Special Measures for Quality Improvement and Challenged Providers: Evaluating the impact of improvement interventions in NHS Trusts

Study protocol

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SUMMARY

Background: The Special Measures for Quality regime (SMQ)¹ provides NHS trusts with increased support and oversight from NHS Improvement (NHSI) following a Care Quality Commission (CQC) inspection that has rated as inadequate the leadership and one other domain. There is also a ‘watch list’ of challenged NHS providers at risk of going into SMQ that receive support (this list is not in the public domain). According to NHSI, trusts in SMQ and on the challenged providers list can receive a combination of three main interventions: 1) Improvement Director, 2) buddying, and 3) access to central funding. These might be delivered in conjunction with other interventions and is often within a context of leadership changes at board level. There is currently limited knowledge about whether, and how, targeted interventions from NHSI drive improvements in quality, how much they cost, and whether the current improvement regime strikes the right balance between support and scrutiny. There is also interest in understanding why some trusts become sufficiently resilient and avoid re-entering special measures or exit the regime sooner than others.

We carried out a three-month scoping exercise to obtain additional information about the SMQ programme and the specific NHSI interventions delivered to trusts, and their expected outcomes. We conducted a review of the types of trusts where interventions have been delivered during the period July 2013 to September 2018 and determined the main characteristics of both challenged providers and trusts that have been in SMQ and their performance trajectories. We also surveyed the academic literature and identified key themes and concepts of relevance to this evaluation, for example in relation to organisational performance and external regulation. Another important component of the scoping exercise was engagement with key contacts at NHSI and the Department of Health and Social Care (DHSC).

¹ For clarity, we will use the term special measures regime for quality (SMQ), but this term refers to special measures for reasons of quality and does not constitute a separate regime.
as well as Patient and Public Involvement (PPI) representatives who have commented on the draft proposal. Finally, the scoping work helped to define the research questions and a methodological design that can be deployed within a limited timeframe – as part of a rapid evaluation as opposed to a longer research study. Information acquired during this scoping phase has been used to assess data availability and the feasibility of different components of the evaluation, such as case studies and quantitative and economic analyses.

**Aims**: The study will seek to evaluate the responses of NHS providers to the SMQ and challenged providers regimes. Specifically, the implementation of: 1) interventions for trusts in SMQ and 2) interventions for ‘challenged providers’. In both cases, the aim is to determine how trusts respond to these interventions and how they may impact on organisations’ capacity to achieve and sustain quality improvements over time. We will include the interventions identified by NHSI as well as any other interventions trusts underwent while being a part of the SMQ/challenged providers regimes. These interventions will be studied within the context, where applicable, of leadership changes at board level associated with the regimes. This study will not focus on interventions delivered to trusts which are only in Special Measures for Finance.

**Design and methods**: This is a multi-site, mixed methods study that will involve case studies and multiple sources of data to study the impact and implementation of the interventions across a number of purposively selected NHS sites. We will use a conceptual framework based on previous models of organisational readiness for change (Nelson 2005) and draw on board maturity research for implementing quality improvement (QI) (Jones et al. 2017). As part of the evaluation, we will also review the types of quantitative metrics and data found to be useful for tracking the progress of improvements in quality of care and sustainability upon leaving SMQ, as well as the costs of specific interventions. The study comprises the following interrelated work-streams:

1. **Literature review using systematic methods**: We will follow a multi-stage literature review process beginning with the conduct of a rapid review of existing empirical evidence, as proposed by Tricco et al. (2017). In the first stage, we will conduct a search of selected health services, business and management journals and the grey literature to draw on a more theoretically-driven body of work to inform the development of our conceptual framework for the second stage (for an example of this approach, see Ferlie et al. 2012). The second stage will be aimed at refining the research questions and identifying evidence on failing organisations in health care and contemporary cases of organisational turnaround and regulation in the health care sector. This stage will also focus on the common characteristics of failing organisations, and the types of interventions aimed at improving performance and quality. Findings from the review will inform data collection and analysis from the multi-site, mixed methods case studies.

2. **Interviews at national level**: We will carry out a small number of interviews with staff at national level, including with NHSI, the CQC and the DHSC. The purpose of these interviews is to better understand the programme theory/ies underpinning the
interventions, and which interventions are viewed as being effective, and under what conditions.

3. **Multi-site, mixed method case studies:** We will conduct comparative case studies, combining interviews, observations, documentary analysis and appropriate quantitative data, such as routinely available metrics i.e. patient-level records from Hospital Episode Statistics (HES). From our scoping study, we have developed a sampling frame of four types of performance trajectories: prolonged poor performers; poor performers; shorter term challenged providers; and clear performance improvers. Two trusts will be sampled for each category (eight in total), taking into account the analysis of trust characteristics conducted in the scoping phase (see Appendix A). Of the two case studies within each performance trajectory, one will be conducted ‘in-depth’ and one at a ‘high level’. In each site we will conduct fieldwork at the ‘top’ of the organisation given the potential significance of board and executive leadership change following entry into SMQ, and with external stakeholders in the local health economy context, such as patient groups/Healthwatch. In all sites, we will collect documents about the SMQ and challenged provider programme produced centrally and locally (such as action plans and board minutes and papers). We will also record the types of quantitative data collected locally and nationally to track performance in quality over time within these eight trusts. The in-depth case studies will in addition involve observations and apply a ‘vertical slicing’ technique to conduct interviews at different organisational layers. The data collected will be analysed and comparisons made across the different case sites to identify themes. Relevant findings on the use of routine data within trusts will feed into recommendations on the use of quantitative data to measure quality improvements.

4. **Exploratory workforce evaluation:** This component will explore any relationships between being in SMQ or on the challenged providers list and workforce recruitment, retention, and turnover.

5. **Cost-consequence analysis (CCA):** We will explore the costs and benefits of different combinations of the interventions typically utilised in the SMQ/challenged providers regimes in a cost-consequence analysis within the eight case study sites. This will take into account the type and intensity of the interventions implemented in practice. The costs of different combinations, as well as the type and intensity, of these interventions will be obtained from the multi-site qualitative component; this component will also be used to identify and measure the main consequences.

**Dissemination and outputs:** we will provide formative feedback to the DHSC, NHSI, and participating sites at regular time points. This feedback will include:

- our evolving understanding of the programme theory,
- insights on the implementation of interventions, and
- staff views and experiences of the SMQ regime and challenged providers programme.

Potential outputs will include:
Lessons for trusts on responding to interventions in SMQ/challenged providers regimes, such as what to prioritise and the organisational capabilities found to support quality improvement

Lessons for the DHSC and NHSI on how to support challenged providers and those in the SMQ regime in light of the varied internal and external contexts of health care organisations facing performance difficulties

Recommendations on the use of routine, quantitative data to track quality improvements, including at system level, and the potential costs and benefits of interventions of the SMQ regime

A conceptual framework to help evaluate the SMQ regime and challenged providers programme in future.

Papers for publication in peer reviewed journals

In any output, all individuals and organisations involved in the study will be anonymised. The team appreciate the sensitivity around this topic, which will need to be handled carefully as the study progresses. The team will maintain the independence of the research.

**Study timeline:** The study will take place over 12 months (December 2018-December 2019), assuming timely access to relevant data and eight NHS organisations. The findings of the scoping phase (April – October 2018) will also be incorporated into our final analysis and outputs.
BACKGROUND

The Special Measures for Quality regime (SMQ)\(^2\) is a targeted and time-limited regime in the NHS in England agreed between the Care Quality Commission (CQC) and NHS Improvement (NHSI). The regime emerged following the Keogh Review into avoidable mortality in 2013 (NHS England 2013). Trusts are put into SMQ only where serious care quality failings are identified and the leadership appear unable to resolve the problems without intensive support and external input (CQC 2017a, 2017b; CQC 2018; NHSI 2017). The SMQ regime provides trusts with oversight and interventions from NHSI to help them address specific failings identified in CQC inspections for reasons of quality. NHSI therefore perceive SMQ as a support regime to bring about improvement (correspondence, October 2018). The interventions typically vary from one trust to another depending on circumstance and may include: the appointment of an Improvement Director, a review of the trust’s leadership capability, access to financial resources for quality improvement, a plan for improvement including options for diagnostic work on assessing medical engagement, buddyng with other trusts, and commissioning external expertise. These might be delivered in conjunction with other interventions, and within a context of significant leadership changes at board level.

*Insights from the literature on failing and poor performing health care organisations*

There may be indications of persistent performance or quality issues in a health care provider long before a crisis comes to the attention of the wider public and regulators. This highlights the need for transparent, integrated, and timely processes for identifying quality and patient safety issues across health care systems (Walshe and Shortell, 2004). Attention has been placed on failing health care organisations, their characteristics and the factors (both internal and external) that might lead to low performance. These include for example low leadership capability, lack of open culture, and antagonistic external relationships (Hockey et al. 2010, Speroff et al. 2010, Ravaghi et al. 2015). A recent systematic review of the characteristics of failing health care organisations in multiple countries and settings identified five characteristics shared across failing organisations: 1) poor organisational culture; 2) inadequate infrastructure; 3) lack of a cohesive mission; 4) system shocks; and 5) dysfunctional external relations with other hospitals, stakeholders, or governing bodies (Vaughn et al. 2018). More specifically, a hierarchical culture and leadership focused on avoiding penalties and achieving financial targets - rather than a patient-centred mission - are characteristics identified in many failing organisations. Available reviews, such as that by Vaughn et al. (2018), suggest that an important next step after diagnosis of problems is the development of high-quality interventions capable of helping struggling health care organisations to improve.

Some of the available literature on the SMQ regime in the UK has highlighted the unintended consequences for trusts of this approach to quality improvement, such as difficulties with recruitment and retention, the lowering of staff and patient morale, increases in financial costs, and external pressures placed on already burdened management systems (Rendel 2015). A recent evaluation of the CQC inspection regime categorises eight types of regulatory impact

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\(^2\) For clarity, we will use the term special measures regime for quality (SMQ), but this term refers to special measures for reasons of quality and does not constitute a separate regime.
arising from the inspection regime: anticipatory, directive, organisational, relational, informational, stakeholder, lateral, and systemic (see Table 1 below) (Smithson et al. 2018). The impact of CQC inspections is found to vary considerably according to type and size of provider, although ‘directive’, ‘stakeholder’ and ‘organisational’ influences appear most applicable to troubled providers that are asked by the regulator to take immediate action to improve quality and enter SMQ.

**Table 1**: Eight regulatory impact mechanisms (adapted from Smithson et al. 2018, pp. 14-15)

<table>
<thead>
<tr>
<th>Impact mechanism</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticipatory</td>
<td>Providers seek to comply in advance of regulatory interactions (e.g. inspection).</td>
</tr>
<tr>
<td>Directive</td>
<td>Providers take direct actions as requested by the regulator. Legal consequences possible in cases of non-compliance.</td>
</tr>
<tr>
<td>Organisational</td>
<td>Providers instigate internal processes not explicitly related to directives on account of interaction with the regulator, such as addressing leadership or culture.</td>
</tr>
<tr>
<td>Relational</td>
<td>Influence of (human, interpersonal) interactions between regulatory staff and regulated providers.</td>
</tr>
<tr>
<td>Informational</td>
<td>Regulatory information on performance enters the public domain and informs decision making.</td>
</tr>
<tr>
<td>Stakeholder</td>
<td>Other stakeholders take action and interact with the regulated provider.</td>
</tr>
<tr>
<td>Lateral</td>
<td>Regulatory interaction results in new inter-organisational actions (across boundaries), such as peer learning.</td>
</tr>
<tr>
<td>Systemic</td>
<td>Regulatory information on providers is used to identify wider issues in systems of care, beyond a single provider.</td>
</tr>
</tbody>
</table>

There nevertheless remains limited understanding about whether and how interventions within the SMQ/challenged providers regimes instituted by NHSI are effective in supporting failing organisations. This study will therefore build upon and contribute to the available academic literature about hospital failures and regulatory regimes, especially the work of Smithson et al. (2018), to address this knowledge gap.

**The special measures regime: findings from scoping work**

We analysed data supplied from the DHSC and NHSI on trusts that have entered SMQ since the regime began in July 2013 up to the end of September 2018. A total of 35 trusts have entered SMQ; four trusts have returned to SMQ (giving 39 episodes), 25 have exited SMQ, and as of the end of September 2018, there were 14 trusts in the regime.
In addition to trusts in SMQ, since July 2015, providers deemed at risk of going into SMQ have been placed on a ‘watch list’ of challenged providers. The trusts on this watch list receive interventions to prevent them entering SMQ. At the end of September 2018, there were 17 trusts on this list. Since July 2015, 44 trusts have been placed on this list, with 17 trusts leaving the list because they entered SMQ, and one trust who left the list and subsequently returned.

There is also a Special Measures for Finance programme (SMF; also managed by NHSI), which was introduced in July 2016. Of the 15 trusts to enter SMF, only four have left as of September 2018. Nine of the 15 trusts ever in SMF have also been in SMQ, with six being in both special measures regimes simultaneously, and a further two being on the challenged providers list and in SMF simultaneously.

Altogether we have identified 73 episodes of trusts entering SMQ, SMF or challenged providers regimes for the period July 2013 to 30th September 2018. Of these, 59 NHS trusts have been in SMQ or on the challenged providers list (see Table 2 for trust type).

Table 2: The types of NHS trust entering SMQ or on the Challenged Providers list (July 2013-end September 2018)

<table>
<thead>
<tr>
<th>Trust type</th>
<th>Number of trusts ever in SMQ or on challenged providers list</th>
<th>Trusts currently in SMQ</th>
<th>Trusts currently on challenged providers list</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute services only</td>
<td>33</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>Acute and community</td>
<td>18</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Acute and mental health</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Ambulance</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Community and mental health</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Mental health</td>
<td>4</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>59</strong></td>
<td><strong>14</strong></td>
<td><strong>17</strong></td>
</tr>
</tbody>
</table>

**STUDY AIMS**

The study will seek to analyse the responses of providers to the implementation of a) interventions for trusts in SMQ and b) interventions for challenged providers to determine their impact on these organisations’ capacity to sustain and achieve quality improvements. We will focus on the main interventions that NHSI has identified as forming part of the SMQ and challenged provider regimes:

1) appointment and use of an Improvement Director;
2) buddying with other trusts;
3) the opportunity to bid for central funding to spend on quality improvement.

We will also include any other interventions participating NHS trusts identify as being part of the SMQ regime, and consider these interventions within a wider context of any leadership changes.
at board level. We will also draw on evidence from the academic literature (e.g. on organisational failure, turnaround and performance) to explore these issues and apply a range of appropriate quantitative, economic and qualitative research methods. This study will not focus on interventions delivered to trusts that are only in the Special Measures for Finance regime.

**RESEARCH QUESTIONS**

1. What are the programme theories (central and local) guiding the interventions delivered to challenged providers and trusts in the SMQ regime?
2. How and why do trusts respond to SMQ/challenged providers regimes and the interventions within these regimes?
3. Which features of trusts in SMQ/challenged provider regimes, and their wider context, contribute to their differing performance trajectories?
4. What are the relative costs of the interventions and how do these compare with their benefits?
5. How are data used by trusts in SMQ/challenged providers regimes, and how do these contribute to the understanding of impact on outcomes?
6. Do trusts in SMQ (or on the challenged providers list) find it more difficult to recruit and retain staff?

**DESIGN AND METHODS**

This is a multi-site, mixed methods study that will combine qualitative and quantitative approaches to analyse the implementation of the interventions delivered to challenged providers and those in SMQ and the impact of these interventions on trust performance, quality of care, patient experience, and costs. We will apply a conceptual framework based on previous models of organisational readiness for change and board maturity for quality improvement.

**Scoping and initial data gathering phase**

In developing this protocol, we conducted a scoping exercise over three months to obtain additional information on the NHSI interventions to be evaluated, their expected outcomes, trust performance trajectories and inspection results, as well as identifying key trust characteristics for comparison. We also used this time to undertake a feasibility analysis of our study plans.

As part of this scoping we plotted trust performance trajectories over time, since the establishment of the CQC inspection regime in 2013, to identify any trends or patterns (Appendix A). This led to the development of a typology of trusts to categorise providers that have been on the challenged provider list and/or entered the SMQ regime since 2013. We identified different sub-groups of trusts during this time-sensitive analysis, such as those that have been in SMQ and have re-entered, or those that have gone on to achieve a ‘good’ or ‘outstanding’ CQC rating and never re-entered. We plan to apply our research questions
across these different organisational categories and use the typology for purposive sampling of the case studies (n=8).

We are developing a database of trust characteristics which includes information such as trust type (e.g. mental health, community, ambulance, acute), interventions received, trust size, time points of the interventions received (e.g. CQC inspections, directorate visits/appointments/changes in leadership), demographic context, workforce status and statistics (e.g. vacancies, agency spend), and financial status over time.

A large part of the scoping work has involved regular email correspondence and discussions with key stakeholders (e.g. DHSC and NHSI), review of relevant documents (e.g. trust board papers, CQC reports) and assessment of data availability and quality.

Lastly, as part of this phase we assessed the feasibility of undertaking an economic analysis of the interventions that form the SMQ and challenged provider regimes. This included identifying the main cost components of the interventions received, and examining the various combinations of interventions to determine whether or not it would be possible to identify separate consequences of the individual interventions. The feasibility phase showed that a cost-consequence analysis was feasible, if carried out as part of the multi-site, mixed methods case studies, and that it would be necessary to measure the costs and consequences of different combinations of interventions (i.e., it would not be possible to isolate the effects of individual interventions). This would take into account the likely variation in the type and intensity of these interventions, e.g., percentage of FTE time the Improvement Director spends at the trust, different buddying models, varying receipt of funds spent in different ways. We will explore the impact of this variation on both costs and consequences.

The scoping work produced the following outputs which have been used in the development of this protocol (an anonymised version of the main findings from the scoping work are included in Appendix A):

- Performance timelines for all challenged trusts and those in SMQ, 2013-2018
- A typology of SMQ and challenged providers based on their performance trajectories and CQC ratings (e.g. amount of time spent in both regimes, identification of cases that have gone from challenged provider to SMQ, changes in trust status such as exit or re-entry to SMQ)
- A purposive sampling framework for identifying the case studies and ensuring a range of trusts are covered (based on the typology and descriptive categories developed from the above, and adapted in light of feedback from external reviewers)
- A list of the main characteristics of challenged providers and those in SMQ (e.g. type of trust, geography, characteristics of the health care economy, etc.)
- A comprehensive list of NHSI improvement actions implemented to drive changes locally
- An assessment of the quality of quantitative, routine data sources that might provide markers of quality improvement
Feasibility study for economic analysis

Our study consists of five inter-related elements, set out below:

1. **Literature review using systematic methods**
   We will conduct a rapid literature review of organisational failure in health care following the rapid review method proposed by Tricco et al. (2017). It will build on the review of organisational failure published by Vaughn et al. (2018). The rapid review method follows a systematic review approach, but proposes adaptations to some of the steps to reduce the amount of time required to carry out the review (i.e., the use of large teams to review abstracts and full texts, and extract data; in lieu of dual screening and selection, a percentage of excluded articles is reviewed by a second reviewer, and software is used for data extraction and synthesis, as appropriate [Tricco et al. 2017]).

   The first step will be to conduct a search of specific health service, business and management journals, and review the grey literature (e.g. think tank reports) to develop a theoretical understanding of the main characteristics of organisational failure and turnaround, and the types of interventions implemented to improve quality (for an example of this approach see Ferlie et al. 2012). This literature will be used to develop a clearer conceptual and theoretically-informed framework to inform the review's research questions, search strategies, and interpretation of findings.

   We will use the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement (Moher et al. 2009) to guide the reporting of the methods and findings. The review protocol will be registered with PROSPERO.

   **Review research questions**

   The review will seek to answer the following questions (although these may be revised in light of step 1):

   1. How are ‘failing health care organisations’ defined?
   2. What are the main factors that lead to organisational failure?
   3. What are the main characteristics of ‘failing health care organisations’? What are the main interventions delivered to improve quality? Who delivers these interventions?
   4. What are the programme theories guiding these interventions?
   5. What are the main processes of implementation?
   6. What is the impact of the implementation of these interventions?
   7. What is the sustainability of improvements produced by these interventions (if any)?
   8. Have any of these interventions been evaluated? If so, how?
   9. What are the costs and potential benefits of these interventions?

   **Search strategy**

   We will use a staged search approach (Tricco et al. 2017). The first stage will be broad, covering literature from the fields of health services research, management and business.
studies to identify overarching themes on regulation, performance and quality improvement in health care organisations and the public sector. The theoretical content from this literature will be used to develop a thematic framework of organisational failure and turnaround that will be used to inform the second stage. The second stage will be targeted and focused only on organisational failure and turnaround in health care settings.

We will conduct a review of published literature using multiple databases: MEDLINE, CINAHL PLUS, EMBASE and Web of Science. Results will be combined into Mendeley (Mendeley 2018) and duplicates removed. The reference lists of included articles will be screened to identify additional relevant publications. We will also hand search other relevant databases such as the King’s Fund library. We will search for relevant grey literature using Open Grey and TRIP.

Selection

Following rapid review methodology (Tricco et al. 2017), one researcher will screen the articles in the title phase, and three researchers will cross-check exclusions in the abstract and full-text phases. Disagreements will be discussed until consensus is reached. The inclusion criteria used for study selection will be: 1) focus on failing organisations, defined as not meeting the required quality standards (self-defined), 2) describes empirical research, 3) describes a study in a health care setting, 4) published in last 20 years, and 5) published in English.

Data extraction and management

The included articles will be analysed using a data extraction form developed in REDCap (Research Electronic Data Capture). The form will be developed after the initial screening of full-text articles. It will then be piloted independently by two researchers using a random sample of five articles. Disagreements will be discussed until consensus is reached. The data extraction form will be finalised based on the findings from the pilot.

Data synthesis

Data will be exported from REDCap and the main article characteristics will be synthesised. The information entered in free text boxes will be exported from REDCap and analysed using framework analysis (Gale et al. 2013). We will use the thematic framework developed in the first stage of the review to guide our exploration of themes.

Quality assessment

We will use the Mixed Methods Appraisal Tool (MMAT) to assess the quality of the articles (Pluye et al. 2012). Two researchers will rate these articles independently. In cases of disagreement, the raters will discuss their responses until consensus is reached. Inter-rater reliability will be calculated using the kappa statistic (Landis and Koch 1977).

The findings from the review will inform data collection and analysis from the multi-site, mixed methods case studies.
2. **Interviews at national level**

We will carry out a small number of interviews (5-7) with staff at national level, including with NHSI, the CQC and the DHSC. The purpose of these interviews is to better understand how the interventions deployed to support trusts are perceived by the different stakeholders in relation to their programme theory/ies, and which interventions are viewed as being particularly effective, and under what conditions.

3. **Multi-site, mixed method case studies**

We will conduct eight case studies (four ‘high level’, four ‘in-depth’), combining qualitative and quantitative approaches.

Case study research is common in management, business and organisational research and policy evaluations. Yin defines the case study as an ‘in-depth inquiry into a specific and complex phenomenon’ (Yin, 2013: 321). Case studies typically employ a range of data collection methods – quantitative, qualitative or a mixture of both - to ‘construct narratives of past events, or accounts of specific cases’ (Giacomini, 2010: 136). The case study is particularly advantageous where there are a number of data points, variables or factors influencing a policy or organisational issue and where different factors or variables intersect dynamically and are difficult to control. For these reasons, case study researchers do not attempt to control complex factors (as in experimental or randomised research designs) but instead try to understand interactions between factors in ‘real life’ settings and contexts (Gibbert and Ruigrok, 2010; Yin 2003).

**Conceptual framework**

The case studies will explore the implementation of interventions in challenged provider trusts and those in SMQ, reflecting on any observed changes in processes and outcomes reported across specified time points (e.g. point of entry into, or exit from, the SMQ regime), combining qualitative and quantitative data. To do this, we will use the findings from the literature review. We will apply a board maturity framework (Jones et al. 2017) developed in previous research conducted at UCL which found that boards with higher levels of maturity in relation to governing for quality improvement were able to effectively balance short-term (external) priorities against long-term (internal) investment in quality improvement and engage staff and patients in the process of change.

For understanding processes of quality improvement beyond board level, especially amongst “clear improvers” that exit SMQ and sustain change, we proposed to use the concept of absorptive capacity and dynamic capabilities from the strategic management literature to identify any routines or processes that have helped staff - from senior leaders to frontline clinicians - to learn from external information about performance and quality to sustain performance objectives (Harvey et al, 2015). Absorptive capacity refers to the ability of organisations to acquire and exploit new information and knowledge and successfully transfer it internally - across organisational sub-units - to support their learning and
performance (Cohen and Levinthal, 1990). Dynamic capabilities refers to patterned activities and routines that require dedicated resources and long-term commitment to effect impactful change (Winter, 2003). Applying such concepts will help the research team to distinguish between evidence of incremental or ad hoc changes in trusts arising from SMQ interventions that are externally driven, and more radical or novel service innovations that improve quality and trust performance and have become embedded in new ways of working over time at trusts. Indeed, these temporal and contextual dimensions (see Figure 1) are critically important for understanding whether organisational change is sustained within trusts and leads to new developments or whether momentum stagnates once external and regulatory interventions cease (Buchanan et al. 2005). For example, the evaluation of the CQC regime by Smithson et al. (2018) suggests that we might find that some acute and mental health trusts develop new quality improvement organisational capabilities due to the mobilisation of resources and support from NHSI, in which case activity may go well beyond the ‘anticipatory’ affects associated with CQC inspections.

**Figure 1**: Components of Analysis: Context and Process (adapted from Pettigrew 1985: 37 by Nelson 2005)

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**Sampling**

**Sampling framework**

**Inclusion criteria:**

- NHS trusts (ambulance, acute, mental health and / or community providers) that have entered SMQ and/or been placed on the challenged providers list before 30th September 2018

**Exclusion criteria:**
• Trusts placed in SMQ or on the challenged providers list (for the first time) after 30th September 2018.
• Trusts placed in Special Measures for Finance only and never in the SMQ or challenged provider regimes.

The total number of trusts that meet these criteria (n=59) are shown above in Table 2.

Sampling Strategy

Following our scoping phase, we determined to purposively sample eight case study sites (from a total of 59), according to their performance trajectories which is based on the amount of time spent in SMQ or on the challenged provider list, and their progress over time (see Figure 2). We will attempt to take into account provider size and type to ensure a range of organisations. The overall objective of the case studies is to understand dynamics within trusts and their local contexts at different ends of the performance spectrum, hence a need to sample across different performance trajectories following entry into SMQ or being placed on the challenged providers list.

We will conduct eight case studies, sampling two from each performance category below:

• ‘Prolonged poor performers’: Trusts that have been in SMQ for two years or longer since the introduction of the regime, including those trusts that re-enter SMQ after a period of exit
• ‘Poor performers’: Challenged providers who end up in SMQ
• ‘Shorter term challenged providers’: Challenged providers who avoid entry into SMQ and have not previously been placed in SMQ. This may include trusts that merged with higher performing providers.
• ‘Clear performance improvers’: Trusts that have previously entered SMQ or been on the challenged providers list but later achieved a strong CQC rating, without re-entry into either regime.

Figure 2: Purposive sampling model for case studies
(i) **Qualitative fieldwork**

**Data collection**

The qualitative fieldwork will combine semi-structured interviews, meeting observations, and documentary analysis (Table 3). Data collection will follow a rapid qualitative research design involving: teams of field researchers, participatory approaches, and iterative data collection and analysis (Beebe 2014). The interviews will be carried out with a range of staff members to ensure a plurality of perspectives are captured (see Sampling for more information). The interviews will be carried out in person or over the telephone (although our preference is for the former). Non-participant observation will be carried out in the four ‘in-depth’ sites during board meetings and other relevant meetings taking place at other levels of the organisation where quality improvement and/or NHSI interventions are on the agenda. Relevant meetings will be selected during the first weeks of fieldwork, as the researchers become familiar with the organisational context and build upon the findings from the scoping phase.

The interviews and observations will document the processes used to implement the interventions based on available data to plot a chronology of the quality improvement changes at each site. We will note the internal (inner) and external (outer) contextual factors that might influence participation in the interventions, including leadership changes at board or senior management level. We will remain open to understanding the interventions NHS trusts perceive to be a part of a SMQ support regime, in addition to the ones identified by NHSI as being effective for driving change.

To better understand the wider context and possible external constraints on performance, we will gather perceptions from the wider community and stakeholders in the local health economy (e.g. from Sustainability and Transformation Partnerships, clinical commissioning groups, local Healthwatch, Local Authority health scrutiny committees) and include the views and perspectives of patient representatives/groups within and external to the trust. Any examples of patients and the public being directly involved in delivering interventions introduced to make quality improvements will be captured. As an aid to the quantitative analysis, we will study how people within trusts use data with an emphasis on whether and how data are used to track improvements in the quality of care. Examples of changes in the use of data to track measures of quality of care will be recorded.

To facilitate the economic analysis, through the interviews, we will ask about the resource use and costs incurred by the different interventions and their perceived impacts on quality, and additional unintended consequences (positive or negative).

Documentary analysis will be used to identify the organisational strategies and variables that appear to indicate change over time (i.e. since point of entry into SMQ) - such as shifts in organisational composition (e.g. workforce numbers and vacancy levels) and changes in organisational structure (e.g. new governance systems or mergers). This analysis will also seek to compare the central and local theories guiding quality improvement efforts.
Participants

Previous ‘deep dive’ work undertaken by the DHSC Implementation Unit at trust level has had an executive leadership focus on quality improvement driven at the apex of the organisation. We therefore propose to use a vertical slicing technique in the four ‘in-depth’ case study sites in order to conduct interviews across different organisational tiers as well as with external stakeholders, including with patient groups. Around 15 interviews will be completed at each in-depth case study site (n=60 interviews). The types of interviewees will depend on the context of each trust, but are likely to include divisional/clinical directors, and may include staff from a clinical unit which the CQC has flagged as ‘inadequate’.

In the other four case studies (the ‘high-level’ sites), we will conduct 8-10 interviews at the ‘top’ of the organisation and with key external stakeholders (n=32-40 interviews in total).

Non-participant observations of meetings

We will observe board meetings and meetings of operational or medical directors with permission at the four ‘in-depth’ sites. We will use the board quality improvement maturity framework (Jones et al 2017) in our observations of boards and other relevant meetings. If granted access, we will focus on critical quality incidents or issues where progress in quality improvement appears ‘transparently observable’ (Pettigrew, 1990, p. 275). Thus, we might study a particular clinical unit that has been flagged as in need for improvement in earlier CQC inspections. Part of this study would entail finding out what information is being used to monitor the effectiveness of improvement interventions.

Documents

We will collect documents on the SMQ and challenge provider regimes produced centrally (e.g. by the DHSC or NHSI), as well as those developed by the sites to operationalise improvement efforts and recommendations from the regulator. For example, we will examine relevant meeting minutes (e.g. of board meetings and operational units) and strategic performance documents and business plans to help triangulate findings from interviews and observations.

Table 3. Summary of qualitative and quantitative data collection at in-depth vs high-level sites

<table>
<thead>
<tr>
<th>Qualitative Components</th>
<th>In-depth sites</th>
<th>High-level sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-participant observation</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>(e.g. board meetings, operational</td>
<td></td>
<td></td>
</tr>
<tr>
<td>meetings)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interviews</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Participants: from across different</td>
<td></td>
<td></td>
</tr>
<tr>
<td>organisational</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participants: from the top of the</td>
<td></td>
<td></td>
</tr>
<tr>
<td>organisation + key external stakeholders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Documentary analysis</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>---------------------</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td><strong>Quantitative Components</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trust use of quantitative information relating to quality of care</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Tracking of outcome measures against improvement actions</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Trust use of metrics to monitor impact of SMQ regime and challenged provider interventions</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Recruitment approach**

**Sites**

Senior leaders in local sites will be approached with information about the study asking them to participate. We will carry out telephone conversations (or site visits if required) to answer any questions about the study. If the site senior leaders decide to take part in the study, we will undergo local approval processes as necessary to access the site for data collection. We fully appreciate the need for developing a sensitive approach when handling this topic, both in relation to recruitment and fieldwork, since being placed in the SMQ regulatory regime may have a profound influence on staff at different levels. We will discuss our recruitment approach in advance with the DHSC and NHSI. We also acknowledge the fact that access to sites will be challenging and we might need to modify our sampling strategy accordingly.

**Interviews**

Potential participants will be approached in person or via email by the researcher to see if they would like to take part in the study. The researcher will provide them with a copy of an information sheet, which includes general information on the study, what participation will entail, and potential risks and benefits of taking part. The potential participant will then be given at least 48 hours to consider the information, contact the researcher/others with questions, and decide if they would like to take part in the interview. If the potential participant agrees to take part in the study, they will be asked to sign a consent form before any research activity takes place. Participants will be allowed to withdraw from the study at any time.

**Observations**
For the observations during meetings, permission will be obtained from the person chairing the meeting before the meeting begins. Information sheets will be circulated to all attendees prior to the meeting and will also be made available during the meeting. At the start of each meeting, the researcher will give a brief description of the evaluation aims, what participation entails, and the possibility of not being included in the observations. Verbal consent of the participants will be recorded by the researcher. If staff members do not agree to participate, any contributions they make to the meeting will be excluded from the researcher’s field notes, or the researcher will withdraw from the meeting if appropriate.

(ii) Quantitative analysis

This part of the study will link with the qualitative element to validate insights on quality of care. We will also use emerging qualitative findings on how trusts use data to make recommendations on the use of data to track quality improvements.

Analysing whether and how sampled trusts choose to track progress against required improvements could offer insight into whether trusts will be resilient to future challenges. For all of the case study sites, we will explore how they use or have used quantitative information relating to quality of care and the influence this might have on their improvement or otherwise. We will include in this analysis any relevant improvement actions highlighted by the qualitative interviews where the effects can be monitored with available data. For the four in-depth case study sites, this will be supplemented by combining the qualitative and quantitative components. For example, for a trust in SMQ, there may be some improvement actions for which it may be possible to track changes in related outcomes using information from trust board papers, published statistics, or patient-level records from Hospital Episode Statistics (HES). Where possible, we will compare these outcomes with those from other trusts that have not received a similar intervention in order to understand the impact of the intervention. For other improvement actions there may not be enough evidence of a change in outcomes. In this way, we can relate decisions to bring organisations out of SMQ with the way such data are used and interpreted. For challenged providers, some similar analysis may be possible depending on the metrics used to monitor the progress of these trusts.

Insights from the qualitative fieldwork may suggest pressures on some outcomes are related to outcomes for other providers in the local health system. Where feasible, we will attempt to investigate potential relationships between these outcomes.

Information on the metrics that trusts use to monitor the impact of SMQ and challenged provider regime interventions will be compiled from trust board papers for each case study site. The extent to which trusts monitor this information before, during, and after being in SMQ (or on the challenged providers list) will be reported. More in-depth study will be carried out at the four in depth sites where our analysis can be supplemented by information from site interviews. Please refer to Table 3 above for a summary of the quantitative data analysis.

(iii) Case study data analysis
Triangulation of interview, observational, documentary and quantitative data will produce eight local case studies that will be analysed thematically and comparatively, consistent with suggestions in academic literature on analysing processes of change in organisations (Pettigrew, 1999; Eisenhardt 1989; Buchanan et al. 2005; Nelson 2005) and on receptive contexts for sustaining quality improvement in health care (Fulop and Robert, 2014; Robert and Fulop, 2015) (See also Figure 1).

4. Exploratory workforce evaluation

This additional quantitative component will explore the relationships between workforce data and being in SMQ or on the challenged providers list. We will explore whether trusts find it more difficult to recruit and retain staff, or whether staff turnover increases after entering SMQ or the challenged provider list.

This will require trust-level workforce recruitment, retention, and turnover data from NHS Digital and information on vacancies and agency staff from NHSI. These data will be combined with trust inspection information from CQC, and details of the time spent in any quality regime. Additional trust information such as trust size, trust financial situation, whether a trust has teaching status, measures of underlying patient need, or rurality will be taken into account. This proposed analysis is exploratory and subject to construction of a consistent and comparable workforce dataset.

5. Economic analysis

The aim of the economic analysis is to quantify the costs and benefits of different combinations of interventions used in SMQ/challenged provider regimes from an NHS perspective, using a Cost-Consequence Analysis (CCA) approach. As described above, the 3 main interventions are:

1. Allocation of an external Improvement Director to direct culture change, quality and performance improvement locally;

2. Buddying / partnering with a higher performing trust;

3. Access to, and approval for, use of funds to support improvement (up to £200,000 for challenged providers and £500,000 for SMQ trusts).

A CCA is a form of economic evaluation comparing interventions in which the components of incremental costs (direct or indirect) and consequences (e.g., knowledge, behaviours, processes) are computed and listed, without aggregating these results into a cost-effectiveness ratio (Drummond, Sculpher, Claxton, Stoddart, & Torrance, 2015; Greenhalgh, 1997). This approach enables one to look into process measures and qualitative findings in a quantitative manner and compare them to the costs of interventions, allowing for some insight as to how potential benefits compare to the cost of interventions.

The feasibility study for the health economic analysis found that:
1. A CCA was feasible, but it would only be possible to evaluate different combinations of interventions, i.e., it would not be possible to evaluate the benefits of each intervention individually. It would need to take into account the likely variation in the type and intensity of these interventions, e.g., percentage of FTE time the Improvement Director spends at the trust, different buddying models, varying receipt of funds spent in different ways. We will explore the impact of this variation on both costs and consequences.

2. Costs could be measured using resource use and unit cost data collected during the multi-site mixed methods study.

3. Consequences could be measured using qualitative data collected during the multi-site mixed methods study.

**Measuring Costs**

Each intervention will be costed using data collected during the case studies. We will calculate the costs of appointing an external Improvement Director based on salary costs plus other costs incurred, accounting for whether and how these costs may be shared across different trusts. We will identify the activities that typically occur with different models of buddying (e.g., meetings, site visits, etc.), and calculate the costs of these different models, including costs incurred by both the trust in SMQ and the ‘buddy’ trust. We will obtain information on the funds received to support improvement (challenged providers may access up to £200,000, while SMQ trusts may access up to £500,000), and identify what these monies, when received, are spent on. For each intervention, we will also identify who incurs the costs associated with that intervention. We will also include other opportunity costs as perceived by recruited SMQ/challenged providers from an NHS perspective. This will be done by identifying other possible cost components associated with each intervention as part of the multi-site qualitative study.

**Measuring Consequences**

Based on the feasibility study, the CCA will be applied as follows. We will evaluate the consequences of different combinations of interventions, taking into account type/intensity, and compare these with their costs. The consequences will be measured using qualitative data collected during the multi-site mixed methods component.

Consequences for each intervention bundle will be derived from the case studies, drawing on qualitative findings and transforming them into a meaningful scale, to quantify relative impacts of the intervention bundles. This approach allows for emerging findings of the process evaluation to be understood as a relative impact, which can be balanced against costs.

The analysis will be further complicated by the fact that there will be between-trust variation in the type and intensity of the three main interventions, as indicated above; we will explore how consequences vary by this type and intensity.
Given that the measurement of both costs and consequences will depend on data collection from the case studies, the economic analysis will take place in two phases: 1) a cost analysis to take place in the initial months following access to selected NHS trusts and 2) a cost-consequence analysis following data collection in the case studies.

PATIENT AND PUBLIC INVOLVEMENT (PPI)

Two patient representatives have provided feedback on the protocol design and will provide ongoing review and feedback throughout the study (including dissemination). We have also presented the study topic to the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) North Thames Research Advisory Panel (RAP), composed of patient representatives and members of the public. The RAP will provide programme level involvement for the RSET throughout its work as distinct from individual evaluation-level and engagement activity. RAP feedback also informed the development of this protocol, and additional feedback will be requested throughout the duration of the study.

We have also devised a local involvement and engagement strategy where we will contact local patient groups, or individual key informers to obtain their views on the study. These contacts will be made once the site sample is defined.

ETHICAL ISSUES

The study protocol and study materials have been reviewed by our local R&D Office and UCL Ethics Committee and the study has been classified as a service evaluation, thus not requiring approval by a research ethics committee. As stated above, we are aware of the sensitive nature of this research for organisations and individuals. The research team has experience in conducting research on similar sensitive topics.

Information sheets will be provided to potential participants with information on the study (purpose, design, expectations, risks, benefits) before they are asked if they would like to take part in an interview or allow the researcher to shadow them. The information sheet will indicate that the researchers carrying out the study act independently, operate under a professional code of conduct, and are interested in all aspects of the SMQ and challenged providers regimes (both positive and negative). We will maintain the anonymity of the participating organisations and individuals.

We realise not all staff members will be comfortable with being observed and might think we are interfering with their work. We will ensure staff members are aware of the purpose and design of the study before the observations begin. We will give staff the opportunity of not having their activities recorded in our observations and assure them that the researcher has previous experience working with this method and will withdraw from situations where it is not appropriate for observations to be carried out.

PROJECT MANAGEMENT
This study will be led by Professor Naomi Fulop (UCL) and team members will comprise Cecilia Vindrola (UCL), Jean Ledger (UCL), Chris Sherlaw-Johnson (Nuffield Trust), Jonathan Spencer (Nuffield Trust), Estela Capelas Barbosa (UCL), and Steve Morris (UCL). The team will meet at least monthly throughout the duration of the project, and report on progress at monthly RSET meetings.

**INSURANCE**

University College London holds insurance against claims from participants for harm caused by their participation in this study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is a NHS Trust or otherwise.

**DATA MANAGEMENT**

**Data Transfer**

In the study, interview data will be collected from participants in accordance with the participant information sheets and the section on recruitment in this protocol. Interviews will be recorded on an encrypted, password-protected digital audio recorder to which only the researcher knows the password. These data will be taken directly by the researcher to the UCL Department of Applied Health Research (1-19 Torrington Place, University College London WC1E 7HB). There, the data will be anonymised and stored securely on a shared drive within a password-protected IT network, which can only be accessed by named members of the qualitative team. The data will be cleared from the digital audio recording device when it has been transferred. These data will be kept completely separate from other study data. Anonymised interview data will be organised by participant codes. Participant identifier codes will be stored in a password-protected file on a secure drive to which only named team members have access via password-protected computers at the UCL Department of Applied Health Research. Participant identifier codes will be stored separately from the anonymised interview transcripts.

The digital audio recordings of interviews will be appropriately sent to Essential Secretary via secure FTP system (http://www.essentialsecretary.co.uk/) for transcription. Digital audio recordings of interviews, the anonymised interview transcripts, data for the documentary analysis, and quantitative data will be stored for analysis on a secure drive to which only named team members have access via password-protected computers at the UCL Department of Applied Health Research.

All electronic data (except HES data) will be held on the UCL file servers, in shared or in personal folders. Access to data is granted after login with valid accounts and according to access permissions. The accounts are created centrally only for personnel registered at
UCL. The data can only be accessed through the Department of Applied Health Research secure server and only by identified UCL researchers.

HES data are held on a secure server based at the Nuffield Trust, which acts as the data controller for these data. The access and use of HES data for this project will be governed by a data sharing agreement with NHS Digital covering RSET work. Prof Naomi Fulop will act as the data controller of all non-HES data for this study. She will process, store and dispose data in accordance with all applicable legal and regulatory requirements, including the Data Protection Act 1998 and General Data Protection Regulation (GDPR) and any amendments thereto. Data will not be transferred to any party not identified in this protocol and are not to be processed and/or transferred other than in accordance with the participants’ consent.

Data Archiving

The participating site recognises that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The research team will store personal identifiable data up to one year after the study has ended. Participants will be informed of this storing requirement through the participant information sheet. The Chief Investigators confirm that they will archive the study master file at UCL for 10 years from the study end.

RISK AND RISK MANAGEMENT

The timeline proposed below is based on the following assumptions: 1) the team successfully negotiate access to organisations which have been/are in the SMQ regime or challenged providers list, 2) the team have timely access to the data required for the quantitative and economic analyses.

FUNDING

RSET is funded by the NIHR Health Services and Delivery Research (HS&DR) programme (HSDR 16/138/17).

QUALITY CONTROL

The study protocol has been reviewed by two independent experts in health care organisation and management - one from academia and one with knowledge of the SMQ regime and experience of NHS management. It has also been reviewed by representatives from NHSI, DHSC, the UCL/UCLH Joint Research Office, National Institute for Health Research (NIHR) and patient representatives. The final protocol will be approved by the funder (NIHR) and, once approved, be submitted for publication.

DISSEMINATION AND OUTPUTS

We will share feedback on a regular basis with the DHSC, NHSI, and participating sites. Formative feedback can include: (1) sharing our evolving understanding of the programme theory and suggested refinements; (2) providing ‘real-time’ insights on implementation of
interventions that are being used to enable organisational change and improvement and the data used to track improvement; and (3) analysing staff views and experiences with processes of change and improvement.

We will produce a final report to the NIHR HS&DR programme. Findings will also be shared through articles published in peer-reviewed journals and papers presented at academic and professional conferences. In addition, we propose to produce a number of more accessible outputs summarising our findings targeted at a range of audiences, including trusts, regulators, policy makers, and patient groups. The team will maintain the independence of the research.

We anticipate that we will be able to generate the following outputs based on the research findings:

1. Lessons for trusts on responding to interventions in SMQ/challenged providers regimes;
2. Lessons for the DHSC and NHSI on how to support challenged providers and those in the SMQ regime in light of the varied internal and external contexts of health care organisations facing performance difficulties;
3. Recommendations on the use of routine and quantitative data to track quality improvements, including at system level, and the potential costs and benefits of individual interventions of the SMQ regime.
4. An evaluation framework for the SMQ and challenged providers regimes.

**STUDY TIMELINE (dependent on access to study sites)**

- **December 2018**: Study set-up and obtain access to national participants and case study sites
- **December 2018 – March 2019**: Literature review
- **January 2019 – March 2019**: Cost analysis
- **January 2019 – August 2019**: Data collection at national level and for the multi-site mixed-methods component
- **January 2019 – August 2019**: Exploratory workforce component data collation and analysis
- **April 2019**: Sharing of emerging findings
- **July 2019**: Sharing of emerging findings
- **August 2019 – October 2019**: Cost consequence analysis (if feasible)
- **September – December 2019**: Final data analysis and drafting of final report
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Walshe K, Shortell SM. When things go wrong: how health care organizations deal with major failures. Health Affairs, 2004; 23(3), 103-111.


APPENDIX A

NHS Trusts Special Measures for Quality (SMQ) and Challenged Providers: A Provisional Typology of Trust Performance Trajectories over Time and Following NHSI Interventions

Version 1.4, 16th October 2018

Background

The Special Measures for Quality (SMQ) regime provides NHS trusts with increased support and oversight from NHS Improvement (NHSI) to help them address specific failings. There are also a number of trusts on a ‘watch list’ of challenged providers at risk of going into SMQ that receive support from NHSI. However, there is limited knowledge about what interventions are most effective and how much they cost, whether the current regime strikes the right balance between support and scrutiny, and how trusts can be made sufficiently resilient to avoid re-entering SMQ over time.

As part of our study’s scoping work, we have developed a provisional typology of trusts that have entered SMQ or been placed on the challenged providers list (Table 1) and plotted trust performance trajectories over time. The analysis includes all trusts that have entered SMQ or challenged providers regimes up to 30th September 2018.

Methodology

We examined the performance trajectories of 73 NHS Trusts using data available from the Care Quality Commission (CQC) and provided by NHSI. We conducted a time-sensitive analysis of NHS Trusts to identify trends and trust performance trajectories longitudinally - for the period 2013 to 2018 - in the context of CQC inspections and NHSI interventions. Our analysis provides a ‘snap shot’ of national performance and regulatory interventions (at the macro level) and assessments of quality at trust level (the meso level).

The following events were plotted over time:

- NHS Trusts identified by the Keogh review (n=14)
- NHS Trusts that have entered SMQ since 2013 (n=35)
- NHS Trusts that have entered Special Measures for Finance (SMF) (n=15)
- NHS Trusts have been on the challenged providers ‘watch list’ at some point since 2015 (n=44)
- NHS Trusts that have merged, or been in merger talks, and been in SMQ or challenged providers regimes (n=7).
- NHS Trusts that have been in SMQ or have been on the challenged providers ‘watch list’ but left by the end of 2016 and have a latest CQC rating of ‘good’ (n = 10)

Some trusts have merged or been in merger talks during this time period and this is factored into the analysis below. For example, a high performing trust in the CQC inspection may have merged with a low performer in the CQC inspection.
- NHS Trusts that have re-entered SMQ (n = 4)

A total of 73 trust performance trajectories for quality were plotted for the period 2013 – 2018 using data provided by the Department of Health and Social Care and NHSI, and data from the CQC website. The chart was created using R (version 3.5.0) and the package ggplot2 (version 3.0.0). From this we identified a number of performance patterns according to when each trust entered and exited the SMQ or challenged providers regimes. We then created a second plot displaying trust performance trajectories relative to the time that each trust entered SMQ or challenged providers list and received interventions. These charts are not included in this document to prevent premature identification of trusts designated as challenged providers.

Below we present trusts under different descriptive categories - according to their performance and entry and exit to the SMQ or challenged providers regimes (Table 2) and trust type (Table 3). The descriptive categories we focus on are: 1) trust performance outcomes (as determined by CQC inspection ratings); 2) time to enter and exit SMQ or challenged providers due to performance issues; 3) trust type; and 4) the type of regime entered into (SMQ or challenged providers list). A time-sensitive analysis reveals those trusts that have managed to exit SMQ or challenged providers regimes at 12 months and those have taken longer (24 months or more). Table 3 shows trusts according to the types of services they are commissioned to provide: acute, community, mental health or ambulance services. Many trusts feature in more than one descriptive category.

Results

59 NHS trusts have been in SMQ or on a list of challenged providers. 14 additional trusts have been included in the analysis for consistency and completeness: eight of these trusts have merged with a challenged provider or SMQ trust and six have been in SMF.

Table 1: Types of trusts entering SMQ or the Challenged Providers list

<table>
<thead>
<tr>
<th>Trust type</th>
<th>Total number of trusts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute services only</td>
<td>33</td>
</tr>
<tr>
<td>Acute and community</td>
<td>18</td>
</tr>
<tr>
<td>Acute and mental health</td>
<td>1</td>
</tr>
<tr>
<td>Ambulance</td>
<td>2</td>
</tr>
<tr>
<td>Community and mental health</td>
<td>1</td>
</tr>
<tr>
<td>Mental health</td>
<td>4</td>
</tr>
<tr>
<td>TOTAL</td>
<td>59</td>
</tr>
</tbody>
</table>

Table 2: Trust descriptive categories (performance and time in SMQ or challenged providers regimes)
<table>
<thead>
<tr>
<th>No.</th>
<th>Performance categories</th>
<th>Category description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>‘Keogh’ Trusts</td>
<td>This subset of 14 trusts includes those that were first identified as having quality of care and treatment issues by the Keogh Review. These trusts had higher than average death rates as measured by the Hospital Standardised Mortality Ratio (HSMR) or the summary hospital level mortality indicator (SHMI) in the two years prior to the Keogh Review (2011-2013). According to our data plot, 12 of these trusts were placed in SMQ in 2014. Of these, half had exited SMQ by 2015, although five displayed longer-term performance issues and either remained in SMQ up to 2017 or re-entered after exiting.</td>
</tr>
<tr>
<td>2</td>
<td>From Challenged Provider to SMQ</td>
<td>This subset of 15 trusts has been put on the challenged provider watch list since mid-2015. Later they received a ‘Requires Improvement’ or ‘Inadequate’ CQC inspection rating for quality and fully entered the SMQ regime. Three of these trusts have been in SMQ before. These trajectories suggest that the challenged providers regime could act as an early warning signal for trusts that are at risk of entering SMQ.</td>
</tr>
<tr>
<td>3</td>
<td>SMQ ‘inadequate’ alerts and entry</td>
<td>This subset of non-Keogh trusts received a CQC inspection report rating them as ‘Inadequate’ and then immediately entered the SMQ regime. This was in the period prior to the creation of the challenged providers list. The trusts later received an improved CQC rating and exited SMQ.</td>
</tr>
<tr>
<td>4</td>
<td>Challenged Providers</td>
<td>This subset of trusts is on the challenged providers watch list, or have only left it during 2018. They have not been in the SMQ regime previously. Many have been rated by CQC for quality as ‘Requires Improvement’. There are some outliers that have received an ‘Inadequate’ CQC quality rating and not entered the SMQ regime for local reasons.</td>
</tr>
<tr>
<td>5</td>
<td>SMQ to SMF</td>
<td>This subset of trusts has been in SMQ and then entered the SMF regime whilst being in SMQ.</td>
</tr>
<tr>
<td>6</td>
<td>Merged trusts (mixed quality performers)</td>
<td>A small group of trusts have merged or been in merger talks whilst being in the SMQ or challenged providers regimes. In some cases, a trust with a higher CQC inspection rating for quality has merged with a trust that has a lower quality rating.</td>
</tr>
<tr>
<td>7</td>
<td>Long-term improvers</td>
<td>This small subset of trusts has been in SMQ or on the challenged providers list previously but exited before the end of 2016 and have not re-entered. Their most recent CQC rating was ‘Good’.</td>
</tr>
<tr>
<td>8</td>
<td>Return to SMQ</td>
<td>This small subset of trusts has exited SMQ but then returned. Three of the four trusts were on the challenged provider list when they re-entered SMQ.</td>
</tr>
</tbody>
</table>
Table 3: Time in regime by type of trust

<table>
<thead>
<tr>
<th>Trust type</th>
<th>Special Measures for Quality</th>
<th>Challenged Providers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>In regime</td>
<td>Exit within 12 months</td>
</tr>
<tr>
<td>Acute services only</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Acute and community</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Acute and mental health</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Ambulance</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Community and mental health</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mental health</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

We observe that only a minority of trusts in the SMQ regime make improvements within 12 months and then receive a ‘Good’ CQC inspection rating, suggesting that quality improvement change takes longer for most trusts.
Figure 1: Number of trusts in each special measures regime.

Figure 1 shows the number of trusts in each regime over time. The number of trusts in SMQ has remained similar since SMQ was introduced in 2013. The sharp dip and increase in early 2017 is a possible indication that the number of trusts in SMQ is influenced by other policy, regulatory or quality improvement interventions. There has been a sharp increase in the number of trusts on the challenged providers list since late 2017. The number of providers in SMF has also increased over time, but this regime only began two years ago.
Figure 2: Average length of time in regime, including those that have not yet left, by year of entry

Figure 2 shows the average length of time in the regime for each regime, by year of entry. This shows that providers have typically spent longer in SMQ than they have on the challenged providers list. The figures for a given year will not be accurate until every trust that entered the regime that year has left.