Final report (programme evaluation)

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Evaluation of CQC’s national maternity inspection programme

The Healthcare Improvement Studies Institute

# Abstract

This report presents findings from an evaluation of the Care Quality Commission’s (CQC) national maternity inspection programme, led by The Healthcare Improvement Studies Institute (THIS Institute) between May 2023 and February 2024. The study had two objectives: to characterise what good safety culture looks like; and to evaluate the programme and capture learning to inform future inspection.

This report focuses on the second objective, evaluating the inspection programme. We aimed to maximise learning from the approach taken in the maternity inspection programme. Using mixed methods, including literature review, document analysis and interviews with stakeholders, the findings will help to inform CQC’s approach to inspection, rating and assessment of services in maternity and beyond.

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# Executive summary

## Background

Maternity services in England face significant challenges. In 2022, the Care Quality Commission (CQC) – the independent regulator of health and adult social care in England – began a new maternity inspection programme, covering all maternity services in England that it had not inspected or rated since April 2021. The programme focused on two of CQC’s five quality domains: ‘safe’ and ‘well-led’. CQC commissioned The Healthcare Improvement Studies Institute (THIS Institute) at the University of Cambridge, with RAND Europe, to undertake an evaluation of the maternity inspection programme. The evaluation had two objectives:

1. To characterise what good safety culture looks like in maternity services and the factors underpinning it;
2. To evaluate the national maternity inspection programme to maximise learning for maternity services, inspection, and the health and care sector more broadly.

This report provides an overview of key findings relating to the second objective, evaluating the national maternity inspection programme.

## Study design and methods

Conducted between May 2023 and February 2024, the study involved six workpackages in total, of which three were particularly relevant to the second objective. In brief, the workpackages and associated methods and data that related to the second objective were:

* Workpackage A: A **literature review on optimising regulation and inspection**, selectively examining the literature on regulation across healthcare and other sectors, using an author-based approach to identifying and synthesising relevant literature;
* Workpackage B: A **documentary analysis of maternity inspection programme documents**, which examined 25 documents describing the programme and anonymised notes from inspections to identify the programme’s ‘theory of change’ and characterise key features of the approach taken to inspection in practice;
* Workpackage C: **Interviews with selected programme stakeholders**, which involved semi-structured interviews with inspectors, senior staff from CQC leading and managing the programme, and people from inspected organisations including senior managers and maternity staff at the ‘sharp end’ of care (23 interviews);

Summaries of the methods used for each workpackage are provided in the chapters that follow, with full details provided in working papers that underpin the report.

## Literature review on optimising regulation and inspection (workpackage A)

In this part of the study, which is reported in Chapter 2, we examined the evidence base on regulation and inspection from multiple sectors, including healthcare and others, to identify key implications for CQC as it reviews and updates its approach to regulation.

The available academic literature identifies challenges in reconciling effectiveness of regulation (how well it delivers its aims) with efficiency (ensuring appropriate and proportionate use of resources) and legitimacy (ensuring that the actions, approach and values of a regulator are accepted as appropriate and valuable). For legitimacy in particular, it may not be easy to meet the expectations of all the audiences – or ‘legitimacy communities’ – of a regulator, since they may have different views of what its aims should be and what might constitute an appropriate approach to delivering them.

Given inherent challenges in the nature of regulation (including disputes over its principal objectives and the difficulty of finding counterfactuals), definitively answering questions such as ‘Does regulation work?’ and ‘Do inspections work?’ is difficult, if not impossible. However, the literature does offer some insights into effectiveness, efficiency and legitimacy of different approaches to regulation in different contexts, including the role of inspection in relation to monitoring organisational performance.

The available evidence is clear on the need to set the standards that are to be monitored through inspection at a level that is reasonable, and that avoids both ‘over-triggering’ (deeming services to be unsatisfactory when they are not) and ‘under-triggering’ (deeming services to be satisfactory when they are not). However, specifying standards that are clear, achievable, interpreted consistently, proportionate and recognised as legitimate is not straightforward. Choosing which areas of organisational activity should be monitored through such standards is also not straightforward. Arguments are made for generating standards that relate to outcomes and standards that relate to processes, but both kinds of standard have advantages and disadvantages. In standard-setting and inspection, it is also important to account for both specific, observable activities and for the more amorphous features of an organisation, such as its culture.

Standards further need to strike a balance between prescription and principle. Prescriptive standards (such as measures of activity that need to be attained) are generally more easily observed, quantified and measured, and thus transparent. However, relying on prescriptive measures alone can result in unintended consequences and may distort the focus of organisations. Therefore principle-based approaches, focusing on less tangible notions such as organisational commitment (rather than organisational compliance), may have an important role in regulation and inspection. But these too may have problems: for example they may allow organisations too much flexibility in their approaches, may be more challenging in terms of the discretion afforded to inspectors, and may be difficult to use when seeking to enforce improvement.

Many authors argue that inspection has an important place in a wider regulatory regime, but it is resource-intensive and has its limitations: for example, in relation to the extent to which it is feasible to use inspection to forensically examine the full activities of an organisation, and in relation to the role of human judgement in making assessments. Enforcement following inspection is a vital part of a regulatory regime, but faces its own challenges, including questions about the right type and form of enforcement, who is responsible for securing, and unintended consequences for inspected organisations relating, for example, to staff morale and organisational reputation.

## Documentary analysis of maternity inspection programme documents (workpackage B)

In this part of the study, we examined a range of documents provided by CQC relating to the maternity inspection programme, including its design and the way that it was being put into practice. The documents included anonymised notes from real inspections, and notes from meetings where inspections were discussed and ratings confirmed. Using these documents, we sought to identify the underlying ‘theory of change’ for the maternity inspection programme – how its activities were expected to give rise to its intended outcomes. This analysis is reported in Chapter 3.

While the documents analysed did not explicitly set out a theory of change for the programme, they did offer clarity on the programme’s ‘key ingredients’, why these were important, and how they were expected to translate into practice. The documents featured: a focus on the ‘safe’ and ‘well-led’ domains as the key challenges facing maternity care quality; the role of a specialised programme in driving improvement; and the potential impacts of the programme locally (in providing an up-to-date assessment of maternity safety and quality, with clear areas for improvement identified as appropriate) and nationally (by offering an evidence-based assessment of the state of maternity services broadly, identifying common challenges, and sharing learning from across the programme).

We found a reasonable level of consistency between the documents that described the programme, which were intended to inform inspections in practice, and the documents describing what had occurred during inspections. Our analysis also suggested that the programme made use of a good range of standards, for example covering both prescriptive and principles-based approaches. There was a consistent focus on the two domains covered by the programme (‘safe’ and ‘well-led’), and inspectors were provided with guidance on how to operationalise these in practice.

Issues of equality, diversity and inclusion were less evident in documents that described the plans for the programme, though they were considered more explicitly in templates and tools used by inspectors themselves. Nevertheless, it appeared that issues relating to inequality were more challenging for inspectors to cover in practice.

## Interviews with selected programme stakeholders (workpackage C)

In this part of the study, we sought to gain a clear view of the programme as it was being put into practice by interviewing those involved in it as inspectors, as programme managers and leaders, and in organisations that had been inspected. Findings are described in full in Chapter 4.

There was agreement across participant groups on the importance and legitimacy of the goals of the national maternity inspection programme. The focus on maternity care and on safety was recognised as important, and (building on the insights into the theory of change identified in workpackage B) those involved noted that the use of a specialised team of inspectors, guided by advisors with strong clinical knowledge, was intended to deliver in-depth, focused, nuanced and meaningful inspections.

There were more mixed views on whether the focus on the two domains of ‘well-led’ and ‘safe’ was warranted, and about the extent to which it was feasible and meaningful to separate these two domains from the other three (‘effective’, ‘caring’ and ‘responsive’) in practice. Some participants also felt that the focus on *maternity* services alone (divorced from services covering the full perinatal pathway) was problematic both in theory and in practice, given organisational interdependencies, the importance of experiences across the pathway for maternity service users, and the impact of decisions made earlier in the pathway for safety during delivery.

In practice, there were concerns from participants that the objectives of the inspection programme had not been fully realised. Many participants noted that the organisation, governance and resourcing of the programme had proved challenging, including the pace at which it had been delivered, as well as the skill, expertise and capacity of inspection teams.

Some participants suggested that the problems in maternity care identified through the programme had been on a much greater scale than expected. This caused extra work for CQC itself, arising from the need to validate concerns. It also resulted in burdens for inspected organisations and for other parties with a responsibility for assuring and improving the quality of care.

Participants noted that practical issues, such as size of organisations and their locations, had had an impact on the thoroughness of inspections. Some participants from inspection teams felt that the resources provided to support the inspections, such as templates and the ‘maternity app’, were clunky and overly prescriptive. Inspectors found it difficult to include women and parents meaningfully during inspection schedules, and sometimes struggled to do justice to issues of equality and diversity within the inspection framework.

For all three groups interviewed (inspectors, programme managers/leaders, and those in inspected organisations), challenges in programme implementation led to some doubts about the quality and consistency of inspections. Particularly for those in inspected organisations, there were substantial doubts about validity, fairness and consistency of ratings. There was, however, acknowledgement from some participants of the positive and proactive way in which CQC had sought to respond to concerns and improve the programme continuously.

## Conclusions

Based on the findings across these workpackages, we synthesised key implications for CQC in relation to its approach to the maternity inspection programme and to regulation more broadly (Chapter 5).

# Plain-English summary

## Why it matters

Reviews and inquiries in recent years have raised concerns about the safety of maternity care in England. In 2022, the Care Quality Commission (CQC) began a new maternity inspection programme aiming to review all maternity services in England that had not been inspected or rated since April 2021.

In 2023, CQC commissioned The Healthcare Improvement Studies Institute (THIS Institute) and RAND Europe to evaluate this programme. The evaluation had two objectives:

* Identify and describe what good safety culture looks like in maternity and the features underpinning it;
* Look at the maternity inspection programme to learn about how it had been delivered and learn from it to inform the work of maternity services, inspectors, and the health and care system more broadly.

This report describes the work we did to evaluate the maternity inspection programme. This evaluation produced insight into what has gone well and what has gone less well in the inspection programme, and offers practical suggestions on how to improve it. Separately, we produced a learning resource, set out in a companion report, which describes what good maternity care looks like.

## Our approach

We used a range of different research methods in our work to evaluate the national maternity inspection programme, including:

* reviews of existing publications to identify the challenges involved in inspection, and the evidence for how best to regulate services;
* a review of 25 documents describing the national maternity inspection programme and looking at how inspections are intended to work;
* interviews with 23 people involved in the programme (including inspectors, managers in CQC, and people from organisations that were inspected) to look at how inspections work in practice.

## What we found

Programme documents were clear and consistent about the aims of the inspection programme. Broadly, what was described in the documents was reflected in what happened during inspections. For example, inspections focused on two key aspects of quality: how safe maternity services are, and how well managed and well led they are. But some other issues that inspections were meant to focus on, for example relating to how services tried to address inequality, were more challenging for inspectors to cover.

Participants in interviews generally supported and agreed with the aims of the programme and the approach it took. But people also reported challenges in putting the programme into practice. For example, some people in inspection teams felt that they could have benefitted from learning more about the maternity setting at the start of the programme, and found that it was difficult to do justice to services in the time allocated for the inspection programme. Some people also expressed doubts about the fairness and consistency of the ratings given by inspectors. Participants offered ideas for how inspections and regulation might be improved.

The evaluation offers a snapshot of a programme that was evolving while being delivered at pace. It found some gaps between how the programme was expected to work and how it worked in practice, and identified suggestions about how best to develop, organise, and enhance inspections.

# Introduction

In April 2023, the Care Quality Commission (CQC) commissioned The Healthcare Improvement Studies Institute (THIS Institute) at the University of Cambridge, together with RAND Europe, to undertake an evaluation study of CQC’s national maternity inspection programme. The inspection programme involved the inspection and rating of all NHS acute hospital maternity services that CQC had not inspected or rated since April 2021, focusing on two of CQC’s five domains of quality: ‘well-led’ and ‘safe’.

The evaluation had two specific objectives, aligning with CQC’s intentions in commissioning it:

1. To characterise what good safety culture looks like in maternity services and the factors underpinning it;
2. To evaluate the national maternity inspection programme to maximise learning for maternity services, inspection, and the health and care sector more broadly.

The aim was that the study would help to inform CQC’s approach to inspecting, rating and assessing services in maternity and beyond, as well as informing its approach to supporting cultures of improvement, safety and learning in services. The study had a particular concern to improve understanding of inequalities in maternity services. CQC was also interested in developing a resource (e.g. tool, toolkit or framework) to support the improvement of safety culture in maternity services.

In this report, we describe work undertaken to address the second objective: evaluating the national maternity inspection programme to maximise learning for maternity services, inspection, and the health and care sector more broadly. A companion report describes work relating to the first objective and developing the ‘what good looks like’ learning resource.

## Work undertaken

The evaluation study, designed to run alongside the inspection programme running at the time, took place from May 2023 to February 2024. It involved six mixed-methods workpackages and a final synthesis. We report here on the three workpackages (labelled here as A, B, and C) that related to the objective of evaluating the national maternity inspection programme to maximise learning for maternity services, inspection, and the health and care sector more broadly.

**Table 1: Study workpackages**

|  |  |
| --- | --- |
| **Workpackage** | **Description** |
| **A. Selective review of evidence on optimising regulation and inspection** | Author-based review examining the literature on regulation across healthcare and other sectors |
| **B. Selective review of relevant documents from the national maternity inspection programme** | Analysis of documents describing the inspection programme and anonymised notes from inspections to identify the programme’s theory of change and characterise key features of the approach taken |
| **C. Interviews with selected stakeholders** | Semi-structured interviews with those involved in the programme, including inspectors, senior staff from CQC, and people in inspected organisations, including senior managers and sharp-end maternity staff |

Chapters 2 to 4 of this report present high-level summaries of each of these workpackages. In keeping with the preferences of CQC, these chapters are short, with methodological and technical information kept brief. Further detail can be found in working papers (available to CQC on request) used to prepare the summaries.

Chapter 5 offers brief conclusions from the evaluation as a whole and identifies potential next steps. **Along with the executive summary, Chapter 5 summarises key findings relating to the objective to evaluate the national maternity inspection programme to maximise learning for maternity services, inspection, and the health and care sector more broadly.**

## Study governance

The evaluation benefitted hugely from the input of an advisory group comprising members from service user, medical, midwifery, managerial, academic and inspection backgrounds. The group met three times during the study, advising on evaluation design, data interpretation, and dissemination among other things. The eight members of the advisory group were:

* Zenab Barry
* Tim Draycott
* Teresa Kelly
* Tony Kelly
* Victoria Komolafe
* Devender Roberts
* Susanna Stanford
* Justin Waring

The evaluation also benefitted from the assistance and input of CQC, for example in relation to recruitment of interviewees, feedback on drafts, and advice on the format that outputs should take. We are grateful to Alison Thwaites and Ian Russell for timely and helpful advice throughout the study, and for coordinating input and feedback from other colleagues in CQC when needed.

### Ethical considerations

This evaluation involved discrete sub-studies adopting a range of methodological approaches, and so tailored approaches to ethical and governance approvals for each sub-study were needed. Since workpackage A involved literature review only, no ethical approval was required. Workpackage B, involving the secondary analysis of documents provided by CQC, did not require ethical approval but did require a data protection impact assessment from CQC, as well as full anonymisation (including both organisations and individuals) of the inspection notes covered.

For workpackage C (qualitative interviews), we used the Health Research Authority’s decision tool to determine whether ethical approval was required. Following the recommendations of the tool, we sought and were granted approval from the University of Cambridge Psychology Research Ethics Committee. Recruitment and data collection did not involve NHS organisations.

### A note on language

We recognise that not everyone who is pregnant or gives birth identifies as a woman. The term ‘maternity service user’ is used inclusively in this report, including pregnant and birthing people and their birth partners. Although we do use the words “woman” and “women”, we aimed throughout the study to be inclusive of the views of all people who have experienced pregnancy, labour and birth, including women, trans and gender-diverse people.

# Literature review on optimising regulation and inspection (workpackage A)

Our second workpackage focused on the evidence base on regulation, assessment and inspection across multiple sectors, seeking to draw out key implications for CQC as it renews its regulatory approach (including the introduction of a Single Assessment Framework to guide regulation of organisations in all sectors) and delivers the national maternity inspection programme.

The findings from the review informed the approach taken towards analysis of the documents relating to the national maternity inspection programme provided by CQC (workpackage B; Chapter 3), and towards the interviews with stakeholders involved in the programme (workpackage C; Chapter 4).

## Methods

We used an author-led approach to reviewing the literature on regulation and inspection.1 We selected empirical and theoretical literatures to identify features of regulatory design and operation likely to be important for the national maternity inspection programme specifically, and for CQC’s thinking as it develops and implements its revised approach to regulation. Our review incorporated references to over 100 sources, including academic research evidence, policy documents from governments, legislatures and regulators (including CQC), and commentaries on the strengths and weaknesses of different regulatory regimes.

## Key findings

### Managing the competing considerations for regulation and inspection

A key and repeated lesson from the literature on regulation across multiple sectors is that regulation must seek to strike an optimal balance between effectiveness, efficiency and legitimacy. These three considerations are not always easily reconciled. Evaluation may attend to one or more of them. **Effectiveness** describes how well a regulatory regime delivers, or is likely to deliver, on its aims. **Efficiency**, or regulatory economy, relates to the extent to which a regulatory regime makes appropriate and proportionate use of resources, given competing priorities.2,3 Finally, **legitimacy** is fundamental to the success of a regulatory regime, relating to the extent to which actions and values of an institution or organisation are perceived to be desirable, acceptable, proper and appropriate.4,5

Legitimacy may vary by group: regulators themselves, regulated staff and organisations, and the wider communities served (governments, publics, clients or service users) may have different views of the legitimacy of a regulatory regime, and correspondingly divergent views on its effectiveness and efficiency. They thus constitute different **‘legitimacy communities’.** What is appropriate and proportionate for one legitimacy community may not be so for another: thus ‘legitimacy paradoxes’ may arise, where meeting the criteria of effectiveness and efficiency held by one group means contravening the criteria held by another.4

In broad terms, regulatory regimes are likely to be concerned in particular with three fundamental objectives, set out by George Boyne and colleagues: detecting failure to provide services to a minimum standard; improving the quality of service standards across the regulated sector; and providing assurance and reassurance to a range of stakeholders.6 Since each of these implies a different range of stakeholders and legitimacy communities, addressing all of them within the same regulatory regime may not be straightforward.

### Evaluation and regulation: do inspections work?

All sectors have struggled with evaluation of regulation and inspection, with healthcare no exception. Applied health services research to evaluate “what works, what doesn’t, and why” in regulation and inspection remains limited, and the kinds of study designs considered most robust in the health field (including, for example controlled trials) have only rarely been used to examine regulation. However, recent years have seen a small literature begin to grow, both in relation to inspection specifically (as one tool of a wider regulatory approach) and in relation to regulation more broadly.

At a theoretical level, one prominent and useful approach to understanding regulation is the ‘cybernetic model’ originally devised by Christopher Hood and colleagues.7 This model identifies a generic trio of three elements – standard-setting, monitoring, and mechanisms for modification – inherent in any system of control.

Inspectionfocuses primarily on one of these three elements: monitoring. Defined as “one element of a system of regulation, [which] is likely to utilise information provided by other elements, entails site visits to service providers and has a strong focus on service standards and outcomes,”6 inspection typically takes the form of externally led assessments of organisations against a framework that codifies expectations of those organisations. The regulatory studies literature broadly supports the principle of inspection as a regulatory technique,8 but the empirical literature on effectiveness has remained small and methodologically weak9,10 – in part because of the challenges of evaluating inspection posed by disagreements about objectives noted above, difficulties in finding valid and reliable measures of impact, and limitations posed by available study designs.

In healthcare specifically, studies using non-trial designs conducted internationally (generally of “accreditation” rather than inspection or regulation specifically), have produced conflicting and sometimes contradictory results, and also appear to indicate that the impacts of accreditation vary according to different features of quality and safety.11 Two Cochrane reviews (one an update of the other) identified that the research base is very small and of poor quality, typically failing to use high quality controlled study designs for assessing the effectiveness and cost-effectiveness of externally-led inspections. It suggested that no firm conclusions could be drawn on the effectiveness of inspection on compliance with standards.12,13 A series of studies relevant to CQC has identified only a weak relationship between readily available indicators of service quality and inspection outcomes.14,15 Taken together, these kinds of studies may seem to indicate that inspection is assessing quality and safety in a distinctive way that cannot be directly substituted for by other metrics or measures, so a gold standard for assessing effectiveness of inspections is likely to remain elusive.

### The national maternity inspection programme

For the national maternity inspection programme specifically, several key objectives are identified in programme specifications (see also Chapter 3). These include: showing how services are responding to current challenges and what extra help they may need; giving women and their families an up-to-date view of the quality of maternity care at their local hospital trust; giving hospitals an objective assessment of what they are doing well and how they can improve; helping CQC to understand what is working well so that it can share good practice to help services learn and improve; and helping CQC show where there needs to be national action to combat the challenges services face.16 In addition, equity is identified as a focus for improvement in the guidance provided alongside the programme assessment framework.17

These objectives map broadly on to the three overarching objectives for regulatory regimes identified by Boyne et al.6 and outlined in section 2.2.1 above. However, they also imply a range of legitimacy communities, and thus a range of criteria by which success of the programme might be evaluated. The legitimacy of the national maternity inspection programme goals for the various legitimacy communities, including for example provider organisations, staff, and maternity service users, is not currently known. This is important, because different stakeholders may disagree about the proper goals of regulation and on how potentially conflicting goals should be traded-off.18 This formed a key focus of inquiry in the interviews with stakeholders in the inspection programme (workpackage C), presented in Chapter 4.

### Implications for the design of inspection programmes

Several key considerations arise from the literature on how to enhance the role of inspections in achieving regulatory effectiveness, efficiency and legitimacy. These relate in particular to the first component of Hood et al.’s cybernetic model: setting the standards that are then subject to monitoring in the inspection process.7

First, a key goal of any inspection regime is to ensure that it does not miss areas of significant concern, but at the same time minimises the risk of ‘over-triggering’ by deeming services to be unsatisfactory when they are not. In other words, it must minimise the risk of both ‘false negatives’ and ‘false positives’. Achieving this balance through inspection, however, is not straightforward. Finding standards that are clear, achievable, consistently interpreted, proportionate and widely recognised as legitimate is very challenging,19 for example.

Second, and related, standards that might be subjected to inspection fall into two broad categories: standards for outcomes and standards for processes. Neither is likely to be sufficient on its own: a portfolio of standards is likely to be necessary. However, it is important to be frugal in the number of standards to be inspected, to avoid the risk of overwhelming regulating organisations – and associated risks, such as ‘gaming’, or ‘hitting the target but missing the point’.20-22

Third, it is generally easier to set standards for procedures and systems that is it to set standards for more amorphous – but fundamental – organisational features, such as culture, behaviour, and relationships. Where attempts are made to select particular indicators of culture for inspection – for example, leadership walkarounds or team huddles – the risk is of encouraging compliance-oriented behaviours.23

Related to this point, a fourth implication is that inspections need to strike the right balance between, and find ways of accounting for, prescriptive standards and broader principles. Prescriptive standards, often taking the form of fixed, perhaps numerically bounded, prescriptions, offer several attractions: they appear easy to measure, easy to inspect, and easy to use as the basis of enforcement action.24 However, they do not adequately cover the range of relevant aspects of organisational performance, and again they may provoke unwanted organisational responses such as goal displacement (a disproportionate focus on what is measured, at the expense of other, less tangible but equally important, priorities) and gaming.25

In response to critiques of the fallibilities of use of rules and prescriptive standards in inspection, the idea of ‘principles-based’ regulation has gained traction. By allowing scope for inspected organisations to respond to regulators in flexible, adaptive, innovative and reasoned ways, principles-based approaches seek to prioritise reflective commitment over compliance, empowering professionals to take ownership while also supporting the ability of inspectors to exercise discretion. However, principles-based approaches too have their limitations: for example, they may allow excessive latitude and reduce the effectiveness of regulators in enforcing improvement.26

Fifth, the scope of inspections to fully and forensically examine all aspects of an organisation’s activity is inherently limited. If whole systems are to be understood and effectively regulated, rather than solely what can be observed empirically, then a wider range of sources of evidence is necessary. Alongside in-person inspections, therefore, inspectors have to rely on indirect sources of evidence about the quality of services provided by inspected organisations.26 At first glance, this has a number of advantages – instead of mandating particular processes, this kind of systems-based approach might enable more flexibility and autonomy to organisations in how exactly they meet a regulatory goal – for example, in terms of how they choose to encourage a positive workplace culture or how they manage risk. Regulators can then inspect these control systems, which might include, for example, documentation showing that risk management systems are in place. But regulating on this basis may also be subject to the fallibilities noted above, including for example an orientation towards compliance that prioritises paper trails over effective implementation of risk management in practice.27 Moreover, risk management systems can themselves generate new risks.28

### Implications for the implementation of inspections

Much of the effectiveness of inspection rests on the activities of inspectors, who are key to the monitoring component of the cybernetic model. Yet empirical studies of inspection and inspectors are rare. In those studies that have taken place, consistency has been a prime focus. Studies of inspections across a number of fields within and beyond healthcare suggests that, though it is possible to structure inspectors’ observations and assessments, some element of subjectivity is often present.29-31

Inconsistency of this kind, where evidenced or suspected, can pose a major risk to legitimacy across communities. However, improving consistency of inspector decision-making is not straightforward. Discretion and judgement are not just sources of inconsistency: they may be key to ensuring fair inspections and assessments that are sensitive to the particularities of the organisations being regulated. Second, actually achieving consistency is likely to be a hugely laborious, resource-intensive process, with uncertain prospects of success. Third, efforts to constrain discretion among inspectors may result in excessive rigidity, including shrinking of complex dilemmas to simplistic processes and procedures. Fourth, in reducing inspectors’ scope for discretion, their ability to identify and account for untoward organisational responses to regulation, such as compliance-orientation, goal displacement and gaming, may also be constrained – and inspection might be reduced to a focus solely on rules rather than principles.

Therefore some variability in inspector decision-making is likely to be inevitable. This is not to say that inspectors may do and say as they please: they should commit to making judgements that reasonable people could accept. One way of managing the need to enable appropriate discretion is through systems of bureaucratic accountability, including checks and reviews of inspectors’ judgements and actions – analogous to a quality assurance process, so that learning and norming of good practice are part of the cycle. However, these systems have their limits, so a complementary approach involves professional controls, which seek to shift the emphasis to proper exercise of professional judgement.32 Inspectors also need to be reflexive and responsible in their decision-making. Similarly, satisfactory and effective appeal mechanisms are necessary, as are accountability and transparency in the way verdicts are given, and the way appeals are considered.

### Implications for the role of inspection in an effective regulatory regime

Alongside standard-setting (see especially section 2.2.4) and monitoring (see especially section 2.2.5), the final component in the cybernetic model is enforcement. An effective system of regulation needs to be able to induce or enforce improvements where monitoring activities identify shortfalls against standards. This does not necessarily, however, mean that the regulator itself must be the body responsible for enforcement: it could fall to other agencies. However, Hood et al. identify enforcement as a common “Achilles heel” of regulation.

CQC, of course, has wide-ranging powers of enforcement, established in both civil and criminal law, and may choose from a wide menu of options in seeking to stimulate or force improvement. For understandable reasons, CQC has tended to be reluctant to use the more draconian options under its ‘urgent’ powers. It falls to other agencies, such as NHS England, to seek to ensure improvement where organisations fall short of regulatory expectations.

Maternity care in England has been seen a large number and wide range of improvement initiatives, including ones seeking to address the sector as a whole and ones targeted towards ‘struggling’ organisations. These include the NHS England Maternity Safety Support programme, which enrols organisations rated ‘requires improvement’ or ‘inadequate’ in CQC’s well-led or safe domains. However, the available evidence appears equivocal at best about the effectiveness of current efforts to secure improvement, including those that follow a poor outcome of an inspection.33 For maternity services that receive low ratings in particular, there are likely to be distinctive challenges that need to be addressed in improvement support activities. A further challenge is that healthcare staff may experience an emotional impact of a poor rating, perhaps feeling ashamed, demoralised, or stigmatised, which may itself act as a barrier to improvement and recruitment.34

The number of organisations involved in the NHS regulatory environment, besides CQC, may also pose challenges to effective regulation and to high-quality care. One review from 2019 identified over 120 organisations with regulatory influence on NHS provider organisations in England.35 Even though the number has reduced since then, institutional complexity remains. Some bodies and agencies are formally established as regulators. Others function *de facto* in a regulatory capacity, even if they are not defined as such. The result is that services may become answerable to a number of different regulatory agencies whose rules, principles, and procedures conflict or fail to cohere, and who demand different information – or the same information in different forms – and impose varying requirements. This proliferation of regulators can be harmful, because multiple competing pressures, expectations and priorities may be created, resulting in confusion and demotivation.36 Different agencies and bodies with a say in the NHS can contribute to fragmentation, ambiguity and diffusion of responsibility, leading to “the problem of many eyes” where accountability for quality is not clearly demarcated, coherent or authoritative.37

## Implications

Our review has implications for the design of regulatory systems and the role of inspection within those systems, including how best to ensure optimal realisation of the three components of the cybernetic model: standard-setting, monitoring, and enforcement. For the national maternity inspection programme specifically, our analysis suggests some key challenges in how it has operated to date. Some of these may be addressed by the new regulatory approach adopted by CQC, which, through the Single Assessment Framework, will involve less of an emphasis on inspection and more focus on collection of evidence to monitor performance. Such an approach is broadly in line with the findings of our literature review. The literature suggests that while inspection’s role in wider systems of regulation is an important one, it is also a limited one, and that a range of sources of evidence is necessary. Inspection cannot reveal all aspects of an organisation to a regulatory body. There is some evidence for the distinctiveness and significance of insights that inspection provides, but relying on inspection alone will leave some important aspects of organisational work unseen – and may risk encouraging behaviours that further limit the validity of the insights it brings. A wider range of sources of evidence, therefore, is likely to be crucial to effective regulation, and is the direction of travel for the Single Assessment Framework. In the new system, inspection will primarily be deployed where risk is identified and/or where it is the most appropriate method to gain evidence on key areas (for example through observations). The implications of the findings of this workpackage should be considered in this broader context.

Several specific challenges are worth reiterating. First, while the goals of the maternity inspection programme are clearly stated (e.g. by CQC), it is less clear whether these are fully accepted by the various relevant audiences (or legitimacy communities) of the programme. Second, the analysis also suggests some potential tensions with way the inspection programme operates in practice, which are picked up in Chapters 3 and 4. For example, a major concern of CQC in practice is to identify poorly-performing organisations, yet that is not fully explicit as a goal of the programme in its documentation. Third, and similarly, although a focus on equality and diversity is implied by the programme assessment documents, this is less evidently a priority in the published aims of the programme. Fourth, reflecting the predominant approach to regulation in healthcare in England, responsibility for improvement lies not primarily with CQC but with multiple other organisations in the system – but the improvement system itself is fragmented and variably effective.

Overall, the literature suggests that principled pragmatism and balancing of competing priorities are required across the components of regulation. In setting standards, for example, the regulatory studies literature acknowledges trade-offs, including those between congruence, transparency, and consistency, and the need to focus on the nature of the regulatory target and the goals to be achieved in guiding choice of approach, as well as having regard to the relationship between the regulator and the regulated organisation and the processes of implementation. High-quality monitoring through inspection depends on a highly qualified and experienced workforce, working within a structured framework, but equally capable of exercising discretion and judgement. Inspection is likely to work best if a focus on serving the spirit of regulation is promoted at the same time as discouraging mechanistic adherence to rules and displays of procedural compliance. The evidence suggests that this requires that inspectors must be sufficiently experienced, sensitive, and knowledgeable in the particular areas in which they are reviewing to identify lapses and the action to be taken.

# Documentary analysis of maternity inspection programme documents (workpackage B)

Workpackage B, led by colleagues at RAND Europe, involved an analysis of a range of documents supplied by CQC relating to the national maternity inspection programme, including publicly available documents covering the objectives of the programme, internal documents relating to design and delivery, and documents from inspections conducted as part of the programme, including anonymised inspector notes and examples of reports.

The goal of this workpackage was to understand the objectives of the programme, examine how the expectations set out in formal guidance were reflected in the activities of inspections, and identify the key elements of the programme’s theory of change – that is, how the activities encompassed in the programme were expected to give rise to its intended outcomes.

## Methods

In consultation with CQC, we identified 25 documents for inclusion in the analysis, with a view to sampling from a variety of document types, and prioritising documents on the basis of their relevance to the objectives of the evaluation. The documents included eight public-facing documents (including online guidance, blog posts, a report on themes emerging from the programme produced by CQC, and four published inspection reports), six sets of inspection notes (relating to maternity services other than those covered by the published inspection reports reviewed, to ensure anonymity), and 10 other internal CQC documents (including an updated inspection framework, a template provided to inspectors, output summaries from the programme, and notes from internal meetings such as oversight groups and meetings to review provisional ratings).

We used a qualitative content analysis approach to collate and analyse data from these documents. This encompassed both inductive and deductive methods, using a thematic framework derived from programme documentation as an initial coding framework, and supplementing and enriching this with further codes that were constructed by the team as analysis proceeded. This process also included a systematic mapping of the activities identified in documents that described the programme as delivered (such as templates for inspectors and notes from inspections) against the declared foci of the programme, as articulated in documents such as the overarching assessment framework and public-facing documents describing its objectives.

## Programme goals, objectives and theory of change

### Programme goals and objectives

As noted in the previous chapter (section 2.2.3), the overall aims of the national maternity inspection programme are clearly articulated in public-facing documents, and broadly map on to the feasible objectives for inspection programmes identified by commentators such as Boyne et al.6 The original imperatives for the programme (including national priorities to improve the safety of care by reducing rates of maternal and infant mortality and morbidity, challenges identified in various reviews, inquiries and investigations into maternity safety, and stagnation or deterioration in quality and safety of maternity services identified in CQC’s own inspections) were reflected in the key stated goals of the programme. Two goals were stated consistently across the documents analysed:

* To ensure an up-to-date view of quality and safety across all maternity services in England;
* To support learning and accelerate improvement at local and national levels.

Other goals were more implicit, or present only in certain documents – and were not in those that set out the programme’s objectives prospectively. These included exploring and understanding women’s lived experience of maternity services by listening to the voices of women and maternity staff, and moving the dominant narrative towards a focus on ‘what good care looks like’.

### Theory of change for the inspection programme

We found no explicit theory of change or logic model for the programme that described how the programme activities were expected to result in intended outcomes in the documents we reviewed. However, it was possible to identify key components of a theory of change from the descriptions of the programme presented in the documents.

Rather than covering all five of CQC’s domains or key questions (“is the service safe, effective, caring, responsive, and well-led?”), the national maternity inspection programme focused on just two: safe and well-led. The reasons for this focus were set out explicitly in the programme documents: the safe and well-led domains were seen as the most critical to addressing the concerns about maternity safety that had driven the inception of the programme, and would be vital in providing an accurate picture locally and nationally, and identify priorities for improvement.

Our analysis suggested that a guiding assumption was that a comprehensive and up-to-date picture of the state of maternity care nationwide could be drawn by ensuring that all services that had not been inspected and rated since April 2021 were included in the inspection programme. The validity of this picture was to be ensured by the use of specialist maternity advisors with relevant clinical expertise, and use of an inspection framework that had been constructed with input from multiple relevant stakeholder groups.

Similarly, the projected outputs from the programme were evidently designed with the overarching programme objectives in mind, including both service-specific and aggregate outputs that would speak to local (organisation and service user) and national (whole-NHS, national agency, and public) audiences alike. The range of formats intended for the outputs that aggregated learning from across the programme was particularly eclectic, encompassing detailed reports and short-form outputs such as blog posts, and service-oriented outputs such as resources to inform improvement.

Less evident in the main programme documents was a focus on diversity, inclusion, equality and equity. However, this focus was made more explicit in documents such as the inspection framework, and was prefigured in pilot focused inspections that preceded the programme and helped to shape the approach to inspection it took.

## The programme in practice

In examining how well the objectives and foci set out in section 3.2 translated into inspectors’ practice, we considered documents setting out the objectives alongside documents intended to be used during inspections, and notes and reports that depicted what was inspected in practice.

Inspectors were provided with five ‘key safety issues’ that cut across the safe and well-led domains and which were intended to inform their focus during inspections:

1. Leadership, safety culture and staff attitudes to each other;
2. Risk management, robust governance framework & evidence-based practice;
3. Teamwork and training, communication, escalation of staff shortage or strain and lack of hierarchy;
4. Staff competence and multi professional training (including human factors training);
5. Recognition of the change from low risk to high risk and escalation processes for clinical deterioration.

The programme assessment framework instructed inspectors to make assessments on each of these issues, which would feed into overall judgements on performance in both the well-led and safe domains.

There was generally good read-across between the five key safety issues listed above, the issues foregrounded in the documents to be used during inspections, and the notes and reports from inspections. In addition to the explicitly listed key safety issues, the documents used for inspections also encouraged inspectors to consider other, related areas.

Within the *well-led* domain, these included the vision and strategy set out for the service, the degree to which voices of women and families were heard and supported by services, the support in place for staff (including efforts to encourage wellbeing and to promote equality and diversity), the encouragement of innovation, and the systems in place to effectively manage information.

Within the *safe* domain, they included staffing (including prevailing numbers of staff at different levels, steps taken to promote recruitment and retention and mitigate turnover, policies and practices relating to staff leave, and so on), staff competence and training, the physical environment, support for and safeguarding of women and babies, and approach to managing safety-related incidents.

A range of sources of information used by inspectors was in evidence in their reports and notes of inspections, including observations, documents produced by organisations, meetings, interviews, data from external sources such as national audits, and broader intelligence from other organisations such as NHS England, NHS Resolution and the Health Service Safety Investigation Body. Generally, the notes from the inspections were explicit in identifying the sources of information that had informed judgements of services.

A focus on equality and diversity was, as noted above, less prominent in early programme documents. However, it was more clearly set out in later documents, such as the updated programme framework intended to directly inform the work of inspectors. We found that in practice, inspectors drew on a broad range of data with relevance to equality, for both staff and service users. These included both data relating to the characteristics of service users and staff, and aspects of service delivery, including the extent to which services appeared to make provision for diverse populations, and the extent to which they sought to engage people from across diverse communities in co-producing improvements.

A clear process was in place for reviewing, moderating and signing off draft inspection reports and ratings, including senior review and peer review within CQC, clear guidance on what reports should include, and tiered processes for sign-off depending on the provisional rating (with ‘good’ ratings requiring inspection manager sign-off, ‘requires improvement’ ratings requiring additional sign-off by the programme deputy director, and ‘outstanding’ and ‘inadequate’ ratings requiring extra review at ratings approval meetings). Notes from the ratings approval meetings suggested a transparent process that appeared to be applied consistently.

## Conclusion

The findings of this review suggest that, overall, there was reasonably good read-across between documents setting out the objectives and approach of the national maternity inspection programme prospectively, documents intended to be used to inform inspections in practice, and documents recording what was actually covered in inspections. The activities of inspectors, and the information they used to inform their judgements, were broadly in line with expectations as set out in formal programme documentation.

In line with the recommendations for inspection set out in the literature and summarised in Chapter 2 (section 2.2.4), the inspection framework appeared to cover both prescriptive standards and broader principles, though for some aspects of safety the balance was perhaps a little skewed towards prescriptive standards. For example, the information considered in relation to services’ approaches to ensuring inclusion of diverse populations included a large number of points that could be reduced to ‘yes/no’ answers. Ensuring that, for example, the presence or absence of ‘culturally tailored information’ is a genuine indication of services’ appreciation of and focus on the need to make services culturally competent may thus depend to a significant extent on the skills (and time) available to the inspection team.

Templates and reporting structures used to guide inspection conduct and write-up appeared to be in place to ensure consistency in ratings and reporting. How inspectors collected the information required to inform inspection judgements and ratings involved a wide range of sources, and the activities undertaken during inspections appeared to reflect those intended. Again, there were some signs that the assessment of risks relating to inequality was an area that was more challenging for inspectors, perhaps indicative of its less clear specification in guidance materials in terms of the methods and sources to be used.

It should be noted that these findings are based on the analysis of a relatively limited set of documents, linked to a small number of inspections. Accordingly, the analysis may not be generalisable to the programme as a whole. Moreover, documents only ever tell a partial story, especially perhaps those composed with an eye to public scrutiny, accountability or audit.38 Particularly in relation to their accounts of the following of protocols and procedures (for example, in relation to the operation of ratings approval meetings), they may present a process that is more structured and less messy than reality. Interview data, too, often present polished accounts of the real world, but the interviews with stakeholders described in the next chapter offer a somewhat different perspective on the realisation of the maternity inspection programme in practice. These points notwithstanding, however, our analysis suggests that while there is not an explicit theory of change that sets out the mechanisms through which the programme is intended to achieve its aims, the aims are consistently described in guidance and are broadly reflected in the activities conducted.

# Interviews with selected programme stakeholders (workpackage C)

Our fourth workpackage built on the work of workpackages A and B to examine the work of the national maternity inspection programme in practice. It was designed to address our objective to evaluate the programme to maximise learning for maternity services, inspection, and the health and care sector more broadly. Interviews were carried out by colleagues from RAND Europe, with analysis carried out jointly by RAND Europe and THIS Institute.

## Methods

We sought to interview participants from three groups:

1. those with experience of the national maternity inspection programme as inspectors;
2. leads and managers within CQC; and
3. staff at the sharp and blunt ends of inspected organisations.

Recruitment was coordinated by CQC, which contacted potential participants with information about the evaluation and offered them the opportunity to express an interest in participating. Where individuals responded confidentially to RAND, they were provided with further information and given the chance to ask questions; interviews by Microsoft Teams were then arranged with participants who consented. The identities of those who took part are confidential to RAND.

The topic guide for the interviews, developed in consultation with CQC and our advisory group, covered stakeholders’ views on the design of the programme, the methods of inspection, the data used in reaching judgements, the place of equality and diversity in inspections, and the overall mechanisms of regulatory impact. Interviews also covered stakeholders’ experiences on the programme in practice and suggestions for improving the inspection programme. Interviews were audio-recorded, transcribed verbatim and analysed using the framework approach.39 All transcripts were fully anonymised. It is not possible to attribute any finding or quotation to any individual participant.

In total, 23 people participated in interviews, including eight leads from CQC, six inspectors, and nine participants from inspected organisations (including leads and maternity staff).

## The programme as designed

The stakeholders we interviewed largely had a common understanding of the drivers behind the national maternity inspection programme. In line with the documentary evidence covered in Chapter 3, they noted the impact of negative reports and press coverage which had heightened public and parliamentary concern over safety of maternity services. They described an increased imperative to ensure consistency of oversight and inspection, and the potential insights the programme could offer in understanding challenges and informing improvement at local and national levels.

The inspection programme was seen by interview participants as relevant to a wide range of audiences, including inspected trusts themselves, various national bodies, and patients and the public. The public (including local patients, service users and potential service users) was seen as a particularly important audience, though it was less clear to participants that the outputs of the programme were taking a format that was useful to them. Indeed, as some participants pointed out, many service users would in practice be able to make limited use of findings of inspections given their limited choice about where to receive maternity care.

In line with the components of the theory of change we could elucidate from the documents reviewed in workpackage B (see section 3.2), participants from within CQC noted distinguishing features of the maternity inspection programme that were likely to be important in delivering the kinds of outcomes anticipated. They highlighted:

* the use of inspectors who devoted their time to maternity services alone (thereby, in theory, increasing the quality and consistency of inspections),
* the focus on the national and system level (rather than on individual inspected organisations alone),
* the intention that inspections guide improvements (for individual organisations *and* across the whole system), and
* an emphasis on delivering in-depth, nuanced and meaningful inspections, assisted by the focus on just the well-led and safe domains.

However, as we discuss in more detail in section 4.3, the extent to which all these intentions were realised in practice was variable. Moreover, there was concern that while these intentions may have been well communicated to internal audiences within CQC, the extent to which they were understood by NHS organisations was less certain.

There were mixed views among participants about the appropriateness of the focus of the programme on the well-led and safe domains to the exclusion of the others. Some noted that this focus had been chosen carefully and with clinical input, but some inspectors found that it was difficult to separate these domains in practice. They felt that inspections had to account for the other domains in some way to give a full and accurate picture.

Participants also expressed some concern about the exclusive focus on maternity care, rather than the whole perinatal pathway. Some felt that this was problematic both in principle – since the quality of maternity care relied on action across the care pathway – and in practice – since perinatal services were often interdependent in terms of staffing and management. Findings from the parts of our evaluation aimed at developing a comprehensive understanding of what safe, high-quality maternity care looks like, reported in the companion report, reinforce the point that from the perspective of the service user, maternity services are best understood holistically – not least because many of the issues of safety that occur in the intrapartum phase may be identified, managed or even mitigated in the prenatal pathway, or that may need to be addressed postnatally.

Reflecting the findings of the documentary analysis (section 3.3), participants noted that equality, diversity and inclusion had been foci for the programme that emerged over time. Participants from CQC felt that these issues might have been better addressed in the programme had they been articulated earlier, perhaps for example through better training and support for inspectors and greater consideration of the implications for data collection.

## The inspection programme in practice

Participants identified numerous benefits or potential benefits of the inspection programme in practice. For example, they pointed towards the impact of the programme in ensuring that the need for improvement in maternity services remained high on trusts’ agenda, and in giving greater impetus to existing improvement initiatives led by maternity staff. Some felt that the inspections’ attention to equality and diversity issues were prompting a new focus within trusts on demographic data and how to reduce inequalities in service provision and outcomes. Where maternity services were weaker, participants noted that inspections could prompt greater support for improvement, for example from NHS England, and also suggested that the public and media scrutiny that followed could act as a positive impetus for change. Conversely, good ratings could have a much-needed positive impact on staff morale, and the process of preparing for inspections could itself encourage maternity teams to pull together.

However, participants also often found that many of the ambitions of the programme had not been fully realised in practice, and that this had had important implications for the quality, thoroughness, consistency and legitimacy of individual inspections and the programme as a whole.

### Capacity and capability

Many participants noted that the organisation, governance and resourcing of the programme had proved challenging. Participants from CQC highlighted the pace at which the programme had been both set up and delivered, and noted that, in the absence of its own dedicated budget, resources had had to be borrowed from other programmes (with consequent impacts on the resourcing and delivery of those programmes).

These challenges were exacerbated by what some participants saw as a failure to anticipate the scale of the programme – including the numbers of services that would need to be inspected (and the implications for inspectors’ time), and the scale of the problems in the quality and safety of maternity care nationally that the programme was destined to reveal. Identifying such problems had implications for inspected organisations themselves and for the national improvement programmes designed to support struggling services. It also had consequences for the maternity inspection programme itself, since where more negative (‘requires improvement’ or ‘inadequate’) ratings were anticipated, additional evidence and a more extensive sign-off process were required (as noted in section 3.3).

Concerns about *capacity* to deliver the programme were accompanied by concerns about *capability* to deliver high-quality, rigorous inspections. As noted in section 4.2 above, both the specialised expertise developed by the team within CQC running the programme, and the additional insight and clinical knowledge offered by specialist advisors, were seen as crucial components in the distinctiveness of the programme, and in its potential to achieve its objectives. In practice, however, both of these features were inconsistently present.

Participants noted that knowledge of maternity care took time to accrue, and felt that inspectors who had previously undertaken most of their work in unrelated areas (for example, adult social care) were less well equipped to inspect maternity – and that their training and familiarisation with the maternity context had to continue as they headed into the field. Similarly, recruiting and retaining specialist advisors to support inspections proved challenging in practice. Obstetricians in particular were in short supply, and this was attributed both to shortages in the workforce and low reimbursement.

### Quality and consistency of inspections and ratings

These challenges in programme implementation and delivery led to tangible doubts, expressed by participants from all three groups – CQC staff, inspectors, and those in the inspected organisations – about the quality and consistency of the inspections carried out under the programme.

Across participant groups, there was general agreement that inspection itself was a vital part of effective and accurate regulation, since some aspects of quality, safety, culture and leadership were simply not amenable to assessment through secondary sources. However, particularly early on, inspectors acknowledged that their inspections had not been as thorough or as nuanced as they might have liked, owing partly to their inexperience in the maternity field, and partly to the very limited time available for each inspection. Some participants felt that the process for aggregating ratings across domains, and integrating them with ratings from previous inspections was complicated and not transparent, which impacted on the perceived validity of the ratings. Their experience of the process did not entirely mirror the impression given by documents in workpackage B (section 3.3) of a transparent, highly structured and consistent process: applying this process in practice required a good deal of deliberation and judgement, rather than a straightforward application of structured rules.

Participants noted that many of these concerns had been taken onboard by CQC, and they were heartened by the steps that had been taken to address concerns as the programme had progressed. Participants from CQC commended the work of the team leading the programme, which had helped in identifying areas for improving the programme and creating opportunities for learning and discussion across inspectors.

However, participants in inspected organisations shared substantial concerns about the quality of the inspection process and the consistency and validity of the ratings it produced. Some of these participants were sceptical about the consistency of ratings, and gave examples of ratings that they thought were unfair, based on their experience of inspections in their own organisations (for example, the ‘read-across’ between what inspectors had seen and the rating given), and on inconsistencies of judgement they felt they had identified when comparing published CQC reports relating to different organisations.

Participants had varying views on the role of inspector discretion and the legitimacy of its contribution to the inspection process. CQC leads were relatively confident about the validity and consistency of ratings, and pointed towards the checks and balances in place to secure this, and ensure that outlying judgements were appropriately moderated. Inspectors tended to feel that their own professional judgement was not only inevitable, but essential to the quality of inspection. They noted that some of the sources of data on which inspection relied required careful interpretation if they were to be relied on: for example, audit data supplied by organisations might vary in their accuracy, and might not align with what was observed during inspection.

Staff in inspected organisations expressed concerns about the fairness of the rating process, linked in some cases to what they saw as examples of inappropriate or even unprofessional acts on the part of inspection teams, including for example rudeness. Echoing debates in the literature discussed in Chapter 2, some participants felt that inspectors had excessive discretion in the way they made judgements and that the reasoning behind judgements was often not transparent. The inclusion of inspectors who had less expertise and experience in the maternity field was also seen by some staff from inspected organisations to cast doubts over the validity of their assessments.

### Further challenges in delivering the programme as intended

A range of seemingly more prosaic – but highly consequential – challenges also affected inspections. Some were specific to the programme; others had their roots elsewhere. Linked to the challenges of resourcing noted above, inspectors found that simply carrying out the tasks of inspection to a high standard within the very limited time available was extremely challenging.

Variations in travelling time or size of organisation, for example, could have major impacts on the thoroughness of inspections (and on the wellbeing of inspectors seeking to complete the necessary work). Tools introduced as part of the inspection programme, including the OneNote template with its resources for inspections and the maternity app, had a mixed reception. Some felt that the templates provided for inspection were overly prescriptive and overly long, resulting in an approach that reproduced the fallibilities of rules-based regulation described in section 2.2. The maternity app specifically was described as poorly designed, clunky, and difficult to use – problems often compounded by patchy wireless internet access in the organisations being inspected. As a result, the app was often not used as intended (i.e. to guide inspections as they proceeded): instead, the required fields were filled in after the fact.

Giving attention to service users’ views, and particularly to issues of equality, diversity and inclusion, was also sometimes problematic. While the emphasis on the view of the user in the programme’s theory of change was welcomed, in practice inspectors found it difficult to include parents meaningfully during their packed inspection schedules – and were understandably reluctant to demand too much of new parents at what was already a potentially overwhelming time for them. The apparently late incorporation of equality and diversity into the programme’s materials meant that this, too, was often marginal in the work of inspectors. Notwithstanding the efforts noted in Chapter 3 (section 3.2.2) to foreground equality and diversity in the assessment framework, inspectors noted that the inspection template offered no specific sections in which inequalities could be assessed. Nevertheless, inspectors were keen to ensure that they incorporated these considerations in their assessments, and described the ways in which they sought to weave them into their reports, for example by foregrounding issues relating to equality, diversity and inclusion under other headings.

From the perspective of inspected organisations, maternity inspections added to already high levels of scrutiny from regulatory and quasi-regulatory bodies, particularly in relation to maternity services. Participants in these organisations experienced significant burdens through, for example, urgent demands for information and accountability requirements. Participants from inspected organisations were not always convinced that CQC understood the impact of these pressures and the additional burden created by inspections; they sometimes struggled to provide information required by CQC at short notice ahead of inspections.

Participants in organisations reported that the particular purpose and distinctive focus of inspections was not always clear. Some overlap was noted with peer review visits organised in local maternity systems following the Ockenden review. Sometimes the verdicts of these peer reviewers conflicted with the assessments made by the CQC programme, creating issues of legitimacy. In some cases recounted by participants, the two processes had come to very different conclusions, further compromising the confidence of participants in inspected organisations in their validity, and giving rise to challenge to inspectors and managers in CQC.

Staff in inspected organisations also highlighted the negative impacts of inspections – and particularly ratings that fell short of ‘good’ – for their organisations. Echoing issues in the literature summarised in section 2.2.6, participants noted that a negative rating could have a serious impact on staff morale and organisational reputation – and one that could be difficult to shake even after improvements had been made. They noted too that for local populations, negative reports could result in little more than anxiety (warranted or otherwise), given the limited availability of choice of maternity service in most areas. They were therefore unconvinced of both the appropriateness of addressing service users and local publics as an audience for inspection reports, and of the likely effectiveness of doing so as a component of the programme’s theory of change.

Finally, as noted above, some participants suggested that the programme had unearthed more numerous and more serious problems in maternity care nationally than had originally been anticipated. Besides the direct impact on the resourcing of the programme, participants noted that this had also impacted the levels of support available for organisations rated ‘requires improvement’ or ‘inadequate’. Support programmes run by NHS England for struggling organisations were themselves finitely resourced, and so their capacity had to be spread more thinly.

## Conclusions and implications

We found agreement with, and even enthusiasm for, the objectives and approach of the national maternity inspection programme across many people we interviewed, but participants also identified some serious challenges in translating the goals and ideas behind the programme into practice. Resourcing and organisational issues, particularly early on in the programme, were seen to have compromised the quality of inspections and even the validity of ratings. Participants noted that the challenges had been acknowledged by CQC, and welcomed CQC’s efforts to address them through continuous improvement. However, some challenges remained. For example, the size of the task, many felt, had been underestimated, and consequently challenges of resourcing persisted – at least as of the point at which most of our interviews took place, in late 2023. There were also some discrepancies between features thought to be important to the success of the programme (for example, expert inspectors informed by specialist clinical advisors) and what happened in practice.

Participants noted that experience and expertise in maternity inspection was indeed accumulating across the programme team. This led some to suggest that maintaining a specialised maternity team beyond the terms of the programme would be valuable, and might help to address any issues of consistency that had emerged earlier on. A wide range of suggested improvements to the programme was identified by participants, relating for example to resourcing, timescales, activities to be prioritised during inspections, and the approach to engaging with inspected organisations. These are summarised in the appendix to this report.

It appears that CQC has some work to do in allaying the concerns of at least one legitimacy community: staff in inspected organisations. Whereas CQC staff were relatively confident about the quality and consistency of ratings (or at least felt that this was improving), participants from inspected organisations were much less convinced. The views of people from inspected organisations were informed by their own experiences of inspection, by their perceptions of inappropriate behaviour on the part of some inspection teams, by their comparisons of the content and ratings presented in different reports, and by perceived inconsistencies between conclusions drawn by CQC and by others, such as those put forward by local peer reviewers. The demands placed by the programme on organisations, and the huge influence ratings could have on organisations, staff and patients, furthered their doubts about the programme’s legitimacy. These are important challenges given that, across participant groups, the value of on-site inspection in making valid and useful regulatory judgements was broadly accepted – and, indeed, some participants from inspected organisations went even further than CQC inspectors in arguing for the potential of much more sustained inspector presence in services over time.

Participants were also doubtful about the extent to which results from the inspections spoke to local maternity service users in particular, and the degree to which they would be able to play a role in effecting local change.

Just as the documents examined in Chapter 3 have limitations as a data source, so too do these interviews. Selection of interviewees depended on decisions made by individuals about whether to participate, having been approached by CQC on the basis of their involvement in the maternity inspection programme or in maternity care more broadly. This may have resulted in sampling bias towards those more sympathetic to the programme and its aims – or, equally, may have attracted participants with negative things to say about the programme. All interviews are retrospective accounts, and may therefore be susceptible to various forms of bias: in terms, for example, of what participants recall, and the ways in which they present themselves.

Potential implications of these findings for CQC include:

* Be clear and explicit about the theory of change for the maternity inspection programme and its realisation in practice, particularly as the role of inspection evolves in the new regulatory framework.
* Continue to work in the spirit of learning and continuous improvement highlighted by some participants, to optimise inspection and how is done within the new regulatory framework.
* Recognise that the quality of inspections is very dependent on the behaviour and practices of individual inspectors and teams, and accordingly requires significant attention in both standards for inspector conduct and practice, and investment in training, support, and quality assurance.
* Identify opportunities for CQC to work with others – notably NHS England – to avoid overlaps and underlaps in focus and accountability demands, and to understand and address the reasons for inconsistencies in regulatory activities.
* Communicate the purpose of the programme to NHS organisations more effectively.

Further consideration is also warranted of how best to secure the centrality of inequalities in inspections in practice, including consideration of the particular needs of populations and the work of inspected organisations to address them.

# Concluding remarks

In this final brief chapter, we identify key points in relation to each of the two objectives the evaluation sought to address, and suggest key implications for CQC.

## Summary of the work of the evaluation

Spanning a 10-month period from May 2023 to February 2024, our evaluation encompassed six workpackages that used mixed methods to achieve its objectives, plus final integrative activities to bring learning from the workpackages together and produce a ‘learning resource’ for CQC and other stakeholders that seeks to encapsulate ‘what good looks like’ for maternity service users and staff.

This report focuses on the objective to evaluate the national maternity inspection programme to maximise learning for maternity services, inspection, and the health and care sector more broadly. We conducted a wide-ranging literature review examining theory and empirical evidence relating to inspection and regulation across multiple sectors (Chapter 2), an analysis of documents pertaining to the national maternity inspection programme including public-facing and internal guidance documents, and documents produced by individual inspections (Chapter 3), and interviews with a range of individuals involved in the programme as inspections, leaders, and staff of inspected organisations (Chapter 4). Key lessons for the design and realisation of the programme and of CQC’s approach more broadly are included in those chapters; we summarise further implications below.

## Learning from the national maternity inspection programme: implications and next steps

Our evaluation of the maternity inspection programme offers a snapshot of a regulatory effort that was being delivered at pace and that, as acknowledged by stakeholders across the programme, was still evolving, and at a time when a new approach to regulation (the Single Assessment Framework) was emerging. Inspection will have a somewhat different role in the new approach, but it will nonetheless be an important one – as the literature shows, inspection can get to the parts other methods of monitoring cannot reach. Given this, key learning for the maternity inspection programme (and inspection generally) can be identified.

A clear and explicit theory of change could not be identified in the programme documentation, but many components of such a theory were described. Gaps between the programme ‘as imagined’ (as found in the documents examined in Chapter 3) and the programme ‘as done’ (as found in the accounts of those involved in it in Chapter 4) suggest that what was intended or hoped for was not always being realised in practice. For example:

* An important role was envisaged for experienced, expert inspectors supported by specialist advisors with important clinical knowledge, but securing this for all inspections was not straightforward.
* There was some uncertainty over the key audiences for the outputs of inspections and how they would act on them.
* Participants from CQC described a validation and quality assurance process that in practice was more burdensome, opaque and contested than the process clearly described on paper would suggest.
* There was acknowledgement from some inspectors that the quality and consistency of their inspections early on had not been as high as it might have been, due to the pace of the programme and the limited opportunities to develop specialised expertise early on.
* Some of logistical elements (e.g. the app) were poorly optimised.
* It was often hard to access the views of maternity service users (women, birthing people, and birth partners).
* Some behaviours and practices of some inspection teams were regarded as unprofessional or unacceptable by staff in inspected organisations.
* The credibility and legitimacy of inspection findings were prone to being contested.
* The programme also brought to the fore some tensions between CQC, inspected organisations and other parties such as NHS England, for all of whom the ratings selected could have significant implications in terms of the actions that needed to follow (especially if lower than ‘good’).
* Beyond CQC, attention is needed to the “Achilles heel” of regulation, enforcement to secure improvement; it is not clear that the current mechanisms are working as well as they should.

In many cases these deficits had been recognised and programme leaders were seeking to address them. However, it was clear from this work that continuing improvement is needed, and that CQC still needs to address the concerns of at least one audience or ‘legitimacy community’ (staff in inspected organisations) if its assessments and ratings are to be regarded as credible, accepted, valued and put to productive use.

Planned outputs from the national maternity inspection programme offer opportunities for speaking to a range of legitimacy communities and to ensure that the programme offers benefits to the maternity system as a whole. For example, CQC plans to develop an improvement resource for healthcare provider organisations, which may draw on the learning resource produced in the course of this study. It also plans to publish a national report from the inspection programme, which will seek to characterise the state of maternity care nationally, and identify challenges, opportunities for improvement, and examples of best practice that services might draw on.

This evaluation also contains important learning that may be relevant to CQC’s other programmes, and to its broader work to renew its approach to assessment and regulation. Participants in the interviews were full of creative ideas for how inspections and regulation might be improved, and learning relating to how best to develop, organise and enhance inspection teams will likely have wider resonance.

# Appendix: Interviewee suggestions for improvements in the inspection programme

This appendix summarises suggestions made by participants in workpackage C, including inspectors, other CQC staff and people in inspected organisations, for improvements to CQC’s national maternity inspection programme and to its approach to inspection and regulation more broadly.

## Improvements suggested by CQC leads and inspectors

Many CQC leads and inspectors felt that the initial programme set-up, project management and governance could have been improved. Specific areas identified included:

* Better and more formalised resourcing for the project, including a dedicated budget for the programme, formal secondments for a set amount of time from the start, a larger pool of inspectors and a larger pool of specialist advisors.
* Better planning around the availability of the specialist advisor resource (particularly obstetricians) to ensure presence on site during every inspection, and greater incentivisation through increased reimbursement for obstetricians (obstetric and midwifery specialist advisors are currently paid the same).
* More realistic timescales for getting the programme up and running, with participants suggesting the process should have been slowed down with a later start date to ensure resources were in place and staff trained to the appropriate level before inspections began.
* More consideration of and planning for inspector training needs at the start.
* More engagement with local inspection teams from the outset, to strengthen their link with the programme. Initial agreements for local teams to contribute to inspections with resources (a local inspector on each team) and data had not come to fruition.
* Better anticipation of the likely requirement for enforcement action among organisations that had not been inspected for some time. This could have been better planned into the programme in terms of support for carrying out enforcement alongside the programme and building in follow-ups to check improvement. Having an enforcement member of staff who knows the legal context and is a point of contact who can provide support was also suggested as an improvement.
* Improvements relating to the nature of data requests to trusts and dependence on this data: suggestions from inspectors included greater flexibility in terms of the data requested from trusts (asking for what is required rather than using a standard request) and addressing dependence on data that is reported by trusts (challenges around assessing accuracy and whether trusts were reporting everything that they should be reporting).It was suggested that to streamline inspections there should be a system of centralised databases of information that trusts constantly update and to which the CQC have automatic and easy access; this would remove the need to ask staff at each trust to provide this information.
* Provision of more time for the CQC to take stock and learn from each inspection to improve its own practices.
* The introduction of further mechanisms to support learning and consistency, for example a database of elements that contribute to a site being judged as ‘requires improvement’
* More focus on the corroboration of findings and pulling together the national report as the programme went along and auditing and ensuring the consistency of individual reports earlier in the programme might ensure they provided a sound basis for the national report. Further development of the maternity app based on observation of how it was working in practice might ensure that it was fit for purpose and could be used in preparing the national report.

Another issue identified by participants included the amount of time devoted to inspections. Many participants indicated that increasing the time spent on site would be a priority for improving the programme. Conducting inspections over two full days was a common suggestion. One inspector suggested that one day could focus on data collection and observation and the other on speaking to people once the inspector had identified the most pertinent questions to ask, while a CQC lead suggested that more time was needed to review the submissions from the inspected organisations.

Participants also highlighted the need for a much greater focus on inequalities from the start of the programme. Having a specific inspection domain dedicated to inequalities (instead of including it implicitly as part of the ‘safe’ and ‘well-led’ domains), thus ensuring that data about inequalities was built into the methodology and that enforcement action was taken to address health inequalities, was seen as a potential way of securing greater attention. Other suggestions included adding more demographic content to the inspection reports, and ensuring that demographic information was provided where possible in responses to the Give Feedback on Care programme. More broadly, some participants called for a greater focus on service user feedback and building service user engagement more explicitly into the inspection programme. This might include, for example, spending more time speaking to women and birthing people on site, engaging remotely with service users in the months following labour, and utilising maternity and neonatal voices partnerships as sources of feedback by contacting their members. It would also need to be accompanied by a greater focus on (and accompanying resources for) the analysis of service user feedback.

Some participants felt that increasing the breadth of the programme would be beneficial. They suggested, for example, expanding the programme to cover neonatal care as well as maternity (since issues such as health inequalities are applicable across settings), and covering gynaecology, antenatal care and community provision. It was suggested that services should be inspected from a system perspective, covering the whole maternity journey from the first contact (commonly with the GP). Others suggested that the programme needed to expand its remit beyond well-led and safe to cover all five domains, if inspections were to be comprehensive and fair, and organisations were to be given a fair chance to display their strengths and achieve an appropriate rating. It was also suggested that covering all five domains would make the ratings more useful for service users as they may be particularly concerned with the ‘caring’ and ‘responsive’ ratings.

Some participants similarly suggested that extending the timeframe for completion of the national maternity programme would help to relieve some of the pressures it faced, while for others, there was a case for creating a permanent specialism in maternity. This, they suggested, would ensure that those services that fell outside the time-limit for inspection under the programme would not fall through the net. Additionally, some form of permanent specialism for maternity inspection would ensure that the specialised knowledge built up was not lost.

## Improvements suggested by staff from inspected organisations

For staff from inspected organisations, particular priorities for improvement to the programme included longer deadlines for provision of required information prior to inspection, greater appreciation on the part of inspectors about how records are stored and how onerous a process it can be to access such information, and a greater role for professional peer review, for example through a stronger presence of specialist advisors (especially more senior ones) who might have a better sense of what ‘well-led’ looks like.

Participants from inspected organisations also felt that CQC could do more to understand and acknowledge the reality of being a provider, and the competing demands placed on provider organisations by CQC requests alongside other the day-to-day and one-off demands, for example from NHS England. In a similar vein, they felt that more could be done to reduce overlap between the maternity inspection programme and the peer reviews initiated by NHS England following the Ockenden review. Echoing the views of some of the CQC staff participants, those from inspected organisations felt that a single day was often insufficient to create a fair judgement. Some suggested that a much more prolonged engagement would be beneficial, for example spending as much as a month on site, working alongside staff to produce a fuller sense of how a trust runs, its strengths and its weaknesses.

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