The Health Foundation
Inspiring Improvement

Asymmetry of influence: the role of regulators in patient safety

Douglas Bilton and Harry Cayton

In this thought paper, Douglas Bilton and Harry Cayton discuss the relationship between regulators and those they regulate – be they people, places or products – and the impact this can have on patient safety. They propose that regulators should work together to create a regulatory system which minimises the multiplicity of different sources of guidance and direction, which is consistent and clear, and which can be seen to be a single regulatory force with different elements. By working together to create conditions which promote engagement with professional responsibility and identity, regulators can create a consistent regulatory system within which safe care can flourish.

The Health Foundation is calling for a stepwise change in thinking about patient safety. This paper forms part of a programme of work we are undertaking to help answer the question *How do we know care is safe?* We want to build on a culture that has focused almost exclusively on measuring past harm and enhance this to incorporate approaches to measurement that also establish the presence of safety.

Health Foundation thought papers present the authors' own views. We would like to thank Mr Bilton and Mr Cayton for their work, which we hope will stimulate ideas, reflection and discussion.

Thought paper

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Foreword

This paper follows from the Health Foundation's publication of a report by Charles Vincent and colleagues, *The measurement and monitoring of safety*.[1]

The report proposes a framework for safety measurement and monitoring (see figure 1 below) and we found the framework's five dimensions reflected in different aspects of the relationship between regulators and those they regulate – be they people, places or products – which were the subject of our current reflections. For example, the importance of clear guidance from regulators touches on the dimensions of 'reliability' and 'anticipation and preparedness', since the guidelines that are in place will impact both on the ability of organisations and individuals to offer high quality care reliably, and their ability to react quickly in response to new situations, problems and crises. The importance of being vigilant to registrants who have become disengaged from their professional standards speaks to the dimensions of 'past harm' and 'sensitivity to operations'. 'Integration and learning' encompasses the way in which standards, rules and guidelines are interpreted and implemented, which we think requires time, thoughtfulness and inclusiveness of all staff concerned. We are grateful to the Health Foundation for the opportunity to set out some of our thoughts in this area.

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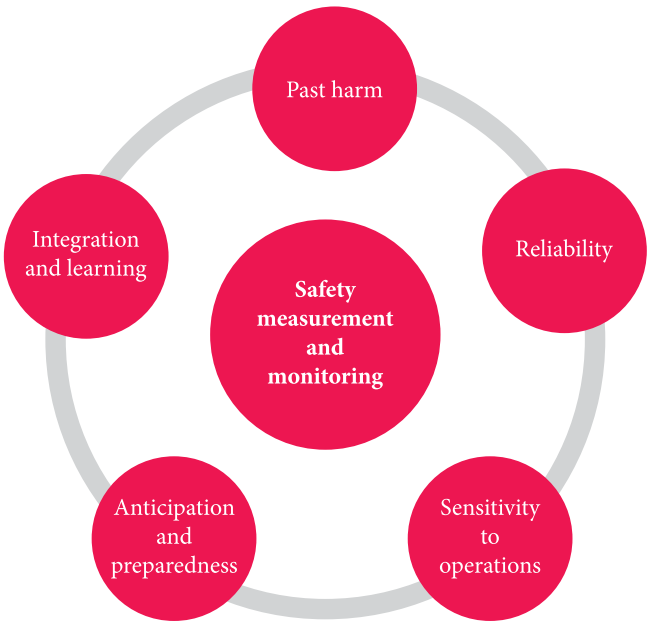
Figure 1: A framework for the measurement and monitoring of safety



Introduction

A promise to learn – a commitment to act, the report of the National Advisory Group on the Safety of Patients in England, led by Don Berwick, states that:

> *the current NHS regulatory system is bewildering in its complexity and prone to overlaps of remit and gaps between different agencies. It should be simplified.*[2]

There is no doubt that the structures of regulation are confusing; the activities of regulators are similarly so. The statutory bodies overseen by the Professional Standards Authority for Health and Social Care provide a useful starting point to demonstrate the complexity involved.

Nine organisations regulate health professionals in the UK and social workers in England. Some of these nine 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.[3] 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 much 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 and effectiveness, among others.

This complexity may be increased by the accreditation scheme for voluntary occupational registers.[4] Under this scheme, established in the Health and Social Care Act 2012, the Professional Standards Authority accredits registers of health and social care occupations that are not subject to statutory regulation. In an earlier article, we described how the process of introducing this scheme brought together for the first time the organisations which hold such registers into an identified group within the Authority's remit as accredited organisations, or at least potentially accredited organisations.[5] The scheme is not mandatory and, just as people in these occupations may choose not to be registered, the register holders themselves may choose not to seek our accreditation. Nonetheless, the scheme brings into the fold of consumer protection a large number of health and care occupations which have not previously been recognised in this way; by the end of 2013, the Authority expects to have considered applications for accreditation relating to around 70 occupational groups – more or less double the number of professions subject to statutory regulation. While we now arguably have a continuum of regulatory force from employer-led codes of practice, through accredited voluntary registration to statutory regulation, we have no consistent

application of risk in determining which occupations are subject to which level of assurance.

The sector which the Authority oversees is but one element of the wider arrangements for regulating care. In the past we have referred to these as the five p's: regulators of people, places, products, prices and procedures. Within the 'people' sector the bodies are (mostly) UK-wide yet, for example, the regulators of places (in others words, the 'system' regulators) are specific to the country of the UK in which they operate: the Care Quality Commission in England, Healthcare Improvement Scotland, Healthcare Inspectorate Wales, and the Regulation and Quality Improvement Authority in Northern Ireland.

We have attempted to map out the different regulators' roles and remits across the five p's, in order to elucidate gaps and overlaps and to, in some way, make sense of the inter-relationships between organisations. However, whatever map or model has resulted (be that a jigsaw or a London Underground style flowchart) they have faltered because the attempt to map comes to suggest that there is a degree of design and logic in the way that the institutions interrelate. This, in turn, suggests a coherent intention, which is false and misleading. In fact, these bodies have come into being at different times, under different governments, to suit different purposes without any overarching design, and the way that they do or do not relate to each other has been largely dependent on the organisations themselves building relationships with others where necessary or expedient, often driven by the efforts and leadership of individual members of staff.

From our position of oversight of the regulators we have sought to develop new ideas which can be applied across the sector and outside it, such as our 2010 paper on right-touch regulation (defined as the minimum regulatory force required to achieve the desired result).[6] We see quality as coming from a number of actors, working collaboratively: regulators, employers, professionals, people and the law. The specific contribution of any of these actors differs according to specific circumstances.

The practical consequence of the existence of so many different regulatory organisations is a plethora of sources of advice and guidelines to people and organisations on how to act, and how not to act, in particular professional situations. Guidelines may be produced by national organisations including the professional regulators, the National Institute for Health and Care Excellence (NICE), and professional associations. Employers will also produce guidelines and policies specific to their own workplaces. For example, in a 2011 article Jane Carthey and colleagues found that the NHS Library had a list of 152 publishers of guidelines and 17 references to guidelines about how to develop guidelines.[7] Their article pointed out that there are over 3,000 guidelines on the Department of Health's (DH's) website, and 1,000 on the NICE website. As an example, the article lists 21 professional bodies and national agencies who publish guidelines for anaesthetists. The authors conclude that:

clinical guidelines are undoubtedly an essential foundation of high quality patient care. However, their extraordinary and uncoordinated proliferation in the NHS confuses staff, causes inefficiencies and delay, and is becoming a threat to patient safety. We need to recognise the problems caused by current approaches and introduce greater rationalisation and standardisation at both national and local levels.

The Authority itself recently had cause to research the process of a doctor securing consent for use of an adult's tissue post-mortem. This was in order to contribute to a presentation entitled 'Finding a way through' for a seminar run with the Human Tissue Authority (HTA). While we found no obvious contradictions in the different guidance from the HTA, the GMC, the DH and the Department for Constitutional Affairs (as was), the mere existence of guidance on the same issue from different sources gave rise to doubt and concern that somehow something was being missed. To try and find a way through was like being a servant to many masters, trying to ensure that what seemed the right course of action would be acceptable to all, and possibly manipulating the situation to ensure that it was, given the subtly different ways that processes, principles and concepts were being described.

This is a recipe for moral and cognitive confusion. It is challenging enough to have to apply one set of guiding abstract principles to behaviour in a real-life situation. Ruthanne Huising and Susan Silbey describe:

the impossibility of perfect conformity between abstract rules and situated action, while nonetheless managing to keep practices within a band of variation surrounding, but not perfectly coincident with, regulatory specifications.[8]

How much more complex is it, therefore, to have to reconcile multiple guidelines and their differences in language, tone and style before deciding how to act in any specific situation? This may risk alienating professionals and cause them to disengage from the ethical decisions in front of them. It may also be true that the stress resulting from such moral confusion and cognitive overload is itself depleting and risks distorting professional judgement.

An asymmetry of influence

Further confusion arises from the asymmetry of influence on the workplace of different kinds of regulation. While the regulators of products, for example, can exercise direct control through the specification of the equipment that is used every day, the influence of the professional regulators on the behaviour of their registrants is far harder to determine – in terms of its nature, its scale and its outcome. In 2011, in order to begin to understand this relationship, we commissioned a scoping study from Dr Oliver Quick (Bristol University) on the effects of health professional regulation on those regulated.[9] Quick found that few studies have directly addressed this point. In the review, he identifies that regulation is just one among many influences on registrants' daily behaviour, judgements and decisions.

While he found that it is more likely that regulatory goals will be achieved where 'a number of sources of influence all nudge practitioners in the same direction', and regulation which has the buy-in of the regulated is more likely to be complied with, little is known about the nature or extent of the influence of the different regulatory forces. Other research among social workers by Dr Lel Meleyal (Sussex University)[10] found, among other things, that regulators' interventions may have perverse behavioural consequences, and that professionals' perception of the role and purpose of the regulator may be somewhat different from that which the regulator intends.

We also do not know how those different regulatory influences might fluctuate in different circumstances. In other words, in what situations might a registrant be mindful of the codes and guidelines of the regulator and in what situations might they not? It could be argued, for example, that a professional facing a dramatic ethical dilemma (when to use a 'do not resuscitate' order, for example) is far better supported and guided than when facing the smaller ethical dilemmas of daily work (whether to give one patient a glass of water, or to change the catheter of another, when both are urgent). Such acute ethical issues are the focus of professional training, ethical debate and of regulatory guidance. However, we have been very interested to learn of research being conducted at Staffordshire University, which we have been discussing with Derek Beeston and Dr Paul Kingston, into 'small ethics' – the fine but undramatic decisions and dilemmas of everyday working life, many of which have the potential to affect significantly the quality and safety of patient care but about which there are few sources of guidance and advice.

What seems clear is that professional regulation does not have the resources to lead the small ethical decisions of daily life – the regulator is never in the room. Even if regulators were able to exert behavioural control in a direct way, such power would not be without risks and undesirable consequences. Regulators and their registrants are engaged in a delicate balancing act between provision of guidance on the one hand and the exercise of professional autonomy and judgement on the other. In order to understand how regulation can use its power and influence most effectively, we need to seek to understand how it can do so from its position within the architecture of care, in a relationship with many of its registrants that is geographically and perhaps psychologically distant but a relationship which is, nonetheless, mandatory for all.

System, situation and disposition

In his book *The Lucifer effect*,[11] Dr Philip Zimbardo describes his 1971 Stanford Prison Experiment, in which a group of students were randomly assigned the role of 'guard' or 'prisoner' in a simulated prison. Within just one week the 'guards' were abusing the 'prisoners' to the extent that the experiment had to be terminated early to protect participants from harm. Zimbardo goes on to analyse the experiment and, in particular, to identify why it was that the

guards behaved in ways which were so profoundly inconsistent with their known previous conduct. In doing so, he looks at 'System', 'Situation' and 'Disposition', a framework which we think provides a useful focus for thinking about the place of regulation in influencing behaviour and ensuring patient safety in care settings – for influencing and supporting professional behaviour. 'System' encompasses institutional design, legislation, rules and guidelines, all of the conditions or precursors to 'Situations'. Within this, 'Disposition', of course, refers to the character of the individuals involved.

One of Zimbardo's main propositions is that in the analysis of situations that have gone wrong, too much focus is placed on the disposition or allegedly flawed character of individuals, often to little avail since frequently they have no previous history of misconduct or immoral behaviour. Without wishing to diminish individuals' personal responsibility for their actions (an important point that we will return to later), Zimbardo argues for a shift of emphasis onto situational and systemic factors. He argues that two conditions need to be present for evil to flourish: a combination of 'deindividuation' of perpetrators of abuses, together with 'dehumanisation' of the abused. When these factors are present, our moral compass can spin out of control. 'Deindividuation' can occur either when people are out of sight or beyond scrutiny, sometimes, perhaps ironically, because they are part of a group or team and thus lose a sense of their individuality and personal responsibility. 'Dehumanisation' occurs when the recipients of abuse are not acknowledged as fully human, or worthy of respect. The way that systems are constructed and governed, and the way that situations – workplaces – are managed, should be vigilant to the possibility that deindividuation and dehumanisation are present and should work to prevent the toxic mix which, according to Zimbardo, can result.

Zimbardo's findings are powerful but extreme and arise from a particular set of experimental conditions; we plan in the future to write in more detail on the extent to which they can be applied to understanding the reasons health and social care professionals abuse those in their care.

Closer to home, we were struck by a presentation made by Professor Zubin Austin (University of Toronto) in his keynote address in June 2013 to the Third International Congress of the Council on Licensure, Enforcement and Regulation. The subject of Austin's address was 'How competent are we at assessing competency?'. Given the complexity of what 'competency' means to different people or stakeholders (the patient, the practitioner, the regulator, the educator, the lawyer) he argued that instead of aiming to create competent practitioners, we should perhaps be seeking to create 'engaged' practitioners. He argued that 'those most likely to be deemed competent are those who:

- are connected/networked professionally
- express satisfaction with their career choice
- express satisfaction with their personal lives.'[12]

The converse, therefore, is that those deemed incompetent are most likely to be disengaged from their professional peers, from their careers or from their personal lives. Just as we recommended vigilance to the possibility of 'deindividuation' and 'dehumanisation' emerging, similarly we should be alert to signs of professional, social, or emotional disengagement; any such signs could be an early warning of practitioners at risk of delivering unsafe care.

Creating a consistent system: a framework for safer care

Zimbardo's concept of 'deindividuation' and Austin's of 'disengagement' both share the idea that risk arises when people do not fully occupy their professional role, or when they lose touch with their personal identity. When identity is lost, personal responsibility for one's actions is lost with it. In a professional setting, this is likely to result in a practitioner delivering unsafe care. In light of these ideas, we might want to draw parallels with care professionals not as the prison guards, but as themselves prisoners, subject to multiple, seemingly arbitrary and inconsistent orders, and thus becoming detached from decisions and judgements in which they should be fully engaged. How can care professionals be expected to assume full responsibility for their actions if the policies, regulations and guidelines governing their work and workplace are a haze of demands, orders and contradictions?

To seek to answer this question, in this section we will discuss how we think the regulators could work to create conditions which promote engagement with professional responsibility and identity, which focus not on their direct relationship with individual registrants, but instead, on working with other regulators to create a consistent 'system' or framework within which safe care can flourish, and which seeks to alleviate the moral and cognitive confusion which we have described.

We propose that the regulators should work together to create a regulatory system which minimises the multiplicity of different sources of guidance and direction, which is consistent and clear, and which can be seen to be a single regulatory force with different elements. In this way, we believe that regulators can exert beneficent influence on the behaviour of registrants from their position within the system.

Within the regulatory sector we have already seen initiatives that seek to create a regulatory system that is a consistent framework for safe care. For example, the HCPC sets out standards of conduct, performance and ethics[13] which apply to all of the 16 professions which it regulates, with additional guidance specific to each professional group. There is considerable diversity of practice across the HCPC's registrants yet the organisation has shown that core standards of professional conduct, performance and ethics can be shared across all of them – be they orthoptists or radiographers, psychologists or biomedical scientists, physiotherapists or hearing aid dispensers.

In some areas we have seen considerable efforts being made to map out the ways in which particular regulators across sectors

relate to each other, how their processes are potentially mutually informative, and how they could share information in specific circumstances. In some cases, this has resulted in agreement on a Memorandum of Understanding (MoU) between organisations, with protocols for information sharing and collaborative working of various kinds. Our concern, however, is that despite the enormous efforts and good intentions behind these agreements, they do not become embedded in everyday practice. This is probably not due to any lack of good intent, but because of the pressure on staff to deliver their day job first, and to think about collaborative information sharing second. We are not convinced that individuals' collaborative efforts are duly recognised and rewarded; without such an incentive, MoUs are unlikely to be enacted.

We believe that, before further efforts are made, a more radical project is needed, involving all of the regulators of care in the UK, be they regulators of people, places, products, prices or procedures. The aim of our envisaged project would be to identify a shared set of values of safe care on which all regulators can agree, expressed in a consistent language, style and tone. With such a set of values in place, it would then be possible to articulate, again in a shared language and tone, the specific contribution of each of the different regulatory bodies, and to begin to express regulatory requirements on both individuals and regulated organisations in a more consistent way. This would be a first step to achieving the regulatory system that we envisage, one which would provide a coherent ethical framework for safe care, and which would begin to alleviate the cognitive and moral confusion that we described earlier. Without this, we are concerned that future collaborative efforts will be built on weak foundations. Further to this there needs to be a review of who and where and what is regulated based on a proper methodology of risk and an understanding of whether or not regulation is the appropriate tool for improving quality.

One of the roles specific to professional regulators, as we have set out, is to articulate to their registrants the standards, responsibilities and behaviours that together constitute safe practice. With a set of shared values in place across the regulatory sector as a whole, together with agreement on the contribution of the different parts, a next step within professional regulation would be to define a shared, core set of standards of conduct and ethics across all care professionals. These standards would apply both across professions, and across different sectors and workplaces. They would not differentiate between work in the independent sector, as a private contractor, or as an NHS employee.

Creating safer organisations

While the responsibility of regulators is to provide assurance that registrants meet their standards and are therefore capable, the role of employers is to monitor and support a registrant's competent performance in a particular role. Regulators should set a consistent framework within which organisations and individuals manage

and realise safe practice, delivery and performance. If regulators were to establish a common and consistent ethical framework in the way that we have described, the role of organisations delivering care would then be to create within that framework workplaces where the right and safe thing is easy to do.

Organisations should be responsible for creating a culture of shared problems and learning, where transparency and candour are valued. In this ideal environment, care professionals and other colleagues would feel comfortable and safe to make a full contribution to team work and would also feel confident in raising concerns, whatever their place in the hierarchy and without fear or deference to others of supposedly greater power or status. The way in which rules, guidelines and policies were interpreted and implemented would be discussed by all concerned, and time would be given to do so thoughtfully and considerately.

We were struck by the idea of 'slow ethics' proposed by Dr Ann Gallagher as an antidote to what she describes as a 'moral winter'.[14] She writes that slow ethics:

> *would require the institutionalisation – indeed normalisation – of space, time and coaching so that people more fully understand the implications of their actions and omissions; actions and omissions that can result in distress, humiliation and even death. It would go beyond performance management that focuses on technical competence, and instead engage meaningfully with humanistic dimensions of practice.*

While we agree with the findings of *A promise to learn – a commitment to act* that fear in the workplace is 'toxic to both safety and improvement', nevertheless, we believe that it would be counterproductive to seek to diminish the sense of personal responsibility for error. To seek to remove personal responsibility risks deprofessionalising highly skilled people and creating an environment where inappropriate risks are taken. As Dr Kaveh Shojania and Professor Mary Dixon-Woods state:

> *there can be no doubting the ongoing need to tackle the multiple deficits in how healthcare systems are designed and organised. Encouraging examples of just how much safety and other aspects of quality can be improved by addressing these problems continue to appear. Yet, recent years have seen increasing disquiet at how the importance of individual conduct, performance and responsibility was written out of the patient safety story… we need to take seriously the performance and behaviours of individual clinicians if we are to make healthcare safer for patients.*[15]

Personal responsibility is a central tenet of professionalism and an important motivator of safe practice. Part of this responsibility is the appropriate management of risks and taking risks; we should seek to understand better the place of risk taking in individuals' engagement with, and interest in, their work. This will include looking at how the enjoyment of risk can motivate individuals to act against the interest of patients, for example in cases of theft, dishonesty and boundary violations.

Concluding remarks

The ambitious vision that we have described cannot be achieved without a concerted effort on the part of all regulators to identify a common set of objectives and values, and agreement on a shared model of regulation. As we have set out, a next stage would then be for regulators to seek to articulate their individual contributions in a shared language, such that these can be seen to be part of a greater whole. This course of action, we believe, would help to maximise the contribution that regulators can make from their place in the system that governs the way that care is delivered in the UK, and which will help to bring about the behaviours that they require of their registrants. All too often any attempt to achieve this by regulators and those they regulate is destroyed by short-term political intervention. Politicians of all colours constantly call for 'an end to red tape' while simultaneously passing legislation to support the red tape industry; contradictory orders to the guards abound.

However, we do propose that regulators should work with employers, occupational associations and others who are closer to the delivery of care to seek better understanding of the full range of factors that influence care professionals' behaviour in work. Through this essay we have touched on just a few examples of academic research that we think provide valuable insights. We believe that there is enormous potential for further research, and indeed for applying what is already known in social psychology and the behavioural sciences, to achieve a better understanding of care professionals' behaviour and, in particular, to identify those professionals who may pose an unacceptable risk to patients. Better understanding will, in turn, help in identifying more effective strategies to manage that risk; this too will involve considerable application and commitment to working across organisational boundaries in pursuit of safer care.

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