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Impact of the Care Quality Commission on provider performance

Room for improvement?

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Key findings

This report summarises findings from the first major evaluation of the Care Quality Commission's (CQC) approach to inspecting and rating health and social care providers, which was introduced in 2013. The King's Fund and Alliance Manchester Business School have developed a new framework that outlines eight ways in which regulation can affect provider performance, to help regulators, providers and policy-makers understand the impact of regulation. It shows that impacts can be produced before, during and after inspection, and through interactions between regulators, providers and other key stakeholders. We used this framework to examine the impact of the first cycle of CQC inspections in acute care, mental health care, general practice and adult social care services in six areas of England. Our research led to a number of findings.

- Providers accepted and generally supported the need for quality regulation
 within the health and care system. They saw the approach introduced by CQC
 in 2013 as a significant improvement on the system it replaced, which had
 been widely criticised.
- We found examples of CQC producing each of the eight types of regulatory impact in our framework, although there was more evidence of some types of impact (eg, anticipatory impact, where providers make changes in advance of an inspection) than others (eg, systemic impact, where the regulator effects change beyond individual providers). To maximise the value of its regulatory interaction, CQC, providers and other stakeholders must consider the full range of ways in which inspection and rating can foster improvement.
- We also found significant differences in the way that impact works across the
 four sectors that we studied. For example, a provider's improvement capability
 and the availability of external improvement support were more often present
 in the acute and mental health sectors than in general practice and adult social
 care, and we found these were key determinants of impact. This highlights
 the potential for CQC to develop its model in different ways in each sector,
 depending on factors such as the size and number of organisations being

Key findings 3















regulated, their capacity to respond to its recommendations, and the other resources available to support improvement.

- The relationships between CQC staff and health and social care professionals and managers fundamentally affected the way regulation worked and its impact, and contributed to variation in providers' experiences of inspection. This highlights the importance for CQC of investing in recruitment and training of its staff, to create an inspection workforce with the credibility and skills necessary to foster improvement through close relationships, while maintaining consistency and objectivity. For providers, it emphasises the need to encourage and support their staff to engage in open, improvement-focused discussions with inspection teams.
- The inspection model we studied was focused on individual providers. As health and social care provision becomes more integrated, this focus will become less tenable, and place- or service-based regulatory approaches that cross organisational and sectoral boundaries will become increasingly important. This highlights the need for important work which is already under way to align the activities of regulators, commissioners and other improvement-focused organisations to gain pace and depth.
- Our quantitative analyses found inspection and rating had small and mixed
 effects on key performance indicators in accident and emergency services
 (A&E), maternity services and general practice prescribing. The effects of
 regulation in these areas may be difficult to measure with routine data sources,
 and the impact of CQC is difficult to isolate from other factors affecting
 provider performance.
- We found that the Intelligent Monitoring (IM) datasets that CQC used to risk assess provider performance and prioritise inspections had little or no correlation with the subsequent ratings of general practices and of acute trusts. This highlights the limitations of risk-based regulatory models, using routinely reported performance data, in targeting regulatory interventions.
- Inspection and rating have dominated CQC's regulatory model, consumed most of its available regulatory resources, and may have crowded out some other potential regulatory activities that might be more impactful. Given the range of ways in which CQC can have an impact, our findings suggest that, to yield the maximum positive impact from its available resources, CQC should develop and use regulatory interactions other than comprehensive inspection.

Key findings 4













It should draw on its intelligence and insight to support providers, foster improvement and prioritise its use of resources.

Now that CQC has completed its first full cycle of inspecting and rating health and social care providers, it is implementing a new strategy for regulation that addresses some of the issues raised in our research.

We welcome CQC's efforts to develop a more insightful system for prioritisation. This system must draw together both hard and soft intelligence from a wide range of sources, and take into consideration providers' own ability to accurately and honestly self-evaluate. However, the difficulty of doing this in practice should not be underestimated. This challenging work must engage patients, users, providers and commissioners in the development of a multifaceted monitoring process.

We also welcome the greater emphasis placed on relationship management and the development of system-wide approaches to monitoring quality.

As CQC works to implement its revised strategy with stakeholders across the health and care system, our research emphasises the need to take a prospective and deliberative approach to designing, piloting and testing regulatory interventions in order to measure their impact in practice.

Key findings 5













Introduction

In 2013 the Care Quality Commission (CQC) introduced a new approach to inspecting and rating NHS acute hospitals, as part of its new regulatory model (Care Quality Commission 2013). This has since been adapted for use in other sectors that CQC regulates across health and social care. As it neared the completion of the first full cycle of inspection and rating, CQC issued a revised strategy detailing how it plans to develop its regulatory model, covering the period 2016 to 2021 (Care Quality Commission 2016a).

Between 2015 and 2018, The King's Fund and Alliance Manchester Business School undertook a study, funded via the Department of Health's Policy Research Programme, to examine whether and how CQC's programme of inspection and rating was having an impact on providers of care. This research was conducted during the first full cycle of inspections, before implementation of the revised strategy. We considered four sectors subject to CQC intervention: acute care, mental health care, general practice and adult social care. In this report, we present an overview of our findings about the impact of CQC's inspection regime, and discuss what regulators, providers and others in the health and care system might learn about how to target, understand and evaluate impact.

More detailed findings from this study have been submitted to the Department of Health as an overview report and a series of working papers. Appendix A lists these 12 working papers and includes details of how to request copies.

CQC's approach to inspection

The inspection approach introduced in 2013

The approach to inspection and rating that CQC introduced in 2013 was radically different to the model it replaced, which used generic care standards and inspection staff, and short, fairly superficial inspections.

The introduction of this new approach was triggered by several high-profile failures of care which raised questions about the ability of existing regulatory













mechanisms to identify and act on poor performance. Critical reports by the National Audit Office and the House of Commons Health Select Committee, as well as the Department of Health's own *Performance and capability review*, all argued that the regulatory model used at the time was not fit for purpose (Department of Health 2012; Health Select Committee 2012; National Audit Office 2011). The Francis Inquiry also examined the systems for oversight, scrutiny and regulation in the NHS that had permitted the failures in care at Stafford Hospital. Its many detailed recommendations reinforced the need for a change in how health care regulators identify and respond to variations in performance (Mid Staffordshire NHS Foundation Trust Public Inquiry 2013).

To address these concerns, CQC's new approach generally used larger and more expert inspection teams; longer and more in-depth inspections; a wider range of data on performance; and fieldwork during inspection. It produced provider ratings for five domains (safe, effective, caring, responsive and well-led) on a four-point scale ('inadequate', 'requires improvement', 'good' or 'outstanding'), and the process and findings from each inspection were all described in a detailed inspection report. The key purpose of these inspections and ratings was to identify poor care and drive improvements in quality of care and provider performance. The approach was tailored to the needs of different health and social care sectors during implementation. Table 1 provides a summary of the differences between the sectors studied in this report.

The new approach also provided CQC with a broader range of enforcement levers, which are outlined in Figure 1. This includes 'special measures', which involves a higher than usual level of regulatory supervision for providers that are failing to meet the expected standards of care (*see* box below).

Special measures

When a provider receives an 'inadequate' rating for 'well-led' and at least one other quality domain, CQC can recommend to NHS Improvement that the provider is placed in special measures. CQC will then work with other relevant agencies and oversight bodies to ensure the provider improves. If the provider does not improve within a specified timeframe, CQC may cancel its registration; something that in practice has happened to social care providers and GP providers, but not to NHS trusts.













Table 1 The first cycle of CQC inspections of NHS acute trusts, NHS mental health trusts, general practices and adult social care services: 2013–17

	NHS acute trusts	NHS mental health trusts	General practices	Adult social care services
Dates of the first cycle of inspections (excluding services)	April 2014 to March 2016	October 2014 to March 2016	October 2014 to January 2017	October 2014 to January 2017
Number of providers inspected	136 NHS acute non-specialist trusts	54 NHS trusts	7,365 GP practices	Approx 24,000 locations
Ratings	Outstanding – 4%	Outstanding – 2%	Outstanding – 4%	Outstanding – 2%
	Good - 29%	Good - 56 %	Good - 79%	Good - 77%
	Requires improvement - 59%	Requires improvement - 39%	Requires improvement - 8%	Requires improvement - 19%
	Inadequate - 9%	Inadequate - 2%	Inadequate - 2%	Inadequate - 2%
How the inspections worked	Trust inspections were announced beforehand and were comprehensive. They were conducted by large multidisciplinary inspection teams of typically 25 to 40 people, and lasted between 3 and 5 days.	Trust inspections were announced beforehand and were comprehensive. They were conducted by large multidisciplinary inspection teams of typically 25 to 40 people, and lasted between 3 and 5 days.	Inspections were announced beforehand and were comprehensive. They were conducted by a small inspection team of typically 2 or 3 people, and lasted 1 or 2 days	Inspections were usually unannounced, although community-based adult social care services were given 48 hours' notice. They were conducted by small inspection teams of typically 2 people, and lasted around 1 or 2 days.
Support following inspection	Commissioners and local stakeholders involved in action-planning. A range of NHS Improvement support provided, including intensive support for those in special measures.	Commissioners and local stakeholders involved in action-planning. A range of NHS Improvement support provided, including intensive support for those in special measures.	Support provided by the Royal College of General Practitioners, clinical commissioning groups and NHS England.	Local authorities provide some support. Some have improvement teams that support providers, but this is variable across the country, as is the extent of the support provided.

Source: Care Quality Commission 2017a, b, c, d











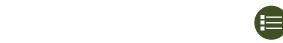


Figure 1 CQC's enforcement powers and how they relate to the purpose of enforcement

K

Increasing severity

Purpose: Protecting people who use services by **requiring** improvement

- Requirement Notices (formerly known as 'compliance actions')
- Warning Notices
- Section 29A Warning Notices

Purpose: Protecting people who use services by **forcing** improvement

Civil enforcement powers

- Imposing, varying or removing conditions of registration
- Suspending registration
- Cancelling registration
- Urgent procedures

Special measures

- Time-limited approach ensures inadequate care is not allowed to continue
- Co-ordination with other oversight bodies

Purpose: Holding providers and individuals to account for failure

Criminal powers

- Simple cautions
- Penalty notices
- Prosecution

Holding individuals to account

- Fit and proper person requirement
- Prosecution of individuals

Source: Care Quality Commission 2015













CQC's strategy for 2016 to 2021

More recently, CQC has issued a revised strategy for the period 2016 to 2021, which sets out how it plans to further develop its regulatory model in health and social care (Care Quality Commission 2016a). While the approach that is described above is largely maintained, the overall aim is to move towards a 'more targeted, responsive and collaborative approach to regulation'. CQC sets out four main intentions in its new approach:

- to encourage innovation, improvement and sustainability in care
- to have an intelligence-driven approach to regulation
- to promote a single shared view of quality
- to improve its own efficiency and effectiveness.

Broadly, CQC's new strategy is to continue to rely mainly on inspection as the mechanism for monitoring quality of care, but with smaller inspection teams, and more focused and targeted inspections. The rationale is that, having completed comprehensive inspections of all providers, CQC has robust evidence on service quality that can be used to determine where to focus future inspections. It is particularly targeting areas of poor performance or areas where performance may be changing, and there will be fewer inspections and longer periods between inspections for providers who are thought to be performing well. These providers will be largely trusted to manage their own performance in the short and medium term, while CQC and other stakeholders will intervene more with those providers with enforcement actions, and/or that are rated as 'requiring improvement' or 'inadequate'.

CQC will make more use of performance information and has developed a new system for monitoring the quality of care – 'CQC Insight'. It also plans to find ways to look at systems of care which cross organisational boundaries, and other new organisational forms, such as chains or networks of providers (Care Quality Commission 2016b). As part of this, CQC recently published a summary of its first 20 reviews of the care of people aged 65 and over in 20 areas of England (Care Quality Commission 2018).













CQC and the wider system

CQC is part of a network of organisations that regulate and oversee health and social care providers. Other organisations include NHS Improvement, which regulates the finances of NHS trusts and supports them to improve; NHS England, which oversees the operational performance of the NHS; commissioners (including clinical commissioning groups (CCGs), local authorities and NHS England), which assure the quality of the health and social care services they commission; professional bodies that regulate individuals; and a range of other organisations that provide training and support.

There are a number of overlaps and interdependencies between these functions. Critically, CQC is not an improvement agency; its inspections diagnose issues in health and care providers, and it catalyses other parts of the system to take action. This means that CQC's impact is dependent on others supporting providers to improve. In 2016, all the organisations that oversee and support health and social care providers made a commitment to better align their work, in order to reduce the burden of regulation on providers and better support improvement (National Improvement and Leadership Development Board 2016). CQC's most recent strategy states that it will work with other national agencies to develop a shared vision of quality, and it has already agreed a joint approach to assessing the 'well-led' domain with NHS Improvement (Care Quality Commission 2016a). Developing a shared vision of quality is intended to provide a clear message about what 'good' looks like, and avoid providers having to submit multiple responses to information requests from different regulators, with variable definitions and metrics of quality.

In doing this, these organisations have to strike a delicate balance: on the one hand, they must form effective relationships with providers to ensure they gain an accurate understanding of performance and can influence effectively; on the other hand, they must retain the distance necessary to be objective, ensure compliance and avoid being 'captured' by those they regulate.

Our approach to evaluating impact

We undertook a mixed-method study, combining a literature review and qualitative fieldwork – including 170 interviews with representatives from CQC, other national agencies, providers and other local stakeholders such as CCGs, NHS England, Healthwatch and public and patient groups – with quantitative analyses of national













data on provider performance, ratings and activity. Appendix B describes our methodology in more detail, and further information is available in our working papers, which can be requested from the authors (*see* Appendix A).

The impact of regulation is difficult to isolate because regulation is just one of many factors that have an effect – both positive and negative – on provider performance. In England, frequent changes in the organisations responsible for carrying out this work, and in the methods they use, further complicate the task.

Our work uses a framework to examine the impact of CQC's inspection and rating process (during the first full cycle of inspection), and to consider how CQC's impact will continue to evolve as it introduces a new approach. The recent shift in strategy provides an opportunity to consider what CQC might learn from its previous inspection regime, and what it might continue, modify or cease to include as it continues to implement its new approach. It was outside the scope of this study to seek to quantify the costs and benefits of CQC's regulatory approach.

In section 2, we start by briefly describing a framework of eight types of regulatory impact, which we derived from the literature on regulatory impact and tested in our fieldwork. In section 3, we describe how each type of impact was experienced by providers of acute care, mental health care, general practice and adult social care services, drawing on our qualitative research findings. Section 4 has a summary of our quantitative analyses of how effective performance data is in predicting ratings, and the impact of inspection and rating on performance and service volumes. In section 5, we discuss the key implications of these findings, before setting out our conclusions in section 6.













2 A framework for understanding the impact of regulation

We know that inspection can produce a complex range of impacts that go beyond a simple direct response to an enforcement action. We used our review of literature on the impact of regulation in health and other sectors to derive a framework of eight 'impact mechanisms' – that is, a series of ways that inspection and rating might have an impact on providers that are regulated by CQC. This provided us with a framework for describing and evaluating impact across the inspection process, and broadened our understanding of impact. Through the latter phases of our research, we tested this set of mechanisms with providers and patient and public groups to explore how it operated in practice.

Table 2 sets out the framework, explaining briefly how each mechanism might work and highlighting specific examples of the mechanism in practice from our fieldwork. For each mechanism, we have included an example of it having a positive impact, as well as an example of it having a negative impact (where applicable).

While anticipatory impact clearly relates to the period before inspection, the other mechanisms do not fit as neatly within a chronology. For example, relational impact could be considered as an ongoing process between inspectors and a provider; and informational impact could be triggered as CQC inspectors make their judgements, and then later in how patients and the public respond to a rating and inspection.

Our aim in producing this framework is to promote a wider and more reflective account of how regulatory regimes may have an impact on organisational behaviour and performance. This is not intended to be a full or final account. We acknowledge that there may be other forms or types of impact mechanisms at work, and that our framework contains some ambiguities and overlaps that might benefit from further exploration.















Impact mechanism	Description of logic/ causal chain/process	One positive and one negative example reported by interviewees
Anticipatory	The regulator sets quality expectations, and providers understand those	Before their CQC inspection, a trust held discussions to develop its values and behaviours, and to encourage a sense of ownership of these among staff.
	expectations and seek compliance in advance of any regulatory interaction.	A lot of time was spent gathering data and undertaking 'rehearsals' in advance of a CQC inspection, which was a distraction from activities that could improve services.
Directive	Providers take actions that they have been directed or guided to take by the	CQC inspected and then closed a GP provider. Others in the system said they had been aware of a performance issue, but didn't have the evidence or power to address it.
	regulator. This includes enforcement actions and, at the extreme, may involve formal legal repercussions such as prosecution or cancellation of registration.	Actions in a CQC inspection report had a disproportionate focus on paperwork rather than things perceived as having an impact on 'actual' quality of care.
Organisational	Regulatory interaction leads to internal organisational developments, reflection and analysis by providers that are not related to	Motivated by a CQC visit, a mental health trust became much better at setting organisational objectives, giving them a greater focus on ongoing improvement, with staff and managers regularly reflecting on the direction of travel for their service or organisation, and the resources they need to deliver those objectives.
	specific CQC directions. This leads to changes in areas such as internal team dynamics, leadership, culture, motivation and whistleblowing.	A CQC inspection led to a culture of increased reporting within a trust, which took time away from patient care.
Relational	Results from the nature of relationships between regulatory staff (ie, inspectors) and regulated	A mental health provider had regular meetings with CQC, at which the provider highlighted the challenges the organisation was facing and received verbal feedback from CQC.
	providers. Informal, soft, influencing actions have an	A social care provider reported that during its inspection

a CQC inspector would 'carry on digging' until they found

something that wasn't right.

impact on providers.









Table 2 Eight regulatory impact mechanisms (contd.)





Impact mechanism	Description of logic/ causal chain/process	One positive and one negative example reported by interviewees
Informational	The regulator collates intelligence and puts information about provider performance into the	Relatives of those living in a care home, as well as potential residents or their relatives coming to view it, mentioned they had looked at the home's CQC report online.
	public domain or shares it with other actors who then use it for decision-making (eg, commissioning, patient choice).	A patient and public group found rating information on CQC's website for a particular hospital was unhelpful because it was four years old.
Stakeholder	Regulatory actions encourage, mandate or influence other stakeholders to take action or to interact with the regulated provider.	NHS Improvement and NHS England worked with a trust following their inspection to address quality issues identified in their report.
		A quality summit held after a CQC inspection (at which local stakeholders discussed action planning with an inspected trust) was poorly attended and no one had prepared. Issues that needed stakeholder input were not addressed.
Lateral	Regulatory interactions stimulate inter-organisational interactions,	An acute provider encouraged its staff to take on inspector roles so they could learn to better gauge their own performance and prepare for their inspection.
	such as providers working with their peers to share learning and undertake	GPs discussed their inspection reports at a network meeting and identified inconsistencies, which they then highlighted to COC, which would not change its report

highlighted to CQC, which would not change its report.

CQC fails to bring together information on a recurring

opportunity to aggregate individual findings to provoke

theme in its inspection reports, and so misses an

CQC's annual *State of care* report focused national attention on the challenges around the sustainability of

the social care sector.

systemic change.*

Note: * We did not hear any negative examples of systemic impact in our interviews, so this is a hypothetical example.

This framework draws attention to the diversity of impact pathways. It shows that there are alternative impact mechanisms to those which traditionally focus

improvement work.

Aggregated findings/

identify systemic or inter-

organisational issues, and

to influence stakeholders

other than the regulated providers themselves.

and wider systems

information from regulation are used to

Systemic













on directive enforcement at the level of the single regulated organisation. It may also help regulators and providers to think through the nature of regulatory processes, such as registration, monitoring, inspection, reporting and enforcement, and the way in which their use or implementation may trigger particular impact mechanisms. Furthermore, it may also be helpful in considering both the intended and unintended consequences of particular regulatory processes, and how the regulator can seek to maximise the former and minimise the latter.

Another area for further consideration is the relationship between these different impact mechanisms, and the extent to which they may complement or conflict with one another. For example, we might hypothesise that the relational impact mechanism, which prioritises and gives particular value to the interpersonal relationship between regulatory staff and regulated organisations, could at times be at odds with the directive impact mechanism, where the regulator issues clear directions to the organisation and may use robust enforcement methods to drive their implementation.

The next section describes more broadly the impacts that we saw 'in action', using this framework. It also discusses some of the challenges in understanding impact and some key determinants of impact: the size and type of an organisation, and its level of improvement capability.















3 How do the different types of impact work in practice?

Some commentators have argued that regulators such as CQC impose a great burden of inspection and oversight on health and social care providers, but that their interventions have very little actual positive impact, or their impact is temporary and diminishes or vanishes once the regulatory intervention ends (Toffolutti *et al* 2017; Lind 2015; Greenfield and Braithwaite 2008). While this perspective was sometimes found in our analysis, it was rare to find providers who saw no value in, or rationale for, the role of CQC and its inspection and rating process.

Rather, the majority of people we spoke to expressed general agreement with the principle of, and need for, regulatory oversight in health and social care. They often pointed to their own evidence or experience of poor-quality care and variations in care; the vulnerability of service users and patients; the institutional power and standing of health and care organisations; and the need for political and social accountability for public services and resources. They seemed to largely accept the need for health and care regulation, and the debate was much more about the practice of regulation. While CQC's new regulatory model was still seen as problematic in some important respects (for example, some interviewees saw some tasks as box-ticking exercises), many interviewees saw it as a major improvement on what went before.

I'm not going to sit there and rant about the fact that the CQC are a nightmare et cetera, et cetera. I am really clear. We are a public body, we are funded by the NHS, we are here to serve our citizens and our public. The principle of having another body coming in to tell us how we're doing, impartially as possible, I value, and I think it's a good thing. However, sometimes the devil is in the detail isn't it? (Clinical director, mental health)

In the subsections that follow, we outline the range of ways in which CQC's inspections and ratings have affected providers across four sectors. We describe how our eight impact mechanisms are working in practice, based on findings from













our interviews and observations. As this section shows, we found more evidence of some types of impact than others. We also found some differences between sectors, which we have highlighted under each mechanism.

Anticipatory impact: before the inspectors arrive

The regulator sets quality expectations, and providers understand those expectations and seek compliance in advance of any regulatory interaction.

We found extensive evidence of anticipatory impact. CQC framed or set quality expectations, and providers responded to these in advance of inspection and rating. Providers wanted to achieve compliance for a number of reasons, including because they recognised both the need for change and the legitimacy of CQC's quality expectations, and because they wanted to perform well at inspection and secure a good rating. It was clear that many providers had read CQC's inspection handbook and other guidance very carefully, and sought to check their own performance against CQC's expectations through a variety of internal reviews, mock inspections, peer reviews and other activities. Sometimes providers sought help from external organisations, such as their local commissioner or external consultancy firms, to support this preparation.

A key issue raised by some interviewees was the clarity and objectivity of CQC's guidance and the underlying expectations of performance. Some felt it was not straightforward to interpret and apply, and expressed concerns that inspection processes were not always consistent with that guidance and differed according to the make-up of the inspection team.

Interviewees described a combination of positive and negative anticipatory behaviours. On the one hand, these behaviours raised awareness, improved engagement and helped to prioritise quality issues. On the other hand, anticipatory actions were often activities that sought to achieve superficial or ritual compliance; focused more on getting through the inspection process than on really changing the quality of care. This often generated anxiety or concern among staff. In particular, the period immediately prior to inspection (where inspections were announced) was often a frenzy of preparation focused largely on inspection processes and administrative issues.













I think the preparation that was required for the deep-dive inspection was totally disproportionate to perhaps the positive outcomes for the organisation. So from October, when we were alerted to the fact that our deep-dive inspection was going to happen, you know, in three months' time, the intensity of preparation was absolutely remarkable. In a sense of we needed to have a weekly exec-led preparation team [meeting], we were preparing teams for what to expect... if you can imagine preparing for probably one of the biggest exams you're ever going to have, it was that. And in fairness... you would have to question whether that was of such value to the public in a sense of time taken away [from] clinical activity in preparing for the big exam, really.

(Director of nursing, mental health)

There were some differences between sectors in the extent to which CQC inspections had an anticipatory impact. For example, in acute and mental health organisations, preparations for CQC inspections were reported to have a positive impact on communications and staff engagement with the organisation's work on quality improvement (albeit often short-lived), but this was not the case in general practice and social care. In addition, there was more evidence of CQC's view of quality being embedded into organisations' governance processes in advance of an inspection in the acute and mental health sectors than in adult social care and general practice. This may be explained by the greater resources that acute and mental health organisations have to implement changes to their processes in advance of a CQC inspection, and the greater potential for standardised processes and staff engagement to have a positive impact, because of their larger size. In addition, unlike their inspections of health care organisations, CQC's inspections of social care providers are unannounced.

Directive impact: responding to specific requirements

Providers take actions which they have been directed or guided to take by the regulator. This includes enforcement actions and, at the extreme, may involve formal legal repercussions such as prosecution or cancellation of registration.

CQC drew upon a range of materials when making an enforcement decision: data derived through intelligent monitoring; information from previous inspections and ongoing interactions with the provider; information from CCGs, patient groups and













other local stakeholders; information from whistleblowers; and observation and other data captured during inspection.

Providers that had no enforcement actions and received a rating of 'good' or 'outstanding' were subject to considerably less follow-up than poorer performing providers. There did not appear to be clarity among respondents around a reinspection schedule for those at the higher end of performance (with some reporting that they would be reinspected in three or five years).

As might be expected, the greatest directive impact tended to apply at the lower end of the performance range: in organisations rated as 'requires improvement' or 'inadequate', and those subject to special measures and enforcement actions. For more information on the special measures process and the enforcement levers available to CQC, see pages 7 and 9.

At this end of the spectrum, changes were often more substantial and significant, though the issue of the organisation's capacity and capability to make those changes remained problematic. Acute and mental health care providers had access to national bodies such as NHS Improvement and NHS England, who were expected to take on responsibility for supporting and overseeing change in these organisations. Social care providers, however, were far from clear about where such external support and continuing oversight might come from. General practice had access to some oversight from CCGs and NHS England, and access to the Royal College of General Practitioners' peer support programme. However, in reality, many practices did not seem to access much support.

Although the four sectors that we considered are now subject to the same or similar enforcement sanctions, they have historically had different experiences of regulatory enforcement. Acute and mental health trusts have been subject to different inspection regimes for many years, some of which have included a provider rating. They have, however, always been inspected by CQC or its previous incarnations. For GP practices in particular, the current approach to inspection and rating presented a radically different interaction and outcome.

We also saw directive actions working in different ways in different sectors. For instance, an acute trust in special measures is very unlikely to close (although a formal process may be triggered through which members of the management or













board can be replaced, or a commissioner can suspend or restrict certain services, or it could be taken over by a neighbouring trust). As such, the action taken by the provider and other stakeholders will reflect that, and typically involve supporting the provider to improve.

The multi-agency involvement in the post-inspection action plan is largely driven by the severity of the issue, so if a trust is in special measures as a result of our inspection then you'll guarantee everyone will want to be round the table because they consider it to be significant, but if it's a trust like this trust where it was good with a series of 'requires improvement' services, the trust would be largely left alone to manage that action plan and we would take our assurance from the trust in line with any other inquiry noise we hear.

(CQC staff, acute sector)

However, in the GP and social care sectors, the most severe enforcement actions led to services being closed, rather than being supported to improve.

The impact of stakeholder involvement and how this varies between the sectors is discussed in more detail in the subsection below, 'Stakeholder impact: improvement support from system partners'.

Organisational impact: providers reflect and enact broader changes

Regulatory interaction leads to internal organisational developments, reflection and analysis by providers that are not related to specific CQC directions. This leads to changes in areas such as internal team dynamics, leadership, culture, motivation and whistleblowing.

We found many examples of changes in areas such as power dynamics, leadership, culture and motivation, which were clearly in part attributable to CQC's inspection and rating, but did not flow directly from recommendations in the inspection report.

Changes in leadership sometimes resulted from an adverse CQC inspection, as organisations and other stakeholders sought to both hold people to account for the situation and to address the concerns raised. Interviewees also reported wider organisational changes as systems for quality improvement or reporting were













strengthened, or additional resources were invested in improvement capabilities. There were some parallels with the anticipatory impacts outlined earlier, but in this case the impacts were after inspection, when perhaps organisations had a better understanding of CQC's requirements, and sought to respond and align their own priorities with those raised by CQC's inspection.

However, the relationship between these organisational impacts and CQC's inspection and rating was not always clear. Interviewees often spoke of a range of influences exerted to bring about change, of which CQC's intervention was part.

I think we're doing it because it's the right thing and it's come from a number of areas. I mean everyone's signed up to that now. So, they're [CQC] just one of the drivers. I don't think we're doing it just to keep them happy.

(Senior nurse, acute care)

Relational impact: regulation as a social process

Results from the nature of relationships between regulatory staff (ie, inspectors) and regulated providers. Informal, soft, influencing actions have an impact on providers.

Although the guidance provided to CQC inspection teams has become more detailed, this is still a process in which much is left for inspection teams to determine. As a result, there is a great deal of variation in inspection practice within and across inspection teams. Our previous research on the early implementation of CQC inspections found that what inspectors actually do may often be shaped as much by their own prior experience or background, their personal interests or concerns, and their sub-team colleagues, as it is by CQC guidance or by the needs of the particular service being inspected (Walshe *et al* 2014).

Interviewees described several important and desirable attributes of the relationship between CQC staff and provider staff. They valued longitudinality – seeing the same people over a period of time, and doing so often enough that there was the opportunity to build and sustain a relationship. They also sought a 'no surprises' approach, characterised by openness and transparency on both sides, mutual trust and respect, and sufficient consensus or convergence of underlying values and ways of working. This mutual respect and trust, or two-way relationship,













could mean that providers felt more confident in having open and honest conversations with CQC about their organisation's performance.

Having some space for informal interaction was important, outside the setting of formal regulatory interventions. Through these informal interactions, providers could share ideas, solicit advice or share soft intelligence.

I think centrally our team... had a really good relationship, and has still, with the CQC and has really invested in that. They communicate in between inspections. They definitely have a toing and froing. So I've been to some of the feedback sessions and you can see there's a sort of respectful... It's not a hostile relationship at all, it's mutually respectful.

(Clinical lead, mental health)

We heard from both inspectors and those that were inspected that the characteristics of CQC staff (inspection team members, but also relationship managers and inspection managers) are perhaps the most important determinant of the quality of those relationships. Interviewees from inspected organisations often spoke either very positively or very negatively about their interactions with CQC staff and their behaviours. The characteristics that they particularly valued, and felt were sometimes lacking from their interactions with CQC, were consistency, fairness and objectivity, experience and credibility, and a strong orientation towards patients or service users. They also highlighted the importance of what might be termed soft or interpersonal skills – such as sensitivity, kindness, putting people at ease, showing empathy and facilitating discussion or enquiry. However, sometimes CQC staff were quite negatively perceived, for example as being aggressive, nitpicking, critical or confrontational.

Informational impact: responses to published data on performance

The regulator collates intelligence and puts information about provider performance into the public domain or shares it with other actors who then use it for decision-making (eg, commissioning, patient choice).

We found that the informational impact mechanism worked less well in practice than might be expected. While CQC puts a great deal of information into the public













domain, there are many barriers to its use by the groups it is shared with, including the public, patient and service user groups, health and social care commissioners, and the media. This is the case even when such use might be expected, for example when a health or social care provider has been rated 'inadequate'. Barriers included limited awareness and interest from these groups, a delay in the publication of inspection findings, and perceptions that the information was inaccurate, not relevant or difficult to understand.

It seemed from our interviews that the group most exercised about the information produced and published by CQC was the providers themselves (in line with other studies on the impact of accreditation schemes and league tables). Other groups – such as health and social care commissioners, and national agencies such as NHS Improvement – tended to engage only when performance was poor and concerns were raised. The media also show relatively little interest, except in extremes of performance, such as major failures of care, or exceptional achievements. Providers and patient and public groups told us that awareness of CQC and use of CQC information in the context of choice still seems quite low among the general public and service users when compared with, for example, sectors such as education. Our quantitative research about maternity services also suggested that provider ratings have little impact on patients' choice of provider. This is discussed in more detail in section 4.

However, there were differences between sectors. While providers and patient and public groups told us that patients rarely use CQC reports to choose a hospital, we did hear examples of social care users and their families accessing CQC reports to help them when choosing a care home, so they could avoid lower-rated providers.

So, my starting point has been the CQC website. So, I'll trawl, I'll look at the homes in a particular geographical area and then I will look at the CQC website and discard any that require improvement or are inadequate.

(CCG patient and public representative)

I have had relatives, and also people that come to look around, and they'll say, oh, yes, I've looked up your report online.

(Registered manager, adult social care)















Stakeholder impact: improvement support from system partners

Regulatory actions encourage, mandate or influence other stakeholders to take action or to interact with the regulated provider.

We found that external stakeholder engagement was greatest around the time of an inspection, particularly when the results were poor or raised concerns. However, this support varied a great deal between sectors. Providers of NHS care would typically interact with NHS England, NHS Improvement and/or their local CCG in action planning and implementing any improvements. However, some interviewees from the acute and mental health sectors suggested that stakeholder engagement through the quality summits (which followed every comprehensive inspection) was sometimes rather limited, and in general practice, these summits or equivalent forums were not routine.

Care homes that participated in this study reported that they only received limited support from other stakeholders. As providers of social care services, care homes interact with local authorities (as the commissioner) following an inspection, but not all authorities have quality improvement teams to support care homes. Some interviewees described stakeholder involvement quite negatively as providing scrutiny without support.

[If] you are a hospital, an acute trust, and you are in special measures, the government will give millions of pounds to sort it, they'll send a hit squad in, you'll get all the help under the world [sic] that you can get, to get yourself out of special measures. If you are a care home, and you are in special measures, you'll get no admissions, you'll be starved of money, you'll have CQC and the council, and the CCG, basically encamped in your care home. Your reputation will be ruined, because they put it in the newspapers, and the release is to everybody, so that everybody can see how poor you are, and you get absolutely no help whatsoever. (Managing director, adult social care)

Differences between sectors in the extent of external improvement support may, in part, be down to different assumptions about how improvement works in different parts of the health and care system. For example, in the social care sector, where

many providers are private enterprises, there is an underlying assumption that













market forces will drive poor performers out of the market. In the NHS, there is an assumption that poor providers will be supported to improve rather than being closed down (especially in the hospital sector).

External stakeholders may also be more involved, depending on the internal capabilities of the provider to help itself. This, in part, reflects the perceived ability of the provider to recognise and respond to the issues it faces. For example, NHS Improvement may nominate an improvement director to an acute trust in special measures; a CCG or GP network might work closely with a GP practice that lacks the capabilities or infrastructure to develop and deliver an action plan; or a CCG or local authority would intervene when a GP practice or care home closes in order to manage the patients or residents.

Lateral impact: peer learning and support

Regulatory interactions stimulate interorganisational interactions, such as providers working with their peers to share learning and undertake improvement work

We found less evidence than might be expected of what we have termed lateral impact. That does not mean that lateral learning between peers does not take place (interviewees spoke about a wide range of networks and relationships that they used to share learning or for support), but, as far as we could tell, most of that activity was not particularly connected to CQC inspection and rating, or was intentionally influenced or engaged with by CQC. However, some interviewees identified activities such as using the inspection reports of other providers to learn about the inspection process or good practice, or to explore inconsistencies or differences in inspection judgements. Some had asked staff to take part in CQC inspection teams so they could learn about the process, or had made contact with other organisations that had already been inspected.

We'd got two or three people that were already special advisers, that had done previous inspections, so we brought that learning back. We were able to say where... as I say, which areas do we need to focus on, and how was the inspection going to be managed?

(Senior nurse, mental health)













After an inspection had taken place, especially when the outcome was poor or concerns were raised, some providers spoke of providing peer support to the organisation concerned. For example, general practices in a network might support a poorly rated practice to address CQC concerns. There were clear differences between sectors again, with the strongest networks and examples of lateral impact being in the acute and mental health sectors, some lateral learning in general practice (often via GP networks), and the least in adult social care, where some interviewees thought competitive pressures and a lack of networking structures left some providers quite isolated. Social care is a sector with relatively little infrastructure and support for quality improvement. This makes it an area where CQC could potentially have a big impact, as there is little other information available to support organisations to understand what best practice looks like, and how they might monitor and evaluate quality.

Systemic impact: aggregated findings provoke wider change

Aggregated findings/information from regulation are used to identify systemic or interorganisational issues, and to influence stakeholders and wider systems other than the regulated providers themselves.

We found some examples of CQC ratings being used in aggregate across an area in adult social care and general practice, and of thematic work by CQC being used by health and social care providers and other stakeholders. However, there was some concern that the organisational focus of CQC's regulatory model was not well suited to an increasingly integrated health and social care system, or to provider organisations that work in partnerships, chains or networks. Some of CQC's national work which might be expected to have systemic impact, such as the *State of care* reports, did not appear to have much impact in our case study areas.

And taking a system approach, I think, is much more complex. But taking a system approach as opposed to an approach that's focused on hermetically sealed compartments of health and social care... will be a much more value-adding approach, and that's very difficult to do. But I think the post-modern version of inspection will include that rounded assessment, as opposed to a very focused assessment.

(Senior manager, acute care)













Recognising the need to move away from an organisational focus, in 2017 CQC carried out 'system reviews' in 20 local authority areas. These were focused on the way in which health and social care services are working together to provide care to those aged over 65, and resulted in a report highlighting areas where the system is making good progress, as well as areas requiring improvement. In each of the areas, the review will be followed by a local summit, bringing together local leaders and representatives from the national bodies, including the Local Government Association, NHS England and local Healthwatch (Care Quality Commission 2018).

Challenges in understanding impact

Although our analysis has considered each impact mechanism separately, in practice they do not operate as discrete pathways. A single CQC process (such as the publication of ratings) may trigger behaviours that lead to multiple impact mechanisms.

By applying the impact mechanisms framework to CQC's regulatory process, we have been able to unpick a complex set of relationships between processes, behaviours and outcomes. The framework has provided a useful tool for exploring the very broad concept of impact and has helped to focus our research on outcomes rather than processes.

However, it is important to unpack the way that interviewees spoke about the impacts of CQC's inspection and rating programme. They described what they regarded as both positive and negative impacts, and some impacts for which categorisation was mixed or ambiguous. For example, commonly cited positive impacts included:

- concerns about quality of care being surfaced or made explicit
- specific changes and improvements in care processes or delivery
- greater attention to quality of care from organisations and particularly from organisational leaders
- more robust internal systems for managing and improving quality.















On the other hand, common negative impacts included:

- a diversion of effort to doing box-ticking compliance tasks before an inspection
- a range of negative effects on staff morale and culture
- implementing recommendations or requirements that were not viewed as high priorities (or were even disagreed with)
- the scale of effort and investment of resources required by the inspection process.

Some impacts were more ambiguous – for example, changes in organisational leadership which happened after inspection and rating could be seen as disruptive and unfair by some, but necessary and productive by others. Most of the negative impacts of inspection described by interviewees were largely about aspects of the inspection and rating process, the behaviours and actions of CQC inspection teams and staff, or the way provider organisations interpreted and responded to CQC in more superficial ways, without really doing anything about the underlying issues of quality of care. This suggests there is real opportunity to reduce or minimise the negative impacts of inspection and rating through the careful design and implementation of the systems and processes used.

What might be called the 'causal chain' of impact was also often complicated. Understanding how this works may provide CQC with some insight into how and whether it is having an impact. However, we found that the logic linking a regulatory process to its ultimate impact is usually not fully articulated or understood by the provider or regulator. For example, CQC is clear that regulation, and the associated inspection and enforcement activity, will help facilitate improvement, and on what the ultimate impacts of its regulatory model will be. However, it is less clear about the stages in between: how and why its processes affect behaviour, and the likely intermediate impacts. This applies to CQC at both a corporate level, and to individual CQC inspectors who may not always be clear about how the processes they use, and their approach, will affect the providers they regulate.

Interviewees often asserted that a problem was already known about or recognised within the organisation, and that action was already planned or under way to address it. Interviewees commonly argued that CQC inspection reports had told













them little that was not already known about their organisation. However, it was important to deconstruct what 'already known' might mean. It could mean that some people knew about the issue but perhaps it was not widely known or voiced in public, and CQC's report led to the issue being surfaced or formalised.

... strangely people came forward and said oh yeah, we always knew they were rubbish. All the GPs in the area knew that they were really poor, NHS England knew they were poor, the CCG said we knew they were poor, but we didn't have the power to do anything about it. And it's in those circumstances that I think the CQC's remit really is so important because we were able to do something about it. (CQC staff, GP sector)

CQC's inspection and rating approach was seen as helping to drive change by providing legitimacy to particular points of view, creating consensus and building momentum around a change, and helping secure necessary resources. Interviewees often described the impact of CQC as catalytic, speeding the pace of change, rather than transformative, uncovering new knowledge and setting new directions for change.

Some key determinants of impact

CQC introduced a system of inspection and rating that was intended to be similar across all the sectors it regulates. However, these sectors operate differently, and have different histories and experiences of inspection (see Table 1); all of which can impact their ability to plan for, and respond to, inspection. Many of the findings we have reported above do carry across the four sectors we considered, although often there were differences and we have highlighted these, particularly in the case of adult social care. Below we describe three factors that we identified as having an effect on impact, which seem to influence some sectors' response to inspection more than others.

Size of provider

We found that the size of a provider had some impact on the way the provider and other stakeholders responded to an inspection and rating, particularly where there were enforcement actions or a poor rating.













Providers of different sizes, and different provider types (see below), have different criteria by which they determine a responsive action. A small provider might choose to close, for example, if there are any financial constraints on making the necessary improvements or if the owner/partner is nearing retirement anyway. Independent providers (particularly care home chains) might decide that the investment in improvement is not going to be of value for their business and can decide to close.

Also, some of the anticipatory benefits of inspection may occur only in large providers, where increased communication in advance of an inspection has more scope to have a positive impact, such as through increased staff awareness of the organisation's quality improvement agenda, and increased staff engagement generated through events organised to prepare for CQC inspection.

Type of provider

Linked to the above, the characteristics of different organisation types, and the market environment in which they operate, can also influence the way in which providers – and other stakeholders – respond to inspection and rating. In particular, we noted several differences between responses in the acute and mental health sectors, where most providers are NHS organisations, and responses in the social care sector, where most providers are independent, either for profit or not for profit.

For example, an acute trust in special measures is very unlikely to close (although it may be subject to a takeover), and stakeholder action will usually be aimed at supporting the provider to improve. In contrast, a care home or single GP surgery can decide to close, or a commissioner can decide to restrict or suspend a contract in response to a poor rating or enforcement action. In addition, because care homes and home care agencies compete for business, they tend to be less willing to share learnings from inspections with one another. As a result, we found less evidence of lateral impact in the social care sector than we did in the acute and mental health sectors.

Capacity and capabilities of provider

The extent of the provider's capacity and willingness for change and improvement was a central determinant of impact. Interviewees sometimes viewed a provider as lacking the necessary capability and capacity to address concerns raised through inspection.













So it varies from provider to provider and sector to sector based on where the big priority areas are, and also organisational state, so whether they've got the skills and expertise internally to do the turnaround or whether they need a bit of support to do it. So that's kind of what they do. Some organisations really value improvement support, others expect it to happen internally. (CCG staff)

In some cases, interviewees argued that these more resistant providers had a long history of poor performance, which past efforts, before CQC became involved, had failed to change. In others, they asserted that the provider's improvement capacity or capability was fundamentally constrained by other health and social care providers, or the wider system. The combination of the provider's own improvement capability and the availability of external support for improvement emerged consistently as a likely predictor of impact. In short, interviewees reported that providers with little internal improvement capability and/or limited external support for improvement made little progress even in the face of inspection, rating and subsequent enforcement action by CQC. Any progress could often be temporary and easily reversed.

For CQC, understanding these issues of improvement capability and improvement support was important in order to take the regulatory action most likely to lead to the organisation making improvements (including through support from elsewhere in the system). CQC reports that this capability is more important in triggering improvements than the enforcement action or rating received. At the time of inspection, some providers are on an improvement pathway and others are starting to decline. When providers are on their way up, they want to hear and learn from the inspection. When they are on their way down, they may not have the motivation or capacity to hear what they are being told.

Many interviewees discussed how this issue specifically affects general practice. It can be the case that GP practices that receive an enforcement action or an 'inadequate' rating are those that do not have the capability or resources to respond, and cannot make progress. In some instances, these can be single-handed practices where the GP realises that they cannot continue to practise any longer or are unable to make the necessary improvements. They will voluntarily cancel their registration, retire or merge the practice into a larger practice that can support them.













What does performance data tell us about impact?

This section summarises the findings of three analyses that used routine data sources to explore whether the impact of CQC inspections can be measured quantitatively. The first looks at whether key performance indicators can predict the outcome of inspections. The second examines whether, on the basis of routine data, reported performance in A&E services, maternity services and general practice improves following an inspection. Finally, we consider whether patients and others use CQC data to guide their health care choices, by examining the impact of CQC ratings on maternity service volumes.

Here we describe the high-level findings from detailed analytical studies. More information on the methodologies and findings is available in a series of working papers that can be requested from the authors (see Appendix A).

Can performance data predict inspection ratings?

To help CQC assess the risk of poor performance prior to an inspection, it compiled a large set of routine data indicators called Intelligent Monitoring (IM). CQC wanted to improve its approach to inspection by using IM data to help it decide when to inspect a provider and what to focus on during inspections.

The Intelligent Monitoring datasets

The IM datasets are sets of indicators used by CQC to assess the level of risk of poor performance prior to an inspection. The datasets bring together a range of existing data sources, including provider activity data, staff and patient surveys, electronic staff records, and complaints.

The CQC began using the IM datasets in 2013. They evolved over time, with indicators being added, removed or changed. By the time the datasets were retired,















IM was in its fifth iteration for acute hospitals (released in May 2015) and its second iteration for general practice (released in June 2015).

CQC has now developed a new system for risk assessing trusts called CQC Insight. CQC Insight was in use by all sectors by July 2017Our analysis uses the previous IM datasets.

We examined whether the IM datasets for acute hospitals and general practices could be used to predict subsequent inspection ratings, and therefore whether they were a useful way of assessing risk and prioritising inspections.

It is important to consider what kind of predictive value or contribution we might expect from the performance indicators. On the one hand, inspections draw on a wide and varied range of data, including indicators in the IM datasets, alongside quantitative and qualitative data collected during the inspection, and the judgements and experience of inspection teams. Therefore, we would not expect IM data to be able to predict inspection ratings perfectly (and indeed, if they could, then we would question the added value of inspections). On the other hand, as the IM datasets were meant to help CQC make better decisions about when, where and what to inspect, to do this effectively it must have some demonstrable validity as a measure of the quality of care or of performance, most obviously through some association with subsequent inspection ratings. The predictive capability of performance data is an important part of the 'intelligence-driven approach to regulation' set out in CQC's revised strategy for 2016–20 (Care Quality Commission 2016a).

Our analysis found that the quality indicators used in CQC's IM datasets had little or no correlation with the subsequent ratings of general practices and of acute trusts. In general practice, the model we constructed predicted the correct rating 80 per cent of the time, but this was mainly because most practices were rated 'good'. The model did not correctly predict any of the 270 practices that received an 'outstanding' rating, or the 172 practices that received an 'inadequate' rating. In the acute sector, our model predicted just 24 per cent of ratings correctly. Therefore, we conclude that the IM datasets were probably not very useful for prioritising inspections.

This raises important questions about what those indicators and CQC inspection ratings are intended to measure. If we think that both are seeking to measure the













quality of care or wider aspects of provider performance, it is perhaps a surprise that there seems to be little association between them. While inspections draw on a much wider set of information than performance indicators, the poor predictive value of performance indicators for inspection ratings may call into question the validity of indicator data, rating data or both. It also highlights the need to combine both qualitative and quantitative sources of information when risk-assessing providers and targeting inspection activity.

Does provider performance change following inspection?

We undertook analyses in three areas – general practice, A&E, and maternity services – to explore whether provider performance changed after inspection, and whether any change in performance was related to the provider's rating category. To do this, we looked for changes in performance six months after an inspection, and six months after a rating was published. We hypothesised that performance might improve after inspection and rating, and that improvement would be most likely to be found in providers with poor performance who had been rated 'inadequate' or 'requires improvement'.

We chose areas to study where there was routine data available and some established clinical quality or performance indicators that we could use to explore the association with inspection and rating. This meant, for example, that we were not able to analyse the impact of inspections in social care, where there is little available routine data on performance. We were also not able to measure the impact of inspections in mental health trusts, as the relatively small number of providers meant it would be difficult statistically to draw any meaningful conclusions.

General practice

In general practice we examined whether prescribing behaviours changed after inspection and rating, using data from 6,600 practices on four prescribing indicators relating to antibiotics, hypnotics and non-steroidal anti-inflammatory drugs. The indicators measure things such as the proportion of prescribed antibiotics that are broad spectrum rather than narrow spectrum (the latter should usually be prescribed), and the number of hypnotic drug items prescribed (these drugs have a high risk of side effects when used for long periods of time and should only be used when clinically appropriate).















The four prescribing indicators we studied were used in CQC IM datasets, as well as in the National Institute for Health and Care Excellence (NICE) key therapeutic topics. Data on prescribing formed part of the data briefing on practices that was made available to CQC inspection teams, although inspections do not particularly focus on prescribing behaviours. Our use of these indicators was in part pragmatic – prescribing data is one of the very few high-quality, routinely collected time series datasets available for general practice.

Our analysis found that, in the six months after practices were inspected, prescribing behaviour generally improved slightly for practices rated 'inadequate' or 'requires improvement', but worsened slightly for those rated 'good' or 'outstanding'. Although these effects were small, the changes made post-inspection appear to be long lasting. However, there was no evidence of a change in performance associated with the date of the publication of the inspection report and rating.

Accident and emergency

We used data on CQC inspections of A&E services in acute trusts and linked this to a set of six NHS England indicators that are routinely used to measure the performance of A&E departments. The six indicators were:

- time to initial assessment
- time between arrival and the start of treatment
- total time spent in A&E
- proportion of patients who left department before being seen for treatment
- total time spent in A&E is four hours or less
- unplanned reattendance within seven days.

Timely care, A&E waiting times and unplanned reattendance are areas covered in CQC's inspection handbook, which guides inspections of A&E departments. Inspection reports often describe performance in areas such as patient flow, triage, review and admission, and in so doing refer directly to the indicator metrics. Therefore, we hypothesised that those A&E departments that do well on the NHS England performance indicators should also perform well when inspected and rated by CQC, and vice versa. We also hypothesised that, after an inspection,













performance on the NHS England indicators should improve, especially for A&E departments that were rated 'inadequate' or 'requires improvement', as these departments probably have both the greatest scope for improvement and the strongest incentive to do so.

Our analysis found no clear pattern in changes in performance after inspection and rating, and certainly no evidence that performance improved either overall, or for trusts with poorly rated A&E services ('inadequate' or 'requires improvement').

A&E departments are subject to a pervasive and ongoing performance management regime, which involves intensive attention from both NHS England and NHS Improvement, combined with the publication of regular performance statistics. This may leave little room for CQC's inspection and rating process to generate additional improvement. In addition, the impact of rising demand for A&E services, financial pressures on hospitals and staff shortages may override the impact of regulation on A&E performance.

Maternity

We linked CQC ratings of maternity and gynaecology services to maternity performance, as measured by 14 quality indicators developed by the Royal College of Obstetricians and Gynaecologists (RCOG). The RCOG developed the indicators as a way to measure patterns in maternity care and outcomes across providers and over time, and in so doing stimulate a discussion about how improvements can be made. However, the indicators are limited in scope because they are derived from routine data sources.

Maternity services' relative freedom from mandated performance management, and the fact that they are to some extent self-contained and insulated from the performance of other hospital services, means there is potentially greater scope to observe change driven by CQC inspection and rating programme.

However, our analysis of the quality indicators found no statistically significant changes after inspection for any of the 14 indicators, for any rating score. We therefore found that CQC inspection had little apparent impact on available quality performance metrics in maternity services.















Do provider ratings affect service volumes?

Finally, we explored whether CQC ratings affect where patients seek treatment. We hypothesised that if CQC inspection reports and rating scores are used by patients or GPs to choose a service, the area of health care where we would be most likely to see their impact would be in hospitals with a very poor rating, for services where patients have scope and agency to choose another provider. We explored the impact of CQC inspection and rating on service volumes in maternity services, by examining whether publication of an 'inadequate' rating for a hospital appears to affect referrals to hospitals, or parents' choice of hospital for delivery.

Prospective parents have the time and motivation to consider the options in relation to maternity services, and ready access to a wide range of information and advice. However, the availability of alternative maternity service providers varies between areas, and we addressed that issue in our study.

We set out to identify NHS hospital sites that had been rated 'inadequate' for their maternity and gynaecology services, and then to examine whether the volume of births at those sites changed after the rating had been published and potential service users had had the opportunity to respond by seeking a referral to a different hospital site (one with a higher CQC rating).

Our analysis found that CQC inspection and rating of maternity services at hospital sites that have received an 'inadequate' rating on a prominent aspect of care (overall, safe or caring) seems to have little measurable impact on subsequent service volumes, and we therefore conclude there is little evidence of parents (or their agents) exercising choice in response to such ratings.

It would be interesting to analyse the impact of poor ratings in other sectors such as social care, where there is arguably more scope for service users and families to exercise choice, especially when entering residential care. Unfortunately, there is no activity data available in social care to enable a similar analysis to be conducted.

Interpreting the findings

Our attempts to measure the impact of CQC by analysing changes in routine performance indicators found little or no impact across a range of sectors, services and indicators. This contrasts with the findings of our qualitative fieldwork (outlined













in section 3), where we heard about providers responding to inspection in a range of ways, including making improvements to organisational processes and to services. In the next section of the report, we discuss why this may have been the case.

Importantly, our analyses – and their apparent contrast with the findings from our qualitative research – show the need to combine both qualitative and quantitative data sources to gain a full understanding of impact, and to meaningfully prioritise regulatory activity.













Discussion

As CQC shifts to a more focused approach to inspection – more reliant on gathering insight through performance metrics and other sources of intelligence, and less reliant on routine inspections for all providers – our findings can provide useful insights.

Measuring quality

In its strategy for 2016 to 2021, CQC articulates its aim to move to a more intelligence-driven model of regulation and inspection across all health and social care sectors, and it has replaced IM with a new system, CQC Insight (Care Quality Commission 2016a). In that light, it is worth considering what lessons can be drawn for CQC Insight from our research.

Proportionate or risk-based regulation requires the regulator to be able to monitor performance and adjust its regulatory response accordingly. We would therefore expect CQC's quality monitoring systems to have some predictive value. We do not think that the system of IM has been able to support such prioritisation and targeting of regulatory resources. The predictive value of quality-monitoring datasets might be improved by using more up-to-date data; using time series data to take into account changes in provider performance over time; and using a wider range of data sources. However, our research suggests that there are limits to how much regulators such as CQC can design and implement risk-based or responsive regulatory models that target regulatory interventions to providers based on available performance metrics.

We welcome CQC's efforts to develop a more insightful monitoring system, which draws together both hard and soft intelligence from a wide range of sources, and takes into consideration providers' own ability to accurately and honestly self-evaluate. However, the difficulty of doing this in practice should not be underestimated. This challenging work must engage patients, users, providers and commissioners in the development of a multifaceted monitoring tool.













Our efforts to measure the impact of inspection and rating quantitatively have largely drawn a blank, and it is worth reflecting on why that is the case. There is a long and complex causal chain between CQC's regulatory interventions and many of the things that we were able to measure in acute care and general practice, using the limited available routine data sources. There is also a range of factors that affect provider performance, both internal and external to the provider, and isolating the effect of inspection from these other influences is challenging. In addition, our qualitative research shows that regulation has an effect on providers before, during and after inspection, which may make it difficult to measure impact using the point of inspection (or report and rating publication) in a before and after comparison.

Nonetheless, it is notable that what has been a resource-intensive and very highprofile system of inspection and rating does not seem to have had more than quite small and mixed effects on available performance indicators in areas such as A&E, and maternity services, or on general practice prescribing. Inspection and rating dominate CQC's regulatory model, consume most regulatory resources, and perhaps crowd out some other potential regulatory activities that might be more impactful. There is a risk that inspection, which is just another regulatory process, becomes perceived as a purpose in itself. We recognise the value of inspections in identifying poor-quality care, and the many pressures on a regulator such as CQC to inspect. However, we would question the value of wholesale, comprehensive inspections, which – due to the inevitable accompanying periodicity of inspection oversight – can paradoxically mean long periods without much regulatory scrutiny. CQC's new approach to inspection might address this by using monitoring data differently; having more graduated, proportionate and frequent regulatory contact (avoiding long intervals without significant interaction); alongside less use of comprehensive, intensive inspections.

Importance of relationships and social processes

Our focus in this research was primarily on understanding the impact of inspection and rating, rather than studying the processes involved. However, our interviewees often wanted to talk about those processes, not least because of their perceived consequences for the impact of inspection and rating. It became clear that the two are difficult to disentangle in practice. 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.

Many respondents, to varying degrees, spoke about how their interactions with CQC, through inspection and rating, evoked feelings of fear and anxiety in both provider staff and managers, and sometimes contributed to the development of cultures of fear. A small number of provider staff and managers, and CQC representatives, described how management used the threat of CQC as a means of influencing people's behaviour, although it was rarely viewed positively. We also heard CQC process sometimes described as an 'exam' or similar, with associated 'exam anxiety' cultivated among staff, which was not viewed as wholly productive or positive by providers.

This all demonstrates the importance of the relationship between inspectors and providers, and highlights the influence they can have on regulatory impact. For the regulator, it seems its credibility, authority and effectiveness are only as good as the people who make and sustain regulatory relationships with providers. CQC is reliant on expert inspectors (representing professional groups or patients and users) in their inspections. It is important that expert inspectors and CQC staff all appreciate the importance of these relationships.

Providers must also play their part in developing this new type of regulatory relationship by supporting their staff to be open and improvement focused in their interactions with inspectors, rather than defensive and closed.

Our interviewees identified some attributes of a good regulatory relationship (see box below).

Evidence on the influence of regulatory relationships highlights the value of investing in building and sustaining these relationships. This has important implications for the selection and training of the inspection workforce. It also underlines the need to ensure that, in addition to formal communications between regulator and provider staff, there are opportunities for informal interactions enabling the exercise of interpersonal skills and soft influencing behaviours.













Characteristics of a good regulatory relationship identified by interviewees

- Continuity a longitudinal relationship with the same inspector
- Openness and transparency
- Mutual trust and respect
- Shared values
- Mutually agreed ways of working
- Space for informal interaction
- Credible inspectors who are consistent, fair, objective and experienced
- Inspectors who have excellent interpersonal skills.

An additional challenge for inspection staff, as they seek to maximise the value of their regulatory relationships, is maintaining consistency in the way they regulate different providers (something that is essential in order to preserve the integrity of their process) and not being 'captured' or losing the objectivity required to make accurate regulatory judgements. Again, recruiting and training an inspection workforce with the credibility and skills necessary to be open and flexible, while also retaining objectivity and consistency, will be key to ensuring the regulatory process remains both uniform and personal.

Work to develop this type of regulatory relationship has started within CQC and across the other health and care arm's length bodies. Regulatory relationships are given a much greater emphasis in CQC's current strategy and, through the *Developing people – improving care* framework, regulators and other arm's length bodies have committed to taking a more compassionate approach to system leadership and to giving providers time and space to develop their own improvement capabilities (National Improvement and Leadership Development Board 2016). However, as the national organisations acknowledge in their strategy, behaviours are currently a long way from where they would like them to be, and this is a key area in which to track progress and ensure strategic commitments are turned into operational changes in practice.













Embedding quality improvement

CQC explicitly recognised several levers that it used to encourage providers to improve. It directly encourages improvement through its use of enforcement, where it believes its people are at risk of harm and so urgent action is needed. Improvement is also encouraged through their other feedback. Indirectly, it shares findings, analysis and insights to encourage regulated providers and stakeholders to act on learning and make changes, including by recognising and championing good and outstanding care. And its model for quality provides a framework that providers can embed into their own ways of working to facilitate improvement.

There is an expectation that providers will learn from one another's experiences of inspection, both positive and negative, although the extent to which this happens varies between sectors. In the case of social care, we found minimal evidence of this lateral learning, and infrastructure to support quality improvement is relatively limited. As such, there may be a particular opportunity for CQC to have an impact in social care by helping organisations understand what good looks like, and how they can monitor and evaluate quality.

However, unless providers have internal quality improvement capacity, CQC can only have limited impact. For example, anticipatory impact depends on organisations knowing about, and understanding, CQC's expectations; being motivated (intrinsically or extrinsically) to comply with them; and having the capacity and capability to do so. If CQC has clearly communicated meaningful quality expectations, finding an organisation that has not responded to those expectations before an inspection, or that does not have an accurate self-evaluation of its own compliance with those expectations, could be in itself a cause for concern about the organisation's culture and capability.

A recurring theme in our data was the importance of fostering commitment rather than compliance within NHS and social care organisations to bring about improvement. This means tapping into the intrinsic motivation of staff to do a good job, and relying less on extrinsic motivation, which, at its worst, can descend into fear and risk aversion. Inspection can only be effective if frontline teams and leadership teams are fully engaged in delivering the highest possible standards of care within available resources. The challenge for CQC is to use its powers to facilitate reform from within, encouraging organisations to develop the capability they need to improve, and catalysing other parts of the system – such as NHS













Improvement, NHS England and local commissioners – to support them. To do this, the role of regulation in improvement needs to be considered alongside other improvement approaches. First, this should be done to ensure the approaches are complementary, so that regulation supports rather than stifles organisational efforts to improve. Second, other improvement approaches may provide learning that can be used to develop the regulatory model.

The role of inspection in systemic transformation

In order for CQC to have impact at a system level, there is a presumption that stakeholders in the system agree on the diagnosis, and have the capacity, capability and will to unite and take action. If CQC is reliant on wider stakeholder groups to support providers towards compliance, this support must be available on a more consistent basis across sectors, and stakeholders need to be aware of their role. CQC needs to work more closely with stakeholders (particularly commissioners and other regulators) to support providers to improve, and, when appropriate, manage the consequences of a closure. This includes further alignment of the regulatory processes of the different regulators to ensure they complement, and do not conflict with, one other.

NHS England and NHS Improvement have recently announced their intention to work in closer partnership in overseeing the health sector (NHS England and NHS Improvement 2018). CQC could play a significant role in this partnership, through aligning regulatory processes and maximising the potential systemic impact; building on work already under way to agree a consistent approach to defining and measuring quality with other arm's length bodies (Care Quality Commission 2016a). In order to have a sustainable impact on local systems, CQC needs to join up its assessments with NHS Improvement and NHS England, as well as commissioners, professional networks and other key actors in local systems; something that has been found to be difficult in the past.

CQC's impact is fundamentally shaped (and constrained) by the wider system of care. While its regulatory interventions typically address the performance of individual health and social care providers, they have less insight on the wider context or setting. Especially in the short term, it may be easier for CQC to effect change through bilateral actions such as enforcement; but in the medium and longer term, CQC needs to be able to co-opt other stakeholders to the













purposes and processes of performance improvement, and secure engagement and collaborative effort. The way this works in different sectors and regions is dependent on the internal improvement capabilities and motivations of provider organisations, and the existence of external improvement support and infrastructure from other stakeholders.

As health and social care provision becomes more integrated, regulatory approaches that are more multilateral – such as the recent local system reviews – are likely to become more useful and effective. While regulatory action will continue to take place at all levels of the system, the balance will shift somewhat from regulatory approaches that focus on sectors or individual providers, towards system-wide action.













6 Conclusion

We noted at the start of this report that the regulatory model adopted by CQC in 2013 (Care Quality Commission 2013) was a major departure from its previous, somewhat discredited, regulatory arrangements. It was developed at a point in time when CQC had faced widespread criticism from many quarters including the National Audit Office (2011), the Health Select Committee (2011) and the Department of Health (2012). CQC was perceived as having failed to detect or prevent some major problems in health and social care in the past. It had seen a virtually complete change of its board and senior leadership, and the new regulatory model was clearly intended to mark a fresh start for the organisation, and for health and social care regulation. It was much more resource intensive and involved changes to almost every aspect of the regulatory regime, albeit without much revision of the underlying statutory legislation.

In this research we have tried to add to what is known about the impact or effects of regulation. We wanted to move beyond just measuring the scale or type of such effects, to understand how they come about, and what we, CQC and other stakeholders might learn that would be useful in designing and implementing future regulatory models.

We present a mixed and nuanced picture of the effects of CQC's new regulatory model, and particularly of the system of inspection and rating. On the one hand, our interviews show that providers have responded to inspection and rating by taking a wide range of improvement actions before, during and after inspection. On the other hand, we also identify some important limitations to the effectiveness of the model, note some negative or unintended consequences, highlight an absence of quantitative data on impact, and describe some differences in how it has worked in different health and social care sectors.

We found evidence of impact across all the four sectors that we studied: acute care, mental health care, general practice and adult social care. The model put in place by CQC had been internalised and adopted by many providers in their own organisational systems and processes for quality improvement perhaps more so in acute care and mental health care than in adult social care or general practice.

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Most obviously, CQC's conceptualisation of the quality of care in five domains – safe, effective, caring, responsive and well-led – had been embraced and had become a pervasive framing of the quality of care.

We highlight the multiple pathways or mechanisms through which CQC can influence the performance of health and social care organisations, and the systems of care they work in. That raises an important question: where should a regulator such as CQC invest its limited regulatory resources in order to yield the maximum positive impact on performance? Our findings suggest that the current model has been driven predominantly by the processes of inspection for individual health and social care providers, and that it is worth considering how CQC could more effectively broaden its impact across systems of care.

CQC has to tread a difficult line in maintaining sufficient critical distance from the health and social care system. It must be seen to be objective and impartial, and at the same time sufficiently engaged to develop the necessary credibility, authority and mutual trust and respect with organisations and the wider system. Our work has highlighted the social dimension of regulation and the importance of relationships between CQC staff and those working in health and social care provision, and suggests that a more transactional approach to regulatory interventions risks undervaluing the soft, informal, influencing power of regulation. It suggests that, however well conceptualised, designed and planned the regulatory model may be, its impact is fundamentally shaped by how it is experienced, how it is implemented, and the skills and values of those who are involved in regulation.

Providers also play a critical role in the regulatory relationship. Our research shows that the benefits a provider derives from regulation can be related to the effort it puts in to the process. Social relationships are two-way, and the impact of CQC on quality is not only affected by how CQC interacts with providers; it is also critically affected by how providers interact with CQC. The providers likely to gain most develop strong ongoing relationships with CQC staff; seek to engage staff in improvement throughout the year, rather than episodically in response to regulation; embed CQC's quality definitions into their quality monitoring processes; and draw on CQC's broad knowledge of quality across the system as a tool to help them improve.

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Our research found a general consensus that quality regulation is a necessary function in the health and care system. It also found room for improvement in how organisations on both sides of the regulatory relationship, and stakeholders in local systems, work to maximise its value.

Conclusion 49













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Appendix A: Overview and working papers

Overview report: The effects of the Care Quality Commission's new inspection and rating system on provider performance

Working paper 1: Understanding and evaluating the impact of regulation: a literature review

Working paper 2: Understanding and evaluating the impact of inspection and rating by the Care Quality Commission: developing theories of impact

Working paper 3: Understanding and evaluating the impact of inspection and rating by the Care Quality Commission: from theory to practice

Working paper 4: The impact of CQC inspection and rating on user voice and choice in health and social care

Working paper 5: The human side of regulation: emotional responses and relational impact

Working paper 6: The sharp end of regulation: inspection and enforcement

Working paper 7: Help or hindrance? The Care Quality Commission's role in quality improvement

Working paper 8: Do quality indicators predict regulator ratings of health care providers? Cross-sectional study of general practices in England

Working paper 9: Do performance indicators predict regulator ratings of health care providers? Cross-sectional study of acute hospitals in England

Working paper 10: The impact of regulator inspection and ratings on primary care prescribing

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Working paper 11: The impact of inspection and rating on clinical indicators and service volumes in maternity services

Working paper 12: The impact of regulator inspection and ratings on performance in accident and emergency services

Those interested in reading the overview and working papers can request a copy by contacting the following email address: website@kingsfund.org.uk

Appendix A 54















Appendix B: Methodology

We first undertook a review of the literature on regulatory regimes and their impact, and developed a theoretical framework based on eight identified impact mechanisms. We also undertook a review of documents and held interviews with senior CQC leads and people from other national organisations (19 interviews). We sought to understand the design of CQC's new regulatory model, which was adopted in 2013, and how it was expected to impact on the performance of health and social care organisations.

We then looked at the impact of inspection and rating in four sectors: acute care, mental health care, adult social care and general practice. We observed some comprehensive inspections, and then chose six geographic case study areas for more detailed analysis. These areas were chosen to represent a variety of contexts. Consideration of CQC inspection coverage and ratings suggested they were broadly representative, with a combination of organisations that had already been inspected and that were still to be inspected at the time we started our fieldwork.

In each case study area we first interviewed CQC staff involved in inspections and representatives of stakeholder organisations such as local Healthwatch, NHS England and CCGs (a total of 49 interviews). We also interviewed a range of staff from health and social care provider organisations in all four sectors: at different levels and from different backgrounds (a further 81 interviews). In addition, through local Healthwatch and other avenues, we identified and approached a range of patient and public groups in each case study area and interviewed representatives of those groups (21 interviews). We also collated a wide range of documents through our fieldwork.

The interviews were recorded, transcribed and initially coded deductively by the research team in Dedoose, a qualitative software tool, using the impact mechanism framework. During this process the research team inductively identified additional codes, and themes emerging from a close reading of the data, and regularly discussed and compared coding as it progressed.

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For our quantitative analyses we used routine information sources in acute care and general practice to examine changes in performance indicators and other measures before and after inspection and rating. Comparable data was not available for mental health trusts and adult social care providers.

To study how providers perform before inspection and the use of IM in acute care and general practice, we aimed to test the power of IM (used by CQC to prioritise inspections) in predicting the rating score made at the first inspection of a provider. In both sectors, our statistical approach involved performing an initial regression that modelled CQC rating on IM indicators.

To study how provider performance changes before and after inspection and rating, we used data from CQC on the first inspection of a general practice or acute hospital. This data was linked to performance indicators specific to the three areas we studied: general practice prescribing, A&E services, and maternity services. Prescribing data is publicly available at a monthly level for all general practices. Indicators for A&E and maternity services were generated from Hospital Episode Statistics, which were obtained from NHS Digital.

To study how service volumes change after a provider was rated 'inadequate', we examined maternity service volumes in hospitals rated 'inadequate' for maternity and gynaecology. Service volume was calculated from Hospital Episode Statistics data, which was obtained from NHS Digital. Our approach was to determine, graphically, if maternity service volume decreased in the period of time after an 'inadequate' rating was published.

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Disclaimer

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How does regulation affect the performance of health care providers? In 2013, the Care Quality Commission (CQC) introduced a new approach to inspecting and rating health and social care providers.

Impact of the Care Quality Commission on provider performance, presents findings from the first major evaluation of this approach, carried out by The King's Fund and Alliance Manchester Business School. The report presents a new framework for understanding the impacts of regulation. The framework outlines eight ways in which regulators can have an impact – such as 'anticipatory impact' (changes made in advance of inspection) and 'relational impact' (the impact of ongoing relationships).

Between 2015 and 2018, this framework was used to examine how CQC's inspection and rating model was working in acute care, mental health care, general practice and adult social care in six areas of England. This was combined with quantitative analyses of national data on provider performance, ratings and activity and produced a number of key findings.

- Regulation can have an effect before, during and after inspections through interactions between regulators, providers and other key stakeholders.
- There are significant differences in how impact is achieved between sectors.
- Relationships between CQC staff and health and social care professionals affect how regulation works and what impact it has.
- Providers involved in the research generally accepted the need for quality regulation and saw the approach CQC introduced in 2013 as an improvement on the previous system.

The report highlights issues for CQC, other stakeholders and providers to consider as they continue to develop the regulatory model.

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