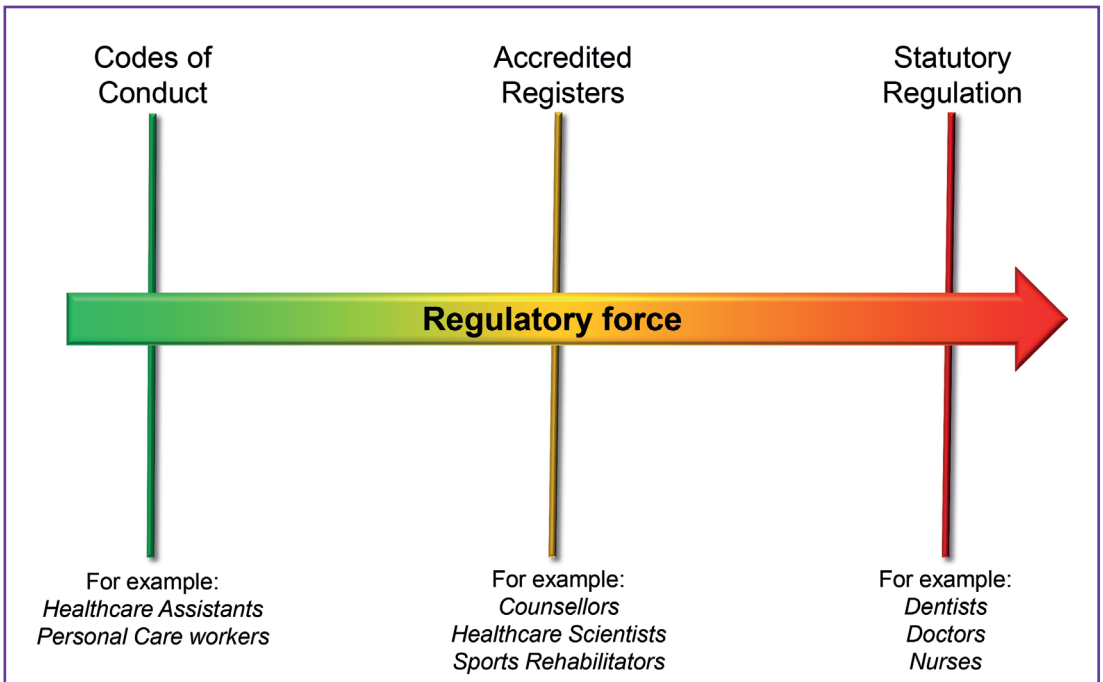

Figure 1. Continuum of Assurance.

Yet, when we talk of the level of risk that arises from the practice of each of the professions and occupations, we do not have a consistent way of assessing it, which we can apply to any or all of them. This seems to us to be a crucial missing element. How can we assess where an occupation or profession sits on our continuum, and thus the most appropriate means of regulating it, unless we have a way of assessing or measuring how risky their practice is, and how effective other contributors to risk management are? How can we feel confident that we are neither over- nor under-regulating particular groups? The lack of a proper and consistent mechanism for assessing which occupations should be regulated creates a vacuum in which decisions to regulate may be made as the result of political campaigning without any serious reference to public protection.

There are some good examples of risks from professional practice being thoroughly and carefully assessed and appropriate assurance put in place. For example, the *Report on the Regulation of Herbal Medicines and Practitioners*[27] this year gave careful and detailed consideration to the risks of practice and the legal and regulatory context. It recommended that 'it would be helpful for the sector organisations to develop an umbrella voluntary register that could support the development of standards and begin to collaborate on the collection of safety data and the establishment of an academic infrastructure to develop training and research. This voluntary register could in due course seek accreditation from the Professional Standards Authority for Health and Social Care'. This was the working group's considered conclusion instead of going to the unnecessary expense of

statutory regulation. By contrast, in the case of the small number of public health specialists, already covered by an accredited register, the decision to statutorily regulate was against the evidence of the existence of any risk for which statutory regulation was the appropriate instrument.[28] We note and welcome the fact that the government has yet to implement this decision.

We are currently working on a risk matrix. This matrix will help us to assess the appropriate level of assurance needed to protect the public. A benefit of such a model would also be the ability to reduce cost and increase flexibility by deregulating some occupations with no detriment to public protection, as well as to decide which new occupations should be regulated, if any.

The absence of a consistent risk-assessment methodology is manifest in the current structures of statutory regulation, as we described at the beginning of this paper. There is no rational or overarching design for these arrangements, based on risk or anything else; there is no consistently applied justification for why some occupations are in the statutory framework, and why some are outside it. Despite the commitment of successive governments to deregulation, once a health profession has become statutorily regulated it seems there is no going back. The UK is not unique in this; across Europe there are approximately 200 occupations that are regulated in only one member state.

While it may be true in a general sense that those professions that present the highest risk to patients are included in statutory regulation, it is also true that some of those that are outside statutory regulation may present a greater risk to patients than some of those that are inside. Under-regulation of risky practice exposes the public unnecessarily to risk of harm. However, it is also in everybody's interests that regulation is conducted in as efficient and cost-effective manner as possible. Over-regulation (either in the sense of regulating too many groups, or of excessively onerous regulatory practice) generates unnecessary costs without any additional benefit to the public. As a result of the potentially demoralising impact of over-regulation on professionals, in particular where regulation demands too much, it may in fact also expose the public to risk of harm. We discuss this in the next section of this paper.

As we develop our approach, as set out in *Right-touch regulation*[7], we are refining our evaluation of risk. One element of this is to assess the way in which risk has featured in regulatory policy in the past, and to take account of contemporary ideas, such as the work of Professor Malcolm Sparrow of Harvard University[29]. Sparrow 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 that 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.

We propose to make the way that risk informs regulatory development and improvement a major focus of our policy and research programme. This will include engagement with the sector in how a consistent method of assessing risk can be achieved, which can apply across professions and occupations, and how this in turn should inform the redesign of regulatory operations, processes and organisations. Professional regulation presents its own unique challenges as compared to the regulation of businesses, organisations or

systems, because it relates to people.

The relationship between professional and system regulation

Quality of care depends upon the work of the people who provide it, be that boards, managers, practitioners or other staff. The evidence of the link between the behaviour and competence of people providing care and the contextual environment in which they do so is now compelling, both from human factors research, but increasingly now also in terms of human psychology. It seems strange to us therefore that people are regulated separately from the systems and places in which they work.

If engaged staff provide better care as the evidence shows and if staff are motivated by their colleagues as evidence suggests, then the goal of good quality care is best achieved through developing positive cultures. It is time for a more nuanced, more sophisticated use of professional and system regulation working in concert to ensure that professionals are personally able to provide good care and are supported to do so within their workplace.

Currently, system regulation has if anything an even more confused role and complicated set of responsibilities than professional regulation. Over the years, since the creation of the Commission for Healthcare Improvement (CHI) in 2000, successive governments have merged, abolished, altered, added to and reconstructed the system regulators. As Sparrow has observed, the range of demands made of them are often contradictory:

- 'be less intrusive – but be more effective
- be kinder and gentler – but don't let the bastards get away with anything
- focus your efforts – but be consistent
- process things quicker – and be more careful next time
- deal with important issues – but do not stray outside your statutory authority
- be more responsive to the regulated community – but do not get captured by industry'.[29]

Devolution of health services within the UK has added complexity to regulation. While the professional regulators mostly have a UK mandate, pharmacy is separately regulated in Northern Ireland and social workers separately regulated in each of the four countries. System regulation is entirely devolved and the system regulators have very different mandates from each other.

In system regulation the challenge also lies in a lack of an agreed theory of regulation to underpin their activities. Are system regulators improvement organisations, inspectors or regulators? These are different roles and not easily made compatible. Added to which, although generally referred to as 'system regulators', UK regulators' remits have focused on individual organisations with only passing reference made to the wider system in which they operate.

In England, all three consecutive regulators, the CHI, Healthcare Commission and Care Quality Commission (CQC) were each established quickly, with little time for preparation. The CHI entered with a particular goal in mind: to raise the standing of clinical governance alongside that of corporate governance to ensure that quality was at least as important as finance. Its regulatory premise was that NHS Trusts with sound clinical governance systems and processes would provide good quality care. Investigation was used sparingly as a tool for improvement. Ultimately, however, lack of clarity over its goal, or at least a mismatch between the expectation of government

that it would operate as an Ofsted-style inspectorate and its own conviction that it should act as an agent for improvement, led to it being replaced by the Healthcare Commission.[30]

The Healthcare Commission's regulatory premise was three-fold. First, that its attention should be directed to areas of risk identified through data; second, that regulatory attention should be focused on whether boards were receiving sound and sufficient assurance to govern effectively; third, that investigation was a diagnostic tool for detailed analysis where failure was suspected.

Frustrated by the apparent persistence of poor quality care, the government sought to turn it from inspectorate to regulator, giving it enforcement powers and finally merging the Commission for Social Care Inspection, Healthcare Commission and Mental Health Act Commission into the CQC. Government has continued to add new responsibilities to the CQC.

As independent evaluations of the work of these bodies have shown, they have had a positive impact whether by causing organisations to get on with fixing problems already known to them or sometimes shedding light on poor practice.

However, a regulator's role is to minimise harm and to seek to do so by changing individual or organisational behaviour. It is not at all clear whether system regulators have improved the quality of care in a significant, sustained way, or if the benefit of this approach outweighs the very considerable costs.[c] In England, CHI's budget grew from £1.5 million to approximately £32 million in four years. The CQC's operational expenditure in 2014/2015 was £211 million[31] Wales, Scotland and Northern Ireland have their own regulators and inspectorates of health and care, including regulators of social care professionals. The most recent figures available online suggest a total annual expenditure of £89 million.[d] The 2014/2015 expenditure of the financial regulator Monitor was £72 million. The most recent calculation of the annual operating cost of the regulators overseen by the Authority was £195 million in 2010/2011.[e] Thus it is reasonable to assume that the current total annual operating costs of regulation are in the region of £600 million. This does not include the whole costs of compliance to the organisations they regulate. From the outset, organisations have complained that they are inspected and reported on too many times, by too many bodies all of whom require data in slightly different formats.

If what was being assessed genuinely drove improvements in outcomes and quality then that might be a price worth paying. As Professor Gwyn Bevan of the London School of Economics and colleagues said[32], 'what is measured starts to matter'. Wherever a regulator turns its attention, so will the organisations it regulates. That could be beneficial but it can also be an expensive and unproductive distraction. As a senior leader charged with turning around Mid Staffordshire NHS Trust once remarked, 'In their desire to become a Foundation Trust people thought they were working for the regulator and forgot they were working for

[c]The National Audit Office report published in July 2015 recognises that CQC has made 'substantial progress', but also states that it has a considerable challenge ahead to establish that it is effective and value for money, and recommends that it introduces benchmarking measures to assess its impact on quality and safety.[31]

[d]Figures for regulators in the devolved administrations are mostly from 2013/2014. Does not include the Care and Social Services Inspectorate Wales expenditure, which was not available at the time of writing.

[e]The Centre for Health Service Economics and Organisation calculated combined expenditure of the nine regulators overseen by the Authority for 2010/2011.

patients'.[f] When a regulator stands between care and the people it is for we have surely lost the plot.

Denmark has recently announced it is abandoning hospital inspection as being counterproductive to quality. A recent study of attempts to reduce adverse events in the Netherlands suggests that focussing on measuring the impact of specific interventions rather than attempting broad measures may be a better approach to evaluating attempts to improve quality.[33] The Dutch have recently piloted a new approach using self-assessment in which control of improvement is handed back to the professionals providing care, allowing personal ownership of change and local responsibility to trump a standardised approach.[g]

Added to which, there are now several sources of useful intelligence and comparators, which enable individuals, teams, and organisations to benchmark outcomes and quality and share ideas for improvement. These include Dr Foster, Health and Social Care Information Centre, NHS benchmarking networks,[34] QualityWatch[35] by the Health Foundation and Nuffield Trust as well as initiatives, such as IWantGreatCare[36]. Amongst the professional regulators the GMC and the NMC in particular have made some real advances in sharing intelligence with the CQC. As the National Audit Office states the CQC has made real progress with using intelligence to identify risk.[31]

The regulatory system has arrived at a point where it has some experience with using different regulatory techniques. However, there is still no firm evidence on which to base its decisions about what the goals should be, what to measure and no agreed way to evaluate the impact of regulation on quality of care.

We need learning environments in which staff feel engaged and empowered

As a consequence, the political system is getting increasingly anxious about lapses in quality without an objective way of assessing their significance. We observe with some concern contradictory messages about 'blame' and 'no blame' approaches. The recently published response to the Freedom to Speak Up Review is called *Learning Not Blaming*[37], but at the same time the government has passed legislation to criminalise 'avoidable harm'[38] and plans to do the same to teachers and social workers who fail to report a suspicion of child abuse. Evidence tells us that this is likely to undermine trust and frustrate the improvements needed to meet current and future needs; Berwick[39] and Keogh[40] each came to similar conclusions.

We need learning environments in which staff feel engaged and empowered to listen to their patients and users, make positive changes and have the confidence to innovate. We should not, however, be led to view this as 'going soft', to paraphrase Sparrow. The willingness of the UK health systems, and England in particular, to be self-critical and to subject itself to external assessments published in the public domain is a key strength. However, we should reshape our culture from 'blame' towards 'constructive mistrust'[41] – one in which

[f]Personal communication to the Chief Executive of the Authority.

[g]Dutch Healthcare Authority (Nederlandse Zorgautoviteit) - videoing handovers to improve information exchange and sharing them with the staff concerned (HCPC conference, 24 June 2015, Amsterdam, The Netherlands)

people take responsibility, as part of a team, for being vigilant about each other's work and speaking out in time to avert harm. The use of surgical check lists or structured dialogue between air traffic control and pilots are good examples of this technique in practice.

Our regulatory system should be redesigned to encourage and support people as individuals and as teams to drive achievement and improvement. We must seek to understand what motivates individuals, teams and organisations to succeed, not attempt to frighten them to resentful compliance. Regulators also need the freedom to determine the standards that matter and the approach needed to assess them.

Keogh laid out a useful blueprint for future methods[40]. In his diagnosis of the reasons for high mortality rates in 14 NHS trusts he picks out the following factors:

- '…these organisations have been trapped in mediocrity, which I am confident can be replaced by a sense of ambition if we give staff the confidence to achieve excellence'
- '…the use of patient and staff focus groups was probably the single most powerful aspect of the review process and ensured that a cultural assessment, not just a technical assessment, could be made'
- 'Finally…we convened a meeting of all…parties to agree … a coordinated plan of action and support to accelerate improvement'.
- He also advocates total transparency, boards that use information effectively, and overcoming isolation.

But a note of caution. It is the role of regulators to help in the task of shaping the health and care systems in a way that facilitates achievement and maintenance of standards of care – not to be responsible for their achievement or for improvement. Whether to meet the required standards or to exceed them, improvement is the responsibility and the ambition of boards, health and care professionals and staff.

It is the role of regulators to set standards and to check whether they are met. It is the regulators' role to identify barriers to the required standard of care, to remove those it can and recommend or negotiate the removal of others. 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. It also obscures achievement by pursuing continuous improvement rather than consistently measuring against a benchmark. It loses sight of the progress that has been made and becomes demoralised by the rediscovery of failure. We are seeing many moves currently that blur this boundary and in our view it is a mistake. The desire to make regulators responsible for improvement is triggered by an incomplete diagnosis of the problem of continuing lapses in quality.

We see this risk in the consultancy-like model adopted by the Solicitors Regulation Authority which advises legal businesses on how to meet its own standards thereby seeming complicit in success or failure; we saw it in moves by the NMC prior to 2012 to fill the role of a professional nursing body; we cautioned against it in the proposals in Wales to make the Care Council for Wales responsible for improvement as well as regulation;[42] and we may see it in the proposals to merge Monitor and the Trust Development Authority.

The desire to engage in improvement as well as regulation is also explicit in the CQC's strategy 2013/2016, where the CQC states its responsibility as to 'make sure health and care services provide people with safe, effective…high quality care and encourage care services to improve'.[31] This conflates its responsibility as a regulator with those of the organisations it regulates, which are themselves legally responsible for providing good care.[h] Similarly, the regulators in Northern Ireland, Scotland and Wales combine responsibility for both regulating and improving the quality of care within the same organisations.

It is important that we maintain the right balance of responsibility and accountability between individuals, teams, organisations, and regulators. The places and systems within which people work need to support them to practise safely and professionally over the long term.

Supporting professional conduct and behaviour: understanding what works

Regulators set out the standards that professionals are required to meet, both in terms of their competence and conduct. While we recognise and acknowledge the regulators' efforts to ensure that their standards reflect contemporary practice and the innovative ways they have sought to make their standards engaging for registrants, we have found little evidence that the standards have any direct influence on registrants' behaviour. The evidence that we have found, for example in the literature review that we commissioned from Quick[10], suggested that the regulator's standards are but one of many potential influences on day-to-day behaviour. It is almost certainly true that for working health and care practitioners other factors are far more compelling.

How regulation can become more preventative is now a common theme in regulatory development, at the sector's meetings, seminars and conferences both in the UK and internationally. We understand this challenge to mean, how can regulators, through their interventions and influence, reduce the prevalence of instances of noncompliance with their standards? Just as the *NHS Five Year Forward View*[1] calls for a 'radical upgrade in prevention' in public health, we believe that similarly regulators should aspire to a radical upgrade in their focus on preventative action. This challenge should continue to be at the heart of regulatory policy development, with a focus on defining the behaviour and other outcomes that the regulator wishes to see, together with an understanding of what interventions will support that behaviour being consistently and sustainably demonstrated by registrants. This may involve radically different interventions from those currently familiar to regulators. It should be undertaken with a focus on doing what works, and a readiness to stop doing what does not.

The successful adoption of a more preventative approach would have many potential benefits, the first of which of course would be the reduction of harm to patients. We have seen many cases where harm to patients has lasted for years, sometimes decades, this harm being compounded by their experience of complaints and regulatory processes. Registrants' careers and lives, and those of their families, can often be seriously and lastingly damaged too, sometimes by words or actions lasting not more than a few moments. The costs to colleagues and health and care

[h] The National Audit Office cautioned that until it sets specific targets or benchmarks, the Commission risks the public expecting it to be more a guarantor of quality and safety than is realistic (paragraphs 4.12 to 4.14).

organisations left to pick up the pieces are enormous and again often long-lasting.

With this objective in mind, two pieces of research recently commissioned by regulators in our sector are particularly important. The first is a research report published by the Health and Care Professions Council *Preventing small problems from becoming big problems in health and care*.[43] The report is about engagement and disengagement and its implications for understanding the competence of health and care professionals. The research was in two parts, the first of which was a literature review on competence by Professor Zubin Austin of Toronto University, and the second an empirical study of engagement and disengagement by the Picker Institute Europe. Both elements of the report provide 'insights into the triggers of disengagement and the ways in which preventative action might be implemented'.

In seeking to adjust their focus regulators must remember that their concern is not quality improvement but quality control

The second valuable recent piece of research was commissioned by the General Osteopathic Council (GOsC), and conducted by a team of researchers led by Professor Gerry McGivern of Warwick Business School. The paper titled *Exploring and explaining the dynamics of osteopathic regulation, professionalism and compliance with standards in practice*,[44] amongst many other findings that apply far more widely than osteopathy, outlined that there would be merit in creating what they called 'reflective spaces'. That is, spaces away from the regulator where professionals can discuss professional issues and problems freely with each other without fear of recrimination, and enquire freely of each other about any areas of concern. Like the HCPC's research, this idea has great potential in the prevention of small problems from becoming big problems, and we propose that further such research is pursued in other professional contexts.

That regulation should be targeted is one of the long standing principles of better regulation. But targeting presents problems in the regulation of people. An analysis of past fitness to practise cases would help us to identify categories of registrant who are in some way more likely to cause harm to patients than others. However, it may be discriminatory to target say, older practitioners, or single-handed practitioners on the grounds that they were statistically more at risk of error. By contrast, transparent publication of data by practitioners themselves, such as surgical outcomes published by the Royal College of Surgeons,[45] allows patients and clinicians to examine individual risk profiles for specific procedures. The point is that within any risk group there will be individuals who perform extremely well and those who perform badly. We need to find ways to get to the underlying hazard that creates the likelihood of harm in that group and to target that rather than the group as a whole. This is only one of several challenges which the policy ambition set out in this section poses to regulators. Each situation involving harm to patients turns on its own characteristics, many of which, although not all, are beyond the reach of the regulator.

The regulator cannot know the team dynamics of every situation, the family dynamics of the individuals involved and how it impacts on their conduct at work, or the ways in which those inhabiting a particular working environment are able to employ their knowledge of it for abusive or harmful purposes. It is just too great a wealth of rapidly changing, inscrutable and

personal information for the regulator to map or monitor meaningfully, much less to spot when in some way the different factors are at risk of creating a situation where harm will occur. Yet it is out of the unique mix of details like these that harmful situations arise. If as we discussed in the previous section, regulators' standards do not impact on their registrants, how can they exert influence over the registrants in such a close and personal way, as might be indicated by the HCPC's and the GOsC's research?

The challenge to regulators, of course, becomes one of delivery through others. Increasingly, the body of evidence suggests that it is the people who are working in and managing situations who are best placed to help the regulator achieve its purposes, by taking action when they see that harm has arisen, or by using their judgement and knowledge of their own workplace to identify risks, and to see when possibly quite subtle changes in the workplace might cause risks to materialise into harms. As the GOsC report suggests, this would be most successfully achieved where a culture has been created in which colleagues feel comfortable to question and challenge each other. One way, therefore in which regulators could deliver through others, is by mobilising their own registrants to act as their eyes, ears and agents on the ground – taking action to prevent small problems from escalating before any regulatory involvement is required. We do not underestimate the scale of the task involved in creating such a sense of collective responsibility for regulating.

The challenge of any intervention designed to maintain patient safety cannot be overestimated, whether that is at the behest of the regulator or anyone else. The dimensions of this challenge were set out in a paper by the Health Foundation[46] earlier this year. The paper argues that the health sector is less advanced than other hazardous industries in 'systematically understanding their work processes and the risks associated with them'. It sets out five management issues that act as barriers to progress in improving patient safety: inconsistent staffing; problems with support systems and structures; high workload pressures and multiple competing priorities; organisational and professional cultures; and a widespread lack of process design and standardisation.

In seeking to adjust their focus in the way that we have described in this section, regulators must remember that their concern is not quality improvement, but quality control. The interventions of regulators should have the common purpose of seeking to minimise risk to the public. The aims of regulation and quality improvement are complementary, and regulators should be careful to ensure that their own activities do not constrain innovation, but their own contribution must remain focused on their core purpose.

Governance and purpose

The governance of health and social care professional regulation has made significant advances in the past five years. As we observed in our paper *Fit and proper – governance in the public interest*,[47] the public interest has been manifest in these reforms. The size of the councils of the regulators has been significantly reduced, with equal numbers of public and professional members. The transparency of the appointments process to regulatory councils is also a significant achievement. We argued in our paper the importance of recruiting people with appropriate values to regulatory boards, as well as technical skills, to ensure that the focus of regulation remains firmly on the public interest.

We hope that these improvements will be sustained in the long term. The real and perceived independence of the regulator is as critical to public confidence as the skills and values of its governing boards or council are to its effectiveness.

The governance of the regulatory sector in future will call more than ever for agility – a quality that we added in *Right-touch regulation*[7] to the five principles of better regulation developed by the Better Regulation Taskforce.[48] Earlier in this paper we set out some of the challenges in the delivery of health and social care in the years to come. The different institutions who contribute to the assurance of public safety will have to renegotiate constantly with each other how their different areas of responsibility interrelate as the landscape of care changes, so as to avoid jurisdictional gaps or overlaps and the risks that would result – of harm to patients or wasteful duplication of resources.

A challenge to regulators will be to ensure that despite the changes that may occur in the regulated environment, the organisations involved will be able to continue to articulate the outcomes they seek to achieve. The structures and processes of regulation will need to evolve without compromising the outcomes, which are the business of regulators – patient safety and the public protection. The direction of the research that we have discussed in this paper and others suggests that to achieve positive behavioural change, change in the environment of care will also be needed – which will require professional and system regulators to work in collaboration to regulate for shared positive outcomes.

Professor Mark Moore of Harvard University coined the term public value to describe the value that a public organisation contributes to society.[49] He sets out a 'strategic triangle', the three points of the triangle being operational capabilities; public value; and legitimacy and support. He expanded the three points thus:

- 'First, what was the important 'public value' the organisation sought to produce?
- Second, what sources of 'legitimacy and support' would be relied on to authorise the organisation to take action and provide the resources necessary to sustain the effort to create that value?
- Third, what operational capabilities (including new investments and innovations) would the organisation rely on (or have to develop) to deliver the desired results?'[50]

The strategic triangle provides a framework for regulatory council (and boards) to conceptualise their task. The 'operational capabilities' point of the triangle relates mostly to the oversight of organisational performance. The 'public value' requires a council to ask itself, what is the value that the activities of the organisation are protecting or creating? How are we making the public safer? The 'legitimacy and support' point speaks to the need for a council to make sure that it retains the trust and respect of all of its stakeholders. This last point is possibly the most complex and challenging for the regulators' councils in future, since in an age of social media, trust and reputation can be destroyed in an instant.

Repositioning regulation

Where our current regulatory framework is generally successful in protecting patients and the public it is often against the 'iron cage' of its legislation rather than because of it. For several years the professional regulators have been asking for greater flexibility and freedom to innovate, but the promised revised legislation seems to retreat further and further into the future.

We now have an opportunity to make more radical changes to redesign health and care regulation as a whole. This will ensure that it is focused only on what it should do and can do so that we can hand back to people who work in health and care the responsibility and accountability for quality that is properly theirs.

Some important principles are becoming well established: these are the antiseptic power of transparency, a commitment to both personal and shared responsibility and a renewed engagement with patients and the public. While our regulators, along with other healthcare institutions, have taken on these principles and tried to put them into practice our overall approach to regulation remains well adrift from the right-touch principles that we articulated in 2010 and the better regulation principles adopted by successive governments.

As we have argued in this paper, regulatory intervention is seldom clear about the precise problem it is trying to solve, has limited methods for evaluating risk, invents new regulations instead of using existing tools, is overcomplicated and inflexible and ignores unintended consequences. A right-touch approach to regulatory problems has been applied by many regulators and indeed by government to policy decisions, but it has been done inconsistently thus adding to the feeling that there is no coherent intellectual underpinning, no theory of regulation, informing decisions about what, when and how to regulate.

We propose that to create a regulatory framework for health and care fit for a community based health and care service run by a flexible and diversified workforce, we need:

- A shared 'theory of regulation' based on right-touch thinking
- Shared objectives for system and professional regulators, and greater clarity on respective roles and duties
- Transparent benchmarking to set standards
- A rebuilding of trust between professionals, the public and regulators
- A reduced scope of regulation so it focuses on what works (evidence based regulation)
- A proper risk assessment model for who and what should be regulated put into practice through a continuum of assurance
- To break down boundaries between statutory professions and accredited occupations
- To make it easier to create new roles and occupations within a continuum of assurance
- A drive for efficiency and reduced cost which may lead to mergers and deregulation
- To place real responsibility where it lies with the people who manage and deliver care.

Some of this needs merely a change in thinking, a new attitude, a willingness to do less regulating and to take more responsibility for the quality our own work, our team's performance, our organisation's delivery.

Other changes will need legislation and a willingness to deregulate, and to sharpen regulatory tools where necessary. It will need policy makers and politicians to take a more considered response to problems of quality and the public to understand that no regulator can eliminate risk entirely. Regulation needs to be redesigned for the future of health and care not trapped in its own past.

If regulation was going to improve care, it would have done so by now

It is time for a more nuanced, more sophisticated use of professional and system regulation working in concert to ensure that professionals are personally able to provide good care and are supported to do so within their workplace. If regulation was going to improve care, it would have done it by now. So it's time to improve regulation.

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