# Rapid literature review on effective regulation: Implications for the Care Quality Commission

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# 1 Introduction

This report presents the findings of a rapid literature review on what constitutes effective regulation. The review has been conducted to inform development of the Care Quality Commission's forward strategy.

To answer the overarching question of what constitutes effective regulation, the following sub-questions were set:

a) What activities are available to regulators in undertaking their role?

b) What theories, frameworks and models are used to help understand the role and effectiveness of regulatory activities?

c) What intended and unintended impacts does regulation bring about?

d) Which regulatory activities have the biggest positive impact in different contexts?

e) What factors help contribute to or inhibit effective regulation?

We present what the literature says in answer to these questions in the findings section. In the discussion section, we look at the implications of these findings for CQC, before bringing together the main areas of learning in the conclusion.

# 2 Approach

The approach for the review was designed to allow for rapid knowledge synthesis over a one-month period between December 2019 and January 2020. These timelines meant that we could not carry out a full systematic review. Rather, the review used a 'berry-picking' approach to identify appropriate literature (Bates, 1989). This is an iterative approach to discovering the most appropriate publications, rather than using defined search terms to identify a complete body of material to review. Such an approach has been found to be more effective and offer better value than searching bibliographic databases (Cooper *et al*., 2016).

In line with this approach, we began by undertaking a citation search using Google Scholar of 'seed publications'[1] identified in consultation with the academic advisor for the review as likely to yield relevant studies. Search results were then refined by searching for 'healthcare impact' to identify the most relevant publications. Of the

[1] Seed articles:
Ayres, I. and Braithwaite, J., 1992. Responsive regulation: Transcending the deregulation debate. Oxford University Press, USA.
Brubakk, K., Vist, G.E., Bukholm, G., Barach, P. and Tjomsland, O., 2015. A systematic review of hospital accreditation: the challenges of measuring complex intervention effects. *BMC health services research*, *15*(1), p.280.

remaining articles, an initial review of titles (and abstracts) was undertaken to further refine the list to those clearly related to one or more of the review questions. Articles were also excluded if they related to non-OECD countries, were not available in the English language, or not accessible through either Google Scholar or OpenAthens Portal for the NHS. This identified 54 publication for review. While the review approach meant that much of the literature pertained to the health and social care sectors, articles relating to other sectors were included so long as they helped answer the review questions.

An iterative approach to exploring themes and patterns and filling knowledge gaps was then employed through:

- following up on citations within reviewed publications
- searching for citations of reviewed publications
- searching for publications for cited authors
- identifying gray literature, including through engagement with other European health and care regulators
- including publications known to the reviewers.

This identified a further 42 publications and documents for review.

All relevant information contained in the reviewed literature was extracted and recorded against the questions set out in the appendix. Throughout the review process, regular teleconferences involved members of the review team and the academic advisor to help ensure a common approach to assess article relevance, extraction and recording of information, and to begin the process of identifying themes.

The academic advisor provided advice on identifying literature for inclusion in the review and on the approach to recoding findings from reviewed material. He undertook a quality assurance check during the review process to ensure reviewers were identifying the most appropriate findings from reviewed material and provided feedback to inform the forward process. He also carried out further quality assurance checks during the reporting stage to ensure the quality of synthesis and reporting of review findings.

## 2.1 Limitations and mitigations

The approach taken means it is not possible to draw conclusions about the full body of evidence on the effectiveness of regulation.

By beginning with seed articles, it is possible that bias was introduced towards literature that began from a theoretical perspective similar to those proposed by the

seed articles authors. The choice of seed articles may also have been biased towards literature that had a theoretical base, rather than being purely empirical. However, these risks were limited by the inclusion of a systematic review as a seed publication. Taking this approach also made it easier to assess the relevance of the findings to CQC, which was an important consideration for this review. The reviewers also identified critique, as well as acceptance, of the theories and models espoused by the seed publication authors within the reviewed literature.

Both the language and practice of regulation varies significantly by context, sector, and country, with both the terms used, and what is meant by those terms, differing from setting to setting. This places limitations on the applicability of some of the reviewed literature. To mitigate this, we have sought to use author definitions to determine inclusion or exclusion for consideration of described activities, based on how comparable or applicable they are to CQC's regulatory activities and context. We have therefore defined our terms for the purposes of the review (see section 2.2), and mapped activity described in the literature against these definitions as far as possible. We applied caution when drawing conclusions from literature that was only partially relevant to CQC's context.

We did not set specific exclusion criteria for this review based on methodological approach or standard. This means there was heterogeneity in approaches taken by reviewed publications and varying methodological rigor, validity and generalisability. Such an approach is appropriate for a complex intervention such as regulation, which has multiple interacting components and is affected by a variety of contextual factors. What is most important in this situation is to focus on the relevance of the study to the review questions and to factor any limitations of the reviewed literature into the conclusions drawn in this review.

## 2.2 Defining our terms

**Regulation:** A process for assessing or analysing the delivery of defined activities against a framework of ideas or standards based on evidence and widely accepted good practice in relation to quality. It may involve a range of other activities as defined below.

**Published standards:** Expected level of quality or performance in defined areas of practice, which may be used as a framework for assessment. Comparable activities may be termed: assessment framework, standard-setting.

**Registration:** A process through which an organisation is permitted to undertake specifically sanctioned activities, usually following some sort of assessment that they are capable of meeting certain standards. Comparable activities may be termed: certification, licensing.

**Ongoing information gathering:** This is an ongoing process of gathering, monitoring and analysing data to track performance within a regulated organisation. Comparable activities may be termed: monitoring, risk assessment.

**Point-in-time assessment and reporting:** A process in which characteristics of an organisation, and/or the activities it performs, are assessed or analysed at a point in time against a framework, standards, or measures. This assessment is undertaken by an external body for the purposes of assuring quality and performance. This may involve reviewing the latest performance data, gathering other data, and/or a site visit to the organisation to assess performance. It will also usually involve some form of reporting of the findings and outcomes of the assessment. Comparable activities may be termed: inspection site visits and reports, observations, surveys, accreditation visits, supervisions, information gathering, reviews.

**Improvement activity:** Any activity intended to support improvement. Comparable activities may be termed: behaviour modification, encouraging improvement, support, education, action planning, capacity development, culture change.

**Ongoing relationships and engagement:** Regulatory staff formally or informally meeting with regulated organisations to either monitor performance and quality, or to engage in improvement activity.

**Enforcement:** Tacking formal action to either change or prevent poor practice. Comparable activities may be termed: warnings; (financial) sanctions; preventing or limiting an organisation from delivering core activities; prosecution, withdrawal/cancellation of registration, licence or certification.

**Published information, learning and best practice:** This may include publishing aggregate findings of quality within the regulated sector, or an aspect thereof, and/or published guidance on the delivery of the activities sanctioned or regulated.

# 3 Findings

## 3.1 Theories, frameworks and models for understanding regulation

Theories of regulation and organisational behaviour can help in designing systems of regulation by helping regulators to be more mindful of how and why they are undertaking specific activities and the outcomes and impact they expect to occur because of these activities (Walshe *et al.*, 2007). This section explores some of the most prevalent theories, frameworks and models within the reviewed literature.

### 3.1.1 Responsive regulation

Ayres and Braithwaite (1992) developed a concept of ‘responsive regulation’, which asserts that the type and scale of regulatory response should be dependent on the motivations, actions, and behaviour of the regulated organisation.

Neilsen and Parker (2009) describe responsive regulation as "the most sustained and influential account of how and why to combine deterrent and cooperative regulatory enforcement strategies" (Neilson and Parker, 2009: 377). The aim of responsive regulation is to support the regulated organisations to improve and perform well by creating a balance between punishment and persuasion, where the regulator chooses the appropriate mechanism depending on the circumstances and motivations of the regulated organisation – rewarding compliance and issuing greater sanctions in response to non-compliance (Ayres *et al.*, 1992; Walshe, 2003; Braithwaite *et al.*, 2005; Wiig, 2008; Neisen *et al.,* 2009; Muscini, 2013; Spronk *et al*., 2019).

This balanced approach is supported by the concept of an ‘enforcement pyramid’, where there is a space for regulated organisations to voluntarily comply and engage in self-regulation at the base of the pyramid, but with ever increasing levels of external regulatory intervention, the higher up the pyramid you go (Ayres *et al.*, 1992; Braithwaite *et al.*, 2005; Seddon, 2013; Muscini, 2013; Healy, 2016a). For the pyramid to work there needs to be a genuine threat of sanctions:

> *“An essential element of responsive regulation is that a regulator must have the capacity to escalate upwards if necessary from soft words to hard deeds. Those being regulated must believe in the inexorable nature of sanctions, as polite requests followed by threats only work when everyone knows that sanctions will follow non-compliance. Responsive regulation argues that stern sanctions must loom as a threat in order to ensure that people comply with softer and more conciliatory approaches."* (Healy, 2016a)

By creating this balance, proponents of responsive regulation contend that the regulated organisations will have a better experience of regulation, view the regulator more positively, and be more compliant with the standards set by the regulator (Ayres and Braithwaite,1992; Neilsen *et al.*, 2009).

The idea of responsive regulation proposes ‘tripartism’, where the regulatory process should involve not just the regulator and the regulated, but also other stakeholders. In this context other stakeholders’ cooperation and engagement with each other, including the public and other organisations, is important. They can act as informants, put pressure on the regulated organisations, help ensure compliance, support improvement, and guard against regulatory capture (whereby the regulator begins to over-identify with the perspective of the regulated, rather than remaining focused on the interests of the people using the regulated services) (Ayres and Braithwaite,1992; Wigg, 2008; Bouwman, 2016).

Despite the pervasiveness of the concept of responsive regulation in the literature, a number of studies have demonstrated the challenges associated with instituting a flexible approach in practice. These include challenges with:

- developing regulatory staff with the appropriate level of skills
- requiring information that may not be available
- consistency, with considerable differences having been found between regulatory staff and teams with respect to their regulatory style and the regulatory action they considered most suitable in a given situation
- regulatory staff correctly interpreting the intentions of the regulated organisation and, in turn, the regulatory staff being able to communicate their intentions in a timely manner and in a way that is understood by all the actors within the regulated organisation who need to respond
- re-building trust after enforcement action has been taken (Neilsen *et al.*, 2009; Mascini, 2013; Walshe *et al.*, 2013; Beaussier *et al.*, 2016; Rutz 2017).

Given these challenges, for responsive regulation to work effectively, regulatory staff need to be expert communicators and have strong relational skills to be able to convey complex messages and to understand what is going on within the regulated organisation so that they can move up and down the enforcement pyramid appropriately (Neilsen *et al.*, 2009). Many of these challenges, and approaches for addressing them, will be dealt with in greater detail later in this review.

### 3.1.2 Risk regulation regimes

Much of the literature conceives regulation as a means for managing and responding to risk (Wigg, 2008). The “Risk Regulation Regime” (RRR) perspective proposed by Hood, Rothstein and Baldwin (2001) does see this as the role of regulation, but they also seek to place regulation within the ‘regime’ in which it operates. In doing so, Hood *et al.* recognise a complex range of factors that affect how risk is conceived, perceived, and regulated within a system of interacting and related parts. This context “denotes the backdrop of regulation, comprising, for example, the intrinsic characteristics of the problem it addresses, public and media attitudes about it, and the way power or influence is concentrated in organized groups” (Hood *et al.*, 2001:28). They are interested in the activity of the individuals within the regulated organisations, and the activity of those setting standards, as well as the relationship between the two.

In conceiving regulation as a ‘regime’ Hood *et al.* describe how multiple regulatory actors can influence risk within a given system. So, for example, within health care, the system can be conceived as all of those involved in regulating risks to patients, including the professional regulator, the drug or device regulator, and the organisational regulator. They suggest it is important to consider these “nested” regulatory influences when trying to understand what is going on and to take account

of the relationship between different parts of the regulatory system. In doing so, they argue that if you only focus on the 'standard-setting' aspects of regulation you will miss much of the activity which those standards instigate and the way in which they may influence and modify the behaviour of different actors in the system. You may also miss how factors other than the standards set by regulators can influence behaviour and the need, therefore, to consider multi-casual explanations for what is happening on the ground.

Proponents of the RRR draw on *cybernetic thinking*, which contends that any control system, such as regulation must have a minimum of three components;

> *There must be some capacity for standard-setting to allow a distinction to be made between more and less preferred states of the system. There must also be some capacity for information-gathering or monitoring to produce knowledge about the current or changing states of the system. On top of that there must be some capacity for behaviour-modification to change the state of the system.* (Hood *et al.*, 2001:23)

To work effectively, each of these components must have a sufficient variety of options to respond to an assortment of environments they need to operate in.

### 3.1.3 Quality improvement cycle

Shaw *et al.* argue that "external assessment strategies are built on the idea of a quality improvement cycle" (2019:10). As with the cybernetic thinking within the RRR perspective, this model also illustrates the need for both (1) standards setting, and (2) a reliable point-in-time assessment of whether organisations adhere to those standards, if improvement is to be achieved. However, rather than focusing on the ability of the regulator to achieve behaviour modification, this model stresses the importance of an organisation's improvement capability and capacity to respond to the point-in-time assessment. This includes the ability of staff to draw appropriate conclusions in response to the assessment and to implement plans to improve. In so doing, this model, like both the responsive regulation and RRR approaches, recognises that regulatory impact relies on both the regulator and the regulated, and the relationship between them.

### 3.1.4 The life cycle model

The "life cycle model" proposes that there are a number of phases to an organisation's response to standard setting and having a point-in-time assessment. In the first phase of the life-cycle the organisation is becoming acquainted with the standards and there is a gradual improvement in the organisation's compliance with them. In the second phase, the organisation is readying itself for a point-in-time assessment against the standards. There is thought to be marked improvement in compliance during this phase. The third phase is after the assessment has taken place, where compliance with standards may start to decline. The fourth phase

involves stagnation where there is little change in the levels of compliance, and where other influences on performance may begin to take effect (Devkaran *et al.,* 2019).

There is evidence that each stage of the life cycle model does occur in practice, but also that ongoing activity to support the regulated organisation may reduce variance in performance and offset the decline and plateauing of the third and fourth stages (Bogh, 2016; Bogh *et al.,* 2016; Bogh, *et al.,* 2017; Devkaran *et al.,* 2019).

### 3.1.5 Normalization process theory (NPT)

NPT helps to explain how the implementation, embedding and integration of ideas and practices, such as external standards and point-in time assessments, can work. This consists of four stages:

- **Stage 1: Coherence:** How people and organisations make sense of an approach and begin to see the ideas or standards as aligning to their own beliefs and approaches.
- **Stage 2: Cognitive participation:** This is established when there is organisational buy-in; with champions at a strategic and operational level, and where people at all levels engage and participate with it.
- **Stage 3: Collective action:** Quality improvement though purposeful action in response to observations, findings or learning.
- **Stage 4: Reflexive monitoring:** Organisational self-reflection on the process and its effects (Desveaux *et al.*, 2017).

As with other theories discussed, Desveaux *et al.* (2017) suggest that without flexibility in approach that the four stages are unlikely to occur. They contend that if any of these stages are not realised, then the potential for improvement in performance and quality is unlikely.

### 3.1.6 System based regulation

Systems-based regulation (SBR) is an approach where regulated “organizations … use their existing management system, which may originally have been meant to assure quality, to assure regulatory compliance” (de Bree *et al*., 2018: 6). This can be described as ‘process-oriented regulation’ in that the regulatory approach requires and monitors the regulated organisation’s capacity to self-evaluate, through internal governance and control systems. Therefore, rather than being a prescriptive, strict or reactive approach to regulation, it promotes meta-regulation - with regulators taking on a more proactive and preventative approach of stimulating high quality governance within the regulated organisation to self-assure quality standards.

This approach attempts to address the risk of ‘decoupling’, which “refers most frequently to the process whereby an organization adopts a formal policy to gain legitimacy from its social environment without implementing this policy in daily

practice" (de Bree *et al*., 2018: 3) and promote 'recoupling' where there is greater synergy between the regulated organisations' aims and processes and the aims and expectations of the regulator.

de Bree *et al*., (2018) conceptualise decoupling in three different forms:

- Goals-system decoupling: separation between organisational objectives and management systems (including structures, guidelines, instructions)
- System-practice decoupling: separation between management systems and observed daily practice within organisations
- Practice-outcome decoupling: separation between the effective use of management systems and positive outcomes (e.g. for people using services).

Recoupling is considered by de Bree *et al*., (2018) to occur through the same forms as decoupling, but in 'reverse mode'. Regulators may initiate recoupling through the interrogation of systems, often through observations and discussions, to help identify possible gaps and challenge assumptions about the way these systems work to support goals to be realised in practice. In assessing these areas, the regulator needs to assess the governance and management systems and engage in ongoing discussion with the regulated organisation to support their improvement.

## 3.2 The positive impacts of regulation

### 3.2.1 A complex and incomplete picture of impact

While the reviewed literature presents some evidence for positive measurable impacts of regulatory activities on the quality of organisations, this evidence is of variable validity and not easy to generalise.

There remain significant gaps in evidence relating to the impact of regulation. This limits the conclusions we can draw, and makes it difficult to make any assessment about the comparative effectiveness of different regulatory options (Walshe *et* al., 2007; Greenfield *et al.*, 2008; Hinchcliffe, 2012; Brubakk *et al.*, 2015; Healy, 2016a; Flodgren *et al.*, 2016; Desveaux *et al*., 2017; Schaefer *et al*., 2017; Castro, 2018; Devkaran *et al.,* 2019; Shaw *et al*, 2019; Duckett *et al*., 2019; Allen *et al*., 2019).

The gaps in understanding the impact of regulation are in part because it involves a complex set of interventions, that are introduced into varying organisational contexts, which are themselves multifaceted, and which sit in a system of other influences on quality (Walshe *et al.*, 2007; Greenfield *et al.*, 2008; Walshe *et al.*, 2013; Healy, 2016a, 2016b; Hovlid *et al.*, 2017). Rapidly changing regulatory arrangements have also exacerbated efforts to understand and measure how regulation is working (Walshe *et al.*, 2007).

Attributing impact to regulation is complicated by these multiple influences on quality which creates ‘noise’ in the data when trying to establish a causal effect (Healy, 2016a). The problem of attribution is further complicated by the fact that staff within regulated organisations may not always accredit improvement to the process of point-in-time assessment, and instead ascribe improvements in standards to pre-planned improvement work. In part this may be because of the ‘anticipatory impact’, which may focus attention and galvanise action in areas already known to require improvement but that would not otherwise be prioritised (Bogh, 2016; Smithson *et al.*, 2018).

### 3.2.2 So, what can we say about the positive impact of regulation?

The evidence that does exist on the positive impact of regulation indicates that:

- **Published standards** can signal what the regulator thinks it is important to focus on (although this may also divert attention from other things) (Kok *et al*., 2019). They can also create a framework to support quality improvement, encourage self-assessment, and provide the basis for internal quality assurance processes. They can improve 'quality thinking' in an organisation, especially when it involves all stakeholders (Murakami *et al.*, 2013, Nicklin, 2014; Bogh, 2016; Smithson *et al.*, 2018) and may even lead to demonstrable improvement in quality (Sutherland *et al.*, 2006). In relation to CQC specifically, Smithson *et al.* (2018) demonstrate how CQC’s model and concepts of quality have been internalised by the organisations it regulates to support improvement activity – an effect they term ‘organisational impact’.

- **Expecting and preparing for a point-in-time assessment** can influence ways of working (Nouwens *et al.*, 2015), leadership priorities (Bogh, 2016), shed light and focus attention on processes that might otherwise get overlooked (Bogh, 2016), increase focus and preparedness for quality improvement (Nouwens *et al.*, 2015; Bogh *et al.*, 2018), lead to organisational change and increased achievement in performance measures (Sutherland *et al.*, 2006; Greenfield *et al.*, 2008; Nicklin, 2014; Bogh, 2016; Bogh *et al.* 2016). These types of effect have been conceptualised as the ‘anticipatory impact’ by Smithson *et al*. (2018). They conclude that this type of impact can lead to both short-term effects to ‘game’ the outcome of the assessment, as well as more meaningful change to support improvement.

- **A point-in-time assessment and reporting** can incentivise improvement in performance and quality of services (Sutherland *et al.*, 2006; Greenfield *et. al.*, 2008; Bogh *et al.*, 2016; Bogh *et al.*, 2018), add credibility to the regulated organisations by evidencing performance against specified standards (Leatherbridge, 2006; Greenfield *et al.*, 2008; Nicklin, 2014;) and promote professional development, critical self-analysis, and organisational learning (Sutherland *et al.*, 2006; Nicklin, 2014). Where there are findings of non-

compliance or poor performance this can stigmatise the regulated organisation in the eyes of the public, which may act as an incentive to improve to restore reputation (Ford, 2010).

- **Published information, learning and best practice** can help to identify themes and trends in the delivery of regulated activities. This provides a resource for the regulated organisations, governments, policy-makers and other to inform decision-making, allow for comparative learning, and support improvement activity (Ford, 2010; Nicklin, 2014).

The key word in the above descriptions of possible impacts is 'can'. It is not a given that these impacts will necessarily occur. There are a number of challenges faced by regulators in attempting to achieve their aims, which are discussed in the following section.

## 3.3 Factors and contexts that can enable or inhibit effective regulation

As discussed above, the nature of regulation is complex and the interaction between the regulator, the regulated organisations, and other stakeholders is dynamic and multifaceted. This means that there is a range of factors that can either enable or inhibit regulatory effectiveness. These include the design and characteristics of the regulator and regulatory activities, the characteristics of the organisations being regulated, and the wider system surrounding the two. This section sets out what the literature has to say about each of these.

### 3.3.1 Characteristics of the regulator and the regulatory activities

#### *3.3.1.1 The regulatory methods*

Regulatory methods need to be sophisticated and robust enough if they are to achieve their intended aims. However, there are often challenges in developing methods capable of delivering the impact they have been designed to achieve (Walshe 2013). So, what factors are important, and what are the challenges?

**Ensuring user voice**

Involving the people who use services in regulation improves the standard of oversight provided. It ensures that regulatory decisions reflect their perspectives, provides an important source of evidence about performance, and leads to a greater overall impact. However, doing this effectively is not easy (Walshe *et al*., 2007; Rutz *et al*., 2018; Bouwman, 2016; de Graaff *et al*., 2019).

There is often insufficient service user participation in the development and delivery of regulatory activities (Lodge, 2015) and "the value of their input is often downplayed and not used widely as a driver for broader learning" (Kok *et al.*, 2016). There is also divergence between the areas of quality considered important by the

people using the services and by the regulator (Greenfield *et al.*, 2008; Bouwman *et al.*, 2015; Bouwman, 2016; Rutz *et al*., 2018; de Graaff *et al*., 2019).

Rutz *et al.* (2018) concluded that even where people who use the services are involved in the design and delivery, conflicts between them and the regulator are not easily overcome. When faced with this challenge, regulators may either give predominance to their own perspective or present the views of service users separately to their own. This may lead to conflicting messages to the regulated organisations.

Likewise, in their study on the use of people who use services (referred to here as 'Experts-by-Experience) in the regulation of Dutch care homes, de Graaff *et al*. (2019) found that the definitions of quality of regulatory staff predominated the inspection process. The Experts-by-Experience had to forgo their unique perspective on quality to gain legitimacy with the regulatory staff. They also found that the regulatory methodology they were asked to use could constrain the extent to which they could add new knowledge or a different perspective. Moreover, the evidence collected by the Experts-by-Experience wasn't so much used as evidence in its own right, but was rather only used to illustrate the findings of the regulatory staff.

The different meanings individuals or groups ascribe to words used in regulation can bring difficulties. Newman (2017) references Wittgenstein's term 'language games' (1997) to illustrate that the definition of 'quality improvement in healthcare' is being imposed. It is understandable why such terms can be difficult to define to the satisfaction of everyone, in a way that is acceptable in all circumstances.

However, Bouwman (2016) argues that despite the challenges involved, the very fact that people who use the services have a different perspective means there is value in listening to them and including their views throughout the regulatory process.

**Assessing the reality from the outside looking in**

The point-in-time assessment methodology needs to be capable of 'getting under the skin' of the organisation to determine performance. This includes the need for a reliable and valid regulatory framework, and methods capable of making an accurate and consistent judgement about quality (Boyd *et al*., 2014). However, some of the literature questions the degree to which one-off or periodic reviews of an organisation can get to the heart of how the organisation functions on a day-to-day basis (Leatherbridge, 2006). This includes challenges for the regulator in being able to develop a framework that both provides a thorough assessment of a complex picture of overall quality, while also ensuring consistent and repeatable judgements (Boyd *et al*., 2014). This is further compounded by the high level of skills that regulatory staff need to interpret the signals form the regulated organisation, discussed further in the section on regulatory capabilities below.

### Ongoing tracking of performance and risk

If a regulator is to flex its regulatory action to respond to the relative risk in different organisations, it needs to be capable of tracking the changing contexts and situation within a regulated organisation through ongoing performance monitoring.

Duckett *et al.* (2019) argue that data is key in measuring performance and identifying areas for improvement. They suggest that this should be used to support a flexible approach to regulation by targeting attention on specific issues, in a structured and transparent way to help the regulated organisation to respond to improvement opportunities.

However, what constitutes risk can be hard to define (Self, 2017). In their critique of risk-based regulation, Beaussier *et al.* (2016) highlight the difficulties experienced in identifying risk to poor performance in NHS data. Analysis by both Griffiths *et al*. (2017) and Allan *et al.* (2019a, 2019b), specifically focused on CQC, suggests little or no correlation between routine data indicators of quality and performance, and the outcomes of CQC inspections. Although Griffiths *et al.* (2018) suggest there may be value in developing qualitative measures from feedback from people using the services. Without data that has predictive capability it is difficult to institute risk-based or responsive regulation because the regulatory system will run into the possibility of missing poor quality and performance (Walshe *et al*., 2013).

### Ongoing relationships, guidance and support

A point-in-time assessment may identify issues, but this alone will not necessarily lead to them being fixed. If regulation is to have an effect, then support and guidance is often needed (Layshon *et al.*, 2017). As described in earlier sections, there is a tendency for performance and quality to plateau or even decline after a point-in-time assessment, and "this shows that … professionals [within regulated organisations] … continuously need to be stimulated to fulfil requirements" through ongoing monitoring, engagement, education and feedback.

It may be challenging for regulated organisations to understand the standards expected of them. This is particularly true if they are inaccessible (use of jargon, legal terms, or abstract concepts and theories), if there are contradictions in information provided, or if the information provided is too diffuse, indirect or not sufficiently applicable to the regulated organisations' specific context. To overcome this the regulator needs to provide accessible and relevant information in supporting regulated organisations to implement relevant processes to support regulation, and to enable improvement activity. Ideally this guidance will have been designed with those who intend to use it (Due *et al.*, 2019).

### Impactful reporting

Drawing on the idea of 'Reputation-based governance', Castro-Avila *et al*. (2019) suggest that reporting on the performance of an organisation can have an impact if it can facilitate reputational change. However, they suggest that this is only possible

when the reports are accessible and understandable to the public, features which they suggest CQC reports currently lack.

**Accounting for diversity**
It is difficult to design a single regulatory regime for a wide range of heterogeneous organisations, as there are within health and social care (Walshe *et al.*, 2007; Lodge, 2015; Eisner, 2015). However, if one group of organisations feel that they are being required to apply standards that have been primarily designed for another group of organisations, then this is likely to limit 'coherence' (seeing ideas or standards as aligning to their own beliefs and approaches) (Desveaux *et al*., 2017).

A lack of coherence is in turn likely to affect how much buy-in there is for the regulatory approach and reduce its potential for impact. It is therefore advisable to ensure specific and tailored standards and guidance, and a degree of specialisation among the regulator's workforce. This will help ensure there is a thorough assessment of the specific characteristics of the different regulated organisations within a single regulatory system (Walshe *et al*., 2013; Desveaux *et al*., 2017).

#### *3.3.1.2 Regulatory intent*
The type and extent of impact resulting from a regulatory activity can be influenced not just by *what* is done within those activities, but also the *motivation or intent* of the regulator in carrying out those activities (Walshe *et al*., 2013). So, for example:

- **Registration** can be designed to (a) provide a threshold for new providers to meet; (b) be the start of a regulatory relationship with the regulated organisation; or (c) facilitate administrative data capture to support future regulation.
- **Published standards** can be designed to (a) frame the regulator's values and performance expectations; (b) provide a framework for the regulated organisation to improve itself through self-enforced compliance; (c) provide a mechanism for compliance by assessment and enforcement against them; or (d) provide a mechanism for categorising and differentiating between different regulated activities or organisations.
- **Ongoing information gathering** can be designed to (a) determine when regulatory interventions are used; (b) focus or direct attention during a point-in-time assessment; or (c) make regulated organisations aware that poor performance data may trigger further regulatory activity.
- **Point-in-time assessment and reporting** can be designed to (a) drive improvement in advance of inspection; (b) measure compliance to support enforcement; (c) measure performance to encourage or support the organisation to improve; or (d) instigate or drive other regulated organisations to improve.

- **Enforcement** can be designed to (a) incentivise improvement through the existence of possible enforcement that could have a negative impact on the regulated organisation; (b) incentivise compliance by taking enforcement action that has a negative impact on the regulated organisation that they do not want continued or repeated; or (c) taking symbolic enforcement action that signals to the regulated organisation that they are not achieving expected standards.
- **Published information, learning and best practice:** can be designed to (a) support other stakeholders to make decisions; (b) inform and encourage compliance and improvement within the regulated organisation; (c) support public accountability; or (d) encourage or influence action from other stakeholders to support compliance or improvement (Walshe *et al.*, 2013).

How a regulatory activity is designed will influence which of the possible aims it achieves. However, different potential aims of a single regulatory activity conflict, so it may not be possible to achieve them all. Regulators should therefore be explicit about which of the potential aims it is most important for them to achieve from a particular regulatory activity and design it accordingly (Walshe *et al.*, 2013; Furnival *et al*., 2019).

#### *3.3.1.3 Regulatory capabilities*

In addition to what is done, and why it is done, *how* it is done also matters. If a regulatory mechanism is to be successfully employed, then the capabilities of regulatory staff need to be up to the job (Walshe *et al.*, 2013; Hanser, 2018). Indeed, those involved in regulation need to have a range of advanced skills. These include sophisticated skills to be able to employ the regulatory methods related to both assessment and encouraging improvement in performance and quality (Walshe *et al.*, 2013; Hanser, 2018). However, Furnival *et al.* (2017) conclude that relatively few regulatory staff have improvement skills and that these need to be developed through recruitment, development and investment.

Regulatory staff also need to have the ability to understand the specific circumstances affecting a regulated organisation, understand the different areas of varying performance, as well as, the complex social processes and organisational behaviours which exist within shifting cultural contexts in the organisation. Without this understanding it is difficult for them to choose the most appropriate regulatory response or communicate with the regulated organisation with sensitivity to their context. These skills are most needed if the regulator is to employ a responsive or flexible regulatory approach. Achieving and deploying these skills is neither easy nor straightforward as regulatory staff need to be able to assess abstract concepts like ‘willingness’ and ‘ability’ to learn (Neilsen *et al.*, 2009; Ford, 2010; Kok *et al.*, 2019).

Strong interpersonal, communication, and behavioural expertise to deal with people and organisations in potentially challenging and contested circumstances is

paramount to successful regulation. Because regulation is in large part a communicative process aimed at changing the behaviour of individuals, it is important to encourage respectful dialogue based on trust. Regulatory staff need to be able to build strong, trusting, and open relationships with regulated organisations. This is so that they can explain complex messages about their expectations of cooperation, but also the possibility of enforcement, in a way that will elicit a receptive response by the regulated organisation (Neilsen *et al.*, 2009; Walshe *et al.*, 2013, Healy, 2016b; Furnival *et al.*, 2017; Schaefer *et al.*, 2017; Smithson *et al.*, 2018; Kok *et al.*, 2019; Spronk *et al.*, 2019):

> *"Regulation is clearly seen as a social process. For both the regulator and providers, it is not just what you do, it is who does it and how it is done that matters fundamentally to the way regulation works, and to the impact. That does not mean that regulatory standards and procedures do not matter, but that the human interactions and social dimensions of inspection and rating are very important indeed."* (Smithson *et al.*, 2018: 41).

Perhaps most difficult is the challenge for regulatory staff who have found performance issues and need to convey difficult messages and/or take enforcement action. Regulatory staff need to correctly determine how their messages will land and maintain their relationships with the regulated organisations (Neilsen *et al.*, 2009; Walshe *et al.*, 2013, Furnival *et* al., 2017; Kok *et al.*, 2019).

Kok *et al.* describes the skills required as “pedagogic reasoning” because “the team’s goal is to stimulate hospitals to learn… [and therefore] like teachers, the inspectors [need to] carefully deliberate on what to address and how their feedback should be constructed” (2019: 480). These skills are made more complicated still by the need to maintain relationships and support improvement without being see as subject to ‘regulatory capture’, which could undermine the public’s trust in the regulator (Furnival *et* al., 2017).

In trying to consider the communication skills required by regulatory staff, the concept of ‘relational signals’ may be useful – where the staff in the regulator and regulated organisation try to read the ‘signals’ of the other to understand their goals and motivations. However, there is a potential for misunderstanding the signals and this can influence what information is supplied or obtained, and what actions are taken (Etienne, 2012; Mascini, 2013;).

If regulatory staff can successfully develop the interpersonal and communication skills needed to build strong relationships with regulated organisations then these relationships can have significant power in helping to encourage and bring about improvement- the relational impact (Smithson, 2018).

In addition to the softer relational skills, regulatory staff also require content expertise in the area they regulate, where they have a detailed understanding of the regulated activities. This is needed for both ensuring they can undertake an effective

assessment and are able to convey the credibility needed for the regulated organisations to take notice of them (Walshe *et al.*, 2013; Leyshon *et al.*, 2017):

> *"The team sent to audit an organization must have experience and deep domain knowledge the organization's field. They need to understand how clinical teams work... This will help to ensure understanding of the organization and buy-in from those that they are auditing."* (Leyshon *et al*., 2017: 775-6).

Without these wide range of skills, the regulatory workforce will lack credibility and regulated organisations and other stakeholders may fail to take heed of the regulator's assessments and information. Achieving these capabilities is no easy task, and there is plenty of evidence that the validity and reliability of assessments by regulatory organisations can be inconsistent (Greenfield *et al.*, 2008; Boyd *et al.*, 2014; Duckett *et al*., 2019). This inconsistency may be related to the relative skills of different regulatory staff, but it may also be driven by deficiency in the regulatory methods themselves (as discussed above), or be driven by different backgrounds, perspectives and viewpoints, which can influence the lens through which regulatory staff are interpreting the published standards (Kok *et al*., 2019).

Inconsistency may further diminish credibility and the impact of regulation, so it is important to find ways of minimising it. For example, Rutz *et al*. (2017) suggest that collaborative working and collective processes for decision-making, whereby regulatory staff "engage colleagues, managers and stakeholders to include other perspectives and knowledge, and to gain mandate" help to reduce inconsistency while retaining the discretion required in regulatory decision-making (2017: 19). However, we have already seen that reconciling the views of regulatory staff with the views of people who use services can be challenging. In their article looking at how regulatory teams' function, Boyd *et al*. (2018) also found that there were tensions between regulatory staff, healthcare professionals, and the Experts-by-Experience involved in the point-in-time assessment process, which could limit its effectiveness.

Given all the above, it is therefore important to employ careful recruitment, ongoing training and support for regulatory staff (Boyd *et al.*, 2018). In developing the regulatory methods, and in identifying the skills regulatory staff need, it may be useful to consider what can be learned from behavioural science. For example, in one randomised control study 'behavioural instruction' techniques were shown to lead to positive changes in GP antibiotic prescribing practices. This firstly included 'social norm feedback' where the GP practice was shown that they were an outlier. Secondly, the feedback was issued by a high-profile figure to increase the credibility of its content. Finally, it included specific and feasible actions that the recipient could perform (Hallsworth, 2017).

### 3.3.2 Characteristics of the regulated organisations

Inherent characteristics of specific regulated organisations, such as where they deliver services, or their size, can make it more or less challenging to regulate them. So too can inherent characteristics of the regulated sector as a whole, such as degree of diversity within the sector. In addition, acquired or context specific characteristics of the regulated organisations, such as their culture and motivations, can also impact the effectiveness of specific regulatory tools (Eisner, 2015; Desveaux *et al*., 2017).

#### *3.3.2.1 The influence of inherent characteristics*

The type of regulated organisation can influence how difficult it is for regulators to assess performance. For example, care delivered in a person's own home is inherently more difficult to regulate than care delivered in a setting more open to oversight and review by regulators (Leatherbridge, 2006).

Numerous, small scale services within a single sector under regulation (as with social care), can also make it more onerous for regulators to undertake rigorous regulatory activities. This makes it more imperative to adequately resource regulation if it is to safeguard the people using the regulated activities (Leatherbridge, 2006). Similarly, the size of the provider may influence how a regulated organisation may respond to a negative report or enforcement action. For example, Smithson *et al.* (2018) found that a small organisation may choose to close in these circumstances, whereas larger organisations are more able to adapt their quality improvement agenda to address the findings.

#### *3.3.2.2 The influence of acquired and context specific characteristics*

As previously discussed, different regulated organisations may have different motivations. Which regulatory approach will be most effective will be influenced by these motivations. An organisation motivated by profit may need to be forced to act through enforcement or incentivised to act by publishing findings which affect reputation and therefore the bottom-line. However, an organisation that is motivated by an intrinsic desire to provide good quality services may respond better to support and guidance on how to improve (Eisner, 2015).

Not only do different organisations have different motivations, a single organisation may have multiple competing motivations, influences and actors. This may mean that messages from the regulator are not be uniformly understood or acted upon across the regulated organisation (Neilsen *et al.*, 2009; Hovlid *et al.*, 2017) or that "achieving buy-in is threatened by conflicting attitudes of staff, managers, and senior leadership" (Desveaux *et al*., 2017: 946). Although, there may also be opportunities for regulators in giving voice to certain groups within the regulated organisations who are advocating improvement in quality and performance (van de Bovenkamp *et al*., 2017).

As discussed in relation to the life-cycle model, there is the potential for a decline or plateauing of performance after a point-in-time assessment (Bogh, 2016; Duckett *et al.*, 2019). If regulation is to have lasting effect, then the regulated organisations themselves need to see regulation as a continual learning process, be able to dedicate resource to meaningful engagement, and possess required improvement capabilities, including:

- leaders who see an upcoming point-in-time assessment as a positive learning and improvement opportunity and encourage their staff to engage with it as such, rather than it being seen as a 'stick to beat them with' (Leyshon *et al*., 2017)
- having a clear understanding of the published standards, the time and resources to translate them into their context, and to consider their implications for how the organisation functions (Lewin, 2016; Leyshon *et al*., 2017)
- a clear and embedded approach to continuous improvement and a culture to support it (Hovlid *et al.*, 2017; Leyshon *et al*., 2017)
- engagement of all teams and disciplines, at all levels of the organisation, throughout the improvement cycle (Lewin, 2016; Hovlid *et al.*, 2017; Leyshon *et al*., 2017)
- the availability of resources to engage with the improvement activities and implement the identified solutions (Hovlid *et al.*, 2017).

However, regulatory approaches that rely solely on reporting of findings and enforcement action assume that the regulated organisations have the capacity and capability to change, comply and improve. This assumption is flawed. Some organisations lack this capability (Hut-Mossel *et al*., 2017; Hovlid *et al.*, 2017). In these instances, regulation needs to trigger improvement activity, either from the regulator or from another part of the system, to support the improvement activity or to build improvement capability (Walshe *et al.*, 2013, Hovid *et al.*, 2017; Griffith, 2018).

Trustworthiness is another important characteristic of the regulated organisation. Spronk *et al*.'s (2019) work found that for trust to be developed regulated organisations need to demonstrate integrity; transparency; an ability to learn; acceptance of feedback; and actual change in behaviour. They argue that if regulation can be based on trust that it will be more effective than where this trust is lacking or absent. If a regulator does not trust a regulated organisation, then this is likely to be picked up by them. This can undermine the relationship between the regulator and the regulated, and with it the regulator's ability to persuade and influence behaviour.

### 3.3.3 The wider context and actors

In addition to the characteristics of both the regulator and regulated organisations influencing the effectiveness of regulation, so too can other factors within the wider system. How regulation interfaces and interacts with other influences of performance and quality (e.g. competition, innovation, the role of stakeholders) can shape the system of regulation and the impact it has (Walshe *et al.*, 2007).

Regulation rarely exists as a bi-lateral relationship between the regulator and regulated. Rather, it exists in a networked regulatory environment with multiple other stakeholders (Van Erp *et al*., 2018). It is therefore important for regulators to understand that they "cannot control or manage the quality of services on their own because of the multiplicity of institutional contexts". They should work with other stakeholders and the regulated organisations themselves to achieve their aims (Rutz, 2017: 133). As discussed above, where regulated organisations lack improvement capability then they need support from outside if they are to improve. This may come from the regulator, but if this is not forthcoming then support from other parts of the system can help facilitate change and improvement (Nouwens *et al.*, 2015; Smithson *et al.*, 2018).

Healy (2016b) contends that no individual part of the system alone may be sufficient in influencing performance and quality, but that collectively they can develop an effective web of influence. If regulators are to have the desired impact, then they must pull on other stakeholders to play their part in supporting and realising improvement. To achieve this, regulators need to engage all actors in regulatory conversations to generate a shared way of thinking, joint priorities, and coordinated action. This is concordant with the findings of Smithson *et al* (2018) who found that the degree of support available from other stakeholders in the system could significantly influence the degree to which regulated organisations are able to respond to regulatory findings to improve their performance. Where this support is successfully instigated because of regulatory action, they describe this as 'stakeholder impact'.

Involving the public and public interest groups in the process of regulation can help to combat the risk of regulatory capture by providing oversight to the regulatory process and ensuring that regulators do not loose sight of the public's interests and values when they are trying to understand the situation of the regulated organisations (Bouwman, 2016).

If the standards and definitions of quality are not aligned with the definitions and expectations of other stakeholders, or if there is a "need to meet a range of quality requirements for different stakeholders" then it is less likely that regulation will have the desired impact. This is because "varying conceptualizations of quality creates confusion and competing priorities for healthcare organizations when identifying relevant metrics to fuel quality improvement" (Desveaux *et* al. 2017: 944-5). Equally, if the delineations of roles and expectations of different organisations are not clear, then there is also a potential for risks in the system to 'fall through the gaps' (Carnell *et al.*, 2017).

## 3.4 The unintended impacts of regulation

As well as the direct costs spent on undertaking regulatory activities there is also a 'cost' of not doing the things that would have otherwise been done because time is being diverted to regulation. For regulated organisations, this includes the time taken away from delivering their core activities because they are focused on understanding and engaging with regulatory requirements and activities, and then attempting to demonstrate compliance. It may also lead to over-focus on the specific areas being assessed to the detriment of other areas of focus (Fairebrother *et al.*, 2000; Sutherland *et al.*, 2006; Hinchcliff *et al.*, 2012; Brubakk *et al.*, 2015; Castro, 2018; Devkaran *et al.*, 2019; Bogh, 2016; Bogh *et al.*, 2018; Lewin, 2016; Trigg, 2018; Duckett, 2019). Another potential cost is that regulation may lead to organisations only striving to minimum expected standards, rather than best practice and continual improvement (Sutherland *et al.*, 2006).

Although the literature acknowledges and discusses these costs, the financial and opportunity costs remain unclear and under-researched. There is very little discussion about the relative benefit of regulation compared to the costs, or whether the same resources channelled towards other activity could have a bigger impact on organisational performance (Sutherland *et al.*, 2006; Greenfield *et al.*, 2008; Brubakk *et al.*, 2015; Devkaran *et al.*, 2019; Shaw *et al.* 2019). So, while we may be able to go some way to describe the potential benefits of regulation it is almost impossible to answer the question, "is it worth it?".

## 3.5 Keeping regulation relevant

Regardless of the specific characteristics of the regulatory methodology, the skills of the regulatory workforce, or the characteristics of the regulated organisations, some of the literature also suggests that stability of the regulatory system is likely to contribute to more effective regulation. From this it follows that rapid or repeated reorganisations of the regulatory structures and systems is likely to hamper regulation from having an intended impact (Walshe *et al.*, 2007).

However, health and social care services are adapting at an accelerating pace, with increasing globalisation and digitalisation. This raises important questions about what a regulator's moral response should be to 'risks' that arise from changes that fall outside current regulatory frameworks, but where there is potential for societal harm (Kasdorp *et al*., 2019). If regulators cannot adapt to change then yesterday's regulatory approach will fail to deal with to today's problems (Duckett *et al.*, 2019). Kasdorp *et al.* (2019) suggest that in addressing these issues regulators need to appeal to the societal value of ensuring quality, while ensuring open dialogue, not just about what is currently regulated, but also what should be regulated, and when it is legitimate for a regulator to intervene. This may involve working with other regulators where the innovations cut across multiple regulatory remits.

While there may be good societal and moral reasons to justify regulation adapting to new technologies and innovations, this is far from easy. In their consideration of the regulation of AI, Guihot *et al*. (2017) discuss the challenges for regulators in trying to regulate areas they do not have the capabilities to understand, and trying to keep pace with changes that are adapting and developing at a much faster pace than regulatory structures can cope with. To deal with these challenges they suggest that a more adaptive regulatory approach is required.

# 4 Discussion: What does this mean for CQC?

In this section we try to draw out some of the main findings from across the reviewed literature and identify learning for CQC.

1. **Be explicit about the intended outcomes of each regulated activity**

   **Key findings:** The evidence suggests that there isn't an ideal way to regulate. Rather, a regulator needs to strike a balance between different options and employ a theory-based approach to understanding why they are choosing one set of options over a different set. Regulatory activities such as registration, publishing standards, point-in-time assessments, and enforcement, can achieve several different outcomes. How a regulatory activity is designed will influence which of the possible outcomes it achieves. However, different possible aims of a single regulatory activity may conflict, making it difficult to achieve them all – making it important to choose.

   **Learning for CQC:** CQC should be explicit about which of the potential aims of each of its regulatory activities are most important to achieve. It should then design the regulatory activity with these ends in mind, considering carefully how and why different actions will have the desired impact.

2. **Take a flexible approach to regulation**

   **Key findings:** Not all regulated organisations will respond in the same way to the same regulatory activity. This response will be influenced by: their improvement capacity and capability; their motivations; the expectations of other stakeholders; and the availability of external improvement support. It can be difficult to provide a balance between assessing and ensuring quality standards are maintained on the one hand, and encouraging and supporting improvement on the other.

   **Learning for CQC:** CQC needs to be able to adapt its regulatory approach to the circumstances of the regulated organisations. To achieve this, CQC staff need the skills to understand and correctly interpret the motivations of each regulated organisation and predict how they will respond so that they can choose the most appropriate regulatory action. CQC's purpose already states the dual role of

‘making sure’ organisations provide high quality and of ‘encouraging improvement’. The regulatory methodology needs to support staff to achieve both these roles by being clear about when it is appropriate to take a ‘command and control’ approach and when they should be supportive and enabling. This includes the need to make explicit the tensions that exist between the two, and clarity around potentially vague concepts like ‘capability’ and ‘willingness’ to improve.

### 3. Invest in CQC staff capability

**Key findings:** Regulatory staff require a complex range of skills, including strong interpersonal and communication skills, and in-depth knowledge of the services provided by the regulated organisations. Without these skills they will lack credibility, be inconsistent, and unable to encourage or bring about improvement in quality of care.

**Learning for CQC:** It is important to ensure that regulatory staff are recruited for (a) their interpersonal and communication skills; and (b) their credibility as health and social care professionals who can both understand and assess the services they regulate. Existing staff should then receive the training and support required to further develop these skills. Learning from behavioural science should be considered to inform the skills needed.

### 4. Build ongoing relationships with regulated organisations

**Key findings:** If regulators are to have an impact they need to be able to correctly interpret the ‘signals’ from the regulated organisation and, in turn, ensure that the regulated organisation correctly interprets their intentions. Trust and mutual understanding are required for this. Data on regulated organisations’ performance is not predictive enough to support risk-based or responsive approaches alone. Tracking performance through ongoing relationships is therefore important. Regulated organisations do not always have the capabilities to improve without encouragement, guidance and support. If this is lacking, then quality improvement is likely to stagnate or decline following a point-in-time assessment. There are benefits in helping regulated organisations to develop their own quality and governance systems, through observations and discussions, to identify possible gaps and challenge assumptions about the way they work to realise improvement.

**Learning for CQC:** Strong relationships with regulated organisations are paramount. There is a trade-off involved, but CQC should ensure its staff spend time building and maintaining open and trusting relationships. This will help CQC to be responsive to the circumstances of the regulated organisation, and provide the guidance and encouragement needed to bring about continuous improvement in the quality of care.

5. **Work with other parts of the system to achieve improvements in quality**

   **Key findings:** Regulation exists in a networked environment with other stakeholders where there is a complex range of influences on quality. Other stakeholders can act as informants, put pressure on the regulated organisations, help ensure compliance and support improvement. The amount of support available from other parts of the system can influence the degree to which regulated organisations can improve following regulatory activity. If there are competing expectations on regulated organisations, then this may limit the effect of regulation.

   **Learning for CQC:** CQC cannot achieve improvements in quality alone. It should work with other stakeholders (and the regulated organisations themselves) to achieve their aims. It should, as far as possible, ensure that the expectations it places on regulated organisations does not conflict with the expectations placed on them by other stakeholders. However, this joint working should go beyond developing a shared view of quality to developing joint priorities and coordinated action. Where there are gaps in support for regulated organisations to improve, CQC should consider either filling the gaps itself or influencing others to fill them.

6. **Meaningfully involve people who use services**

   **Key findings:** Regulation is more effective if people who use services are actively involved. It can also help prevent regulatory capture. However, involving them is not enough. There is often divergence between people who use services and regulators in their concepts and knowledge of quality. The regulatory methodology used, and the greater power and influence of the regulatory staff in applying it, can result in less meaningful input than intended.

   **Learning for CQC:** CQC has long intended to put people at the centre of what it does by involving people who use services in the design of its methodology and in its point-in-time assessments of regulated organisations. However, the literature indicates that this may not be enough to ensure the unique insight from people who use services has enough weight in regulatory activities and judgements. It may therefore be useful to further explore how the views and knowledge of people who use services get translated into regulatory outputs and how this may be further improved.

7. **Provide clear guidance and frameworks designed to enable improvement**

   **Key findings:** Published standards can signal what the regulator thinks it is important to focus on. Published information, learning and best practice can help regulated organisations, governments, policy-makers and others to make decisions. They can also support comparative learning and improvement activity. However, if the standards expected of regulated organisations are difficult to understand, or if they lack specificity to be applicable to individual contexts, then these opportunities to enable improvement may be lost.

**Learning for CQC:** It is important for standards and guidance to be designed with those who intend to use them. If a product, such as published standards, needs to be used for different purposes, it may be useful to develop multiple different products to support different audiences to use them, or to develop supplementary guidance to support people to use them. For example, CQC has moved to fewer assessment frameworks to help ensure consistency of assessment and to make it easier to apply them to organisations that deliver multiple service types. However, a lack of specificity may lead to regulated organisations thinking, 'this doesn't apply to me'. To help address this it may be beneficial to think about more specific guidance for different service types to support regulated organisations to translate CQC's expectations into their specific context.

8. **Keep regulation relevant**

**Key findings:** Health and care services are continuing to change at an accelerated pace, including from increased globalisation, digitalisation and innovation. Regulators need to find a way of dealing with this. However, stability in regulation also helps it to achieve its goals.

**Learning for CQC:** If regulation is to continue to be as impactful in the future as it is today, then it needs to keep pace with the digitalisation, technology, and innovations in the system. This may require going beyond existing regulations or working with other regulators when changes span across different regulatory remits. However, CQC needs to find a way to continue to adapt to the changing context without making significant changes that could undo its work to develop a shared view of quality.

# 5 Conclusion

There are many different approaches to regulation. Evidence on the impact of regulation is patchy. It is not possible at this point to make any conclusions about the relative value of different regulatory methods, or whether regulation offers value when considering direct or opportunity costs. However, as Healy (2016) puts it:

> *"While basing strategies on evidence of regulatory impact is an important principle,… the patchy evidence base means that the design of a regulatory framework often must look to general principles… to guide action… evidence-based mantras can be an excuse for not thinking and for not applying systemic wisdom… policy makers must … [take] action when interventions seem promising rather than necessarily proven"* (Healy, 2016a: 14).

There is a strong case for theory-based approaches to regulation. This includes being explicit about choice of approach, including how and why impacts are expected to occur, and what type of benefits can reasonably be expected.

This review has found benefits in taking a flexible approach to regulation, which combines both corrective and deterrence action and supportive and enabling action. CQC already has this dual role built into its purpose, requiring it to both 'make sure' providers deliver high quality, and at the same time to 'encourage improvement'. However, in taking this hybrid approach CQC should recognise the tensions that exist between these two elements and find a way to manage them. This includes providing clarity about when each of these approaches is appropriate, and by recruiting, training and supporting staff to assess a regulated organisation's capability and willingness to engage and improve. Without the ability to make these assessments then it will be difficult to respond in a way that is most likely to elicit a positive response from the regulated organisation.

Flexible or 'responsive' regulation is often equated to a risk-based approach. This is because it often works on the assumption that you only need to respond with certain actions when there is evidence of a risk. The literature shows that performance data and measurement is important to this, but also that it is rarely enough. Gathering 'soft' intelligence through ongoing relationships with providers and stakeholders therefore becomes essential.

The review has pointed to significant evidence that there are a range of factors that can either contribute or inhibit effective regulation. The following table sets out some of the key characteristics required if regulation is to be effective. These includes factors relating to the regulator, the regulated organisations, to other system stakeholders, and the relationship that exists between them. Critically, effective regulation relies on these three parts of the system working together effectively. CQC should consider how it develops the chaticteristics required for regulatory effectiveness, including building into its approach those things that are directly under its control, and how it can influence the things that are not.

## Components of effective regulation

| Regulation will be effective if… | | |
|---|---|---|
| **The regulator:** | **The regulated organisations:** | **Wider stakeholders:** |
| Has staff who have detailed knowledge of the regulated services and strong relational and communication skills. | See regulation as an opportunity to learn and improve and engage openly with it. | Align their expectations with the expectations of the regulator and other stakeholders. |
| Can meaningfully engage people who use services to inform regulatory decisions. | Understand what is expected of them (and do not have competing expectations placed on them from others). | Develop joint priorities and coordinated action across different stakeholders (including the regulator) to support improvement. |
| Can continually monitor performance and risk, which is likely to require ongoing relationships with regulators and organisations in addition to data. | Have a clear approach to improvement and a culture to support it. | Provide improvement support to regulated organisations. |
| Can build strong and trusting relationships with regulated organisations and stakeholders. | Possess the resources needed to identify, develop, and implement improvements. | |
| Provides improvement support to regulated organisations or can lever other stakeholders to provide that support. | Have the motivation to improve. | |
| Provides accessible and specific guidance on what is expected of regulatory organisations. | Have access to external encouragement and support if any of the above are lacking. | |
| Can flex its approach to account for diversity in the organisations it regulates. | | |
| Aligns its expectations with the expectations of other stakeholders. | | |
| Adapts to the changes in the sector it regulates. | | |

This review has been intentionally broad to identify a wide range of factors CQC should consider in the development of its next strategy. It may be helpful to undertake more targeted reviews on specific topics, such as;

- the required capabilities of regulatory staff
- characteristics of strong relationships between the regulator and the regulated
- how regulation brings about ‘coherence’ and behaviour change, including learning from behavioural science
- how regulators can monitor and encourage improvement in an organisation’s internal governance and improvement capabilities.

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# Appendix

1. What is the question or problem the author addressing?
2. What regulatory activities does the author discuss and how are these defined?
3. What are the key theories, frameworks or models used?
4. What are the authors key conclusions, insights and arguments?
5. What does the author say about the intended or unintended impact of regulation?
6. Does the author make any assessment of the value (for money) of different regulatory activities in a given context or contexts?
7. What does the author say about the factors or contexts that contribute to, or inhibit, effective regulation?
8. How does the publication relate to other publications reviewed? Does it confirm, add to, or challenge them?
9. What are the strengths and weaknesses of the research or publication? This includes:
    a) Internal validity: the level of confidence that the findings/conclusions follow from the data collected and/ or the robustness of the methodology employed; and
    b) External validity: how relevant are the findings to CQC.
10. Reviewer reflections: How does or could this publication relate to CQC's context?



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