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Bold thinking for better health

Evidence on what works in regulating health and social care

Report from the scoping phase of an evaluation of the CQC's regulatory model

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What we did and why

The Care Quality Commission (CQC) is rebuilding its approach to the regulation of health and social care, following three major reviews that identified significant issues with its single assessment framework, information technology (IT) platform, and operating model, which were introduced at the end of 2023. This improvement work focuses on tackling immediate issues, such as the backlog in provider registrations and foundational improvements that in the first half of 2025 have included the development of a refreshed organisational vision and purpose that will guide future work. As part of this period of change, CQC has commissioned The King's Fund to develop an evaluation of its future regulatory model. This is an important signal of CQC's commitment to building evidence-based practice and learning into its new approach.

The King's Fund is developing the evaluation with Professor Kieran Walshe from the University of Manchester. Together, we have a history of working collaboratively with CQC over the past decade to support the development of its regulatory model at key moments of change.

This report sets out findings from the first phase of the evaluation – a scoping phase that took place between February and June 2025 and included a review of literature, interviews with experts, and engagement with CQC staff. It outlines relevant insights from the evidence about what works in regulation to inform CQC's work to rebuild its regulatory model. This part of the research sought to answer two overarching questions.

- What works and what does not work in the model of regulation for health and social care?
- What are the implications for the development of CQC's future regulatory model?

The report has also informed the development of a proposal for the rest of the evaluation, which has been submitted separately to CQC.

What the evidence says about what works in regulation

Working with CQC, we identified five challenges facing the organisation where there is an opportunity for evidence to help and used these to structure our review of the evidence.

1 Setting regulatory expectations

Communicating expectations for what good-quality care looks like and how it will be assessed is one of the major ways that CQC can have an impact, but it is not currently using this lever effectively. The recent reviews of CQC found that the single assessment framework is difficult to understand and providers are not clear on CQC's expectations and what they need to do to

meet them. In our conversations with CQC we also heard that some CQC staff are unclear about how the assessment framework is intended to work. Information on CQC's website was criticised for being inaccessible and difficult to find.

Our review of evidence found that an effective regulatory model is one that is fully aligned with the regulator's mission and purpose, uses a range of methods to achieve the regulator's purpose (not just inspection), and is tailored to the different organisations it regulates.

Clearly communicated standards can be a powerful tool for improving quality in advance of any regulatory action, but to be effective they need to be set high, with relevant detail and guidance to support improvement. Co-producing the guidance with regulated organisations can be a good way to do this.

The literature also highlights 'enforced self-regulation' (where regulators specify outcomes and give organisations the flexibility to achieve them in their own way) as a potentially useful component of the regulatory model, but only when accompanied by a facilitative and supportive approach from the regulator. There was no evidence about how enforced self-regulation works in small organisations.

2 Ensuring expertise in the regulatory workforce

The ability of a regulator to discharge its responsibilities well hinges on its inspection workforce and the way it delivers the regulatory model. In relation to CQC, inspectors are the face of the organisation. However, the recent reviews of CQC found that they sometimes lacked knowledge of the sectors they were inspecting, affecting their credibility with providers, and that they did not have enough training and support.

The literature highlights three key skill sets that are needed for inspection teams to be credible and effective:

- sector expertise
- regulatory expertise
- relational skills.

Furthermore, staff with a broad range of experiences should be used to support inspections.

It is also important to develop an approach that allows inspection teams to use their professional judgement. Too much focus on rule-based regulation and not enough room for inspectors to use their discretion can lead to a lack of awareness of risk or inconsistent judgements.

A strong message from the literature is that investing in effective training and development for inspectors is vital. This includes creating mechanisms for peer support, devising ways for staff to give feedback about new ways of working, and structuring workloads in a way that leaves adequate space for learning.

3 Adopting risk-based regulation

A risk-based approach to regulation, where the level of scrutiny applied to a regulated organisation is proportionate to the level of risk they are judged to pose, was central to CQC's latest regulation strategy. CQC prioritised an insight-driven approach and an 'always on' programme of surveillance, alongside an intention to support improvement and innovation. However, the recent CQC reviews identified challenges enacting this, including:

- gaps in the data used to monitor risk
- issues with data-sharing between national bodies
- delays in responding to issues of risk
- problems with the way information about risk is used to decide what an assessment should focus on.

Evidence across different sectors shows it is very difficult to enact risk-based regulation. Although such an approach has become increasingly prominent internationally, it is not universally accepted as the best way to regulate in practice.

Using data models to identify risk is challenging. Risk information is always imperfect and risk-based regulators need to work with significant gaps in data and with information that is often suggestive rather than definitive. Risk-based approaches always involve a process of learning – rather than adoption of a fully formed model – and require ongoing evaluation and development.

The literature also shows that relational factors – for example, how inspectors interact with providers – remain key, and heavily data-driven approaches do not fit readily with a person-centred approach.

Finally, inspectors need support, resources and the capacity to use risk information.

4 Developing relationships and trust

The problems with CQC's current regulatory model have severely damaged its relationships with providers and other stakeholders. Repairing relationships and trust is a key focus of efforts to rebuild the organisation.

The literature highlights the importance of a regulator investing in the development of good-quality relationships with the organisations they regulate. Regulators need to be flexible in the way they work with providers and be able to use different styles of engagement when appropriate.

The literature also highlights the importance of developing public trust in a regulator's work, which can in turn lead to providers having more trust in the regulator.

5 Changing the regulatory model

In 2023, CQC simultaneously changed its assessment model, IT platform and operating model. The complexity and scale of these changes did not leave enough capacity for the planned piloting, testing and evaluation. However, CQC is currently working on a plan for piloting and testing its new approach and has commissioned this evaluation as one signal of its intention to embed learning into its future regulatory model.

Key insights from the evidence about regulators that have changed their model include the importance of:

- piloting new approaches and investing in training to support their rollout – for example, unless inspectors fully understand the new model, they are likely to make assessments based on their old ways of working
- evaluating whether new approaches are achieving their intended impact, based on programme theory, publishing outputs as the evaluation generates learning (which can build trust and support cultural change)
- ongoing work to embed a culture of learning and evaluation.

Piloting and testing should not be confused with a rollout in stages, which does not allow time for learning to be implemented between one phase and the next.

Barriers to developing this type of approach to change include:

- ambitious operational targets that do not leave time and space for developing and testing the regulatory approach
- the introduction of additional responsibilities that take up capacity that might have been used for piloting, testing and evaluation
- a disconnect between evaluation outcomes and decision-making.

What this means for CQC

Evidence from CQC's past experience and other regulators points to five wider learning points for CQC as it develops and implements its future model.

1. Start with, and maintain, an unrelenting focus on the purpose of regulation, and its impacts, rather than starting with the design of regulatory systems and processes.

2. To maintain a focus on impact, articulate the programme theory that underlies the regulatory model, setting out in plain language how regulatory actions or interventions, such as inspections or ratings, will bring about the impacts that are intended.

3. Use the wealth of evidence from CQC's history and elsewhere to inform the design of the future regulatory model – there is no need to start from scratch or 'reinvent the wheel', and there may be benefit in CQC aligning its approach to oversight and regulation with other regulators in the sector. However, because what works in one organisation, sector

or jurisdiction may not work in the same way in others, learning is about thoughtful adaptation, not unthinking adoption of policies or practices from somewhere else.

4. Invest in developing the capacity and capability of the regulatory workforce, including sector-specific, regulatory and relational expertise. Regulation is fundamentally a social process. For a regulator and its workforce, how you do it matters as much as what you do.

5. Build testing and evaluation into the wider rollout of the regulatory model to embed a culture of learning to support ongoing development of the model and provide evidence on its impact.

What next?

Now that the scoping phase of the evaluation is coming to a close, we will work with CQC to agree a plan for the next stage of the evaluation. We recommend this commences almost immediately after the scoping phase finishes, to ensure the research team remain connected with people and teams within the organisation and can feed in evidence and learning throughout the development and rollout of CQC's future approach.

1 Introduction

Context

In 2021, the Care Quality Commission (CQC) launched a new strategy that aimed to simplify the regulatory process for health and social care providers and make it more person-centred and insight driven. This led to the most significant transformation in CQC's regulatory approach since 2013/14. It introduced a single assessment framework across all sectors, supported by a new information technology (IT) platform and a major organisational restructure. CQC started to roll out this approach in November 2023. However, significant problems with its implementation led to the commissioning of three major reviews into the effectiveness of CQC and its single assessment framework, led respectively by Vic Raynor, Dr Penny Dash, and Professor Sir Mike Richards (Care Provider Alliance 2025; Dash 2024; Richards 2024). These reviews identified critical weaknesses in the single assessment framework and broader issues with CQC's systems and organisational structure. In response, CQC is now rebuilding its approach under new leadership, including a largely refreshed executive team and board.

This improvement work is structured around four immediate actions to resolve urgent operational backlogs, and five foundational improvements to rebuild regulatory capability. The detail of this work is set out in the box below.

Box 1: The focus of CQC's improvement work in 2025

There are four immediate actions:

- Completing assessments that are stuck in the regulatory platform.
- Enabling new assessments (increasing the number carried out each month).
- Dealing with information-of-concern cases and the notifications backlog.
- Dealing with the registration backlog.

And there are five areas for foundational improvements:

- Working together on culture – values, behaviours, purpose, ways of working.
- Integration of operational structures.
- The single assessment framework and regulatory model.
- Technology and IT systems.

- Data, ratings and registration.

Source: Hartley (2025)

Within this context, CQC commissioned The King's Fund to develop an evaluation of its future regulatory model.

What we were asked to do

CQC's decision to commission an evaluation at this early stage in the process of developing its future regulatory model signals its commitment to evidence-based practice and responds to recent review findings that its 2023 model did not sufficiently integrate evaluation and learning into its implementation.

The first stage of the evaluation has been a five-month scoping phase. This phase has focused on two things:

- Supporting CQC to think about changes to its regulatory model in light of the recent reviews and the wider evidence base on health and social care regulation.
- Developing a proposal for the two-year evaluation of CQC's future regulatory model that will follow the scoping phase.

This report presents our review of existing evidence on what works in regulation, drawing on academic and grey literature as well as discussions with experts. The research team has already started sharing these insights with CQC through workshops and meetings to inform the development of the new model. Our proposal for the two-year evaluation is currently being agreed with CQC. We will continue to work closely with CQC to identify opportunities to make a positive impact with our evaluation as our research partnership continues.

Methodology

This project combined extensive engagement with CQC staff, a structured literature review, and discussions with experts to explore the evidence base for effective regulation and to support CQC in the development of its future regulatory model. This part of the research sought to answer two overarching questions.

- What works and what does not work in the model of regulation for health and social care?
- What are the implications for the development of CQC's future regulatory model?

Engagement with CQC staff

Between February and April 2025, we held 16 meetings with individuals and groups from across CQC to introduce the research and discuss the current challenges in CQC and how evidence and evaluation might support the development of CQC's future regulatory approach. This

included meetings with people from the interim executive team, policy and strategy teams, and operations teams, as well as associates who work with CQC, such as experts by experience and specialist clinical advisers. We also observed several workshops and meetings to help us understand the work that is under way in CQC to rebuild its approach (*see* the box above). This included staff workshops about a refreshed organisational vision and purpose, provider roadshows, and internal 'workstream' meetings focused on developing the new assessment approach.

These meetings provided critical insights into the implementation and operation of the current regulatory model, including the experiences of those delivering it. They also highlighted opportunities for evaluation to support ongoing development work and the rollout of the future model.

We also reviewed internal CQC documents to understand the context in which the future model is being developed.

This engagement work helped the research team pull out implications from the evidence that were most pertinent to CQC's work and influenced the approach to the next stage of the evaluation.

Literature review

The literature review built on a previous review on this topic (Walshe and Phipps 2013), which remains relevant to the challenges that CQC faces today. Using this as a starting point and a time boundary, The King's Fund library conducted a broad search of literature on health and care regulation published from 2013 onwards, with a primary focus on the system in England but also including international material.

In total, 373 articles were identified from an initial search of Emcare, MEDLINE, Social Policy & Practice, The King's Fund library database and Google Scholar. We then carried out a general online search, followed up on reference citations in key papers, and hand-searched the websites of key organisations for relevant material, bringing the total number of items identified to 521.

Drawing on our initial scan of these documents, insights from our engagement with CQC, and discussion with the policy and strategy team at CQC, we identified five key challenges the organisation is facing where there is an opportunity for evidence to help, and used these to structure our literature review. The challenges are:

- setting regulatory expectations
- ensuring expertise in the regulatory workforce
- adopting risk-based regulation
- developing relationships and trust
- changing the regulatory model.

The research team reviewed the abstracts, allocated them to these themes, and identified 162 documents for a full text review. The findings from that review are presented in sections 3 to 6, alongside insights from our discussions with experts. This pragmatic approach means the review does not cover all of the challenges and opportunities affecting CQC; instead, it provides in-depth tailored insights about five areas identified because of the opportunity for evidence to support current thinking.

Interviews with experts

To complement the CQC internal engagement and literature review, we interviewed 10 experts in regulation and evaluation from other regulators, sectors and countries. We chose these based on examples arising in the literature, our engagement with CQC, and our knowledge of other organisations facing challenges that might provide relevant learning. Our aim was to understand more about what was happening 'on the ground', as a lot of current work is not yet reflected in the literature, and to collect relevant insights from organisations facing similar challenges to CQC (although operating with different powers and in different contexts). These interviews were designed to:

- elucidate the findings from the literature about what works in regulation
- provide examples to support the evidence
- help guide the development of the evaluation approach.

The two overarching research questions and five challenges (*see* above) were used to structure the interviews, which were recorded in Microsoft Teams and stored securely. Researchers took notes, which were used to supplement the literature presented in sections 3 to 6. Insights from these interviews are presented in boxes throughout these sections, giving examples of what other regulators and organisations are doing on these topics.

Structure of the report

In the five sections that follow, we set out key insights from the published literature and our discussions with experts about what works in regulation. The sections are structured based on the five key challenges that CQC currently faces. As outlined above, we identified these challenges based on an initial scan of the evidence and discussion with CQC about the current focus of their improvement work:

- setting regulatory expectations (section 2)
- ensuring expertise in the regulatory workforce (section 3)
- adopting risk-based regulation (section 4)
- developing relationships and trust (section 5)
- changing the regulatory model (section 6).

In section 7, we look across the evidence and discuss wider learning for CQC as it develops and rolls out its future regulatory model.

2 Setting regulatory expectations

Key points

- **The regulatory model needs to be fully aligned with regulatory mission and purpose.** It is important that multiple methodologies are used and that differentiation is a guiding principle to support the regulation of diverse organisations, so that standards are fully relevant to each regulated service sector.
- **Clearly communicated standards are a powerful lever for supporting improvement.** They need to be set high, with relevant detail and guidance, so that providers understand what they are being asked to do and how to achieve it. Co-production of the standards is a good first step towards achieving this.
- **Enforced self-regulation that specifies outcomes rather than processes has potential in the context of a model that is facilitative and responsive.** It can allow organisations flexibility to design processes that are relevant for them to achieve the outcomes. However, evidence about how this can work is mixed, and can depend on the regulator's approach and providers' capacity and capabilities.

The opportunity for CQC

Setting regulatory expectations – for example articulating what good and other rating levels look like, and communicating expectations of quality (including how it will be assessed), is one of the major ways a regulator can have an impact (Walshe *et al* 2014), but at the moment, CQC is not using that lever effectively. Recent reviews of CQC (Care Provider Alliance 2025; Dash 2024; Richards 2024) have found that the single assessment framework is difficult to understand. Providers report that they do not know what they are expected to do or how their performance is going to be assessed or scored, and that there is not enough guidance available to support them. Information on CQC's website was criticised for being difficult to find and inaccessible. CQC is therefore currently reviewing quality statements and writing scoring descriptors and rating characteristics for each sector to address these concerns.

Evidence on what works

The regulatory model should be aligned with the regulatory mission and purpose

Academic experts highlight that whatever shape the regulatory model takes, it needs to be fully aligned with the regulatory mission and purpose (Walshe and Phipps 2013). The regulatory model should 'fall out' of these. Although there may be a single overall regulatory model,

multiple methodologies within it are important for several reasons, as listed below (Weenink *et al* 2021; Carrigan and Harrington 2015; Levi-Faur 2015; Timmins 2013; Walshe and Phipps 2013).

- No one approach can achieve everything – different service sectors require approaches that are tailored to them, and within each sector, diverse organisational characteristics (such as levels and types of risk, management capacity, and public or private accountability) will affect which regulatory approach is the most appropriate.
- There is a need for regulation to fit with providers' differing contexts of other external monitoring/accountability assurance systems and interdependencies.
- Developing the capability to be both consistent and responsive to differing contexts (rather than having a one-size-fits-all approach) may be an ingredient of regulatory excellence.

Setting the standards on which regulatory expectations are based needs to be a group endeavour, co-ordinated across the different organisations that have regulatory responsibilities (Timmins 2013). Standards can differ across sectors but approaches and principles can be the same – what is important is being clear about what differentiation is being made and why. Standards should be co-designed with regulated providers and set high to promote improvement (Walshe and Phipps 2013).

Interview insights – what other organisations are doing

In Australia, a federal agency (the Australian Commission on Safety and Quality in Health Care) sets health care standards and a number of separate bodies administer accreditations against these standards. Although there are different sets of standards for each health sector (for example, there are specific clinical standards for the hospital sector), there are similar elements (such as governance and IT) across all sectors.

In the education sector in England, Ofsted has a single inspection handbook for all state schools but is flexible in the way the criteria are used (within the handbook). It has separate handbooks for early years provision, independent schools, and for further education and skills providers. Inspectors adjust to different types and sizes of organisations. We heard that Ofsted is currently developing new criteria for its assessments, more explicitly based on professional standards, and is hoping to tie these into government standards.[1]

Standards must be communicated clearly

Clearly communicated standards can be a powerful lever for supporting improvement by enabling organisations to comply with them and supporting understanding of quality (Weenink *et al* 2021; Walshe and Phipps 2013). Most regulatory compliance comes from providers understanding and responding to regulators' requirements in advance (known as anticipatory

[1] Please note, since this research was conducted Ofsted has launched its new approach (Ofsted 2025).

impact, *see* (Smithson *et al* 2018)) but also potentially due to other intrinsic and extrinsic motivations, rather than because of other regulatory interventions such as registration or inspection. It is therefore important that regulators take responsibility for communicating what standards mean and their expectations of compliance (Blanc *et al* 2015).

In practice, clear communication starts with co-design of standards with providers and the production of relevant information and guidance. Involving providers and inspectors in developing standards and associated guidance has benefits for both providers and regulators. For providers, it supports improved understanding of what regulators are looking for, while for regulators, it means they can access vital intelligence about the impact of proposed changes on providers (Care Provider Alliance 2025; Kelly *et al* 2023; Cunningham *et al* 2020; Greenfield *et al* 2016; Walshe and Phipps 2013). Additionally, the way standards are framed can be key in signalling how the regulatory relationship should develop – for example, whether it should be directive or open to different means of compliance (Weenink *et al* 2021).

Providers use the regulator's guidance/frameworks as well as previous inspection reports to understand how inspectors interpret their standards – both are useful for regulation to promote improvement (Weenink *et al* 2021). However, it is important that the records and evidence required from providers do not become an overwhelming task for them (Care Provider Alliance 2025; Warmington *et al* 2014). When updating standards, therefore, it may be as important to retire standards that are not useful as to consider additional requirements (Illingworth 2014).

Although registration is a potential moment to set regulatory expectations and drive improvement, we found little evidence on its role in this research. This may suggest a lack of evidence or, potentially, that further research is needed.

Interview insights – what other organisations are doing

Like CQC, Ofsted has suffered criticism for not communicating its expectations clearly. It is currently writing clearer expectations so that schools (and other providers) know what good looks like and what inspectors will be looking for. This means schools can plan ahead to make sure they are meeting expectations and can (if they want) assess how well they are likely to do.

In the Netherlands, we heard that IGJ (the health and youth care inspectorate) does not set standards (although it does supervise standards that professional bodies set). It also brokers agreement on the use of particular standards that different professional and representative organisations within the health and care sector develop. It sees its approach as not to hand down standards from 'above' but to work alongside regulated bodies on understanding expectations.

Enforced self-regulation has potential in the context of a model that is facilitative and supportive

The term 'enforced self-regulation' is widely used in the literature on regulation across sectors. It denotes regulation which seeks to define regulatory outcomes but to allow providers to

determine how they achieve those outcomes in practice. For example, a water regulator might set maximum levels of chemicals or contaminants in drinking water but not mandate how water companies should achieve them. An example in health care might be CQC setting expectations about never events, or acquired infection rates in hospitals, but not defining every detail of the processes that providers should put in place. 'Enforced self-regulation' (also called co-regulation or management-based regulation in the literature) allows organisations the flexibility to design processes that are relevant for them in order to achieve the outcomes (Marsden *et al* 2024; Carrigan and Harrington 2015). This offers a useful alternative to 'means-based' mechanisms – those that specify how a regulation should be met – which become tricky and expensive to implement effectively in the context of heterogeneous organisations, rapidly changing contexts, and difficult-to-measure outcomes (Carrigan and Harrington 2015). Enforced self-regulation is not a new concept. For example, it has been around for a long time in health and safety at work legislation (Walker 2013), and it is increasingly common in education as part of a policy shift towards the decentralisation of assessments in education, although it is working differently in different countries.

Several factors are needed for enforced self-regulation to work well. For example, providers need the right organisational structures and governance procedures to make it work (Cunningham *et al* 2020). There is a risk that the bureaucratic burden of evidencing compliance could divert some organisations from improving care, although it is not clear whether this is linked to organisation size and capacity (Cunningham *et al* 2020). Additionally, the appropriateness of using regulated bodies' own assurance is dependent on those bodies' capabilities and organisational cultures and so these need to be right: analysis of a self-regulatory approach in the financial sector found that it led to an increased risk of regulatory failure due to organisations not truly internalising the process (Moniruzzaman 2021).

There are potential risks in using the self-regulation approach, for example:

- it can be difficult for regulators to ensure that good management is taking place (Carrigan and Harrington 2015)
- it may encourage checklist approaches or a focus on easily auditable risks
- standardisation reduces the value of expert judgement
- it involves extra work for an organisation to document their performance against the outcomes and then 'translate' this for an external auditor (Marsden et al 2024)
- there have been some significant failures of the approach (Samuel 2012).

In addition, in the literature the enforced self-regulation approach is generally applied in larger organisations. We found no evidence in the literature about its use in, or applicability to, smaller/single-handed organisations. Based on the risk of bureaucratic burden, this would need careful exploration with providers of different sizes.

In Australia, 'attestation' – or formal, written, self-reported assurance – may be used as part of health and care regulation. It is not used on its own as it needs external verification, and it carries sanctions for inaccurate or misleading representations. However, there is very little published evidence on its effectiveness as an approach and any use of it may need to be treated as a pilot with evaluation (Travaglia *et al* 2017).

How regulators work with regulated organisations is also a key consideration. Enforced self-regulation implies a facilitative approach to regulation and a more interdependent relationship between regulators and regulatees (Marsden *et al* 2024; Dunbar *et al* 2023; Kok *et al* 2019). The regulator's approach must support providers to achieve or exceed their standards (Cunningham *et al* 2020). This may also encourage improvement, for example where regulated organisations are supported to set their own goals for performance improvement (Walshe and Phipps 2013). It would mean that the regulator contributes to community of practice, rather than sitting separate from it, and therefore is potentially more welcomed (Walshe and Phipps 2013).

Studies looking at improvement capability in UK heath regulators show taking a deterrent approach can backfire. If regulators penalise organisations that are honest and transparent about their risks, it could reduce their willingness to be honest and transparent in the future and undermine relationships (Furnival 2017; Illingworth 2014). When thinking about the different ways in which co-regulation might be used to enhance CQC's approach', it would be important to consider how its processes enable a 'culture of candour about the risks associated with health care, and the efforts that are being made to mitigate those risks' (Illingworth 2014). Other important aspects would be the use of 'soft signals' – or qualitative data – and a focus on how willing and able regulated organisations are to improve (Kok *et al* 2020).

Interview insights – what other organisations are doing

From a safety perspective, we heard that the Health Services Safety Investigations Body (HSSIB) in England is clear about the potential of safety management systems to support providers to proactively understand and manage their safety risks. HSSIB remarked that having a structured mechanism that proactively picks up risk and has a learning element built in can work in smaller settings too but noted the importance of different approaches for large and small providers.

We heard that the Office for Students takes an outcomes-focused approach to specifying conditions of registration. This means they are mostly framed as the benefit to the student rather than what needs to happen to get there, leaving providers with flexibility about how they meet that requirement.

We heard that Ofsted is planning to move away from the requirement for extensively pre-prepared self-assessment in its new approach – instead focusing on a conversation between inspector and school about what is going well and what the challenges are. Similarly, while the Dutch health and youth care inspectorate requires a range of self-reported measures, we heard that it increasingly places value on discussion and an ongoing relationship between the regulated body and its account holder (lead inspector/relationship holder) in order to contextualise these measures.

3 Ensuring expertise in the regulatory workforce

Key points

- **The inspection workforce is central to the delivery of CQC's regulatory model.** Inspectors are 'the face of CQC' for providers and need three core skill sets: sector expertise, regulatory expertise, and relational skills.
- **It is important to develop an approach that allows for professional judgement**, rather than to attempt to eliminate it from the assessment process.
- **It is vital that training and support for inspectors are adequate and effective.** This means, for example, providing peer support, seeking inspectors' feedback on new ways of working, and ensuring that their workloads enable the time and space to focus on learning.

The opportunity for CQC

The inspection workforce is central to the delivery of CQC's regulatory model, but CQC has not consistently valued sector (as well as regulatory) expertise, acknowledged the importance of seniority for the credibility of operational staff, and not always placed a strong emphasis on training and developing them (Dash 2024; Richards 2024). This has led (Ipsos 2024; Richards 2024; Townson 2024) to:

- inspectors sometimes lacking sector knowledge and seniority and, as a result, losing credibility with providers
- a reduction in investment in ongoing relationship management with providers
- staff who feel disconnected from their professional backgrounds
- a lack of training and support, particularly for new staff.

In 2021, CQC split the role of inspector into two new roles – inspectors (who focus on collecting evidence on site) and assessors (who work remotely to synthesise evidence from a range of sources), who were intended to have joint responsibility for the overall assessment of services, working in integrated assessment and inspection teams. This split in the inspection workforce is now being reversed (Ipsos 2024). Integration of the operations and regulatory leadership directorates is part of the foundational improvements CQC is focusing on during this period of change for the organisation.

Evidence on what works

The inspection workforce is central to the delivery of the regulatory model

The context CQC is operating within will determine the style of regulation and skills mix needed, so it is important that CQC is clear on its purpose and its expectations from the system (Hall *et al* 2019; Walshe and Phipps 2013). For example, a focus on a regulator's independence and rule-based regulation can 'reinforce dominance' of some types of expertise over others, rather than highlighting the importance of having a diversity of types of expertise (Levi-Faur 2015).

However, there is general agreement that inspectors need three key skill sets (Levi-Faur 2015; Walshe and Phipps 2013):

- sector expertise – deep content knowledge and experience in the service
- regulatory expertise – understanding of regulatory policy and practice
- relational expertise – including behaviours and values that enable them to understand the organisation's situation, listen, empathise and influence, while maintaining appropriate independence.

These do not all have to be held by the same person, as long as the combination is present in any inspection team. However, this necessitates experienced and senior inspectors – and the right pay level, and good-quality training and development, throughout people's careers (Walshe and Phipps 2013).

Sector expertise is particularly important for credibility and authority (Macrae 2025; Care Quality Commission 2023; Hanser 2018; Greenfield *et al* 2015; Walshe and Phipps 2013). This was highlighted in the first iteration of CQC's regulatory model and was also an issue at Monitor (House of Commons Committee of Public Accounts 2014) – the independent regulator of NHS foundation trusts in England – and led to the development of sectoral, rather than generic, teams as a result. But this learning seemed to have been forgotten when integrated assessment and inspection teams were developed, with some senior staff regarding inspecting as a generic skill (Richards 2024).

However, inspector background can also impact what is looked for in inspections (Hall *et al* 2019; Braithwaite and Braithwaite 1995) so it is important that regulators hold a diversity of expertise – for example, lived experience, clinical insight, safety management, and quality improvement – and are able to flex to ensure relevant expertise is available for different regulatory activities (Macrae 2025). Additionally, Dutch research has shown that regardless of the specific standards in place, in practice all sorts of professional and experiential knowledge come into play when inspectors interact with regulated organisations (Kok *et al* 2019). A British study found some evidence that prior experience and profession can affect ratings and domain allocation but that this accounts for only a small proportion of variance and does not affect reliability overall (Boyd *et al* 2017).

Relational or interpersonal skills are critical in developing trust and a facilitative approach with regulated organisations – showing the human face of the regulator. These kinds of skills, behaviours and values may require time and experience (from life as well as work) to develop (Care Quality Commission 2023; Buckley 2016). However, they need not be particularly complex. For example, CQC found that including pen pictures of team members in pre-inspection information sent to the regulated organisations could help reduce providers' apprehensiveness about the forthcoming inspection (Care Quality Commission 2023).

The risk of 'regulatory capture' is a common concern. There is an inevitable tension between the need for an inspector's sector experience and professional expertise, and the inspector being too close to the sector and overly influenced by this experience (Amalberti *et al* 2024; Kok *et al* 2019; Vogel 2015). There is also a risk of spending too much time with inspectees rather than with colleagues (Loyens *et al* 2019; Levi-Faur 2015). Regulatory capture can affect the leadership of an organisation as well as its operational workforce.

However, the solution should not be generalism (Walshe and Phipps 2013), rather a need to hold tensions and trade-offs mindfully. Trade-offs may be made at different points in different contexts, but for complex adaptive systems such as health care, closeness between regulator and regulated organisation may be most useful, to avoid fragmented information (Amalberti *et al* 2024). Inspectors' relationships with the organisations they regulate is further explored in section 5.

Relational skills are also key for effective teamworking – both within inspection teams and across teams – something that has been highlighted as a challenge in CQC (for example (Ipsos 2024)). Boyd *et al* (2018) explored the functioning of temporary teams for inspections and highlighted the challenges of working in this way and the need for more research on this topic.

It is important to work with professional judgement

There is a fine balance between assuring consistency of process and leaving room for inspector judgement. The use of professional judgement is key to making valid judgements that are sensitive to the context of regulated organisations. Too much focus on rule-based regulation and not enough room for inspectors to use their discretion can lead to a lack of awareness of risk or even less consistent judgements (Hanser 2018; Walshe and Phipps 2013; Braithwaite and Braithwaite 1995). This is because more specific standards can lead to too many detailed issues for inspectors realistically to check, so they pick and choose; and they deprive inspectors of an avenue to step back and focus on overall performance and risk, so they informally find ways to 'mush these in' – leading to less rather than more reliability (Braithwaite and Braithwaite 1995). Reliable processes are important for developing a regulator's credibility (Greenfield *et al* 2015).

While senior officials do not always appreciate the importance of the use of discretion, evidence from other sectors suggests it can increase the impact of enforcement (Curtis and Kaufman 2020). Inspectors may be 'a key source of underutilised information' (Curtis and Kaufman 2020). Braithwaite and Braithwaite (1995) found that experienced professionals generally found

ways to subvert systems that attempted to constrain their professional judgement – their conclusion was to design for this, rather than attempt to counter it.

Interview insights – what other organisations are doing

We heard that Ofsted dedicates a significant amount of inspector and senior leadership time to ensuring consistency in its approach to assessment and ratings. This includes time for inspectors to focus on quality assurance and training, with senior leadership involvement, every week – for example, to discuss difficult cases or for inspectors to shadow each other's inspections and compare learning. Inspectors are seconded into the policy team and many of the policy team still go out on inspections – keeping the link between operational knowledge of the approach and its ongoing development at a policy level.

We heard that the Office for Students dedicates a significant proportion of time to training staff in regulatory operations, using coaching to help with things such as driving consistency in regulatory judgements and writing recommendations that are meaningful to decision-makers in regulated institutions.

We heard that in Australia, regulators have developed an approach so that inspectors do enough assessments to improve and develop consistency – balancing doing too few inspections and taking too long versus doing too many and this becoming too burdensome to moderate.

In both Australia and the Netherlands, we heard working in the inspectorate may be thought of as a mutually useful developmental stage of a broader professional career path (rather than a career path in itself) – bringing current knowledge about practice in from regulated services and, after a few years inspecting, taking valuable knowledge back out to the sector.

Discretion can be individual or team based. In survey research and observation with CQC inspectors, Boyd *et al* (2017) found that the reliability of assessments (the level of agreement across domains and ratings) was higher with groups than individual inspectors, but this raises questions about consistency for smaller services where inspection teams may contain a single inspector. From an educational context, Rutz *et al* (2017) further argue that regulators need to enable and support inspectors to engage with their colleagues and people beyond the organisation to develop processes that enhance collective discretion, rather than attempting to constrain its use. They note that collective discretion has various advantages over individual discretion, such as allowing for both responsiveness and consistency, but it can be time consuming and impact individual autonomy (Rutz *et al* 2017).

There is also research from the education sector about how to resolve tensions between different positions among a school inspection team, which highlights the need for team leaders to exercise judgement in managing interpersonal dynamics within teams as well as in processing factual findings (Dedering and Sowada 2017). Further learning from education highlights the pros and cons of more restrictive and discretionary models, looking at Sweden

versus England where both have faced issues (Baxter and Hult 2017). Ofsted is a key example here as pre-2012 it was criticised for using too much standardisation and so it shifted to a much more judgement-centric model (Baxter and Clarke 2013).

There can be drawbacks to professional judgement or discretion. For example, relying on 'professional judgement' can sometimes be a way of corporately avoiding taking a position (Baxter and Clarke 2013). And interestingly, research from Norway (Johannesen and Wiig 2020) suggests that the reliability of assessments is influenced more by the practicalities of assessment tools, workforce management practices and administrative documentation than by inspectors' approach to working with, or relating to, their regulated organisations. The authors also highlight the need to understand and work with inspectors' approaches based on the reality on the ground, where things get implemented, rather than just on the theoretical regulatory model. Similarly in Utrecht (Loyens *et al* 2019), research with vet inspectors highlighted the need to understand the implementation of the regulatory approach by having regard to both the theory and the practice – for example, it found that providing a rigid protocol but then encouraging a personalised approach led to mixed signals for inspectors.

Interview insights – what other organisations are doing

The Health Services Safety Investigations Body (HSSIB) in England has had to rebuild trust and relationships internally after well-publicised issues with its predecessor organisation the Healthcare Safety Investigation Branch (Collins 2022). We heard about the importance of shared vision and purpose, and clarity about the body's values, for this work. Its learning was that it is necessary to invest time, that people need to feel like they have a voice, and that they need psychological safety. Communication needs to be authentic and unscripted. This is also about having the courage to do difficult things – for example, following up words with actions about what is not acceptable, dealing with poor performance and behaviour, and showing that they will not be tolerated and will be addressed.

It is important to make use of a broad range of staff experience and expertise

Co-opting practising professionals into inspection teams as advisers is not widely discussed in the literature. What we did find was that when first introduced into CQC's 2013 'comprehensive inspection' approach, inspectors sometimes perceived a lack of robustness of evidence recording by special advisers, while special advisers felt that inspectors did not have enough depth of understanding of the issues. However, the relationship did improve as inspectors supported special advisers to evidence their judgements (Boyd *et al* 2018), suggesting that the use of practising professionals requires active management, rather than just 'parachuting' them into teams.

In more recent work, local authorities and inspectors viewed special advisers positively (Care Quality Commission 2023). An evaluation noted that while they have been predominantly involved in the fieldwork and quality assurance of assessment reports, there are further opportunities to include them, such as in pre-fieldwork or post-fieldwork discussions (Care Quality Commission 2023).

Having headteachers who inspect has been a key part of Ofsted's model since the mid-2010s. Moreton *et al* (2017) found that this can have value for both inspections and the headteachers' schools. However, it is not always viewed that way, and headteacher inspectors can sometimes have their insights dismissed by other inspectors. Additionally, they frequently struggle with capacity for inspection alongside their own jobs, which means there is a risk of needing a much larger workforce and increased potential for inconsistencies (Moreton *et al* 2017).

Interview insights – what other organisations are doing

In Australia, we heard that the Australian Healthcare Practitioners Regulatory Agency use a combination of internal and external staff for inspections. For example, clinical advisers are used, and some regulators have rules about how long staff can work as advisers after they leave clinical practice. Assessors take part because the work is interesting and it can help with their career development.

We heard that effective clinical input and leadership are vital to the Health Services Safety Investigations Body (HSSIB) in England, so its team of investigators works with subject-matter experts on the ground. It has a small team but works with staff in organisations across England.

In contrast to what was said in the literature (Moreton *et al* 2017), we heard that Ofsted does not have any current difficulties in sourcing headteachers for inspection teams.

The use of lived-experience experts was not frequently discussed in the literature. There have been concerns about CQC's experts by experience lacking sufficient experience of particular services or having different values (Boyd *et al* 2018). More recently, CQC found that experts by experience did not get feedback on the report they contributed to and did not always feel their role was appreciated (Care Quality Commission 2023). Richardson *et al* (2019) noted that it is important to develop relationships with people using services that are more than transactional to support good-quality inspections – as with special advisers (*see* above), the inference is that their roles and input should actively be managed, rather than 'parachuting' them in.

In the Dutch context (de Graaff *et al* 2024), citizen involvement in regulation (including people with lived experience) is more researched. It has been found that this involvement could increase transparency and trust, but – like with CQC – it is how such roles are used that is important.

It is vital to ensure that training for inspectors is adequate and effective

When developing or making changes to the regulatory model, it is vital that staff who will be implementing it – particularly inspectors – understand and are competent and confident in using the process and tools, and are not making assessments based on their old ways of working (Greenfield *et al* 2015). This requires ongoing investment in the professional workforce (O'Dwyer 2015).

However, at CQC, adequate and effective training and development for operational staff seems to be an ongoing issue. A lack of support for inspectors to develop expertise and experience,

and ineffective training, were highlighted as issues in reviews of CQC's initial regulatory model introduced in 2009 (Comptroller and Auditor General 2015). Insufficient training at the start of its second regulatory model, introduced in 2013, was highlighted in contemporary research (Boyd *et al* 2018), as well as a need for training to support the reliability of judgements (Boyd *et al* 2017). In particular, inspectors needed support with relational skills to have positive discussions when deciding ratings (Boyd *et al* 2017). More recently, Ipsos (2024) found there was insufficient and ineffective training for inspectors and assessors when the single assessment framework – CQC's third regulatory model – was introduced. Although inspectors on the pilot local authority assessments did praise their induction sessions, they highlighted the need for more training on specifics such as local authority duties, structures and governance (Care Quality Commission 2023). Furthermore, where notably experienced or high-performing staff were used in pilots, it was important not to make assumptions that they would be representative of the general level of inspector competence/confidence and need for training.

There has also been criticism from CQC staff of a reliance on e-learning, for example one inspector interviewed for an evaluation about changes to the inspector role at CQC noted that in its provider assessment model, CQC discourages e-learning without follow-up to check understanding, but it does use e-learning in this way with its own inspectors (Ipsos 2024; Comptroller and Auditor General 2015). The same evaluation highlights workloads that are too high to enable inspectors to engage effectively with training. We did not see continuing professional development mentioned much in the literature, but this is also relevant here – as noted in the final subsection of this section, training should not be a one-time thing but part of regulators developing an ongoing culture of learning and improvement. This highlights the importance of an organisational vision for facilitating learning that goes beyond training and an operating environment where regulators see operational staff's expertise as critical to their purpose, and invest in it accordingly, judging operational success by more than the number of inspections delivered (Walshe *et al* 2014).

CQC is not unique in falling short of the level of staff development that the literature indicates is necessary. Learning from the Australian context (Greenfield *et al* 2015) also highlighted a need for improved training and maintaining expertise, especially during transition periods. Suggestions included better peer support and feedback after inspection, and the role of peer observation in developing skills. Research from other sectors (Curtis and Kaufman 2020; Buckley 2016) also highlighted the need for investment in training on relational and regulatory skills – for example, conflict resolution, de-escalation, and routine communication skills – and how to use different enforcement tools in different circumstances to increase consistent proportionality. As before, this is not about every inspector having every capability but about having regulatory teams which have, or have access to, the right capabilities.

Interview insights – what other organisations are doing

We heard that the Health Services Safety Investigations Body (HSSIB) in England is keen to professionalise investigation and that it has developed a competency framework for investigators.

We heard that in Australia, regulators prioritise staff understanding the standards and receiving training, support and education – including on the job, doing enough assessments to get better at it and be consistent. We also heard from Australian experts about the importance of modelling behaviour in how the inspectorate workforce is treated. In turn, this influences how inspectors treat the providers they inspect and regulate – with respect, care and consideration, and with an understanding of the importance of the human role in developing a culture of trust.

We heard that Ofsted provides all of its employed inspectors with regular formal training, and has profiles of inspectors that outline their types of expertise. It also involves inspectors closely in developing the regulatory approach by seconding His Majesty's Inspectors (employed, senior inspectors) into the policy directorate. The policy directorate holds regular conferences to share the developments it is planning with inspectors and collect feedback.

We also heard that Ofsted is building an academy that is going to be responsible for induction, training and continuing professional development, and which should prevent previous regional differences in the management of staff development and inspection methods. As well as full-time inspection teams, it will include the wider cadre of occasional and part-time Ofsted inspectors and advisers.

We heard that the Office for Students developed a course for staff on regulatory theory and is currently developing a course about how to translate theory into operational practice.

In the Netherlands, we heard that the health and youth care inspectorate sees learning and developing reflexivity as fundamentally important. This includes formal inspector training programmes. The inspectorate has been working with Erasmus University Rotterdam as a learning partner for more than 15 years and observes that it increasingly trains inspectors not to be 'orchestral musicians' (following a set sequence of notes) so much as 'jazz musicians' (able to follow written music but also able to play in such a way as to engage with and respond to others).

4 Adopting risk-based regulation

Key points

- **Risk-based regulation is a complex proposition.** There is no clarity in how to achieve its aims of targeted proportionality, or consensus on this overall approach or how the regulators who adopt it should do so.
- Whatever methods are adopted, **skills of judgement and understanding of the sector, individual providers and service users' experiences are needed** as well as data expertise, and there should be clarity about how risk drives regulatory activities and decisions.
- **Risk information is always imperfect.** Risk-based regulators need to work with significant gaps in data and with information that is often suggestive rather than definitive. Risk-based approaches always involve a process of learning – rather than adoption of a fully formed model – and require ongoing evaluation and development.
- **Risk-based regulation requires strong capabilities in the operational workforce.** Using imperfect information intelligently, consistently and proportionately, together with the skills to contextualise it, is a form of expertise. Inspectors need time, training and support to ensure they have these skills.

The opportunity for CQC

A risk-based approach to regulation, where the level of scrutiny applied to a regulated organisation is proportionate to the level of risk they are judged to pose, was central to CQC's latest strategy. CQC prioritised an insight-driven approach and an 'always on' programme of surveillance, alongside its focus on innovation and improvement. CQC's approach to designing and operating its regulatory model, and the fact that CQC's purpose is not only to respond to risk but also to recognise and encourage the absence of risk, have led to several challenges in relation to risk-based regulation. These include what data is available and how it is used, how CQC can respond quickly to issues of risk, and how assessments are focused. CQC has a number of improvement workstreams under way, which between them seek to address these challenges.

Evidence on what works

Risk-based regulation is a complex proposition

Risk-based approaches to regulation have become more widespread in recent years (Rothstein *et al* 2013) and much is written about why a risk-based approach makes sense in theory (for example, it could be more cost effective, transparent and accountable).

Risk-based regulation aims to target limited regulatory resources on the areas most in need of them (Adil 2008 and Hampton 2005, cited by Walshe and Phipps 2013), so that the level of scrutiny applied to individuals or organisations (and associated regulatory burden) is proportionate to the level of risk that each is judged to pose (Walshe and Phipps 2013). However, in practice, this is not straightforward. A review of evaluations of risk-based regulatory approaches across sectors found little evidence that these aims are consistently met in practice (van der Heijden 2021). This is a rapidly developing field, with further potential identified in areas such as artificial intelligence, but the current evidence on the potential of a purely data-driven, algorithmic approach is limited.

Any risk-based model will need to be complemented by an agile, responsive, operational function. Blanc *et al* (2015) found that the impact of regulation will still depend heavily on relational factors, such as the way inspections are conducted and the trust and reputation of the regulator. And excessively data-driven models may not fit readily with a person-centred approach – that is, based on the experiences of people using the regulated service – because 'this is surrounded by complexity and uncertainty and may therefore require a more flexible, reflexive form of regulation' (Poldrugovac *et al* 2023).

In addition, 'risk' may have different meanings to different people, so care is needed because this approach to regulation may not give them all the assurances they seek – for example, service users and health care professionals might want assurance based on different perceptions of what constitutes a risk (Rudkin 2009 and Phipps *et al* 2010, cited by Walshe and Phipps 2013).

Some regulators identify types of activities or services (rather than specific organisations) that they consider to be inherently high risk for more frequent inspection (in the finance sector, the Financial Services Authority takes this approach, but makes clear that it is looking to recognise good practice as well as to check concerns to avoid a perception that the approach categorises all providers as problematic) (Ojo 2010, cited by Walshe and Phipps 2013).

Data-driven approaches (such as ratings compiled from indicators) can affect organisations' behaviour and create perverse incentives. There is well-known literature on this that falls outside of the search period for this review – including analysis of how hospitals in England gamed performance targets in the 2000s (Bevan and Hood 2006). More recent work explored the way in which data rankings affected behaviour in Dutch and Swedish hospitals (Wallenburg *et al* 2021, 2019). This could lead to a regulator having a false picture of risk, and emphasises the need to contextualise quantitative metrics and the importance of a relational approach.

For these reasons and others (such as cultural differences), although risk-based approaches are widely proposed, they are by no means universally accepted as the best way to regulate in practice. For example, the Joint Commission on Accreditation of Healthcare Organizations in the United States and IGJ (the health and youth care inspectorate) in the Netherlands collect extensive risk information to help inform inspections – but not to vary their frequency or intensity. When considering learning from the literature, it is important to keep in mind that the specific UK context may differ from that in other countries. What indicators are available, and the differences between them, 'reflect fundamental differences in national regulatory priorities, institutional configurations of payers and providers, and even understandings of quality itself' (Beaussier *et al* 2020).

Having said that, there does appear to be support for a risk-based approach among CQC's regulated bodies. When surveyed in 2022, most NHS providers (91%) supported CQC's proposed shift towards a risk-based approach, data-based surveillance, and an intention to update ratings frequently (NHS Providers 2022). However, the most recent repeat survey from NHS Providers found them reporting increased regulatory burden and questioning whether reporting requirements were realistic or proportionate (NHS Providers 2024), highlighting the importance of the recommendation that CQC work to make best use of data that is already collected (Richards 2024).

To help navigate these various challenges, Hampton (2005, p31, cited by Walshe and Phipps 2013) provides a set of overall recommendations, also reflected in the broader findings of Walshe and Phipps (2013), that risk-based regulation should:

- be transparent and open to scrutiny
- be balanced in taking account of past performance as well as potential future risk
- use all available good-quality data
- be implemented uniformly and impartially
- be expressed simply, preferably mathematically
- be dynamic, not static
- be carried through into [regulatory] decisions
- incorporate deterrent effects
- always include a small element of random inspection.

Risk information is always imperfect

Both the availability of data on risk (Allen *et al* 2020b) and its quality (Lloyd-Bostock and Hutter, 2008, cited by Walshe and Phipps 2013) are critical to the success of risk-based regulation.

Currently, the availability of risk information is skewed heavily towards NHS providers, especially secondary care, limiting the usefulness of data-based risk assessment in other sectors. Even within the NHS, there are significant gaps in the availability of information, and there are additional gaps from what information CQC chooses (or is able) to use, as well as issues of data quality and consistency, which can all affect how credible and definitive risk assessment is (Richards 2024). For example, some data is not sufficiently granular to allow for

reliable identification of risk other than in major outliers. Also, data-sharing between national bodies has not been optimal, according to the Dash and Richards reviews, and it is not clear how well CQC's use of risk data avoids duplication and joins up with oversight of the NHS (regional offices and integrated care boards) and social care (local authorities) (Dash 2024; Richards 2024).

Additionally, it is not known how effective CQC's analysis ('CQC Insight') currently is in identifying or predicting risk. CQC's analytical approach has changed little since 2017 (other than in primary care) from the previous approach ('Intelligent Monitoring'). The regulatory platform has also made it challenging to always take account of risk information and analysis in inspections and assessments.

Our literature search did not turn up any published evaluation of CQC's current CQC Insight model's ability to identify or predict risk. However, evidence about its previous Intelligent Monitoring statistical surveillance tool shows that there are significant difficulties in predicting poor performers from data in advance of an inspection, even in those services that have the greatest levels of data available.

- The Intelligent Monitoring model had very poor predictive power for acute hospital trusts – it did not predict the vast majority of NHS trust ratings overall or ratings at domain level (Allen et al 2020a).
- Another study agreed – it found that Intelligent Monitoring could not predict inspection ratings for NHS acute hospital trusts or distinguish between trusts performing poorly (ratings of 'inadequate' or 'requires improvement') and those performing well (ratings of 'good' or 'outstanding'), or just identify the worst performing trusts (ratings of 'inadequate' compared with all others) (Griffiths et al 2017).
- In general medical practice it also had very limited ability to predict inspection outcomes or even separate practices out as either relatively 'better' or 'worse' performers. The authors concluded that a data-driven approach to the prioritisation of general practice inspections using Intelligent Monitoring indicators is unlikely to be effective unless significant improvements are made (Allen et al 2020b). They highlighted the importance of CQC testing and evaluating the validity and reliability of both, using performance indicators to predict risk and of generating ratings from inspections, and continuing to monitor validity and reliability routinely.

There is some evidence that combined measures of patient feedback may have some ability to predict inspection ratings for acute hospitals. A study looking at the ability of a predictive judgement score (given to acute hospitals based on a real-time tracking system that combines feedback from NHS Choices, patient opinion, Facebook and Twitter to form a near-real-time judgement score) to predict inspection outcomes found a positive association between the score and subsequent inspection outcome. It concluded that the predictive judgement score could be used to successfully identify a high-risk group of organisations for inspection, and that the score could be useful when used alongside other measures as it is more timely (near real time) (Griffiths and Leaver 2018).

In a predecessor of CQC, Bardsley (2017) inspected a sample of NHS trusts identified as higher risk from a range of indicators of care quality and a sample selected at random. Inspections of the ones selected through risk assessment were more likely to discover non-compliance with standards than those selected at random, indicating the potential for a risk-based approach to inspection. However, this finding could have been a self-fulfilling prophecy, as inspectors were aware of the status of the trusts they were allocated.

Where regulators use their assessment of risk to determine the frequency of inspection, keeping ratings up to date can be a problem. This is something recent reviews noted was a challenge for CQC, and it has also been a challenge for Ofsted (Dash 2024; Perryman *et al* 2023). Regulators need to be aware of the different ways people use ratings in different sectors and the impact the risk-based approach might have on information for the public.

Risk-based regulation requires strong capabilities in the operational workforce

Using data as risk indicators requires specific expertise, both in understanding its fitness for purpose (what is measured and why, its potential limitations and its contexts, rather than just technical capability in statistical measurement) and in understanding and communicating its meaning (as indicators of risk of low-quality care rather than indicators of the quality of care itself) (Poldrugovac *et al* 2023). More generally, data-based approaches require regulators to develop expertise in managing technical risks (such as not being able to monitor or predict all risks) and political ones (such as the challenges of technocratic 'red tape' and burden) (Hutter 2015). This expertise in using risk data does not reduce the need for relational expertise. This is reflected in a Dutch initiative to embed risk-based regulation into relational approaches (Wallenburg *et al* 2021). There are several practical steps that can help enable inspectors to develop this balance. An analysis of the use of performance indicators by organisations regulating long-term care facilities in 10 countries (Poldrugovac *et al* 2023) identified the following approaches:

- developing effective IT support within the regulator, to improve the ease of access to already collected data
- providing benchmarks and identifying outliers to support inspectors in better understanding the data
- introducing dashboards that allow intuitive visualisations of the data considered relevant
- allowing inspected bodies to add contextual information to performance data
- taking advantage of inspectors' knowledge and experience to assign a risk score to the reported indicator values.

CQC is not making use of all its own risk information (information from registration does not feed effectively into subsequent risk assessment). Its IT platform hinders the effective collection and use of risk information. A fragmentation of operational roles, and the loss of relationship management (each inspector's 'portfolio' of providers), have particularly reduced longitudinal information on risk (Richards 2024).

Where inspectors have the ability to collect and use risk information about a provider over time, through constant caseloads and relationship management, it is highly valued. Kok *et al* (2019) found that when risk assessment was transferred from local to national teams of the Dutch health and youth care inspectorate, significant problems resulted because informal knowledge about, and previous experience of, the service concerned turned out to be essential in mediating the assessments effectively.

Interview insights – what other organisations are doing

In Australia, we heard that inspections are based on a timeframe (two to three years depending on the programme), although in some sectors, concerns could trigger an assessment due to risk. In the acute sector, random visits are made at 'short notice' – for example, in a week's time rather than six months. One expert described this as fairly effective in developing good practice as business as usual. They also described this as better for organisations – there are fewer document requests and reviews when going in at short notice, which can be onerous for organisations. Individual inspections may focus on a small number of standards, but all will be assessed within a certain overall period for each provider type.

We heard that the Australian Healthcare Practitioners Regulatory Agency has focused on moving away from waiting for problems to happen to preventing them, which was described as problem-focused regulation. Examples of this include upstream work on emerging areas of risk in cosmetic procedures, telehealth, virtual care models and new services – for example, the prescribing of the new generation of weight-loss medications. This regulator has developed a regulatory rapid response unit to take on time-critical and sensitive problems across the regulated sector and be seen to act. This sits outside the normal regulatory processes for individual providers but feeds into them.

Ofsted has policies on how frequently organisations will be inspected based on their rating – although this is currently being considered in its consultation on a new approach. It has two types of inspection: one that does not change the grade but gives an indication of the direction of travel; and another that would change the grade.

We heard that Ofsted is moving away from old judgements towards a more granular approach: a five-point scale and with more assessment areas. There are different perspectives on these changes, which are out for consultation at present. They are considering how to ensure robust validity and reliability through their consultation, however.

In the Netherlands, we heard that risk information may determine both the frequency of inspection and the intensity of intervention, potentially moving a provider between different levels of standard or enhanced oversight. Account holders (lead inspectors/relationship managers) collate the information to determine this, including their ongoing knowledge of the provider and ability to contextualise it, but decisions are made higher up in order to avoid all decisions resting on one individual.

5 Developing relationships and trust

Key points

- **A modern regulatory approach needs to be able to flex between controlling and supportive styles.** A range of approaches is possible, rather than an 'either/or'. It is therefore important to be able to flex depending on the circumstances.
- **The quality of relationships between inspectors and the organisations they regulate is important.** Inspectors' ability to contextualise information in knowledge of a provider's history, and to encourage providers to share information and be transparent, can significantly enhance regulatory decisions. Ensuring these skills requires time, training and support.
- **When the providers and the public trust a regulator, it can also indirectly support provider compliance.** It is hard to build a good relationship with providers and the public because of the regulator's role – and it is important to realise how vital that relationship is when it is there. Giving priority to engagement and transparency can support this.

The opportunity for CQC

CQC's reputation has been severely damaged by problems with its current regulatory model. The challenges described in previous sections of this report have had a negative impact on the relationship between CQC and providers, and trust with wider stakeholders has been affected. Criticisms from providers include that they were not listened to and that CQC's communications and engagement were overly positive and not transparent, lacking an understanding of CQC's regulatory role. Although it is unclear what damage there has been to CQC's relationship with the public, negative headlines may well have had an impact. It should be noted that while recent issues have led to a marked decline in relationships, this is not a completely new concern for CQC, particularly in relation to its relationship with providers (Iacobucci 2018; Negri 2018; Parliamentary and Health Service Ombudsman 2018; Nuffield Trust and NHS Providers 2015).

Rebuilding trust with all stakeholders is therefore a key focus for CQC's foundational improvement work and its engagement and communications with providers and other stakeholders. CQC has already started work to engage with the sectors to rebuild trust, for example through work including a series of provider roadshows about the CQC's culture, vision and purpose, and sees the recruitment of chief inspectors for adult social care, mental health, acute and primary care as key to regaining CQC's reputation.

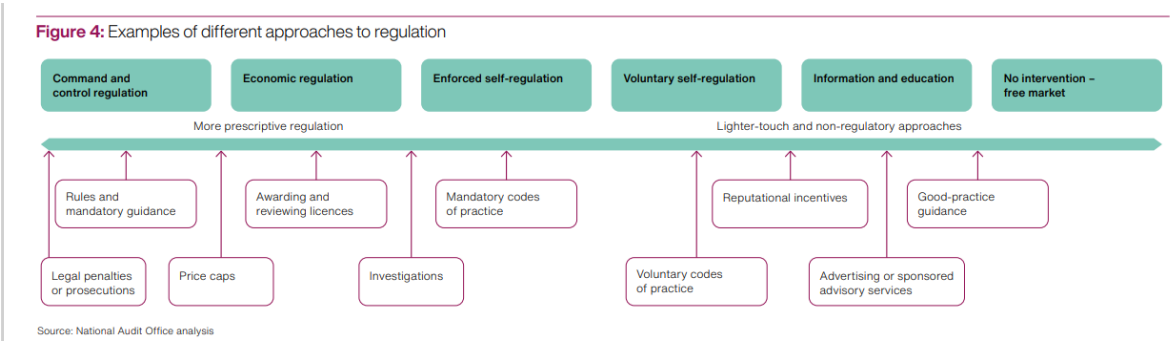
Evidence on what works

A modern regulatory approach needs to be able to flex between controlling and supportive styles.

How CQC views the organisations it regulates is as important as how the organisations view CQC (Walshe and Phipps 2013). Relationships may be transactional or material, and organisations may be partners or adversaries. How the regulator approaches enforcement also influences how the regulated organisation responds. A supportive – or responsive – style increases co-operation, while a critical style frustrates it (Martinow *et al* 2020).

Regulation approaches can be viewed as a range, from more to less prescriptive (National Audit Office 2021), or more or less responsive (*see* Figure 1). Regulators may draw on several different approaches to achieve their aims.

Figure 1: Examples of different approaches to regulation



There is an academic and research consensus that controlling, deterrent and legalistic type approaches to regulation have many downsides, although their aim is increased standardisation or consistency. For example, these approaches can lead to a focus on minimum requirements, adversarial relationships, high workloads for inspectors, and possible missed opportunities for improvement (Walshe and Phipps 2013).

When things go wrong, there is a tendency for a 'risk regulation reflex', 'in which decisions are taken too fast, with too little analysis, no regard for alternatives, and fully unrealistic expectations' (Blanc *et al* 2015). For example, NHS Improvement (2020) notes that in the UK context 'the national bodies' and commissioners' general response to a worsening operational environment has been to increase their grip on local organisations and focus on short term performance management interventions'. However, this risks regulated organisations implicitly prioritising responding to regulators over their operational priorities. Additionally, bureaucratisation, increasing regulation and costs of compliance, which also reduce a professional's autonomy, increase 'distrust and intrusion of the regulator in operational activities' (Amalberti *et al* 2024).

By contrast, more responsive, facilitative approaches as the norm (when inspectors are not in enforcement mode) can encourage improvement, for example via enforced self-regulation (Walshe and Phipps 2013; *see* also section 2). A more facilitative or relational style can also support a collective approach to reliability through dialogue, open standards and gradual assessments (that is, there is more observation and more opportunities to discuss why things are happening the way they are). This enables providers to feel they are able to explain themselves and are treated fairly (Weenink *et al* 2021; Braithwaite and Braithwaite 1995).

The pressure of external regulation can assist with the implementation of health care standards (Kelly *et al* 2023). A more facilitative approach would mean a regulator contributing to community of practice rather than being separate from it, demonstrating an openness to learning and potentially supporting the regulator–regulatee relationship (Vogel 2015; Walshe and Phipps 2013).

Nuance is important here. There are a range of approaches, rather than an 'either/or'. It's therefore important to be able to flex depending on the circumstances, eg different organisations and contexts, for example with a hybrid model that balances deterrence and compliance, assurance and improvement (Carrigan and Harrington 2015; Furnival 2017). This can allow for different levels of stringency and different types of deterrence depending on context, and can enable targeting (prioritising inspections and enforcement actions) (Carrigan and Harrington 2015). Additionally, Rutz *et al* (2017) found that rather than presenting different styles as opposites, in practice, 'street-level bureaucrats' combine consistency and responsiveness through their use of collective discretion (*see* under section 3, 'It is important to work with professional judgement').

Education regulation highlights some of this nuance. Changes made in the 2010s in England and Sweden 'designed to counteract public and political criticism and to enhance the credibility of the inspectorate' have in practice created challenges, despite taking very different approaches (England more discretionary, Sweden more standardised) (Baxter and Hult 2017).

The quality of relationships between inspectors and the organisations they regulate is important

How inspectors interact with organisations is also key to this. For example, Loyens *et al's* (2019) review found that inspectors in different sectors were influenced by the characteristics of individuals in regulated organisations – for example, if they appeared co-operative, they got more leeway.

Balancing 'impersonal authority' (laying down the law) and 'personal authority' (using relationships) is important. Less experienced inspectors tend to favour the former, as the latter is associated with carrying more personal risk and responsibility. However, for inspectors to be able to gather the information they need, co-operative relationships are helpful (Hall *et al* 2019; Walker 2013; Walshe and Phipps 2013).

Inspectors' understanding of their own role also has an influence (Loyens *et al* 2019) – for example, are they focused on responsiveness or rule enforcement? Buckley (2016) found that inspectors 'being human' with their contacts in the organisations they regulate – for example, being interested in their personal lives or learning about their businesses – could support the development of relationships, credibility and the ability to smooth issues. As we already noted in section 3, relational skills are one of the core skill sets required of inspectors and are central to the effective delivery of the regulatory model. We also found that sectoral expertise plays a key role in credibility. Klijn *et al* (2022) found that the nature of inspectors' relationships with inspectees – which are more intense than those of other bureaucrats – can lead to a more facilitative and understanding approach to them in expectation of the same in return. The authors suggest that this mode of interaction would reduce their risk of blame and therefore could be seen as a 'blame avoidance strategy' on the part of inspectors. Openness about a regulator's performance information (for example through a public report) also appears to enhance inspectors' use of more facilitative styles – CQC already does this, but it is interesting that showing the working is important (de Boer *et al* 2018). While these examples come from regulation beyond health and care, they likely have transferability to this context.

Of course, there are also different motivations for organisations to comply with standards – negative or positive. Negative motivations (fear of consequences) may be highest where organisations are more beholden to inspectors. However, this can lead to a focus on looking good versus doing good – and undermine more intrinsic motivations to improve. It can also mean organisational learning processes are lower priority. Conversely, where inspectors' influence is lesser, there may be less 'threat' of inspection and lower motivation to improve (Weenink *et al* 2021).

All of these studies highlight the importance of the relationship between inspectors and the organisations they regulate, and of responsiveness in those relationships. This makes sense: complete homogeneity among inspectors would not be desirable because that comes with its own risks around the ability to notice and respond to change (Loyens *et al* 2019). It also speaks to the importance of training and developing the inspection workforce (*see* under section 3, 'It is vital to ensure that training for inspectors is adequate and effective').

Interview insights – what other organisations are doing

In Australia, we heard that the credibility of the Australian Commission on Safety and Quality in Health Care with acute providers has been linked to strong engagement with the sector, for example on guidance, standards, and how to frame them, building on a long lead-in time to develop this. By contrast, the aged care sector regulator was described as 'blind to issues' which occurred in the aged care sector, where there has been a Royal Commission highlighting major issues in care provision and regulation, and a drive for the regulator to improve engagement and communication with providers.

During our engagement with CQC, we heard repeatedly that the previous relationship management arrangements had been useful for inspectors' understanding of providers and their

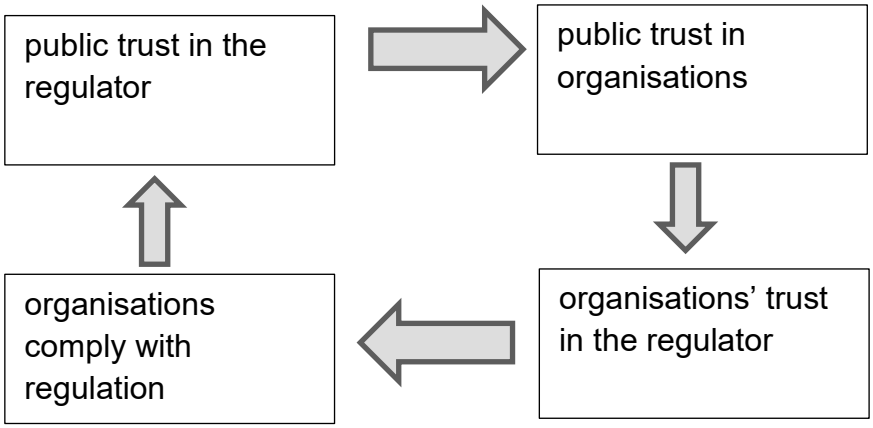
risk patterns. However, some indicated to us that there was no longer sufficient time available for that role, and that it should be specifically carved out.

From our Netherlands expert we heard about the importance of ongoing relationship management. They highlighted several success factors: the account holder must have authority to convene and make decisions and must hold the longitudinal oversight – even though supported by specialist inspectors who come and go – because contextualising information about a provider is as important as the information itself. Longitudinal relationship management was described as the key to updating ratings, understanding context and facilitating shared understanding rather than mechanistic methods. The one caveat is that over-long relationships could risk organisational capture, so it would make sense to have a time limit and clear succession planning in place.

When providers and the public trust a regulator, it can also indirectly support provider compliance

It is hard for regulators to gain public trust due to the nature of their role. When things are going well, they are in effect invisible and only tend to reach the public eye when things go wrong (Grimmelikhuijsen *et al* 2024). However, people have to rely on regulators, because it is not possible for individuals to directly assess the effectiveness/compliance of organisations. This means there is an element of vulnerability in the relationship between the public and CQC (Grimmelikhuijsen *et al* 2024). There is a potential virtuous cycle of trust (*see* Figure 2).

Figure 2: Virtuous cycle of trust between regulators, regulated organisations and the public



Interview insights – what other organisations are doing

Ofsted has a different relationship landscape from other sectors as the education sector trade unions are powerful and have a formal position of wanting the inspectorate to be abolished. By contrast, Dash (2024) found that 'virtually all' stakeholders participating in the review of CQC recognise the need for a strong, credible and effective regulator of health and social care services.

Engaging with the public is a key way that regulators can increase transparency and hence their legitimacy, as long as this is done in meaningful ways (Nash and Walters 2015). The information provision role of CQC (publishing reports and so on) is also a mechanism for increasing public accountability – of the regulator and of regulated organisations (Walshe and Phipps 2013).

However, the literature indicates possible tensions between the independence of a regulator and its ability to be held to account and be transparent (Carrigan and Poole 2015; Nash and Walters 2015). Because of their role, inspectors are often viewed as 'the face of government' by regulated organisations and the public (Loyens *et al* 2019). It is therefore important that they understand their relationship and are aware of public sentiment, even if this is not the sole basis of decision-making (Vogel 2015). When a regulator is not consistent across inspections, this can affect understanding and trust among regulated organisations and the public (Loyens *et al* 2019). However, this should not be at the expense of ensuring responsive and transparent decision-making.

Finally, it is hard to consistently measure 'trust' in regulatory agencies (Maman *et al* 2024). There is also mixed evidence of how regulators' styles affect public trust (although none from the UK context). A Dutch survey found the public preferred command and control/deterrence styles (Cunningham *et al* 2020), while an international one found little evidence that particular styles were preferred (Grimmelikhuijsen *et al* 2024). In the latter, enforcement style generally did not influence citizen trust, and contrary to expectation, people did not seem to prefer more punitive enforcement styles. The authors suggest that people's perceptions are based more on wider relationships between state and market actors, and that regulators do not need to be so concerned about how the public may perceive more flexible or accommodating approaches. However, where trust is low, more coercive or control-style enforcement did seem to increase trust a little (Grimmelikhuijsen *et al* 2024). It may be that England is a context of low trust, for example because of perceived distrust of experts and Members of Parliament, and feels a heightened need to hold regulators to account (Gill *et al* 2024), so this topic would benefit from further research.

6 Changing the regulatory model

Key points

- **Piloting and evaluation are essential for understanding impact** and supporting learning. Changes need to be driven by a clear purpose and explicit programme theory. It is not safe to assume inspectors experienced in a former approach will be competent in a new one without training and support.
- **It is important to be open as new methods are trialled.** Three things that can undermine piloting and evaluation in regulatory approaches are:
    - not allowing enough time and space
    - other things (such as new responsibilities) eating up allocated time and space
    - the quality of connectivity to decision-making.
- **Piloting should not be confused with incremental rollout.** Piloting (a learning process) is different from a phased rollout (a pragmatic operational process).
- **Formative evaluation can support meaningful change.** Initial piloting/testing needs to lead on to an ongoing culture of reflexivity, adaptation, evaluation and improvement.

The opportunity for CQC

Recent external reviews of CQC highlighted two key challenges arising from the last round of changes to its regulatory model, and a need to make further changes and improvements (Care Provider Alliance 2025; Dash 2024; Richards 2024). First, the scale and complexity of changing the assessment framework, while at the same time developing and rolling out an entirely new IT platform, and also simultaneously restructuring the organisation, did not leave sufficient capacity for the planned testing, piloting and evaluation of the planned changes to be confident that they would achieve their intended impact. Second, there were substantial gaps in understanding about the new assessment methods among both regulated providers and CQC's own staff.

To address this, CQC has put an improvement programme in place, including extensive internal and external engagement and independent evaluation.

Evidence on what works

Piloting and evaluation are essential for understanding impact

Boyd *et al* (2017) conducted research from which they concluded that it is not safe to rely on inspectors being experienced in previous inspection and regulatory approaches, and the introduction of new approaches needs to be actively managed with training and pilot inspections. They tested the consistency of CQC inspectors' judgements by asking them to rate

and categorise a set of vignettes via a survey and by directly observing inspections. Their findings include uncertainty and inconsistency in the application of a new regulatory framework, and variability arising from differing processes for corroborating/synthesising information and for decision-making. Similarly, Greenfield *et al* (2015) found that it is vital that inspectors understand and are competent and confident in using new models/tools, otherwise they are likely to make assessments based on their old ways of working.

Walshe *et al* (2014) indicate that piloting and evaluation are particularly useful when developing the approach to inspecting large, complex organisations such as NHS trusts. Stoopendaal *et al* (2016) conclude that piloting and evaluation are also particularly useful when regulators need to translate their regulatory goals to multiple different contexts and when inspection needs to fit alongside other forms of supervisory oversight (for example, reusing findings or data rather than duplicating it). Behan (2024) carried out a review of the English regulator of higher education and similarly concluded that consultation followed by piloting and evaluation can help build up relationships and trust between the regulator and regulated bodies, which he says is fundamentally what effective regulation is built upon.

Interview insights – what other organisations are doing

Ofsted is in a piloting phase with its work. It is currently feasibility testing its approach, and will then trial full inspection visits, including sharing with the organisations in the trial the grade they would have given. We heard that Ofsted plans to undertake a full evaluation of the reforms, although it does not currently have a timescale for this.

The Office for Students undertakes evaluations of their work in phases – these can start with qualitative intelligence gathering to explore whether their theory of change is working in practice, and later move on to quantitative work to explore changes in response to their interventions.

Walshe *et al* (2014) and Walshe and Phipps (2013) emphasise that piloting should not just be about assuring the consistency, feasibility or efficiency of process design but also about ensuring that processes correspond to the regulator's programme theory and achieve their intended impact. This involves articulating and mapping the aims and intended effects of regulatory interventions. When these are clarified, comparing them to the eight ways in which CQC has impact (Smithson *et al* 2018) could also help ensure that the regulatory approach makes good use of the range of potential impacts rather than relying on only a limited set of approaches (such as inspection) and under-using others (Walshe *et al* 2014).

Walshe *et al* (2014) also found that there were clear themes in the criticisms of inspection that interviewees made. Where these can be identified, there is a real opportunity to use piloting and evaluation to ensure that the design and implementation of assessment processes respond to this feedback and not only maximise intended benefits but also minimise negative impacts.

Various reports assert that beyond initial piloting of new approaches, regulators need to foster an ongoing culture of learning and evaluation. Evaluation of its hospital inspections commended

CQC for its pilot programme and identified continuing to draw out learning and applying that insight as 'the key task now' (Walshe *et al* 2014). As a minimum, ongoing learning and evaluation are necessary in order to adapt to a constantly changing context (Marsden *et al* 2020), but how CQC learns is also seen as key to developing its capability (Comptroller and Auditor General 2017) and its relationship with regulated bodies (Boyd *et al* 2020). Timmins (2013) indicates that learning and evaluation are also necessary because regulating health and care is inherently complex and difficult.

Interview insights – what other organisations are doing

We heard that Ofsted has not had as many issues with the reliability of its assessments as CQC has, but it is exploring how to maintain and improve this – for example, through an ongoing programme of trial inspections to test reliability.

We heard that the Dutch health and youth care inspectorate has set up a research programme and has appointed two endowed professors at Erasmus University to ensure testing and the development of new methods of regulation.

We heard that the Office for Students previously undertook some random assessments that could be used as a comparator against which to assess the impact of their risk-based work, although they are not currently undertaking these.

Where adequate piloting does not take place, and/or there is no ongoing culture of evaluation and learning, a drift towards opacity and institutionalised practice can occur. This is illustrated in CQC's own pre-2013 inspection approach (Walshe and Phipps 2013), where processes for decision-making were unclear and heavily reliant on individual inspectors' judgement, with untested assumptions about their knowledge and expertise. CQC's challenges in ongoing learning and improvement are indicated in several reports (Townson 2024; The Healthcare Improvement Studies Institute 2024; Lintern 2019; Parliamentary and Health Service Ombudsman 2018), and is mirrored in other health care regulation (Sethe and Murdoch 2013) and in other sectors, such as education (Perryman *et al* 2023).

Chief inspectors, as decision-making members of CQC's executive team, directly oversaw the piloting of the introduction of CQC's 2013 inspection approach and local authority assessments (Care Quality Commission 2023; Walshe *et al* 2014). However, Dash (2024) found that members of CQC's executive team were unable to describe the single assessment framework and the rationale for how it was applied.

The literature points to three factors that get in the way of piloting and evaluation happening. Most of this comes from literature by or about CQC.

- The most frequent reason given is a disconnect between ambitious targets for delivering inspections (Walshe et al 2014) and the time and space needed for developing and testing a regulatory approach (Stoopendaal et al 2016).
- Particularly for CQC, the introduction of additional responsibilities can eat up whatever capacity there might have been for piloting and evaluation (Comptroller and Auditor

General 2015). This is usually due to government adding responsibilities, but CQC itself also chose to develop regulatory approaches, an IT platform and an organisational restructure all at the same time.
- The outcomes of piloting or evaluation-type activities are insufficiently connected to decision-making – for example, where staff raised concerns about planned approaches but were not listened to (Dash 2024; Townson 2024).

It is important to be open as new methods are trialled

In addition to the external evaluation reports on the 2013 regulatory approach, there were publications of iterations of inspection handbooks (Walshe *et al* 2014) and reflections on the first 'wave' of inspections in each sector (for example, Care Quality Commission 2014a, 2014b). More recently, there has been a report on the evaluation of local authority pilot inspections (Care Quality Commission 2023). Our literature search did not turn up equivalent outputs for the introduction of inspection against the single assessment framework.

Stoopendaal *et al* (2016) note that published outputs that 'documented and reflected on the process as it progressed… helped to translate and communicate learning so as to better understand regulation and to reform and reconceptualize [it]'. Conversely, the Healthcare Improvement Studies Institute (2024) found that although many problematic aspects of inspections were addressed, the lack of published outputs about how CQC was learning meant that concerns about the programme remained in provider organisations. Behan (2024) notes that involving regulated bodies in piloting and developing approaches helped build relationships, which are fundamental to effective regulation.

Interview insights – what other organisations are doing

Many, if not all, of the experts we spoke with emphasised the importance of constantly devoting time to engaging with the regulated sector in order to build up understanding of approaches and ensure a fit with their operational realities. In Australia, we heard that the Australian Healthcare Practitioners Regulatory Agency has taken engagement further and established an international advisory group to act as a critical friend to inspection approaches and promote exchange of learning and expertise.

We heard that the publication of some Ofsted work as academic articles (for example in relation to the positive impact of inspections) can help bolster arguments for financial investment.

Piloting should not be confused with incremental rollout

Our literature search did not reveal outputs of piloting the introduction of the single assessment framework in CQC inspections, but it did include numerous mentions of a rollout that happened in stages (Care Quality Commission 2024). At first glance, this may look like a progressive 'test and learn' approach but there is no published evidence of changes being implemented from one phase to the next. It is important to be clear about the difference between piloting (a learning and improvement process) and phased delivery (a pragmatic operational delivery process).

Formative evaluation can support meaningful change

Walshe *et al* (2014) note that ‘retrospective, summative research and external evaluations like our work have their place, but are no substitute for more formative, concurrent evaluation undertaken by the regulator itself as well as external researchers’. They see formative evaluation as potentially the most powerful means of developing new regulatory methods that are likely to achieve their aims, in addition to building a learning culture and relationships with regulated bodies.

Stoopendaal *et al* (2016) provide an example of what formative evaluation can look like, through the Dutch health and youth care inspectorate’s experience. Over two years, there were ‘numerous iterations between data gathering and feedback in order to orient the next steps of the [development] process’, so that the process was observed, documented, analysed and reflected on as it progressed. ‘The [qualitative formative] evaluation helped the process in all stages by describing what happened and reflecting on why things happened, revealing underlying assumptions.’

7 Discussion

This review of some of the wider literature on what works in health and social care regulation, and our expert interviews with regulators in other sectors and other jurisdictions, was focused on five key challenges that CQC currently faces. It has sought to show that evidence and experience from elsewhere have a really important contribution to make to the design, testing and evaluation of CQC's future regulatory model. Rather than repeating some of the key lessons outlined in this report, in this discussion we seek to draw out some wider learning points.

First, it is vital to maintain an unrelenting focus on the purpose of regulation and its impacts, rather than to start by designing regulatory systems and processes. Those things matter, but there is a real risk that 'the process becomes the purpose' and the focus is all on things such as inspections and data systems rather than on what they are meant to achieve. On that point, CQC's mission and purpose have remained relatively unchanged through a number of regulatory reforms – to assure safe and effective high-quality care and to encourage improvements in care. That is important because a whole set of decisions about how to regulate follow as a consequence of saying that the regulator does not just seek to assure but also to promote improvement.

Second, in order to have this focus on regulatory impact, there is a need to articulate the programme theory that underlies the regulatory model – in plain language, how CQC thinks regulatory actions or interventions such as inspections or ratings will bring about the impacts that are intended. Making that programme theory explicit enables not just the intended impacts but also any unintended or inadvertent impacts it might have to be questioned, refined and thought through.

Third, there is plenty of evidence and experience from elsewhere that CQC can use to design its future regulatory model – it does not have to either start from scratch or 'reinvent the wheel'. Indeed, experience suggests that regulatory reforms that progress incrementally, with careful piloting and testing, are more likely to succeed than those that seek to make wholesale or multiple changes at the same time.

Fourth, it is clear from the evidence reviewed in this report that regulation is fundamentally a social process – enacted by individuals and groups of people and by organisations that are complex social structures, characterised by networks of relationships, hierarchies and interactions that influence and shape regulatory practices and outcomes. This means that people's motivations and behaviours are fundamental to how regulation works in practice, and that for a regulator and its workforce, how you work matters as much as what you do. Regulatory teams should include a mix of sector-specific, regulatory and relational expertise. Whatever is written in regulatory policies, inspection handbooks and the like, what actually

matters is the lived experience of regulatory staff, provider staff, users of services and other stakeholders in regulation in practice.

Finally, the human and organisational dimension of regulation means that what works in one organisation, sector or jurisdiction may not work in the same way in others. This means that learning is about thoughtful adaptation, not unthinking adoption of policies or practices from elsewhere. It also means that the evaluation and testing of regulatory processes should not just be a concern during their piloting or testing but also be something that is built into their wider rollout and ongoing implementation in ways that mean that the regulatory programme produces, as a by-product, evidence of its impact on the quality of care.

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