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The Patient Safety Collaborative Evaluation Study (The PiSCES Study)

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The Patient Safety Collaborative Evaluation Study (The PiSCES Study)

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Executive Summary

The Patient Safety Collaborative Evaluation Study (The PiSCES Study)

Background

Having investigated avoidable deaths and other occurrences of harm to patients at Mid-Staffordshire Hospital, the Francis Inquiry made 290 recommendations for actions to reduce the likelihood of such events recurring. A prominent part of the government's response was to ask Don Berwick to chair a National Patient Safety Advisory Group to advise the government on a 'whole-system' Patient Safety Improvement Programme. The Group proposed establishing Patient Safety Collaboratives (PSC), drawing upon the experience of Quality Improvement Collaboratives, particularly the Institute of Healthcare Improvement (IHI) 'Breakthrough Series'. From 2014, Collaboratives in the NHS were implemented through the regional Academic Health Science Networks (AHSN).

Most research about the effects of Collaboratives has been uncontrolled and fragmented across a range of activities and target outcomes, often self-reported. Few studies report clearly how Collaboratives carried their work out, making it hard to identify what the 'active ingredient' is. Few contained evidence about the determinants of 'success' (as opposed to abundant hypotheses and conjectures). Neither is it known what kinds of clinical work (e.g. for which care groups) may be more amenable than others to improvement by PSC methods, although Collaboratives based hospitals have been most widely reported.

We evaluated how this action taken in response to the Francis Inquiry was implemented and some of the consequences, and used our findings as the evidence base to present some policy implications and further research proposals.

Research Questions (RQ)

This study addressed six research questions:

RQ1: How has PSC implementation varied across the 15 Academic Health Science Network (AHSN) regions?

RQ2: What organisational changes have providers made? How have they done this and what have they learned from the PSCs?

RQ3: How were resources used for PSCs' implementation activities? What are the costs of participation and implementation?

RQ4: Have the PSCs made a detectable difference on rates of harm and adverse events involving patients as measured using routine data?

RQ5: Has change in practice taken place on the front-line of services?

RQ6: What generalisable knowledge can be shared about this?

Methods

We made a mixed methods observational comparison of PSC mechanisms, contexts and outcomes. We combined three methods each of which broadly corresponded to one stage of PSC implementation:

1. An Implementation study of how PSCs were set up, of AHSN roles in establishing and maintaining regional networks, and of how provider-level NHS managers and clinicians used PSC-initiated ideas and resources to influence clinical practice, monitor and improve clinical quality and safety. Our study looked at all 15 PSCs, studied three of them in greater detail, and within them selected different types of provider for in-depth study.
2. Patient safety culture surveys. The Francis and Berwick reports emphasised strengthening safety culture as a method for making clinical practice safer. Using the Safety, Communication, Operational Reliability and Engagement (SCORE) survey, we measured changes in patient safety 'culture' in six clinical teams undertaking PSC-initiated activities. We also analysed NHS Staff Survey data.
3. Analysis of routine administrative data. To assess how much patient safety and outcomes had changed we quantitatively analysed routinely collected administrative data relevant to PSCs' intended outcomes.

Our data sources were 61 semi structured in-depth interviews of key informants: SCORE survey data from 72 sites (first round) and from the six of these sites which had also made a second-round (repeat) survey during the study period: and England-wide data on in-patient satisfaction, quality improvement, managerial support for staff, fairness and effectiveness of procedures for reporting errors, recommendation of one's own work-place, incident reporting and hospital mortality.

Findings

How PSC implementation varied across the 15 AHSNs (RQ1)

Each AHSN applied elements of three strategies for improving patient quality and safety at provider level:

- A facilitative strategy, which built where possible on existing QI and safety work in healthcare providers, but was constrained by the local history and resources – or lack of them – in these areas of work. A facilitative strategy made it harder to attribute any changes in working practices and outcomes unequivocally to PSC activities.
- An educative strategy of educating, training and developing individual 'change agents' to implement changed working practices to improve patient safety at clinic level.
- A national priority focussed strategy of adopting 'work-streams' from among the current national priorities, resulting in several PSCs developing similar work-streams (e.g. sepsis prevention).

There were tensions between the facilitative approach and the national priority focus, which some informants thought was closer to a performance management approach. In general, PSCs and NHS staff favoured shifting from a 'blame' culture to learning culture focused on service development as more conducive to activities to improve patient safety. Where SCORE surveys were used (which was increasingly, but from a small base), they were implemented the same way everywhere.

PSCs differed in terms of which elements and mechanisms of collaboratives they emphasised. Partly because the Francis report was a response to problems in hospital services, and because Collaboratives originated in (US) hospitals, participation was *proportionately* greater among acute hospitals than elsewhere, which partly reflected the technical challenges of making the

Collaborative model relevant to non-hospital services. General practices apart, the only non-NHS providers participating were some care homes and pharmacies.

Organisational changes that providers made and what they have learned from the PSCs (RQ2)

Not all provider organisations participated in the PSCs. The willingness of NHS senior managers to engage with PSCs varied across setting. When they were willing, organisational upheaval including leadership changes made trusts' engagement harder to sustain.

In providers that did participate, the main organisational factors reported to aid PSC implementation were:

- Initial expenditure for start-up training and preparing management information systems to serve (also) as a measurement system for clinical teams' QI work
- Recruiting trained QI and safety experts or 'champions' at all organisational levels, most critically at Board and clinical team levels; this was often done with PSC support and encouragement.
- Ensuring that these champions had the leadership skills to motivate and empower clinical teams and to create safe spaces for staff to speak up or suggest changes.
- Building structures and processes, at both whole-organisation and at clinical team levels, to sustain the changed working practices.
- Allocating staff time not only to engage in QI and learning events, but so that they can subsequently utilise their learning at work.
- 'Bottom-up' approaches to safety improvement promoted provider-level engagement and motivation by adapting the activities that PSCs were promoting to local needs.
- Measurement support for front-line staff

At the time of this study, the development and use of formal measurement systems to support QI activities had not yet materialised. The other change we had expected but did not observe was in safety climate, particularly at clinical team level. Although PSC activity, including the SCORE surveys, had impacts upon clinical teams' working practices in the sites we studied (see below)

these changes occurred without measurable changes in workplace safety climate. In summary, we found:

1. Some qualitative evidence of safety climate change in the intended direction, including increased staff engagement and shifts away from a blame culture towards a more ‘open learning culture’.
2. No significant change safety climate in six study sites by early 2018 on most of the SCORE survey domains.
3. Change in the intended direction in the relevant NHS staff survey data domains, but evidence that this change began before PSCs existed.

To suggest that any safety culture changes in particular clinical teams are diluted within much larger NHS Digital data-sets might be valid for the NHS Staff Survey but is not applicable for the SCORE survey results, which were precisely localised to the relevant clinical teams. A possible explanation is that safety climate changes are as much a consequence as a cause of changes in working practices, in a virtuous circle of mutual reinforcement.

Organisational changes do not occur straight away; sufficient time is required to implement a complex set of activities across all levels of the NHS:

1. At least 18 months for PSCs and then providers to establish themselves and start to change working practices. In practice this can take a lot longer before any impact is seen at the patient level.
2. Allowing individual staff members time at work to attend learning events and then put what they learnt into practice.
3. Continuing the PSCs long enough to engage ‘late adopters’ besides ‘early adopters’.
4. Time for plan-do-study-act (PDSA) cycles and other QI activities be repeated and become institutionalised on an open-ended time-scale.

Other major constraints surrounding the activities of PSCs we found were NHS providers’ concurrent operational pressures and the concomitant resource and financial constraints, staff shortages and turnover. At an individual level the barriers included difficulties utilising expertise post training due to factors including a performance culture (i.e. conflicting priorities in the work-

place), lack of time, high staff turnover (including shift rotations and moves between work locations), and psychological resistance to change.

Costs of participation in and implementation of PSCs (RQ3)

One of our study PSCs provided broad information how spending on PSCs had been allocated at AHSN level (to which programmes, and to broad categories such as support staff, training etc.). At the time of our fieldwork detailed information to account for; the training and network activity the PSCs provided, monetary flows from PSCs to providers, as well as indirect opportunity costs the provider organisations incurred was not completely available. The same applied to information about how these extra resources impacted on health benefits for the patients due to changes in working practices noted below, making it unfeasible to evaluate the cost effectiveness of the PSC programme.

Have the PSCs made a detectable difference to rates of harm and adverse events involving patients as measured using routine data? (RQ4)

We analysed routine administrative data about relevant safety outcomes and found that:

1. Qualitative evidence of changed working practices which one would expect (given *their* supporting evidence) to improve patient safety and service quality.
2. Quantitative analysis of administrative data showed no significant change by early 2018 that could plausibly be attributed to PSCs alone.
3. Longer-term changes in the intended direction were occurring.

In our judgement the reasons for these paradoxical patterns are:

1. Dilution of any effects of PSCs upon service outcomes because the available datasets combine data about activities in which PSCs were involved with data about much larger activities in which PSCs were not yet involved, such as trust-level data.
2. PSCs' effects were constrained by countervailing factors: demand overloads, insufficient staffing relative to demand, staff turnover and financial constraints.

3. Time lags: when our fieldwork finished PSCs were about half-way through their initially-planned life-span and had spent much of it getting their activities started. This meant the period for which routine data could have captured any relevant effects was a year or less.

We infer that PSC activity had many of its intended effects but they were too localised and diluted to be measurable in the larger-scale routinely-reported administrative datasets.

Change in practice on the front-line of services (RQ5)

In our case study sites we found evidence of changes in practice at front-line, clinical team level. In practice the participating clinical teams had become more *multidisciplinary*. They had also started to undertake what in effect was the Model for Improvement: collecting information about their working practices, changing the latter, reviewing the effects, then making further adjustments: the quality improvement cycle. The SCORE survey, and its practical impacts, can be understood as a special case of such activity, and one with a relatively quick impact upon working practices.

SCORE surveys developed beyond measurement activity into a practical intervention on the part of PSCs. Changes in working practices were both clinical (e.g. falls reduction) and organisational (e.g. pathway re-design) and were reported in both hospitals and general practices.

Conclusions: Policy and management implications

The findings summarised above tend to support some of the policy-makers' original assumptions about how PSCs would work but suggests revisions to other policy assumptions that would lead to more effective PSCs and thus safer care for patients:-

1. PSCs have not yet had sufficient time to establish and sustain the clinical team-level safety improvement activities and outcomes that current policy intends. Our evidence suggests three years from the outset is in practice too short a time for that. In our opinion (albeit an opinion consistent with our findings so far) PSCs should continue in their current form for longer before any judgement can be meaningfully made about their impact on patients.
2. The PSCs are complex adaptive systems, reacting and responding to different local situations in varied ways. Attempts to manage PSCs uniformly and force them into particular directions (including work streams) are likely to hamper their ability to promote the locally-originating work that will ultimately lead to better patient care. In our opinion

NHSI should study the emergent systems, support positive behaviours and resist the temptation to apply a 'one size fits all' managerial approach.

3. NHSI and the Department of Health need to provide clear and supportive timelines and financial arrangements for the PSCs. One disruptive aspect of the implementation of the PSCs was the lack of clear direction from the central NHS bodies, partly due to the perceived chaos surrounding the change from NHSE to NHSI, and to the financial uncertainty that PSC leads felt. At the time of writing there are suggestions that NHSI should review the PSCs. In our opinion it is too soon for that and it will again create an impeding uncertainty.
4. Recognition of the influence of the wider evidence-based medicine (EBM) movement and institutions (e.g. NICE) in promoting safety culture, something PSCs' activity reinforced and exploited. However development of EBM is uneven (for example, it is better developed in general medicine than mental health). Start-up support for Collaboratives may be especially important in domains where EBM remains less developed and embedded.
5. Culture change is too big for PSCs alone to achieve without a massive increase in their scale. Learning by clinical teams is a discrete step linking culture change to changed working practices and this has implications for the kind of training required. The necessary kernels for this training are quality improvement methodologies and the psychology of change ('human factors'). As PSCs have shown, clinical teams are the critical audience for this training.
6. If providers are to become 'learning organisations' for PSC purposes the requirements include: a 'bottom-up' approach to safety management; that provider managers allow clinical teams discretion to adapt QI activities to their local needs; that clinical teams are allowed to take ownership of a given project or changes in work processes, something our evidence suggests also promotes staff engagement and motivation. This is a different approach from the work-stream specific collaboratives; mandating clinical teams to work on areas they have not chosen will probably not have as effective outcomes for patient care.
7. NHSI is now addressing the absence of cross-provider measurement systems for PSC purposes (for clinical teams across different providers to compare activities and learn from each other). Caution will be needed in how these cross-provider data are used. The focus has to be on data for improvement; if the data are used for performance management (or even perceived as such) the benefits of the collaborative approach will diminish.

Abbreviations and acronyms used in the report

A&E	Accident and Emergency (department)
AHSN	Academic Health Science Network
AHRQ	Agency for Healthcare Research and Quality (USA)
AKI	Acute Kidney Injury
ALoS	Average Length of Stay
AMI	Acute Myocardial Infarction
BMJ	<i>British Medical Journal</i>
BTS	Breakthrough Series (collaborative)
CABG	Coronary Artery By-pass Graft
CCG	Clinical Commissioning Group
CI	Confidence Interval
CLABSI	Central Line-Associated Bloodstream Infection
C-M-O	Context-Mechanism-Outcome (configuration)
CQC	Care Quality Commission
CQUIN	Commissioning for Quality and Innovation (framework)
CVC-BSI	Central Venous Catheter Blood-Stream Infection
CVD	Cardiovascular Disease
DH	Department of Health (England)
EBM	Evidence-Based Medicine
ED	Emergency Department
GMC	General Medical Council
GP	General Practitioner [medical]

HED	Health Evaluation Data (database)
HIV	Human Immunosuppressive Virus
HRG	Health Resource Group (variant of the Diagnostic Related Group payment system)
HSMR	Hospital Standardised Mortality Ratio
ICD10	International Classification of Diseases, 10 th revision.
ICSI	Institute for Clinical Systems Improvement
ICU	Intensive Care Unit
IHI	Institute for Healthcare Improvement
MAU	Medical Assessment Unit
NHSE	NHS England
NHSI	NHS Improvement
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NPSA	National Patient Safety Agency
PenCLAHRC	NIHR Collaboration for Leadership in Applied Health Research and Care South West Peninsula
PDCS	Plan-Do-Check-Study (cycle)
PDSA	Plan-Do-Study-Act (cycle)
PPI	Patient and Public Involvement
PSC	Patient Safety Collaborative
QI	Quality Improvement
QIC	Quality Improvement Collaborative
QOF	Quality and Outcomes Framework (in GPs' contract with the NHS)
RQ	Research Question
RAMR	Risk-Adjusted Mortality Ratio
RSMR	Risk-Standardised Mortality Rate

SAQ	Safety Attitude Questionnaire
SBAR	Situation, Background, Assessment and Recommendation (communications model)
SCOPE- PC	Systematic culture inquiry on patient safety – Primary Care [in Dutch].
SCORE	Safety, Communication, Operational Reliability and Engagement (survey)
SD	Standard Deviation
SHMI	Summary Hospital-level Mortality Indicator
SMR	Standardised Mortality Ratio
SPC	Statistical Process Control
SQUIRE	Standards for QUality Improvement Reporting Excellence
SSI	Surgical Site Infection
TDA	Trust Development Authority
TQM	Total Quality Management
UTI	Urinary Tract Infection
VTE	Venous Thromboembolism
WHO	World Health Organisation
WHOSCC	World Health Organisation Safe Childbirth Checklist

The Patient Safety Collaborative Evaluation Study (The PiSCES Study)

Chapter 1: Study aims and research questions

Having investigated a series of avoidable deaths and other occurrences of avoidable harm to patients at Mid-Staffordshire Hospital, the Francis Inquiry¹ recommended 290 actions to reduce the likelihood of such events recurring. The creation of Patient Safety Collaboratives (PSC) was prominent in the government's response, and elaborated in the subsequent policy and guidance statements. For this report we evaluated how this action taken in response to the Francis Enquiry was implemented, assessed some of the consequences, and used our findings as the evidence base to present some policy implications.

In part tacitly, NHS policies have assumed that PSCs will work through a specific complex of mechanisms, outlined in Chapter 2. Existing research into PSCs and equivalent collaboratives (see Chapter 3) still contains gaps and ambiguities about whether or how these mechanisms work, and in what contexts, making it hard to predict from existing studies alone what PSCs in the NHS are likely to achieve. In many studies, their 'black box' (associational, correlational) research design leaves unclear what links the establishment of a collaborative and any ensuing change towards safer working practices, and what contexts are required. Taken together, the ambiguities among these findings suggest unrecognised contexts at work, in effect under-defining the mechanisms that were being tested and/or conflation of different types of collaboratives. Furthermore, policy regarding PSCs is likely to be differently interpreted and operationalised by different agents², who will in effect be implementing somewhat different variants of PSC i.e. different interventions.

1.a. Aims

This report summarises the findings of one of five research projects in the overall evaluation of the impact of the government's response to the Francis Report. Our aim in this project was to evaluate the PSCs' work, paying attention to variations in PSC activity, processes and outcomes, in order to produce findings relevant to policy formation, to the ongoing management of the Patient Safety Collaboratives, and to the design and implementation of future improvement efforts. We particularly wanted to examine the mechanisms that PSCs have put in place to achieve their goals. It would be hard to exaggerate how important an issue patient safety is in the NHS and for patients themselves. The National Patient Safety Agency (NPSA) estimated that 300,000 people a year are harmed by

medical error and 30,000 ultimately die from these mistakes: a higher number than the combined annual mortality from breast, prostate and colorectal cancer.³ Other studies have produced even higher estimates, e.g. that up to one in three hospitalised patients experience an adverse event⁴. In 6% of cases the adverse event is severe enough to prolong hospital stay and send the affected patient home with a permanent or temporary disability.^{4,5} The serious consequences added to the large scale, and international recurrence of the problems that Francis and related policy documents reported and tried to address confirm the continued international relevance of research on collaboratives.

1.b. Research questions

Reflecting both NHS policy priorities and some of the research gaps in the existing research on Collaboratives, this study addressed the following research questions:

RQ1: How has PSC implementation varied across the 15 Academic Health Science Network (AHSN) regions?

RQ2: What organisational changes have providers made? How have they done this and what have they learned from the PSCs?

RQ3: How were resources used for PSCs' implementation activities? What are the costs of participation and implementation?

RQ4: Have the PSCs made a detectable difference on rates of harm and adverse events involving patients as measured using routine data?

RQ5: Has change in practice taken place on the front-line of services?

RQ6: What generalisable knowledge can be shared about this?

In these questions we take terms such as 'made' in a realist sense, as referring to 'mechanisms' of action. By 'mechanism' we mean 'individuals' reasoning, action and use of resources', including those whose operation and effects may be hidden from immediate observation⁶ and must therefore be inferred. By 'outcomes' we mean the empirical effects of these mechanisms, intended or otherwise (including for example emergent outcomes and 'side-effects'). We conceptualise the outcome of mechanism A in terms of whether mechanism A helped produce outcome B, where

‘help’ means that the mechanism promoted or increased B, but without claiming that A was the *only* reason why B changed. So in this study we examine what PSCs contributed to the development, activities and outcomes of QI activities generally, both pre-existing and newly initiated by the PSCs. By ‘context’ we mean ‘a moderator, not causally dependent on the mechanism, which is either necessary for the mechanism to produce the outcome, or which intensifies the outcome that the mechanism produces’. Thus contexts do not include intermediate outcomes (mediators), but they do include barriers and facilitators to a mechanism’s work (RQ4). For all practical research purposes, ‘safety culture’ is defined by scores on safety culture surveys.

Chapter 2: Policy background and assumptions

The Francis report did not mention Patient Safety Collaboratives by name. Part of the UK government's response to it was to ask Don Berwick to chair a National Patient Safety Advisory Group to advise the government on a 'whole-system' Patient Safety Improvement Programme for achieving 'zero-harm' to NHS patients. It was this group which proposed establishing PSCs⁷, apparently drawing upon three main prototypes.

1. Quality Improvement Collaboratives (QIC), which originated in the Northern New England Cardiovascular Disease Study Group (1986). Subsequent examples have been reported in Australia, Canada⁸, France⁹, the Netherlands¹⁰, Norway, Russia, Sweden, the UK and the USA, Peru and several African countries.¹¹
2. The Institute for Clinical Systems Improvement (ICSI) approach which concentrates on developing guidelines and promoting culture change across most of the providers in a region¹² more resembles the Wisconsin Collaborative¹³ or indeed the NHS clinical and professional networks of the 2000s.^{14,15}
3. The Vermont Oxford Network ('data-driven') model, centred on a database, periodically reporting mortality, morbidity and patterns of medical practice in each of its member-organisations.¹⁶ The Institute of Healthcare Improvement (IHI) 'Breakthrough Series' (BTS) Quality Improvement Collaboratives were an elaboration of the Vermont Oxford approach.¹⁷

Previous collaboratives have thus used different improvement methods to effect the different aspects of healthcare quality; safety, timeliness of care, efficiency, effectiveness, equity and delivering patient centred care. However the BTS form of Collaborative appears to have had the strongest influence on the development of PSCs. The founders of the IHI developed the BTS Model for Improvement from previous work in other industries such as car manufacturing. The Model for Improvement consists of three questions; what is the aim the project is addressing, how do you measure the system's performance and what changes can be made (e.g. through the Plan-Do-Study-Act (PDSA) cycle). Although not specifically stated at the outset this method was implicitly assumed to be the one the PSCs would primarily use. We therefore have drawn on the North American models to interpret the NHS policy documents where the latter were silent or ambiguous about how PSCs were to work.

The government's response also built upon earlier work by the National Patient Safety Agency (NPSA), the NHS Commissioning Board and Health Foundation's 'Safer Patients' collaborative

which was initiated in 2004, based on a 'change agent' model, and extended in 2008. As early as 2004 the NPSA devised an Incident Decision Tree for differentiating culpable safety failures from system failures.¹⁸ Certain previous lapses in patient safety had also generated their own public inquiries: those regarding breast cancer screening at Exeter¹⁹ and those which led to the Shipman²⁰, Ledward²¹, Bristol Royal Infirmary²² and Alder Hey²³ inquiries. An attempt to replicate the Michigan project copied its approach to training and networked team working, but was centrally-not clinician-led.²⁴ The PSCs were launched in October 2014 as a national programme expected to last at least five years to support individuals, teams and organisations to build the necessary skills and knowledge to enhance patient safety and quality improvement and thus reduce the numbers of avoidable harm cases across England. With an estimated budget of £12 million per annum, of which some was retained for management and measurement at national level leaving £7m for the regional coordinating bodies, the PSCs were to be organised and delivered regionally by 15 Academic Health Science Networks (AHSN) in order to respond to local variation and need. In 2016 NHS Improvement (NHSI) mandated another national set of Collaboratives specifically for maternity services.²⁵

2.a. PSCs as mechanisms for reducing errors and system failures

The overall objective of PSCs was to 'spread best practice, build skills and capabilities in patient safety and improvement science, and to focus on actions that can make the biggest difference to patients in every part of the country [...] to tackle the leading causes of harm to patients'⁷, ¶12. The UK government intended that by 2020 NHS England would create a comprehensive, effective, and sustainable improvement system to 'deliver' a culture of continual learning and improvement in patient safety, 'notably in cancer, heart disease and stroke'.⁷ More specifically, PSCs were to focus on the issues indicated on the Patient Safety 'Wall of Priorities'. Three main policy documents (The Berwick and Keogh reports, and *Hard Truths*) elaborated these ideas.

Don Berwick's report²⁶ made the case for a PSC-based approach. In it he distinguished three main causes of the problems reported at Mid-Staffordshire Hospital and Winterbourne View:

1. Failures in organisational and work-routine systems
2. Human error.
3. Neglect or wilful misconduct – a rare event.

PSCs could address the first two problems. The third would typically have to be addressed by means of sanctions and was therefore outside the possible remit of a PSC. However managers should not usually apply sanctions in response to errors made in good faith.

'While "Zero Harm" is a bold and worthy aspiration, the scientifically correct goal is "continual reduction". All in the NHS should understand that safety is a continually emerging property, and that the battle for safety is never "won"; rather, it is always in progress.¹²⁶

Keogh similarly argued that:

'Understanding the causes of high mortality is not usually about finding a rogue surgeon or problems in a single surgical speciality. It is more likely to be found in the combination of problems that to a differing extent are experienced by all hospitals in the NHS: busy A&E [accident and emergency] departments and wards, the treatment of the elderly in and out of hospital, and the need to recruit and retain excellent staff. Such issues are complex and require a 'whole system' approach to deal with them'²⁷, p.17.

The Keogh report's 'ambitions' focused upon improving and widening the measurement of service quality and safety, and on improving staffing and staff skills relevant to patient safety.

The Department of Health's official response *Hard Truths*⁷ recommended:

1. Preventing such problems by creating an open culture responsive to staff with sufficient 'psychological safety'²⁸ to enable staff and patient feedback.
2. Detecting and dealing with problems quickly by
 - (a) improving information sharing and
 - (b) implementing new inspection regime (an addition to Berwick's proposals).
3. Taking action quickly to ensure quality and safety are maintained.
4. Clarifying accountability (another addition to Berwick's proposals).
5. Ensuring staff are properly trained and motivated to perform their roles.

Therefore NHS policy implicitly took PSCs as involving networked implementation of measures to increase patient safety, through networks centred on AHSNs as the main coordinating body. These

networks were to promote 'learning organisation' methods of 'quick action' for changing working practices through PDSA (also known as Plan-Do-Check-Study (PDCS)²⁹) cycles³⁰, and strengthening staff training and motivation in regard to patient safety. Across primary, community, mental health, acute and 'other sectors' PSCs were to 'use evidence based improvement methodologies', focusing on those with the biggest impacts on patients.⁷

2.b. Components, activities, structures

2.b.i. *Networked implementation*

Since the 1990s UK governments have often used networked structures as the vehicles for the implementation of such policies as managing clinical quality^{31,32} and promoting evidence-based practice. A networked approach avoids the appearance, and to a certain extent the reality, of public bodies directly managing clinical practice. It preserves a *collective* form of clinical autonomy for the medical and other clinical professions. However, putting in place 'centred' networks with an accountable 'network administrative organisation'³³ maintains an element of the public accountability and control that is foundational to the NHS. A more recently realised advantage is that networked approaches are, unlike direct line-management, compatible with the otherwise unconnected policy of 'diversifying' the sources and ownership of NHS-funded healthcare providers.³⁴ The rest of this section describes the characteristics of the PSCs that have been emphasized in this approach to their implementation.

2.b.ii. *A coordinating body*

NHS England (NHSE) was initially designated as the body responsible at national level for coordinating and monitoring PSCs. NHSE nominated and set the main priorities for the Patient Safety Collaboratives to work on, keeping responsibility for professional education and assigning the Care Quality Commission (CQC) responsibility for patient information. Other national bodies, including NICE, remained responsible for developing and promulgating safe, high-quality evidence-based practice. Subsequently national-level responsibility for the Collaboratives transferred from NHSE to NHS Improvement (NHSI). The transfer took over a year to complete and during this period inertia and uncertainty affected ongoing programmes including the PSCs.

Since then the coordination of the PSCs has been the joint responsibility of the PSC leads with a nominated director of an AHSN, with NHSI representatives who report to the board of NHSI board.

At regional or sub-regional level each PSC has a coordinating body whose members typically included an organiser ('lead', director), facilitators, subject experts, change experts, and quality improvement experts. The role of this coordinating body includes:

1. Team building, avoiding didactic teaching in favour of time spent comparing and learning local applications of ideas, so as to reinforce teams' motivation and self-confidence.
2. Providing support from national experts in patient safety, improvement science and 'large scale change'.⁷
3. On-site support (e.g. by visiting facilitators, email, conference calls).

The intention implicit in NHS policy was thus that PSCs

1. Engage local providers and experts in patient safety improvement work, in order to design jointly an innovative approach to large scale change, and
2. build on existing national and regional initiatives in patient safety and upon improvement collaboratives that have had an impact in other clinical areas.⁷

This means a PSC's coordinating body has to manage knowledge diffusion between its member-organisations, not just within the coordinating body itself.

To implement this approach in the NHS, PSCs were established at a regional level as 'centred' networks with AHSNs as the networks' hosts, i.e. their coordinating and managing body, accountable to higher-level NHS bodies. The AHSNs were to provide for each PSC its coordinating infrastructure (staffing, budgets, IT, premises etc.), undertake measurement and monitoring of the PSC as a whole (see below); provide training, organisational and practical support for the provider-level teams; provide a venue for mutual monitoring and reporting back of their PSC's focal activities and corresponding outcomes, within each provider level team and that team's 'home' organisation; and recruit provider organisations to the PSCs, in particular the priority-relevant departments and teams in the main provider organisations in their region. Together the Collaboratives, participating clinical teams and the clinical teams' 'home' provider organisations

were to agree which safety priorities to address. The PSCs were also to help their member-organisations become learning organisations in respect of patient safety. AHSNs administered their PSCs in different ways. Some had the PSC as a separate entity with a specific lead and budget whereas others incorporated the PSC and its associated funding within existing AHSN activity.

2.b.iii. A specified focus

During the set up phase the PSCs were allowed to develop as the regional teams saw fit. Some teams selected specific areas of activity from the ‘wall of priorities’. Others did not focus on specific conditions and let the provider organisations choose their activities, which the PSC then supported in a variety of ways. The wall of priorities were disparate and ranged through preventing specific conditions (e.g. venous thromboembolism (VTE), pressure ulcers) to services for large populations (e.g. ‘People with Mental Health Needs’, ‘Children’) to inter-organisational care coordination (‘Handover and Discharge’, ‘Transition between paediatric and adult care’). By the end of 2017 the priorities had been narrowed to three main themes (‘work streams’): maternity care; care of the deteriorating patient; and safety culture. This represented a significant shift in the priorities for the PSCs, from mostly local autonomy to a more central control. 35% of PSC funding was attached to national and 65% to local priorities.

2.b.iv. Transparency, monitoring, measurement and targets

The Francis report recommended that each NHS organisation should publish, at least annually, a report on its progress in achieving its planned actions. The Department of Health (DH) should also publish a report, at least annually, collating information about the decisions, actions and progress reported by other NHS organisations and the House of Commons Select Committee on Health should incorporate progress on implementation as part of its standard reviewing of organisations. Berwick himself recommended that the NHS ‘Use quantitative targets with caution. ... narrowly’.²⁶ but *Hard Truths* stated that PSCs’ reporting, transparency and monitoring (but not yet ‘targets’) work would mean:

‘Building on the experience of previous improvement programmes there will be a focus on measurement from the outset to ensure that organisations are able to track safety incidents over time as well as testing some innovative measures of safety culture and teams’⁷, ¶1.45.

The measures in question were to include ‘readily available’ comparisons (across providers) of data about safety of care and care outcomes; and the measurement of quality and patient safety and the skills for engaging patients actively. Specifically, the CQC and NHSE would increase the data about safety and quality available to patients, including data on staffing, pressure ulcers, healthcare associated infections and ‘other key indicators, where appropriate at ward level’.⁷ In line with the NHS Outcomes Framework the priorities for measurement were maternity, medication errors and deterioration in children. Additional priorities were (as avoidable sources of severe harm) missed and delayed diagnosis, deterioration of patients, medical device errors and sepsis; and (as vulnerable groups) offenders, acutely ill older people, and patient transitioning from paediatric to adult care.

The corresponding practical steps were to set up a national ‘measurement unit’; to promote understanding and use of measurement for these purposes; to develop measurement tools, databases and an (unspecified) ‘infrastructure’; and to ensure that methods, tools and infrastructures were clearly stipulated, communicated and used. The Francis report also recommended reinstating NHS England’s patient safety alerts to hospitals and the NHS Safety Thermometer. From 2012 NHS providers were paid a small bonus, through the Commissioning for Quality and Innovation Scheme (CQuInS) for collecting data on pressure ulcers, falls, catheter and urine infections, and venous thromboembolism.³⁵ The Patient Safety Collaborative Logic Model³⁶ specified four sequential components through which the measurement aspect would be realised:

1. Set up a measurement unit.
2. Promote understanding and use of measurement.
3. Develop measures and databases.
4. Communicate and use the measures.

Policy makers assumed an improved understanding and use of measurement would stimulate a local review of the underlying problems that caused unstable or deteriorating measures,³⁵ and that this would reduce variability in safety practices across the health and care system; and promote the implementation of larger scale, sustainable, measurable (quality and safety) improvement.

After 2014 the policy emphasis shifted more towards a performance management-like approach. NHS England’s Patient Safety Team published the NHS Serious Incident Framework (2010: revised

2013, 2015) and in 2015 NHSE published a list of National Clinical Audits and Clinical Outcome Review programmes for NHS trusts to include in their Quality Accounts for 2016-17. Hospital, community and mental health trusts were given a statutory ‘Duty of Candour’ that included informing and apologising to patients for any significantly harmful mistakes in care but this accountability appeared hard to balance with the ‘safe space’ policy of allowing blame-free recognition and correction of *bona fide* mistakes.³⁷ At the time of writing (March 2018), the General Medical Council (GMC) appeared to have prioritised candour over ‘safe spaces’ by taking legal action (including an appeal to the High Court) to have a paediatric registrar removed from the Medical Register following her involvement in the accidental death of a patient that occurred in part due to systemic organisational failures.³⁸

More concretely the Keogh Report into 14 NHS hospital trusts with consistently high hospital standardised mortality ratios (HSMR) and/or Summary Hospital Morality Indicator (SHMI) rates, especially for emergency (rather than planned) care, discounted environmental explanations for their safety levels:

‘Factors that might have been expected – and are frequently claimed - to impact on high mortality, such as access to funding and the poor health of the local population, were not found to be statistically-correlated with the results of these trusts. The average for the 14 trusts [with highest HSMR] is broadly the same as the England average in terms of funding and the socio-economic make-up of the populations they serve’²⁷, p.16.

Keogh therefore used multidisciplinary teams to make a ‘rapid responsive review’ of each such trust, followed by a ‘risk summit’ of ‘all involved statutory parties ... to agree with each trust a coordinated plan of action’²⁷, p.4.

Any network aiming to influence quality and safety of care has, by some means, to have an impact upon and within each of its member-organisations. The individual(s) who represent each member-organisation within the network have to transmit its policies into the 'hinterlands' of their 'home' organisation.¹⁵ One thing that PSCs added to earlier professional and clinical networks was that they involved not only individuals but whole clinical teams, who meet regularly and between meetings exchange ideas informally. In the BTS model, organisations work together for 9-12 months, and participants having at least two meetings, each lasting two days, to:

1. Form an initial understanding of what changes they regard as crucial for their chosen focal project(s).
2. Assess progress towards implementing these changes, sharing key findings about the outcomes
3. Learn and disseminate practical lessons about the above.

The participants would report their provider-level changes and results to each other, share experiences, and plan how to spread their innovations to other services.

2.c. Healthcare providers as learning organisations

More generally, PSCs were expected to influence working practices in their member-organisations by helping the latter develop into 'learning organisations'.

*'The most important single change in the NHS in response to this [Francis] report would be for it to become, more than ever before, a system devoted to continual learning and improvement of patient care, top to bottom and end to end.'*²⁶ (original emphasis).

The NHS was 'to become, in other words, the world's largest learning organisation'.³⁹ Implicitly each PSC was intended both to act as a 'learning organisation' itself and to stimulate its member-organisations to do the same.

In the BTS model the participants meet repeatedly to learn quality improvement methods (typically from clinical experts and experts in quality improvement methods³), about practical changes made elsewhere, and about the evidence for resulting improvements. Methods for promoting team learning (and safety culture generally) include leadership walkabouts, multi-disciplinary collaboration, front-line engagement in development cycles, data-driven improvement, protocols for improved hospital communication (e.g. the Situation, Background, Assessment and Recommendation (SBAR) model) and safety-specific communication (e.g., theatre safety briefings, safety huddles).⁴⁰

According to the Patient Safety Collaborative Logic Model³⁶ similar things will occur through the AHSN and a PSC's other member-organisations sequentially:

1. Developing, disseminating and using relevant evidence.
2. Developing relationships with ‘stakeholders’ (whether this means between the member-organisations, within each member-organisation, or both is unstated).
3. Establishing communication and messaging (same proviso).
4. Prioritising (i.e. selection of PSC focus: see above).
5. Establishing effective networks and ‘cluster groups’ (i.e. groups clustered around each focal activity).
6. Establishing an effective communication strategy.

The same source says that ‘local’ (implicitly, provider-level) ‘capability building’ will occur through developing local capability in implementing and spreading patient safety activities, and providing requisite training and ‘tools’. As a result providers will develop the capacity to measure, investigate and improve patient safety.

Learning organisations typically combine learning at three levels: the whole organisation, the work (in healthcare, clinical) team, and individual levels. For PSCs, current policy characterises them as follows.

2.c.i. Whole-organisation learning and leadership

At whole-organisation (hospital, general practice etc.) level ‘learning organisation’ activities were to involve a set of consistent, mutually reinforcing activities including:

1. ‘Leadership activities’, based on a different list of priorities than for measurement work. These leadership activities were to focus on outcomes from the NHS outcomes framework (specifically, venous thromboembolism (VTE) prevention, healthcare-associated infections and pressure ulcers), in addition to major causes of death and severe harm (falls, handover and discharge, nutrition and rehydration, acute kidney injury) and the care of vulnerable groups (mental health, people with learning disabilities, children, offenders, acutely ill old people, children passing into adult care).
2. Developing and applying scientific staffing ratios.²⁶
3. Bringing tacit knowledge into healthcare providers’ organisational learning.

4. Having a clear, simple focus of responsibility for safety and improvement,
5. Internal rather than external monitoring of safety and quality.²⁶
6. Transparency of, and responding to warning signals in, complaints and quantitative ‘metrics’ about any deterioration in quality of care.

2.c.ii. Clinical teams’ learning

For clinical teams the essential activities were to be

1. Standardisation of routine clinical care processes so improve reliability⁴¹ and safety.
2. Continuous improvement for each work-team and its adjacent teams.

As noted above, the quality improvement activities through which this is done were to be organised in a strongly inter-organisational way.

2.c.iii. Individual learning

Individuals within these teams, and by implication including those in management roles, required:

1. Training, education, capacity building in:
 - (a) continuous improvement
 - (b) understanding and use of evidence and investigation.
2. Protected time for reflective practice.

The relevant training was both technical (e.g. about the WHO Surgical Safety Checklist (WHOSCC) and about infection control) and organisational (e.g. how to introduce evidence-based changes in working practice, how to use safety measurement). In addition to establishing the PSC programme NHS England, in partnership with The Health Foundation, created a programme called ‘Q’ with the aim of developing 5,000 improvement fellows across the country.

2.d. Managing climate and culture at provider level

UK policy statements emphasised managing organisations’ cultures as the means through which PSCs and their member-organisations would improve patient safety and quality of care, in this

respect adopting the assumptions of the Michigan ‘keystone’ collaborative.⁴² According to The Commons Constitutional Select Committee, NHSI believed that

‘leadership is the most powerful influence on the culture of an organisation. ... there is a link between chief executives with a clearly communicated strategic vision, long term goals and organisational plans for patient safety and staff well-being and good patient safety performance’³⁷ (p.19).

Through 'learning organisation' methods, the senior management within each provider organisation and each clinical level team would influence the organisation's climate, and in particular its patient safety climate or culture^{43,44} i.e. the subset of organisational culture or climate containing ‘the attitudes, values, norms and beliefs that relate specifically to patient safety’⁴⁵ (p.312). Policy expressly assumed that this management of culture, like organisational learning, would occur at both whole-provider and at clinician (clinical team) level:

‘the Public Inquiry and [...] reviews led by Professor Don Berwick and Sir Bruce Keogh show that safe care is dependent on healthy cultures: having the right values, behaviours and optimum systems and conditions to minimise harm and to learn from patient safety incidents. Professor Michael West’s recent study [...] describes these conditions and how they can generate either “bright spots” or “dark spots” in care’^{7,¶1.48}.

However the Francis report described bullying of whistle-blowers, concealment or falsification of evidence of harm to patients, and an ‘insidious’ tolerance of poor quality and safety standards. Subsequently the House of Commons Public Administration and Constitutional Affairs Committee, among others, noted the persistence of a defensive ‘blame culture’ in the NHS (and the weakness of the powers of the Health Service Investigation Branch).³⁷ Only 43% of respondents to the 2015 NHS Staff Survey responded that their organisation was fair in its treatment of staff involved in near misses, errors and incidents.⁴⁶

In response the Francis report and subsequent policy documents recommended ‘strong and stable cultural leadership’. The normative content of the culture which PSCs were to promote included prioritising patient safety: ‘shared values in which the patient is the priority of everything done’; transparency, including an 'open and fair culture', expectations of openness, candour and honesty’; support for staff to improve their practice continually; ‘abandon blame as a [management tool] and trusting the goodwill and good intentions of the staff’²⁶; and zero-tolerance of substandard care. It recommended ‘empowering front-line staff with the responsibility and freedom to deliver safe

care'. This policy tended to assume that managers can change an organisation's climate or culture^{47–49} (which although not easy might be easier than changing, say, a hospital's physical infrastructure, workforce or socio-economic setting).

The leadership element would arise through³⁶:

1. Facilitation of patient and public engagement in the co-production of care and decision making.
2. 'Leadership' (senior management) understanding of quality improvement for patient safety purposes.
3. This understanding becoming 'embedded ward to board'.
4. The above will lead to increase patient and public 'engagement' in improving services, and in turn to
5. 'Visible leadership' for patient safety and quality improvement.

The culture or climate described above would arise through³⁶:

1. Promotion of a climate of openness, person / patient centeredness and clinical effectiveness, which would lead to:
2. Organisational listening, learning and support for staff.
3. Team working (implicitly, by inter-professional clinical teams) and
4. A 'culture of openness'.

Policy statements expected these changes in patient safety *culture* to influence each PSC member-organisation's patient safety *climate*. 'Climate' denotes the organisation's observed environment, objectives, norms, activities, resources and membership as front-line workers perceive them. Brand names notwithstanding, 'culture' surveys⁴³ usually measure workplace climate: that is, what the members of clinical teams think and feel about patient safety in their workplace, as opposed to managers' and policy makers' beliefs and attitudes (organisational 'culture') concerning patient safety. There is some evidence that attitudes to inter-organisational relationships reciprocally both influence and reflect the ways in which organisations collaborate in practice.⁵⁰ Analogously, the same might be expected to apply to clinical working practices.⁵¹

2.e. Changed clinical working practices

The collaborative model assumes that teamwork leads to better clinical decisions and hence to better patient outcomes.⁵² The eponymous collaboration is within and between provider-level clinical teams (possibly more than one from each member organisation, in which case a 'site project leader' may coordinate them). The teams are typically multi-professional and typically include a 'team leader', clinician(s), opinion leader(s), and quality specialist(s). The teams adopt quantified, normative goals for improving patient safety and/or other aspects of quality of care. At the outset of their work they set measurable targets, collect baseline and then further data to track their performance, and periodically report it to the collaborative's coordinators. This requires the members to agree what data the collaborative has access to and how it will be analysed, and for the site teams to know the importance of data collection from the outset, and how they will analyse their data. In the BTS prototype the participant clinical teams plan, implement, and evaluate many small changes repeatedly and in quick succession, e.g. by dealing with one defect per month.⁴³ After a problem is identified, debriefing teams is the critical mechanism used for learning and improvement.⁵³ Depending on circumstances the improvements may concern team organisation and relationships, technical (clinical) aspects of work, or both. The methods used are usually adopted more-or-less ready-made from existing quality management methods (e.g. quality circles, statistical process control etc.) and essentially follow the PDSA model.

In PSCs, say NHS England³⁶, team based working will become the norm. Inter-organisational collaboration between clinical teams, 'learning organisation' activities and climate management together would change clinical working practices. Important quick-acting mechanisms that would change working practices in this way were PDSA cycles and activities to increase staff training and motivation. The CQC has also recommended the use of 'human factors principles' and 'root cause' analyses of clinical mistakes. Using the term 'innovation' for these changed working practices, the Patient Safety Collaborative Logic Model³⁶ foresaw them arising through:

1. The development of interventions in different contexts and settings.
2. The use of local investigations (of safety problems) to 'support' innovation.
3. The creation of an infrastructure for innovation use and sharing.

4. Provision of 'local' (provider-level) support to 'deliver' patient safety.
5. An increased proportion of staff capable of innovating.
6. Development of systems for promoting and sharing innovation.

2.f. Improved quality and safety

NHS England anticipated³⁶ that the above activities would, as immediate outcomes, increase safety improvement capability, increase inter-organisational collaboration about safety, reduce variability in safety practices between healthcare providers (see above) and increase the 'alignment of system priorities and policies with improvement goals'. In turn these intermediate outcomes would, NHS policy statements said, lead to the implementation of larger scale, sustainable, measurable improvement. Patients would become more involved in care planning, and care plans would include a summary of patients' needs and preferences. Patients who needed one would have a named care coordinator. NHS providers would make greater use of patient feedback (including complaints) and of patient representation in governance structures. A consequence of 'leadership activities' would be 'greater numbers of patient and public empowered and routinely involved in decision making around patient safety'.

Routinely collected data were to be the measures of the anticipated improvements in patient safety and clinical quality; supplemented with any more specific, locally collected data which may be available and relevant. For attribution purposes, the measures were to be analysed at the level of the providers, of the specialities and clinical teams, and of the care groups, in which PSC-instigated activities have occurred. The timescales over which PSCs were expected to show results is five years (2015-2020) but to secure any continuation of funding early enough to make continuation of the PSCs practicable, 'results' may have to be shown sooner than that, especially if the government's responses to the Francis Report again become politically salient.

2.g. Contextual requirements

Berwick and others stated that various contexts are likely to moderate the implementation and effects of PSCs.

A set of concurrent policies was intended to reinforce PSC activity and its effects. These included the 'Sign up to Safety' campaign⁵⁴ and Health Education England's obligation to ensure staff training focuses upon delivering safe, dignified, compassionate care. The Sign up for Safety initiative aimed to enable organisations and individuals to 'commit to five safety pledges', develop their own local safety improvement plans, share information and learning about methods that increase the safety of care, and promote a 'just culture'.⁵⁴ The Francis Report recommended that not only providers but also commissioning, regulatory and 'ancillary' healthcare organisations should decide how to apply the Report's recommendations to their own work. NHS England established a Health Service Investigation Branch, charged with creating 'safe spaces' in which practical lessons could be learned from clinical mistakes but the House of Commons Public Administration and Constitutional Affairs Committee criticised its limited capacity and weak legal powers, and more generally the ill-coordinated plethora of organisations with responsibilities for investigating clinical mistakes or for promoting a 'learning climate' in the NHS.³⁷

Against this background, certain other concurrent policies appeared to complicate and even impede the construction of PSCs. Berwick found

'The current NHS regulatory system is bewildering in its complexity and prone to both overlaps of remit and gaps between different agencies. It should be simplified.'²⁶

To that end Berwick recommended that the CQC be converted into a non-departmental public body accountable to Parliament rather than the Secretary of State. Another complication was the more diverse (which in practice meant increasingly privatised) range of NHS-funded providers.³⁴

Alongside network structures and in place of line management, two other means were necessary for implementing patient safety policy. One means was by managing safety climate (see above):

'As the NHS evolves into a network of increasingly autonomous units, the overall climate will define what the NHS means and does'.⁵⁵

Contracts were the other means:

'Contractors of outsourced services should also be required to abide by these [NHS constitution] requirements – these requirements could be included in the terms on which providers are commissioned'.⁵⁵

Similar requirements should, Francis argued, apply to individual NHS employees. In these circumstances it was necessary for the success of PSCs that 'all incentives should point in the same direction'²⁶ i.e. that of supporting safety improvement.

Keogh²⁷ noted four main systemic 'foundations' of high quality patient care: using patient experience (e.g. complaints) data to instigate corrective action; ensuring that risks to safety are recorded, understood and managed, and in particular that ward staff carry out basic observation of patients; using mortality and other data to analyse and improve quality of care; and assuring provider-level government and 'leadership', with a coherent connection between 'clinical leadership' and ward level perceptions of what the main risks to safety are. These were largely within managers' and clinicians' control but austerity policies restricted NHS organisations' capacity to meet Keogh's fifth condition: having sufficient staff and a reduction of workforce problems (high sick-rates, unfilled vacancies, use of agency staff). In all 14 Rapid Response Report (RRR) trusts, Keogh's reviewers found that workload and financial pressures impeded the first four conditions to varying extents.²⁷ As Berwick had anticipated:

'Financial goals require special caution; they reflect proper stewardship and prudence, but are only a means to support the mission of the NHS: healing'.²⁶

As further contextual assumptions The Patient Safety Collaborative Logic Model lists (*verbatim*):

1. Continued political backing and available funding for the [PSC] initiative, in particular continued recognition through the system of the importance of the Berwick Report.
2. Transfer of patient safety function to NHS Improvement will retain consistency of leadership.
3. Hospitals have safe staffing levels across the NHS in England.
4. Improvement training of staff 'actually makes a difference' i.e. changes staff attitudes, motivation skills and behaviour.
5. Staff have capacity and time to do improvement work even if they have the skills and knowledge.
6. Leadership team will flex and change over the five years.

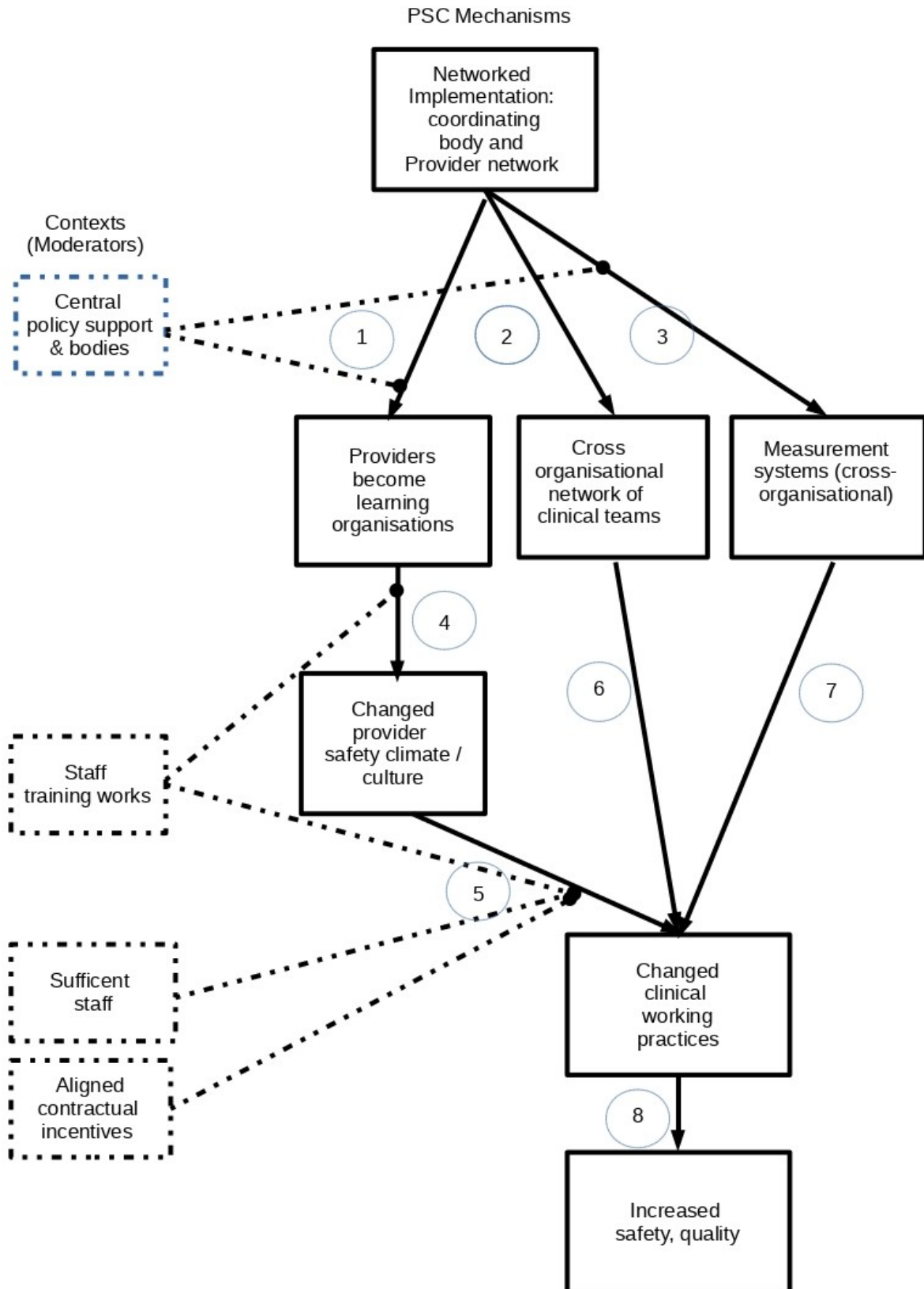
In addition (although more an aspect of the PSC itself than of simple context) AHSNs will continue and maintain a positive leadership role for patient safety.

2.h. How will PSCs work? Policy assumptions, programme theory

Every policy is a theory: that is, a theory that a specified intervention, implemented in a specific context, will cause a predicted set of policy outcomes.⁵⁶ Whilst the policy outcomes are a normative choice, the causal questions of whether the chosen intervention produces them, and if so in what contexts, are empirical questions that can be tested – and refined – by comparison with the relevant evidence. From the above policy statements described above we can therefore connect and summarise the causal and contextual assumptions which together constitute the ‘programme theory’⁵⁷ of PSCs: that is the explicit or implicit ‘logic model’⁵⁸ or ‘theory of change’⁵⁹, whether empirically valid or not, embodied in national policy towards PSCs. In doing so we differentiate the original explicit assumptions from the additional (originally tacit) assumptions that appear to be required to fill any gaps in the explicit assumptions, interpreting the additional assumptions in the most-evidence-based and logically consistent way possible, in order to evaluate the PSC policy and its implementation at their strongest. NHS England also published The Patient Safety Collaborative Logic Model in November 2015, which states (in part) the programme theory for PSCs. It lists as parallel PSC activities, with respective outputs and goals: Measurement; Learning; Capability Building; Leadership; Culture; and Innovation. The ‘core principles’ set out in 2014⁶⁰ stipulated that all PSCs should work on strengthening safety culture, QI capability and measurement. Other prototypes and policy documents (see above) however imply a more coherent sequential relationship between them.

Figure 1 shows the contexts, mechanisms and outcomes that policy-makers’ programme theory of PSCs explicitly or implicitly assume. Given our study design (see Chapter 4) we take these terms in their realist senses.⁵⁷

Figure 1: Policy makers' programme theory for PSCs



In Figure 1 each solid arrow represents one mechanism within the ensemble of mechanisms through which a PSC produces its outcomes. In policy implementation contexts, each *mechanism* consists of individuals' reasoning, action and use of resources. Each dotted line represents a *context* which in the realist sense means a moderator, not causally dependent on the mechanism but either necessary for the mechanism to produce the outcome, or which intensifies the outcome that the mechanism produces. Thus contexts do not include intermediate outcomes (mediators). The 'Sufficient staff' context means that staff have enough time to make use of training and implement improvements (capacity). Lastly, the PSC *outcomes* are the empirical, causal effects, intended or otherwise (e.g. emergent outcomes, side effects), that these mechanisms and contexts together produce.

One requirement for PSC policy to 'work', in the sense of producing the outcomes which policy-makers intended, would be that all the causal links between the above events and activities existed, or were created; and if they were, that they then had the effects that PSC policy assumed. In summary (and for reference in later chapters), the policy of creating PSC assumed the presence and efficacy of the following *mechanisms*, correspondingly labelled on Figure 1.

Mechanism 1: The regional coordinating body and network make providers become more 'learning' organisations, assuming:

Context (1.a): central policy and organisations continue to support PSCs and their activities.

Mechanism 2: Each regional coordinating body establishes one or more cross-organisational networks of clinical teams

Mechanism 3: Each regional coordinating body and network establishes cross-organisational measurement systems, assuming (again) that:

Context (3.a): central policy and organisations continue to support PSCs and their activities.

Mechanism 4: The providers that have become learning organisations develop an organisational culture and climate more conducive to patient safety and quality improvement, which assumes:

Context (4.a): staff training works (i.e. skill training is effective [in changing workplace attitudes and skills]) and that the staff have time once they have returned after training to implement their learning. The availability of time to improve has been a significant problem in previous Collaboratives.

Mechanism 5: Changed safety culture and climate help clinical working practices to change, assuming that:

Context (5.a): staff training helps create or strengthen new working practices

Context (5.b): the provider has sufficient staff

Context (5.c): contractual incentives align with new working practices

Mechanism 6: The cross-organisational network(s) of clinical teams help clinical working practices to change

Mechanism 7: The cross-organisation measurement systems help clinical working practices to change

Mechanism 8: The changed working practices result in the *outcomes* of increased patient safety and quality improvement.

As previously explained, when stating (above) that ‘Mechanism A helped produce B’, ‘help’ means that the mechanism promoted or increased B, without claiming that A was the only reason why B changed. Underpinning the whole ensemble of mechanisms is the assumption that if the working practices and culture (and/or climate) that prevent patient harm in the safest workplaces are transferred to other workplaces, there will be fewer occurrences of avoidable harm to patients and quality of care will improve. Implicitly, the harm and dangers to patients at Mid-Stafford and elsewhere were caused more by unsafe clinical working practices and ‘blame cultures’ than, say, underfunding, non-clinical management practices (e.g. focus on central targets), managerial attention being distracted from other issues by the imperative to become a foundation trust, workforce shortages, or ‘policy mess’. Hence the programme theory of PSC implicitly rests more upon a ‘high reliability’^{61–63} and a ‘latent factors’⁶⁴ theory of safety than upon a ‘normal accident’ theory.⁶⁵ Where policy statements were silent or did not specify very tightly how PSCs were to be constructed, the individual PSCs had discretion in how to interpret the policy and therefore how to design, implement and link the mechanisms shown in Figure 1.

The rest of this report is mostly structured according to this programme theory (‘theory of change’). We use the above list of mechanisms to group and analyse the existing research findings (Chapter 3), and then the key findings (Chapters 5-8). On that basis, the Conclusions (ch.12) uses an develop a revised, more evidence-based theory of change (‘logic model’) for PSCs.

Chapter 3: Research background: Do collaboratives work as NHS policy assumed?

Because Patient Safety Collaboratives in England draw on North American designs and experience, and upon the ‘high reliability’^{61–63} and ‘latent factors’⁶⁴ theories of safety, substantial research already exists about many, but not all, of the policy positions and assumptions outlined in Chapter 2, and therefore about their implicit programme theory. To present this research and explain the selection of research questions for the present study, we therefore follow the structure of that programme theory. For each mechanism we outline what the existing evidence would lead us to expect about the working and impacts of the NHS Collaboratives and in doing so we focus on inter-organisational collaboration rather than quality initiatives limited to one organisation.

3.a. Establishing a collaborative

Before any PSC mechanisms can come into effect the Collaborative must be set up. Collaboratives can be used as a deliberate spread strategy for existing evidence: of practical ideas for services, of the Collaborative method itself, or of quality improvement methods.⁶⁶ Indeed networks appear well-adapted for dealing with complex,⁶⁷ ‘wicked’ problems⁶⁸ such as patient safety because healthcare networks generally, including collaboratives:

1. Establish ‘horizontal’ links for joint working, resource-sharing and information exchange between the different organisations, in particular the relevant clinical teams within each, which all have an interest in the issue.
2. Incorporate and build on existing activities (‘path dependency’).
3. Engage professionals more readily than formal managerial structures often can.
4. Mediate discrepant, even conflicting, interests among the members.
5. Harness their members’ multiple links outside the network to help transmit new knowledge (e.g. evidence-based medicine) into it^{69,70}.
6. Provide a direct means for influencing the ‘hinterlands’¹⁵ where work relevant to the network’s aims actually takes place within each member organisation.

Above all, networks provide a means of coordinating cross-organisational action in pursuit of shared aims.⁷¹ Such 'learning communities' often emerge largely independent of management hierarchies.⁷²

Collaboratives have been described as 'a temporary learning organisation'⁶⁶ (p.347) that function and may originate, as 'communities of practice'⁷³ to stimulate innovation and learning^{74,75} and to promote goodwill, solidarity and collaboration, hence the sharing of learning, across all ranks and professions.⁷⁶ Such collaboratives therefore tend to:

1. Be multidisciplinary.⁷⁷
2. Have a self-selected membership⁷⁷, with the risk of that membership becoming so homogeneous that certain occupations or viewpoints are excluded by default.⁷⁸
3. Adopt goals that emerge from their members' experiences and interests and are not necessarily explicit, especially in the early days of the network, which means members assume that participation is mutually beneficial to themselves^{66,79}, i.e. promotes goals they had before the Collaborative formed.
4. Organise themselves in *ad hoc*, informal ways, especially initially; coordination of activities between the network members occurs through a combination of trust⁸⁰, persuasion and reciprocity in dealings between them.⁸¹

Cunningham's systematic review⁷⁸ found that the networks that contributed most to quality and safety work relied on particular individuals, often managers or clinical leaders, who 'transmit information, bridge disparate groups, liaise across parts of networks and enable social and professional interaction'. Reliance on these members may make networks vulnerable if it becomes too heavy. Hulscher's systematic review⁸² reported finding only a minority of studies stating that the expert ideas and support provided (by the network coordinating body) was related to the 'success' of collaboratives. In some of the Michigan Collaboratives the coordinating body was staffed by one of the participating hospitals⁸³ (rather than a separate organisation). Nevertheless a coordinating body's work in constructing these links, developing and applying these managerial, techniques still incurs transaction costs, in particular the costs of meetings.⁶⁶

An early review⁶⁶ found that 92 collaboratives took a mean of 17 months from project start to first tangible improvements. For the Michigan Surgical Collaborative, Englesbe⁸⁴ estimated that a 1.8%

fall in surgical complications was required to recoup the cost of the collaborative. Voluntary networks have to be financed by the members themselves, raising the question of what the costs of participation are, and Hulscher et al.¹⁶ noted the lack of research about this.

3.b. Learning structures

NHS policy documents describe PSCs as ‘learning’ entities (Chapter 1), implying that the provider organisations within a PSC and the coordinating body all ought to function as learning organisations, together constituting a ‘learning’ network. Örtenblad and Koris⁸⁵ define a learning organisation as one that contains (or ought to): learning at work, organisational learning, learning structures, and learning climate. That implies the presence of these things at both inter-organisational (collaborative, network, PSC) level and within the member-organisations.

Different writers prioritize them differently, but learning structures typically:

1. Undertake systematic ‘knowledge management’.⁸⁶ For a PSC, that includes formalising (documenting) and disseminating workers’ (clinicians’) knowledge⁸⁷ between its member-organisations, not only within the coordinating body itself.
2. Transfer knowledge from outside the collaborative into its member-organisations.⁸⁷
3. Build ‘relational capital’ between the participants.⁸⁸
4. Routinely analyse errors or accidents to reveal any systemic causes arising from the organisation’s structure or working practices.
5. Create flatter managerial hierarchies with decentralized control⁸⁹ to encourage the spread of knowledge, especially ‘whole-picture’ understanding.⁹⁰
6. Measure activities and outputs; discussions of these metrics are themselves a learning activity.⁸⁷
7. Establish a specialised quality or research and development (R&D) department to enable work-teams to improve their performance without relying solely upon audit.⁸⁶ When, as often happens, the links between a healthcare process and its outcomes are tenuous,⁴¹ they can only be discovered through large-scale formal research rather than informal learning-at-work.

3.c. A specific focus

Collaboratives are more likely to succeed when they focus upon care groups where:

1. Evidence-based interventions are known but not universally applied.⁶⁶
2. Practical examples exist showing how improvements were made in practice.
3. Clinicians support the proposed improvement.¹⁶
4. The proposed improvement is strategically important to the clinicians' 'home' organisations and therefore has senior management sign-up (which may literally involve the symbolic action of signing a form¹⁶).
5. The Collaborative set safety and/or quality improvement targets at levels that can be achieved, on present knowledge.¹⁶
6. Monitoring and educating patients is involved.¹⁶
7. The Collaborative focuses on a care model (e.g. the Chronic Care Model) which is already long-established among its member-organisations¹⁶.
8. Teams focus on specific, easily 'digestible' targets.⁹¹

Existing studies offer conflicting findings as to how narrow (specific) collaboratives' focus ought to be. Franco and Marquez argue that Collaboratives with multiple components are more likely to succeed than those using just one.⁹² Against this, Aveling and colleagues argue that attempting to follow too many protocols, especially conflicting protocols and especially in the absence of staff training prevents health-workers implementing working practices that are safe for the patient.⁹³

3.d. PSC mechanisms

3.d.i. Mechanism 1: The coordinating body helps providers become learning organisations

The assumption that collaboratives' coordinating bodies help providers become learning organisations is given some credence by research about healthcare networks generally, collaboratives and learning organisations specifically. Network activity has been found to produce 'cultural convergence among the network member-organisations and individual members.'^{89,94-98}

However the research on networks (including collaboratives) overlaps little with that on learning organisations. Few studies report how networks help their member-organisations specifically become *learning* organisations and some report circumstances in which the opposite may occur. Collaboratives can, and in the NHS are intended to, act as implementation structures on behalf of 'third party payers' (as was the Michigan Surgical Quality Collaborative).⁸⁴ In such cases, collaboratives become mandated 'programme networks'⁹⁹ centred upon a coordinating body ('Network Administrative Organisation' (NAO)¹⁰⁰). Certain characteristics tend to make such networks more effective at policy-implementation, and might therefore be expected to be observed:

1. 'Vertical' links between providers and the network coordinating body.^{33,100-102}
2. 'Reticulist' managerial skills^{71,103} and approaches to problem-solving based around negotiation ('soft') are generally more useful in voluntary networks than directive ('hard') management styles that rely heavily on formal organisational structures.¹⁰⁴
3. Inclusion of experts or researchers who have first-hand knowledge of 'best practice', but who are able to present it in general terms so that network members can re-interpret and adapt it for themselves.
4. Dense networks are not required and may be inefficient^{78,100}, but that point is contestable because dense networks may serve multiple functions besides programme implementation alone¹⁰⁵ so we cannot say anything definitive about network density.

NHS policy assumed (see Chapter 2) that support from central policy and national organisations would help Collaboratives develop their member-organisations into learning organisations. That may depend on whether 'support' means 'assist the activities that Collaboratives already chose independently' or 'select and mandate what Collaboratives are to do'. Over-centralised management appears to inhibit organisational learning and the production of new knowledge.¹⁰⁶ Clear and specific goals are prerequisite for steps to improve patient safety, but NHS hospitals and teams within past collaboratives have faced multiple, overlapping, disjointed, even competing, goals.¹⁰⁷ The contrast between voluntary collaboration and implementation structures led Addicott to regard governments' use of programme networks for policy implementation as '*the distortion of a managerial technique*'³² insofar as:

1. The network members' objectives differ from (or even conflict with) the policy mandate.
2. The network is firmly embedded within a centralised vertical accountability chain.

Analogously, the 'Learning Community' or 'Communities of Practice' have developed from means of personal growth into management tools.^{75,108} Hulscher's systematic review⁸² found that professional performance scores did not vary between clinics that participated voluntarily in Collaboratives and involuntarily-participating clinics.

3.d.ii. Mechanism 2: Collaboratives establish inter-organisational networks of clinical teams

Many studies mention the role of clinical teams in collaboratives and there appears to be a critical mass of 20-40 teams. A consensus on the goals and services is required to focus the teams' joint efforts upon.¹⁰⁹ Both the teams and the Collaborative coordinators require sufficient time for teams to learn what changes to make, as well as how to plan and sustain them.¹⁶ Activities used for inter-organisational collaboration included meetings, tool-kits, 'change packages', coaching, site visits, conference calls and electronic media (such as webinars).¹¹⁰ Inter-organisational collaboration appears to help improve collaboratives' outcomes.^{11,111} through (among other things) sharing practical knowledge: 'vicarious learning'. Few studies however report *how* a collaborative's organising body might help such teams, or a network of them, to form. Khodyakov¹¹² describes how a Rapid Spread initiative (Project JOINTS), a US network of state hospital associations and hospitals, spread adoption of a 'bundle' of interventions to prevent surgical site infections (SSI) using regional meetings, site visits and on-line materials to raise awareness of current practice in SSI prevention, guide teams to develop a QI plan, implement it, conduct small tests of the results and share their experience. Kilo¹⁷ describes BTS Collaboratives having a central planning group of individuals experienced in leading QI activities in a specific topic area (e.g. coronary artery by-pass graft (CABG) outcomes), with 25-40 member organisations as the optimal network size. Hospitals participating in some of the Michigan Collaboratives only received their payment for participation if they sent a physician representative and a programme coordinator to each quarterly meeting of the Collaborative.⁸³

3.d.iii. Mechanism 3: Collaboratives establish cross-organisational measurement systems

Collaboratives' success requires setting targets, collecting data, testing changes.¹⁶ Reames et al.¹¹³ suggest selecting measures of local 'defects' with greatest potential for safety improvements, for

example by using objective measures (e.g. measuring patient temperature) rather than confirming compliance with process (in that example, that a warming blanket was used). An evaluation² of the Welsh Collaboratives mentions the danger of standards becoming little more than aspirational wish-lists. In order to have the potential to generate improvement, the published data and measures would cover practice variations, care improvements, capacity for improvement if additional resources were available, and comparisons with best-in-class providers elsewhere.¹³ The Michigan Keystone surgery collaborative may have been less successful than the Michigan Keystone ICU collaborative because many sites participating in the former lacked means for collecting data and feeding the data back to clinical teams.¹¹³ In the UK, there is more evidence that patient safety failures occur in particular services (e.g. those reported in the public inquiries cited in Chapter 2) than across entire hospitals at once.¹¹⁴ Even when data are fed back, a study of NASA (whose safety management methods some healthcare providers have imitated) mentions the danger of ‘outcome bias’ i.e. of near-misses being perceived as successes because no harm occurred, not as warning-signs.¹¹⁵ So training in data use is also required.

Sharing comparable data puts provider-level teams under competitive and peer pressure that maintains the ‘pressure’ for them to change their working practices.¹⁶ Within a UK stroke collaborative, some (not all) clinical teams took performance benchmarking and comparison ‘as friendly rivalry or as time-consuming’.¹¹⁶ ‘Soft’ governance¹¹⁷ is another motivator. A Collaborative in Wisconsin concentrated on making performance data publicly available to employers and patients because

‘it became evident to all that if the provider community didn’t take the lead in developing it, it might soon be mandated through regulatory means’(p.45).¹³

Publication of quality data is also associated with increased hospital compliance with quality standard, reflecting commissioner interest in, and influence over, that compliance.^{118–120} The Wisconsin Collaborative used the data to counter special pleading (‘Our patients are different’) and found that sharing practical ideas informally was as important to QI as formal meetings among provider organisations.¹³

3.d.iv. Mechanism 4: 'Learning organisations' develop a safety culture and climate

NHS policy documents say little about the internal management and structure of the provider organisations which, partly by participating in Collaboratives, are to become 'learning organisations'. Advocates of the 'learning organisation' say that it involves (or ought to) learning at work, organisational learning, learning structures and a learning climate.⁸⁵ The 'Integrated (Health Care) Team Effectiveness Model' (ITEM) model¹²¹ assumes that a team's organisational setting (its goals, structure, rewards, training, task design, team composition, autonomy, and interdependences) influence the team's work processes (communication, leadership, decision-making) and psychosocial traits (cohesion, norms) and that these in turn impact upon team effectiveness at its tasks. Vogus and Iacobucci¹²² write of 'mindful organizing' i.e. anticipating, preventing and correcting errors.

Several reviews and studies suggest that a supportive 'home' provider-organisation 'amplifies' the ability of teams and individual members of a Collaborative to learn and change working practices.^{11,66} One amplification is that top management¹²³ (and clinical teams' 'champions'^{124,125}) broadly accept the collaborative's aims^{66,126,127} and thus permit¹²⁸, even initiate or reward¹¹, individual and team learning¹²⁹ and (because of their seniority) provide credible feedback to the participants.¹³⁰ Individuals who had themselves been convinced by the collaboratives' activities made persuasive champions in one primary care collaborative.¹³¹ In general, acute hospitals are likely to have fully developed quality management systems, and to comply with quality standards, when the Board (or its equivalent, or a standing subcommittee of the board¹³²) discusses quality issues.^{107,126,133} It is necessary that the senior managers supporting the Collaborative have 'organisational leverage' (are powerful and can call on resources) and technical expertise¹⁶, and often interacted with medical staff regarding quality strategy.¹³⁴ A US study¹²³ concluded that a hospital collaborative was most successful when the 'guiding coalition' in each participating hospital included staff from different professions and of different hierarchical status; when all members participated in its work; and when the coordinating body was able to manage conflicts between them. Doctors were more likely to participate in improvement projects when they perceived that the hospital CEO encouraged such activities¹³⁵ but even so the Welsh PSC experienced some medical disengagement from cultural change activities.²

Interventions such as the WHO checklist were more likely to succeed when they had an enthusiastic or charismatic local (especially medical) champion^{2,16} compared to those perceived as another top-down imposition.^{2,136} Day-to-day support of the collaborative's work by someone who works within the provider team is critical.¹⁶ Against all this, however, the balance of evidence in Hulscher's systematic review⁸² was against the assumption that 'staff involvement' promoted collaboratives' success. Five out of the six papers in that review⁸² reported no relationship between 'leadership support' and collaboratives' 'success' but Singer and Vogus¹²⁷ reviewed 15 studies reporting managerial practices that promoted a safety culture. Rotation of early-career doctors is also an obstacle to their individual learning, at least in terms of learning the work-systems in a particular hospital.² Herepath et al.² describe the 'distributed' leadership of the Welsh PSC but also the risk of 'WalkRounds' becoming an occasion for 'good news stories' rather than transparent discussion.

Another amplification is that managers use the Collaborative's activities not only to solve immediate problems but also to draw organisation-wide lessons from them ('double-loop learning'¹³⁷). When this happens the cycle of learning itself can become something that the participants can reflect upon, creating triple-loop (third-order) learning.¹³⁸ It has been reported¹³⁹ that greater 'structural empowerment' of nurses, including nurses' collaboration with doctors, is associated with stronger patient safety culture. Organisation-wide learning can correct individual errors (e.g. outcome-, confirmation-, recency- and hindsight-bias) in noticing near-misses and other safety defects.¹¹⁵

Although many studies assert that 'culture' change drives quality improvement^{126,140} few define the concept of 'culture' precisely.¹⁴¹ It is multiply ambiguous across studies¹⁴² and often lacks theoretical underpinning.¹⁴³ Drawing out assumptions from previous studies, we define an organisation's 'culture' as the observed set of beliefs and attitudes that those who control the whole organisation (i.e. its owners, top managers) have about how their organisation ought to work and about how it does in fact work. This means it contains both empirical and normative components¹⁴⁴ and is embodied in beliefs, attitudes, documents, artefacts, myths etc.¹⁴⁵ 'Climate' we define analogously as the equivalent beliefs held by the staff in a particular work-unit (e.g. team, department, occupational group).¹⁴⁰ Any organisation with multiple work teams, professions, departments etc. is therefore likely to have multiple local climates although climates and culture approximate to each other except when work teams are particularly alienated from their managers.

Culture and climates guide and reflect the senior managers' and the workplace teams' daily work, influencing their behaviour and organisational effectiveness.¹⁴⁶ A systematic review¹⁴³ found that the most often cited components of patient safety culture were:

1. Leadership commitment to safety;
2. Open communication founded on trust;
3. Organisational learning (see above)
4. A non-punitive approach to adverse event reporting and analysis: 'respectful interaction'¹²²;
5. Teamwork (or 'collectivism'¹⁴⁷).
6. A shared belief in the importance of safety, hence in understanding the causes of errors.¹²⁷

One normative hierarchy differentiates types of organisational culture developmentally, in ascending order of merit, from 'pathological' through 'reactive', 'calculative', 'proactive' to 'generative' (promoting patient safety has become a routine activity).^{148,149} All this takes time; some studies^{145,150} suggest up to ten years.

The trial-and-error character of learning cycles is usually assumed to require an organisational culture that tolerates open dialogue, contested viewpoints, doubts, criticism, and the exposure of mistakes^{151,152}, that is a 'no-blame' culture whose 'psychological safety'^{28,128,153} tolerates human errors arising from bad luck or unforeseen circumstances *provided that* practical lessons be drawn from them. The requisite culture is held^{93,154} also to be a 'just culture' that acknowledges the responsibilities of *both* work-systems *and* individual professionals for patient safety. The practical difficulty however lies in allocating responsibility correctly between them, and in defining what errors are blameworthy.¹⁵⁵ Simple algorithms have been proposed^{18,53} for the purpose, but it might also be argued that they are simplistic given the complex interdependencies of individual agency, professional and organisational structures.⁹³ A safety culture is more likely to develop for projects of high importance to managers.¹¹⁵

Singer and Vogus¹²⁷ argue that interventions to 'shape' a safety culture must target any of three elements: those 'enabling' internal 'leaders' and external actors (including Collaboratives) to emphasise safety; front-line staff 'enacting' actions that deal with threats to safety; and 'elaborating' in the sense of learning from the experience. Without describing the organisation-level mechanisms that did so, Provonost reported that a collaborative among 99 ICUs in Michigan (2004-5) raised

their teamwork climate scores, with the patient outcomes noted below.⁴² In Californian mental health services (with no collaborative) a ‘constructive’ organisational culture was found¹⁴⁶ to influence work attitudes directly, and organisational climate indirectly (and, through both, it influenced staff turnover). A systematic review in 2013⁴⁴ reported mixed findings about the effect attempts to manage patient safety cultures had upon patient safety climate, with four out of eight controlled studies finding no effect. ‘WalkRounds’ (i.e. ward rounds by those leading PSC activity within a workplace and Board members)^{156,157} and multi-faceted programmes at ‘unit’ (departmental or workplace) level may have a positive impact on patient safety climate¹⁵⁸ but the review found no evidence that nine other hospital-level programmes did so.

Obviously other quality improvement initiatives besides a collaborative may also contribute to changing safety climate.⁴³ Speroff¹⁵⁹ found, in America, that hospitals with a ‘group’ culture tended to have higher safety climate scores than those with an hierarchical culture. It is methodologically challenging to disentangle the effects of the many different components of safety culture, organisational culture and the effects of Collaboratives, in the presence of other competing imperatives and pressures.^{16,44} Empirical studies and normative works often assume that organisations usually have just one predominant culture (or climate, at team level). In healthcare organisations, however, official managerial norms and ideologies, including health policy imperatives, usually coexist with multiple professional cultures, the latter sometimes conflicting among^{2,160}, and even within¹⁶¹, themselves, and sometimes motivating resistance to managerial initiatives¹⁶² and changes in clinical practice.⁴¹ In addition to cultural differences between organisations^{148,159}, different professions have distinctive patterns of communication¹⁶³ and this can be a source of communication and therefore teamwork breakdown across professions.¹⁶⁴ Organisational cultures and climates may even be specific to department or team level.^{140,143} When goal alignment and compatibility of interests among a health organisation’s different “stakeholders” are weak, learning organisation activities may be contested^{67,112}. The same applies when safety ‘solutions’ are transferred between sectors. Willmott¹⁶⁵ and Ormerod¹⁶⁶ are therefore sceptical about the possibility of culture-management.

Nonetheless, staff behaviour based on ‘*consulting, mobilizing* [others’ involvement], and *adapting*’¹⁶⁰ (original emphasis) can enhance collaboration and mitigate the often-disputed symbolic boundaries concerning expertise, ‘ownership’ of patients and decision-authority. One attempt at

overcoming these differences has been to develop and apply specially-developed communication tools such as the SBAR tool with the concomitant training, which in a study in Arizona increased 18 out of 27 measures of teamwork climate and safety climate.¹⁶³

3.d.v. Mechanism 5: A stronger safety climate produces safer clinical working practices

To focus on safety climate as a cause of safe (or unsafe) working practices seems to offer the prospects of ‘feed-forward’ methods of predicting safety risks, not just reacting to them, and of managing the ‘human factors’ (management and first-line supervisory style, communication, training, workforce and working practices¹⁴¹) that impact upon safety¹⁶⁷ to create ‘high reliability’ teams or organisations.¹⁶⁸ A stronger safety climate aids front-line staff to develop a heightened commitment to the safety of those with whom they work, eliciting discretionary effort and behaviours that increase patient safety.¹²² ‘Respectful interactions’ facilitate the exchange of information and ‘mindful organizing’ that prevent errors¹²⁷ and presupposes giving front-line employees a degree of control over their work.¹²² The intended changes in clinical teams’ working practices are both:

1. Clinical or technical: the team adopts more strongly evidence-based methods of care and
2. Organisational: closer coordination of work between team members, which involves staff having means of recommending and making organisational changes.

Attempts to improve coordination appear to be successful less often than attempts to change clinical practice⁸² even though (one study¹⁶⁹ found) organisational causes contributed to 93% of preventable adverse events. Analysis of a random sample of US hospitals¹⁷⁰ explicitly assumed that acute myocardial infarction (AMI) readmission is sensitive to medical, and health failure readmission to nursing, working practices. Cross-professional collaboration ‘enables the synergism to solve difficult clinical problems’¹¹⁶ (p.33). Studies outside the health sector report that a safety climate is one factor (among others) promoting compliance with prescribed safety procedures, use of safety equipment, and whistle-blowing.¹⁷¹ A Netherlands study¹⁷² identified four stages by which working practices improve:

1. Orientation and awareness; no systematic quality improvement yet, single-profession peer review at most.

2. Preparation.
3. Experiment and implementation: the start of practical projects.
4. Integration into normal working practices.

Obtaining the practical benefits of an evidence-based working practice such as the WHO Surgical Checklist requires, first of all, fidelity of implementation¹⁷³ and consistent 'leader' emphasis upon safety.¹²⁷

Various studies¹³⁰ give evidence as to whether collaboratives improved working practices, without necessarily corroborating that safety culture or climate was the mechanism specifically responsible. Hansen et al.¹⁷⁰ found modest associations between front-line medical and nursing (but not managerial) staff perceptions of safety climate safety climate and risk-standardised 30-day readmission rates for AMI and HF patients respectively (but not vice-versa and not for pneumonia patients). The strongest associations were for 'unit' safety norms, overall emphasis on safety and collective learning. The most relevant working practices were educating patients for self-management post-discharge and avoiding premature discharge. The NHS primary care Collaboratives claimed a reduction of 34% in coronary heart disease (CHD) risk, and a reduction of one day in orthopaedics average length of stay (ALoS) through an orthopaedics collaborative in the UK.⁶⁶ An overview of 27 BTS-model Collaboratives in twelve middle- and lower-income countries⁹² found that 87% of the Collaboratives showed 80% 'performance' levels, increased from often very low baselines; the lower the baseline, the greater the improvement. Health centres maintained the improvements in performance levels longer than hospitals did. A collaborative in Massachusetts increased compliance with five performance measures for stroke treatment in emergency medical services.¹⁷⁴ Six US hospitals which strengthened their safety climate in respect of learning environment, senior management support and psychological safety achieved greater use of evidence-based strategies for reducing risk-standardised mortality rates (RSMR) for AMI patients and a larger fall in RSMR itself than did four hospitals which were less successful in producing those culture changes.¹⁷⁵ A study of NASA¹¹⁵ suggested that in a climate that emphasised safety, near-misses were more likely to be reported and hence could be used as a warning sign of safety problems. Brewer¹⁷⁶ found an association with a 'group' culture among nurses and reduction of patient falls in 16 US 'medical surgical units'. Supportive organisational climates for NHS staff

were associated with lower hospital standardised mortality ratios.¹⁰⁷ Other studies also report instances in which stronger safety climate was associated with improved patient safety.^{126,177,178}

Against this, a study of primary care in the Netherlands¹⁷⁹ found that a strong 'group' culture was negatively, but a 'balanced culture' was positively, associated with the quality of diabetes care for patients. (These classifications of organisational culture come from the Competing Values Framework.¹⁸⁰) However these relationships were 'rather marginal' and there were no associations between organisational culture, team climate ('teamwork') and clinical patient outcomes. Another Netherlands study¹⁸¹ found that in general it appears difficult to apply QIC methods to care process redesign.

An evaluation⁴⁰ of the UK Health Foundation's Safer Patients Initiative found no evidence of improvement in clinical outcomes or care process quality metrics. The 'Matching Michigan' project's attempt to replicate the Michigan Keystone collaborative in the UK had at best an equivocal effect on clinical practice.¹³⁶ Aspects of non-implementation of the WHO surgical checklist included non-completion of the checklist, the absence of team members whilst the checklist was used, and the checklist design.¹⁸² That collaborative appeared to show a 'decline effect', with parallel practice improvement occurring outside it and safety climate was not related to the maintenance or spread of collaboratives.⁸² Although Dillon and colleagues¹¹⁵ report many studies outside healthcare suggesting that safety climate is indeed associated with safety performance (including accidents), Christian and colleagues¹⁷¹ nevertheless found that personal motivation and knowledge were more closely associated with those outcomes. Yet individual learning is also part of the 'learning organisation', so that finding contradicts neither the 'learning organisation' assumptions nor the assumption that changing organisational climate impacts upon working practice; only the assumption that changing organisational climate has the *most* impact.

It is difficult to see what connection there could be between changes in organisational climate and changes in service safety and quality that did not in some way involve changed clinical working practices ('microsystems'¹⁰⁹). Consistent with that assumption, two studies have found that departmental or team-level initiatives appear more likely to succeed than hospital-wide activities in improving clinical work.^{44,183} To a realist way of thinking, this contradictory pattern of evidence suggests that the mechanism being studied (here, using changes in safety climate to change clinical

working practice) is context-dependent; it ‘works’ for certain care-groups or in certain organisational settings but not others. In the Netherlands, larger hospitals, but not necessarily those participating in a collaborative, proceeded faster through the stages noted above.¹³⁵ In contrast another Dutch study of a collaborative across 17 hospitals (aiming to implement one-stop outpatient services) found that only three out of seventeen teams achieved the Collaborative’s goals, and without using PDSA cycles.¹⁸¹ ‘Normalising’ new working practices was easier when a team was already familiar with similar ideas and working practices, the ‘champion’ was a volunteer, the team was stable and the new working practices were integrated into other existing management (e.g. medical record) systems^{124,182} or the latter could be easily adapted to suit them.¹⁸⁴ Healthcare teams are stable in some settings but in others (e.g. emergency departments (ED)) often temporary and *ad hoc*.¹⁶⁴ Nevertheless, ED caseloads are diverse, variable and unpredictable. ED treatments are often highly interdependent and require a coordination-focused model of patient treatment¹⁸⁵ for which team-based working fits well with existing, technically-determined working practices. It appeared harder to achieve ‘depth of change’ for asthma than for diabetes, heart failure or depression care.¹²⁵ Certain contexts may help the implementation of new work processes including through PSCs. A related factor of importance is the characteristics of the change or intervention itself, e.g. that it is simple.² A qualitative study of six US hospitals¹⁸⁶ found that a ‘positive’, unified culture focused on patient care strengthened attempts to prevent central line-associated bloodstream infections (CLABSI); external support (such as collaboratives) may facilitate existing implementations, although at risk of diverting attention from other safety issues. In hospitals with weaker readiness for change, it was less clear whether collaboratives would produce such changes.

The published research does suggest team learning as a mechanism by which a stronger safety climate can change clinical working practices. Not only does sustaining the hospital or clinic as a learning organisation require managers to promote a culture which supports learning at team level¹⁶²; team learning is required for safe patient care, and has weak to moderate association with standards of technical and clinical performance.¹⁶⁴ (In comparison, teamwork failures figure in between 22% and 32% of research studies of adverse incidents and events¹⁶⁴.) For example, multidisciplinary teams in neonatal intensive care units reduced bacterial infections and oxygen supplementation for low-birthweight babies.⁷⁷ Strong relational coordination within hospital teams was associated with quality of care, ALoS, and outcomes for pain and functioning.¹⁸⁷ Some aspects of teamwork and participation in specific collaborative activities enhanced short-term success, especially if teams remain intact and continue to gather data.⁸² Team agreement about the value of

the WHO surgery checklist led to the intended safety improvements.²⁴ In general, strong leadership in work-place teams predicted the success of QI initiatives.¹²⁶ Conversely, failures of communication within teams are a strong predictor of surgical error.¹⁶⁴ Team composition, including relevant expertise, is a major contributor to QI activity generally¹³⁰, including by implication activity which collaboratives stimulate. Team learning appears more effective than individual learning about complex technologies (and the same appears to apply to relational coordination¹²⁷) but even then its effect depends on how team leaders implement it.¹⁸⁸

Ways in which team members collectively learn to change their clinical practice include:

1. Rapid testing of small changes¹⁶ in particular by using Plan-Do-Study-Act cycles^{17,30}, which are the kernel of clinical audit generally. Additional, recurrent PDSA cycles result in a gradual long-term accretion of a body of knowledge.⁹⁴ Learning to test changes made it more likely that teams would apply these methods to additional settings.⁸²
2. Learning to use discretion in decision-making because of the often unforeseen complexity of patients' care needs or circumstances.¹⁸⁹
3. Understanding the mental models they themselves use, and to appreciate those which others use^{190,191}, so as to promote and exploit divergent, plural modes of thinking; but also to make it easier for team members to 'back up' (assist) each other's work.¹⁹² Nevertheless, a shared mental model of *teamwork* appears necessary for team effectiveness.^{164,192} In anaesthesia teams, standardised work-processes can rely on implicit coordination and less explicit leadership; less structured, familiar or critical situations require the opposite.^{164,193}
4. Making decisions collaboratively, using research findings and adapting to innovations quickly.

Learning also occurs when clinical teams formalise the tacit knowledge that production teams apply¹⁹⁴ across professions and across multiple teams. Such learning requires collaborative communication skills and mutual support¹²⁴ so that team members stimulate each other's practical ideas and motivation to change working practice⁶⁶, but the intensity of interaction in a team does not appear to affect its success in improving care⁸², nor can it be taken for granted that different professions always share knowledge and information.¹⁹⁵ Changes of team leader is often a precursor to a team leaving a collaborative.⁶⁶ Quality and safety of care do however appear to be associated with trust and relational coordination within surgical and intensive care teams.¹⁶⁴

It is a short step from recognising the necessity (for collaboratives) of team learning to assuming that staff training will help clinical teams update their working practices¹⁹², and there is evidence¹¹ to support that view (some of it from outside healthcare¹²²). However, the IHI soon found that uni-professional didactic methods were ineffective for the purpose. Rather, it was necessary to select and train ‘day-to-day leaders’, making clinical content more prominent than improvement methods, while still structuring training around a team’s topic selection, improvement and dissemination work.¹⁷ Training in interpersonal skills is necessary, and selecting (recruiting) staff with those skills.¹²²

The predominant view of learning organisations¹⁹⁶ regards team organisational learning as homologous with individual learning^{197–199} but on a larger scale, as in the Kolb²⁰⁰ learning cycle (on which PDSA is based). Normative works argue that through practical learning at work,²⁰¹ individuals in a learning organisation acquire ‘personal mastery’ of work-related knowledge¹⁹⁰ and a propensity for ‘lifelong learning’.⁸⁷ Normalisation Process Theory sees the connection between individual and team adoption of new working practices (in general, not only in collaboratives) as follows. The four stages of adoption are^{124,188}:

1. Sense-making by the individuals and organisations involved (‘coherence’)
2. Enrolling individuals to engage with the new work process (‘cognitive participation’)
3. ‘Collective action’ that enacts the new practice; and
4. ‘Reflective monitoring’ of its advantages and disadvantages.

Of two systematic reviews in 2010, one⁵² did and another¹²⁶ did not find an association between training programmes and positive outcomes in QI projects (in general, not only for collaboratives) but each review found only weak evidence (especially regarding the circumstances in which the training occurred) that the rather disparate training activities studied tended to improve teams’ non-technical skills. Successful QI activity required both subject expertise²⁰² and knowledge of how to organise and measure QI work.¹³⁰ Informal training can in practice supplement formal training.²⁰² Russ¹⁸² found that training facilitated implementation of the WHO surgery checklist. A US study¹¹ found that learning activities within the participating organisations added to, not moderated, the effect of inter-organisational learning activities, although an organisation’s human resource practices (rewards, training) did multiply the performance benefit of inter-organisational learning.

Conversely, in the absence of training health-workers sometimes devise workarounds to improve their working practices.⁹³ Individual-level intervention such as training requires identifying barriers to adoption of (in the present case) quality and safety improvements, selecting interventions to address these barriers (including, for instance, by applying relevant psychological theory, and consulting those at whom the intervention was targeted²⁰³).

Hospitals participating in the Michigan ICU Collaborative were explicitly required to implement high levels of 'intensivist' medical staffing.⁴³ At least four of the earliest collaboratives there had substantial funding from the main private insurer.⁸³ Conversely, heavy workloads and a perception of lacking support weakened NHS hospital staff motivation and morale to participate in quality improvement programmes.¹⁰⁷ Workload pressure has also been reported to be associated with 'disruptive' clinician behaviour in US (Maryland) hospitals, some of it leading to patient harm.²⁰⁴ High levels of staff burn-out²⁰⁵ and turnover¹³⁰, including turnover among the leaders of a collaborative⁸, also inhibit QI work. More generally, Collaboratives' activities that did not require 'substantial' additional resources (irrespective of their source) were more likely to succeed than those which did.⁹² A degree of organisational slack is necessary, it has been argued, to enable organisations to learn.²⁰⁶⁻²⁰⁸ A point in favour of the PDSA approach in Wales appeared to be that it did not place a high demand on resources.²

Kaplan's systematic review found that sufficient resourcing – which should not (as an English study²⁰⁹ corroborates) necessarily be equated simplistically with extra funding – was associated with the success of QI projects.¹²⁶ Relevant resources include skills, expertise, information and 'connectivity to target populations'¹⁰⁹ (p.37); and (in Singer's review¹²⁷) judicious selection of staff. Length of time engaging with QI initiatives was also predictive of their 'success'.¹²⁶ However the independent (admitting rights) status of many hospital doctors restricted the uptake of the JOINTS project for surgical site infection (SSI) prevention.¹¹² In US hospitals where resources were scarce, technology-based solutions to patient safety problems were sometimes favoured as cheaper, easier alternatives to behavioural changes (such as those which PSCs promote).¹⁸⁶ We found only one published study⁸³ reporting cost savings (US\$20m annually) from a Collaborative.

3.d.vi. Mechanism 6: Networks of clinical teams help teams within providers to change clinical working practices

Spreading learning between providers is a justification of the network approach that BST Collaboratives¹⁷ adopt and some studies^{10,131,175} suggest it helps clinical teams learn new working practices. Evidence conflicts as to whether networks of clinical teams help teams within providers to change clinical working practices. There is some evidence that external support makes clinical teams more likely to implement changes in working practices.¹³⁵ In the Netherlands, external support helped clinical teams within hospitals change working activities, leading to perceived and actual ‘successes’ of the collaborative, particularly in waiting-list, medication safety and process redesign projects (and least in operating theatre and dissemination projects).^{135,172} Factors that appeared to promote these changes included external ‘change agent’ support, team leaders being ‘positive’, and teams’ perception they had been successful due to external support and the team’s own [self-]organisation.¹⁰ In a US cancer screening collaborative, the external network was a source of expertise and facilitators who led regular ‘reflective adaptive process’ meetings for each primary care team.¹³¹ It proved necessary to use a mixture of content and media (formal presentations, group discussions, patients’ own stories, a skit – but locally-developed rather than PSC-distributed materials) to communicate the value of practice changes.¹³¹ Ongoing communication of teams across sites helped support the collaborative implementation of new methods of post-operative care in Canadian hospitals.¹²⁴ An English stroke collaborative produced ‘modest’ increases in practitioners’ compliance with two ‘bundles’ of evidence-based work practices for early hours care of stroke and post-stroke rehabilitation.²¹⁰ In Wales, cross-site exchanges of information advice assisted infection control activities.² An evaluation of the Welsh PSC reported instances of increased compliance with World Health Organisation Safe Childbirth Checklist (WHOSCC) working practices. Praise for staff efforts (even unsuccessful ones²⁰²) was a strong motivator and reinforcer.² A systematic review⁸², however, found that on balance providing expert ideas and support to clinical teams did not help them improve their working practices.

Despite collaboratives’ inter-organisational character, care processes still had to be redesigned specifically for, and the external support and evidence made relevant to, each problem and team, which impedes the standardised, comparable cross-team approach that PSCs require.¹⁸¹ PSCs may therefore have greater effect on work processes which are already standardised across providers.¹²⁷ When one work process is closely linked in a chain with others it is difficult to change that process

in isolation using PSC-like methods.¹⁸¹ For example, in a US primary care collaborative, overcoming doctors' defensiveness and resistance took many weeks.¹³¹

3.d.vii. Mechanism 7: Cross-organisational measurement systems help change clinical working practices

Comparisons among providers create “natural experiments” for identifying what works and what doesn't⁸³ (p.631). The effect of measurement upon collaboratives' attempts to change working practices appears to depend upon who does it, and why, something that may explain why Hulscher's systematic review⁸² reached no definite conclusion about this mechanism. Dixon-Woods and colleagues contrast 'problem-sensing' and 'comfort-seeking' data gathering, the former being necessary to expose areas in which it was necessary to support and strengthen clinical teams' quality improvement work. The corresponding methods included supplementing routine administrative data with qualitative data obtained by (e.g.) 'mystery shopping', other observational methods¹⁰⁷ and new disease registers.⁹¹ Early collaboratives in Michigan used 'regression-based time-series analysis'⁸³(p.638) to assess hospitals' progress. Making favourable comparisons between the work and outcomes of the team(s) who did participate in a collaborative and those who did not helped, in Canadian hospitals, to legitimate and sustain a Collaborative's work.¹²⁴ In NHS collaboratives poorly-designed, fragmented IT systems were an obstacle to improving working practices¹⁰⁷ and hospital teams in a Dutch collaborative found the same when they tried to run PDSA cycles.¹⁸¹ However, strong external monitoring appears to inhibit organisational learning.¹³⁸ In collaboratives, learning occurs above all from making practical small-scale changes, not from prior data collection and analysis.¹⁶ Rather, cross-organisational measurement systems function as a means both to motivate competition between different clinical teams (see above) and to stimulate team learning (see above). In the Welsh collaborative, external audit of services helped promote change by validating 'appropriate' standards of care and identifying service failings.² In general, clinical decision support systems for prescribing appeared more effective in institutional settings (in which professional behaviours and attitudes were more closely controlled) than in community settings.²¹¹

Using measurement to change clinical working practice assumes that the chosen measures are sensitive to quality of services, patient safety or the organisational factors mentioned above; and

that there are easily measurable outcomes, or clear links between clinical acts and outcomes.²⁰² The relationship between Hospital Standardised Mortality Ratio (HSMR), Summary Hospital Mortality Indicator (SHMI) and risk-adjusted mortality ratio (RAMI) and the actual quality and safety²¹² of hospital care is complex and contested^{114,213–215}, as is the relationship between these indicators organisational factors (including learning and PSCs).²¹⁶ Any association between such measures and patient safety is more likely to occur at department than at whole-hospital level.¹¹⁴ Process audits may be a more valid measure, fairer and more informative about what interventions are needed.¹¹⁴ The use of WHOSCC checklists as a central performance measure in Wales resulted in discrepancies between the data returns and actual practice in the operating theatres.² Comparison with other organisations requires linkage between informational systems external and internal to a given organisation.^{91,126} Kilo¹⁷ recommends focussing on just two or three main outcomes at a time, and parsimonious, focussed data collection and presentation (“‘just enough’ data [as] are sufficient to determine if a change is an improvement’ (p.8)). The work-processes to be changed have sufficient patients to ensure quick measurement and feedback¹⁸¹, but it is also important that patients do not pass so swiftly through a care process that data collection is impossible.²⁰²

3.d.viii. Mechanism 8: Changed clinical working practices improve quality and patient safety

The evidence that at least some collaboratives have improved the quality and safety of patient care has been described as 'positive but limited'²¹⁷; it might also be called complex and equivocal. An early review of research on Collaboratives argued that of health providers involved in them, around 30% substantially improved patient safety, 40% achieved little improvement and 30% dropped out⁶⁶, although a later review¹¹⁰ reported less than 20% drop-out. Hulscher's systematic review¹⁶ found eight studies evidencing collaboratives' positive effects on some of their intended outcomes. Two showed no effect. On balance, Hulscher¹⁶ concluded, collaboratives up to 2008 appear to have had '*modest effects on outcomes at best*' (p.28). Wells' more recent systematic review¹¹⁰ found that about a third of the studies included reported collaboratives' impacts on clinical processes, a third their impacts on outcomes, and a third reported impacts on both. The reported absolute differences in these impacts 'ranged from modest to very impressive, with a median of 12% improvement (range 4%–61%)' (p.233).¹¹⁰ Using the stricter of the two criteria applied in Wells' review, 73% of the primary studies reported positive effects on the intended primary outcome.

As evidence that collaboratives changed working practices in ways that improved patient outcomes, initial studies on the implementation of the checklists from which the WHO Surgical Safety Checklist was derived showed improvements in team climate and in adherence to evidence-based catheter infection prevention¹⁸⁴, glucose maintenance and ulcer prophylaxis methods.⁴² There are reports of US collaboratives reducing neo-natal infection rates for coagulase-negative staphylococcus⁷⁷, surgical site infections²¹⁸, and postoperative respiratory failure.²¹⁹ The Michigan Surgical Quality Collaborative reduced risk-adjusted morbidity in a quarter of the participating hospitals (elsewhere these rates remained stable), and reduced 30-day mortality for bariatric surgery, serious complications for percutaneous coronary interventions, and (on a composite measure) the quality of coronary artery by-pass graft (CABG) surgery.⁸³ An NHS attempt to replicate the Michigan project reduced reported central venous catheter blood-stream infection (CVC-BSI) rates by 60%, from an already lower starting point.²⁴ Adaptive team leadership, including explicit task coordination, supported effective resuscitation (trauma, cardiac arrest teams).¹⁶⁴

Various studies give evidence as to whether *Collaboratives* improved outcomes, but not about which specific intermediate mechanisms were responsible. The critical contexts may include the presence of formal risk management systems^{149,167} and the intensity of pressures for high production.^{167,168}

83% of the studies included in Wells'¹¹⁰ systematic review on collaboratives reported that one or more primary effect measures for each study improved. The included studies covered settings which included hospitals, ambulatory, nursing home and ambulance services. In the 'Michigan Keystone project' 72 Michigan hospitals (containing 99 ICUs), collaboratives reduced catheter associated bloodstream infections^{42,43,220} and reported reductions in adverse drug events.⁶⁶ A Collaborative in Tennessee reduced the rates of superficial surgical site infections, ventilator usage for longer than 48 hours, graft/prosthesis/flap failure, acute renal failure, and wound disruption.²²¹ Across 179 US hospitals²²² moderately large correlations were found between the (US) Agency for Healthcare Research and Quality (AHRQ) survey's patient safety culture variables and reduced rates of adverse events and in-hospital complications. Collaboratives in South Carolina, Maine and Canada are all reported²²³ to have contributed to falls in cardiovascular mortality, and in California to reduced hospitalisations for cardiovascular disease (CVD). An Australian primary care collaborative

obtained around a 50% improvement in mean percentage of patients at target for glycaemic control, blood pressure and cholesterol targets.⁹¹

Nadeem's systematic review¹¹¹ reported mixed results with respect to patient experiences, as did a study of a collaborative among medical groups (of primary care doctors) in Minnesota.²²⁴ A UK study²²⁵ of the Health Foundation's Safer Patients Initiative and a study of the Michigan hospitals which participated in a 'Keystone' collaborative¹¹³ argued that it was unclear whether safety improvements were due to secular changes in (e.g.) working practices independent of collaboratives. Even successful collaboratives may face trade-offs. Work practices that increase safety may also cause 'defensive' care; for example isolating patients in order to reduce risk of falls and of infection also reduced their mobility and social contact with other patients and staff.²²⁶

Two studies of asthma collaboratives^{227,228} found that for asthma care QICs produced no significant improvements in care management or outcomes, although Schonlau²²⁷ found that patients did participate more in education groups. The Michigan Collaborative's positive outcomes were not replicated in Ontario²²⁹ nor even, subsequently, in Michigan.¹¹³ An early HIV collaborative increased the proportions of patients with suppressed viral load, screening tests and prophylaxis, but not significantly.²³⁰ A study of Swiss hospitals²³¹ found no correlation between patient safety climate and seven patient outcomes. 'Implicit rationing' (meaning shortage of nursing time rather than nurse:patient ratios *per se* or skill mix) was associated with four outcomes (patient satisfaction; nurse-reported medication errors; bloodstream infections; pneumonia).²³¹ A recent study²³² also showed an association between better patient experience and improvement in some clinical outcomes (central line-associated bloodstream infection, postsurgical DVT, joint replacement complications, and 'a composite measure for all serious complications') for all Medicare patients, irrespective of whether their care providers participated in collaboratives.

An explanation that reconciles these discrepant findings is that the effect of Collaboratives is heavily contingent on their context.^{130,233} Published research reports a wide range of possible determinants (or co-determinants) of success for Collaboratives.¹⁶ Their effects were greater for interventions with a stronger supporting evidence base and when the interventions supported were simple and practicable.¹¹⁰ Collaboratives' effects were greater in larger hospitals⁴⁰ or in complex, highly acute care (ICU, ED, operating theatres) than in general medical or surgical wards.²³¹ The

collaborative across 71 Michigan ICUs had a greater impact on catheter-related bloodstream infections and 'ventilator-associated pneumonia intervention' in smaller and in religious hospitals.⁴³ A PSC in California reduced CVD hospitalisations even though the doctors and organisations involved were, in theory, market competitors.²²³ The English 'Advancing Quality' programme included standardised measurements, data feedback to hospitals, quality improvements within hospitals (e.g. use of specialist nurses) and between hospitals (staff from different hospitals meeting each other) and paying tariff bonuses to hospitals with mortality reductions in the top quartile. It reduced risk of death for patients with acute myocardial infarction, heart failure, and pneumonia. The improvements were greatest for small hospitals that the CQC rated 'good' or 'excellent' before the programme began.²³⁴

Quality initiatives may raise service quality through mechanisms other than influencing safety culture. One study²³⁵ reported significantly reduced catheter associated urinary tract infections but during the intervention period there was no change in safety culture. Conversely, another study showed that the implementation of the safe surgery checklist did not affect mortality and morbidity but did improve safety culture scores.²³⁶ These findings raise the possibility that the relationship between safety culture and changed working practices is reciprocal, even a 'virtuous circle': quality improvement work strengthens safety climate, which then stimulates further quality improvement work.

As noted, many studies report associations, or their absence, between a certain element in the PSC logic model and clinical outcomes. Both sides of the argument may however be setting an irrelevantly high bar to proving collaboratives' effect or value. Existing studies do not necessarily consider or report any intermediate outcomes or mechanisms linking one such element (e.g. training, data-sharing) and outcomes. Evidence based practice (selecting the 'right thing to do') and quality improvement ('doing [those] things right') are distinct but complementary. Process criteria may therefore be more relevant than outcomes for evaluating the 'success' of QI activities, which may be capable of being tested in terms of process even when testing their ultimate clinical outcomes is less (or not) practicable.²³⁷ It is reasonable to assume that when working practices become more strongly evidence-based, patient outcomes will improve as a result.

3.e. Collaboratives: overview of existing research

Various gaps and ambiguities thus remain in research about collaboratives including:

1. Whether support provided by the network coordinating body was related to the ‘success’ of collaboratives, and ‘success’ at what.
2. What the contribution of inter-organisational networks of teams was to making working practices safer.
3. How resources are used in collaboratives, and the costs of collaboratives, both monetary and in kind.
4. What is the optimal number or range of safety issues for a collaborative to focus on.
5. What is the optimal number of participating clinical teams.
6. What tensions arise, and with what consequences, between PSCs’ role as an implementation structure for national policy and their character as a voluntary forum for collaboration.
7. What tensions arise, and with what consequences, between standardisation and transferable learning (on one hand) and local adaptation of PSC activities (on the other).
8. How collaboratives help healthcare providers become learning organisations.
9. What senior managers’ support at provider level contributes to collaboratives’ effects.
10. What collaboratives contribute towards quality improvement in practice, i.e. towards making working practices safer, and how Collaboratives interact with (reinforce or weaken) any other concurrent QI initiatives.
11. The uses and contribution of team training.
12. What effect resource pressures have upon collaboratives’ and clinical teams’ selections of foci of intervention, for instance upon their choices between technical and organisational methods for increasing patient safety.
13. What specific approaches to measurement help, or impede, collaboratives’ work. Hence, what kinds of IT infrastructures help, or impede, collaboratives’ work.
14. What other specific contexts help, or impede, collaboratives’ work.

Most studies of collaboratives' effects have been uncontrolled and rely on self-reported outcomes.²³⁸ The research has been fragmented across a range of collaboratives' activities and target outcomes, and few studies report clearly how their collaborative carried its work out, making it hard to identify what the 'active ingredient' in collaboratives is.¹¹¹ Hence;

'future studies need more detailed information about ... the dosage of individual QIC components; teaching strategies and approaches to fostering cross-site collaboration; use of data to guide QI processes; fidelity to the QIC model; degree of engagement among participating sites; and sustainability of QI activities. To date [2013], there are very few ... evidence-based descriptions of the most effective ways to conduct a collaborative'.¹¹¹(p.386)

In general, studies of Collaboratives have used very disparate, often self-reported measures of outcome or 'success'. Few contained any quantitative evidence about the determinants of 'success' (as opposed to abundant hypotheses and conjectures).⁸² Considering the frequency with which a safety culture is asserted to enhance patient safety, there is across the research literature as a whole a noticeable divergence of evidence about whether such a link exists. It also remains unknown whether some working practices (e.g. bounded unified processes entirely under clinicians' control rather than more complex care¹⁸¹) may be more susceptible than others to improvement by collaborative methods.²¹⁰ An Iranian study¹⁴⁷ found that total quality management (TQM) methods (which partly overlap with collaboratives' methods) had more impact on process management than performance results, strategic planning or the supply chain. Finally collaboratives in hospitals are more widely reported than those in other settings¹⁴³ though patients may take a more active role in primary than secondary care collaboratives.²³⁹

Chapter 4: Methods

4.a. Research design

To understand the complex and diverse mechanisms used to implement Patient Safety Collaboratives (PSC) and their Quality Improvement (QI) work, what effects they produced, how, for whom and in what contexts, required a mixed-methods realistic evaluation, a research design framed specifically to examine such questions.²⁴⁰ This research design would allow us to empirically test the programme theory, i.e. the causal assumptions, both explicit and tacit, built into the policy of constructing PSCs and outlined in Chapter 2. In that sense, the study design was theory-driven.

Since the PSC programme was already running at the start of this study, the strongest feasible research design was observational comparison of PSC mechanisms, contexts and outcomes. The comparison used three methods, each broadly corresponding to one of the successive stages of the PSC implementation:

1. Implementation study: a mainly qualitative investigation of how PSCs were set up by AHSNs at a regional, network level, and how NHS managers and clinicians then interpreted the guidance and actually set up the PSCs. The implementation study explored what mechanisms PSCs used for influencing clinical practice and models of care, especially for the purposes of monitoring and improving clinical quality and safety.
2. Patient safety culture surveys: this element compared the findings of surveys of patient safety climate in providers participating in PSC activities, since Francis and subsequent policy statements (see Chapter 2) emphasised strengthening patient safety culture as a mechanism for making clinical practice safer.
3. Analysis of routine administrative data: changes to patient services and outcomes were the expected consequences of changes in safety culture and climate. To assess how far such changes had occurred we carried out quantitative analyses of routinely collected administrative data relevant to the policy outcomes intended for PSCs.

Ideally each of these methods would cover the range of care group settings found across the NHS: general practice, community health services, mental health services and hospitals but in practice

(see Chapters 5-8). PSCs were developed and implemented more (but not exclusively) in acute hospitals and general practices.

Table 1 shows how the three methods map onto our research questions and the mechanisms (programme theory) of PSCs outlined in Chapter 2.

Table 1: Research Questions, Methods and PSC Mechanisms

Research question	Method(s)	PSC Mechanisms
RQ1. How have the PSCs been implemented in each of the 15 Academic Health Science Network (AHSN) regions?	Implementation study	1,2,3,5,6
	Safety culture survey	4
	Analysis of routine administrative data	4.5,7
RQ2: What organisational changes have providers made? (a) How have they done this? (b) What have they learned from the PSCs?	Implementation study	4,5 (a) 1,4,5 (b) 1,2,3,5,7
RQ3: How were resources used for PSC's implementation activities? What are the costs of participation and implementation?	Implementation study	1,2,3,5
RQ4: Have the PSCs made a detectable difference on rates of harm and adverse events involving patients as measured using routine data?	Analysis of routine administrative data	5,8
RQ5: Has change in practice taken place on the front-line of services?	Implementation study	5,6,7
	Analysis of routine administrative data	5,7
RQ6: What generalisable knowledge can be shared about this?	Contextualisation of the above findings.	All

‘Contextualisation’ means that for each mechanism, we attempted to identify local factors (e.g. the past history of QI work; how much workload and financial pressure each provider was under at the time of this study) that constrained or multiplied the ways in which a PSC and its QI work could be carried out in that network, organisation, or clinical team, or which constrained or amplified its effects. Using secondary evidence we then considered whether these contextual barriers and facilitators were likely to be typical of other NHS providers of the relevant kinds.

This study design confronted four methodological issues:

1. PSC activity was intended to reduce avoidable harm to patients resulting from system failures and human (individual) error. This means the measurement problem in an evaluation is to measure an outcome which consists in the non-occurrence, hence non-observation, of specific events - that is, to identify the counterfactual (hypothetical absence of PSCs) against which to compare PSCs. Since PSCs were introduced simultaneously across England the most appropriate analyses were:
 - (a) Analyses of outcome measures over time, including pre- and post intervention (PSCs) periods.and
 - (b) Narrative comparisons, for the implementation study.

2. For obvious reasons self-reports about how a given innovation (here, PSCs) was introduced and about its effects may err towards over-stating the effects and successes⁹² or towards claiming that the initiative in question (here, PSCs) produced activities or outcomes whose origins lie also, or entirely, elsewhere. Furthermore, ‘This [risk of bias] also applies to QIC researchers who use perceived successes as proxy variables for actual performance.’¹⁰ To minimise this bias we supplemented and triangulated such self-reports with:
 - (a) Informed non-participants’ descriptions of the same activities.
 - (b) Analyses of routine administrative data.
 - (c) SCORE survey data.
 - (d) Empirical findings from other studies of Collaboratives (e.g. Hulscher's checklist¹⁶ for probable conditions for success).

3. Our study involved a potential conflict of interest since it involved AHSN members potentially evaluating the work of their own AHSN and PSC. To obviate this conflict of interest we separated the conduct of:

- (a) Data collection, which required access to AHSN and PSC staff, documents and routinely-collected data (including financial data). This work was partly carried out by AHSN staff.
 - (b) Qualitative data analysis and synthesis of all the data were carried out separately in 'clean room' fashion solely by researchers (ND, MF, IL, RS) not otherwise involved in the AHSN and PSC, hence having no personal interest in reaching particular findings and conclusions.
4. Attributing activities or outcomes to one given policy initiative (here, PSCs) is problematic in contexts when other policies simultaneously impact upon the same activities and outcomes. To minimise attribution errors we:
- (a) Collected data about PSC implementation in a sequence which began with PSC-level activities and followed them through to provider management and then clinical team so that activities could be linked with any consequences, through to any resulting change in working practices.
 - (b) Triangulated data as described for (2).
 - (c) Included in our analyses data about other QI activities in parallel with PSCs and about other policy initiatives that might be expected to impact upon PSC and QI activities.
 - (d) Deliberately checked for counter-explanations and additional explanations of activities and outcomes that informants had also attributed to PSCs, i.e. what other actors, besides the PSCs, may either have potentiated or countervailed the PSCs' activities and their effects.
 - (e) Inducted patterns from the qualitative data in addition to using a framework analysis (see below).

In reporting the study we adhere to the Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines²⁴¹; these are itemised in Appendix 1.

4.b. Implementation study

The implementation study was a multiphase qualitative analysis of PSCs' impacts on organisational culture and climates, staff attitudes, behaviours and teamwork, and any consequences for patients in terms of delivering safe, effective and compassionate care. It also covered the budget allocations of PSCs.

4.b.i. *Sample*

We made a purposive, qualitative sample of study sites and informants so that data collection followed the sequence of PSC implementation (including the flows of knowledge, information, and finance) as it cascaded 'downwards' through the following three levels:

Level 1: Regional network level, i.e. the PSC within its host AHSN, and their interactions with the other provider organisations that participated in each PSC. We collected data from all PSC leads (n=16, including a pilot interview) across 15 AHSNs. To study in greater detail the relationships between PSCs and their member-organisations (providers) we selected three PSC regions (which we have pseudonymised 'Alpha', 'Beta' and 'Gamma') as a maximum-variation sample that contrasted apparently early and late adopters of the PSC model and associated QI activities, with correspondingly contrasting degrees of development, elaboration, and local embeddedness of their PSC activity; and also contrasted city and rural settings. Our purpose in doing so was to identify contexts that appeared to facilitate PSC implementation as well as those that didn't. Interviews with all PSC leads across 15 AHSN regions took place between December 2015 and July 2016. Of the PSC lead participants twelve were female and four were male, with an age range at interview of 42 to 62 years.

Level 2: Provider management level, i.e. the senior managers (medical and non-medical) responsible for leading PSC activity (and often QI activity in general) at provider level across the three regions mentioned above. Within these PSCs we again sampled for maximum variation. We included provider organisations which covered the range of services participating in the PSC in that region, which in each PSC included acute hospitals, general practices, and community mental health services. We also included CCGs, as (*inter alia*) local care coordinating bodies. In general, our rationale was to identify any differences in PSC implementation and its consequences that arose from working in different types of

service. We interviewed the patient safety leads (n=14) within provider organisations. These interviews took place between September 2016 and August 2017. Ten of these informants were female and four were male, with an age range at interview of 27 to 58 years.

Level 3: Clinical team level, i.e. the work-groups of clinicians and other health workers directly providing patient care at department or general practice level, and whose working practices PSC activity (perhaps combined with other QI activity) aimed to make safer and higher-quality. Informants at this level were front-line staff (n=31) across the same three regions. These interviews took place between March and November 2017. 22 of these informants were female and nine were male, and the age range at time of interview was 25 to 63 years.

Table 2 summarises the characteristics of the sample of study sites.

Table 2: Study site sample

Level 1 (PSC networks)	Levels 2 (provider organisations) and 3 (front-line clinical teams)
PSC Alpha (early adopter)	Hospital A
	Hospital B
	Mental health trust C
	General practice D
PSC Beta (middle adopter)	Hospital E
	Mental health trust F
	General practice G
	General practice H
PSC Gamma (later adopter)	Hospital I
	Hospital J
	Hospital K
	Hospital L
	Hospital M
	Hospital N
	Community health services O

The key informants' ages ranged from 25 to 63. 44 were female, 17 male. Appendix 2 lists their job titles.

4.b.ii. Data collection

Following the national launch of the PSCs we began fieldwork in the form of collecting interview data in December 2015. For each study site at each level we first reviewed any available websites and 'grey' publications about it, then carried out semi structured in-depth interviews of the key informants described above. By 61 interviews we attained data saturation and therefore ceased recruiting informants (a standard data collection method in qualitative research²⁴²). As we analysed the data it became clear that patients had no *direct* experience (perceptions) of what the PSCs were doing i.e. trying to change clinical working practices. It was health-workers rather than patients who had first-hand knowledge of whether or how clinical practice had changed. Patients did of course experience the services upon which the PSCs worked, but as the findings and discussion chapters below explain, PSCs' impacts on those services were heavily diluted because PSCs concentrated on improving specific, often narrow, parts of the whole care process, and tended to concentrate on preventing adverse events rather than supplementing or changing the events that did occur. Furthermore, few patients could from their own experience compare a pre-PSC with the same service post-PSC. So PSC impacts were by their nature invisible to patients. We therefore decided that, for these reasons beyond the control of the research team and contrary to our original expectations (stated in the research protocol), interviews with patients would be uninformative about what impacts PSCs were having, even upon patients themselves.

The interview schedules (see Appendix 4) were designed as a semi-structured guide to the topic area. It was devised by a multi-disciplinary research team based upon a review of the research literature and previous research experience. It was piloted in an interview with an AHSN lead, slightly revised, and used as modified for subsequent interviews. Following audio quality check, the first two transcripts were independently coded and the coding checked for inconsistencies by three members of the research team (ND, SC, RS), who then agreed explicit criteria for coding these topics.

All interviewees received information sheets explaining the purpose of the research and what their participation would involve. All returned completed and signed consent forms (see Appendix 3) before being contacted by follow-up phone call to take part in the study. Interviews were carried out by telephone and lasted between 25 and 110 minutes. They were audio recorded, transcribed verbatim, audio quality checked and anonymised. We kept fieldwork notes in order to contextualise the data and detailed summaries of each interview were produced.

Different components of the interview schedule were emphasised for each level of study participants/informants as described above. PSC leads were asked about their experience of setting up the PSCs and specifically about:

- The main aims of the Patient Safety Collaborative (PSC).
- How the PSC was established and what the process of implementation involved.
- To what extent they followed pre-existing activities or introduced new ones (infra-structure; AHSN).
- What they hoped to achieve.
- Experience in practice: what are the barriers and facilitators and lessons learnt.
- Reflexivity measures (inputs/output measures/ process measures).
- Sharing best practice.
- Budget allocations.
- Overall perceptions and experience.

The semi-structured nature of the interview meant that participants determined the order, as well as the extent to which any predefined themes were discussed.

Participants were asked at interview if they would like to receive a copy of their interview transcript to pre-approve prior to inclusion in the study. Out of 61 participants, 45 requested to pre-approve their interview transcripts. All were returned unchanged and fully approved.

Together, our various data sources were intended to highlight differing perspectives and allow exploration of areas of contradiction or agreement in participants' accounts; to help identify any barriers or difficulties encountered in PSC implementation, and possible unintended consequences (both positive and adverse); to discover what the incentives for taking part in the PSCs are and what action the providers feel they need to take to be part of them. At level 3 we sought data on what had actually been done to make clinical work safer: that is, we elicited narratives about the changes that occurred in working practices related to QI and patient safety, and whether this was due to PSC activity or occurred for other reasons. We also included the free-text responses to the Safety, Communication, Operational Reliability and Engagement (SCORE) surveys described below.

We considered information provided in the PSC websites and from the interviews with PSC leads to identify the flows of expenditure from the PSCs to quality and safety activities as well as the outcomes affected by these new financial injections. We also used qualitative data from the interviews with PSC leads to estimate any opportunity costs relating to activities, both clinical and managerial, that were not undertaken as a result of PSC activity within provider organisations. We requested from both NHS Improvement and the individual PSCs their direct budget allocations.

Financial management data apart, we collected data until we reached theoretical saturation, i.e. additional data were ceasing to add any new explanations about how PSCs did, or did not, work and in which contexts.

4.b.iii. Data analysis

All interview data were analysed inductively using thematic analysis techniques²⁴³ to generate descriptions of themes both within and across the data. The analysis began with coding, followed by identification and clustering of themes and sub themes before comparing themes across the dataset. Team members then discussed and agreed the inductive analysis, and how it overlapped or contrasted with the a priori analytic framework (outlined in Chapter 2). This method ensured that the analytical quality and interpretative aspect of the analyses were well justified^{244,245}, after which the themes and sub themes were grouped in order to construct a more descriptive and interpretative summary of recurrent key themes (Appendix 5 is an example) illustrated with verbatim quotes.

Because it was the intended endpoint of PSC activity we took the clinical team as the basic unit of analysis.²

The analysis was therefore informed by interpretive phenomenology derived from hermeneutics^{246,247} an approach that gives primacy to “insider knowledge” and the “lived experiences” of study participants by emphasising the meanings they attach to key phenomena in a given context so as to provide a detailed description and explanation of how they understood, experienced and used PSCs. Through these inductive methods we established the patterns reported in Chapters 5-7.

4.c. Safety culture survey

The Francis Report, subsequent policy statements, and the underlying programme theory of Collaboratives^{178,222,248,249} each assumed safety culture to be a critical factor in improving patient safety. For all practical research purposes safety culture or climate are defined by scores on safety culture surveys. The culture survey was initially intended solely to measure changes in safety climate although in the event, and as the findings chapters (Chapters 5-8) report more fully, the feedback debriefing also became an intervention in its own right for changing both working practices and culture. Implementing the culture survey involved the following steps:

1. Site selection.
2. A first survey administered by staff in each site in collaboration with Safe and Reliable Healthcare (USA).
3. First de-briefing. Site by site, Safe and Reliable Healthcare (USA) summarised the responses to the first survey in a report which formed the basis of a debriefing session with the staff in that site (both responders and non-responders to the first round survey).
4. Second survey at least six months later (time-scales reported below and in Chapter 7).
5. Optionally, further de-briefing followed by further survey cycle(s).

As for the implementation study, the unit of analysis was the front-line clinical team within a hospital or general practice (level 3) because that was the group whose safety culture was, the programme theory of PSCs assumed, critical for patient safety (see Chapter 2).

4.c.i. Measure: SCORE instrument

Building upon questionnaire surveys initially developed in aviation, Sexton developed the first safety culture surveys used in healthcare over 21 years ago. The two most widely used survey instruments for measuring safety climate, the Agency for Healthcare Research and Quality (AHRQ)²⁵⁰ and the Safety Attitude Questionnaire (SAQ)^{251,252} questionnaires, were when we began this study 10 and 21 years old respectively, and 'not intended for use in today's healthcare environment'. The SCOPE-PC instrument is more recent but designed specifically for primary care settings.²⁵³ To measure patient safety climate we used the Integrated Safety, Communication, Operational Reliability and Engagement (SCORE) Survey instrument for Organisational Learning and Improvement (Appendix 6).²⁵⁴

The SCORE survey consists of seven domains: learning environment, local leadership, burnout climate, personal burnout, teamwork, safety climate, and work-life balance. Each domain includes a number of questions, each with responses on a scale from 1 to 5 (disagree strongly, disagree slightly, neutral, agree slightly, agree strongly) for the first six domains (there are some negatively worded questions within the teamwork and safety climate domains but all questions within the other domains are positively worded), and from 1 to 4 (rarely or none of the time, some or a little of the time, occasionally or a moderate amount of time, all of the time) for the work-life balance domain (negatively worded). The survey also records free-text answers to four questions: what the respondent thinks are the greatest risks to patient safety in her workplace; what should be done to address those risks; which other topics the survey should have asked about; and any other comments about the issues that the survey covers. The teamwork and safety climate measures in SCORE derive from SAQ. Although, as noted, SAQ is now rather old it had sound psychometric properties in respect of composite scale reliability, factor structure, between-factor correlation, and sensitivity to variability; and was 'associated with clinical outcomes like hand hygiene or bloodstream infections'.²⁵¹ The personal burnout component has acceptable levels of reliability and factor intra- and inter-class correlation.²⁵⁵ The burnout (work-life balance) components show acceptable reliability and variability²⁵⁶, as does the improvement readiness component.²⁵⁷ The local leadership element (which includes learning environment) is also acceptably reliable.^{257,258}

4.c.ii. Sample

Any NHS site – department, ward, general practice or other clinical team - was eligible to volunteer for the SCORE survey. The sample of sites was therefore self-selected. Within each site the survey was a census of individual staff members. A first round of surveys was conducted across 72 sites, unevenly distributed across 6 PSCs. 36 sites were general practices, 13 were acute hospital wards (including maternity and , paediatrics), and 9 were mental health wards. There were three ICUs, one emergency department, seven other hospital departments, and one CCG. The numbers of individual respondents in each site (more fully reported in Chapter 7) ranged from 9 to 151. Two of these were also sites in which we conducted qualitative fieldwork for the implementation study. At the time of writing only six of the first-round sites had proceeded as far as a second-round (i.e. repeat) SCORE survey: three general practices, a mental health trust pharmacy, an emergency department and a medical admission unit. Time periods for the first and second SCORE surveys and debriefing sessions, in each of the six units, are shown in Table 3.

4.c.iii. Survey data collection

SCORE survey data were collected by Safe and Reliable Health Care, a US company run by the inventors of the SCORE survey and commissioned to administer the survey by a number of AHSNs and the volunteered providers within them. The latter arranged access to the study sites and for the surveys to take place. The individual-level SCORE data were anonymous and only available to this research team. The surveys were carried out between September 2015 and September 2017, the first round in 2015-16 followed by a period of between 11 and 18 months between first and second surveys.

4.c.iv. Analysis

Individual person-level domain scores for the SCORE survey, for each of the six domains: learning environment, local leadership, burnout climate, personal burnout, teamwork and safety climate, are calculated as follows. The response to each question within the domain is converted to 0-100 by subtracting 1 from the numeric response and then multiplying by 25 (inverting any negatively worded questions in the teamwork and safety climate domains). The person-level domain score is

the mean of the 0-100 scaled question responses, based on all of the questions that the individual answered within that domain. This means that if an individual has a domain score of 100 they have responded agree strongly to all questions that they have answered within that domain; 75 means that they have responded agree slightly to all questions; 50 means that they have responded neutral to all; 25 means that they have responded disagree slightly to all, and 0 means that all responses are disagree strongly. Individual-level domain scores for the work-life balance domain are the means of the numeric responses to each question within the domain.

For each of the six units in which the repeat SCORE surveys were administered, individual person-level domain scores are summarised using means and standard deviations, and scores from the first and second surveys are compared using two sample t tests. All analyses are carried out using R statistical software (version 3.4.1)²⁵⁹ with a declared significance level of $p < 0.05$.

We coded the free-text answers into categories emerging from the responses themselves. For the reported risks to patient safety these categories included, for example, making mistakes due to lacking sufficient time to do the work and lack of monitoring equipment. Under each category we recorded the number of responses mentioning that issue. Responses that respondents mentioned in more than one category counted as one mention for each category. The counts included both rounds of the survey, so that issues which a given respondent mentioned in each were counted a two mentions. This means the total number of mentions exceeds the number of respondents. On that basis we report (Chapter 7) simple frequencies of the safety issues which SCORE survey respondents mentioned.

Table 3: Time periods for the first and second SCORE surveys and debriefing sessions, in each of the six units.

Unit	2015							2016												2017								
	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	
General practice C															1st		DB											2nd
Hospital D: ED	1st				DB														2nd									
Hospital D: MAU				1st			DB																2nd					
Pharmacy E							1st						DB										2nd					
General practice A								1st		DB								2nd										
General practice B							1st								DB											2nd		

1st – launch date of first survey

DB – date of debrief

2nd – launch date of second survey

4.d. Analysis of routine administrative data

We analysed routinely- collected outcome data, reported at trust level, for acute trusts within all AHSNs in England for the years 2013 to 2016 inclusive. This includes data from: annual NHS inpatient and staff surveys, monthly classic safety thermometer, six-monthly incident reporting (between April 2014 and March 2016), and, from annual Standardised Hospital Mortality Index (SHMI) data, the observed numbers of deaths and in-patient spells.

Because PSCs were introduced in October 2014 we used 2014 as the reference year in all analyses, estimating differences in outcome measures in 2013, 2015 and 2016, compared to 2014. This gave us an indication of any change in measures between a year with no PSCs in place (2013), and the year in which they were introduced and so were partly in place (2014) as well as allowing us to estimate any changes in outcome measures between two years (2015 and 2016) in which the PSCs were largely or wholly in place, compared to 2014. This allows us to assess the stability of measures across 2013 and 2014; if measures are stable across these years, any differences observed in 2015 and 2016 can be more confidently attributed to the intervention (PSCs). If there are trends in outcomes across all four years, we would have less confidence that any differences seen post 2014 are due to the PSCs and not just secular trend.

For all of the outcomes described above, as well as overall analyses across all AHSNs, we focus on the three AHSNs in which we undertook the implementation study.

Time periods for routine outcome measures are shown in Table 4.

Table 4: Time periods for routine data analysed in the PiSCES study.

Routine data	2013												2014												2015												2016											
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
NHS inpatient surveys^a	Annual survey for each trust												Annual survey for each trust ^d												Annual survey for each trust												Annual survey for each trust											
NHS staff surveys^b	Annual survey for each trust												Annual survey for each trust ^d												Annual survey for each trust												Annual survey for each trust											
Classic safety thermometer	Monthly data for each trust, aggregated over year												Monthly data for each trust, aggregated over year ^d												Monthly data for each trust, aggregated over year												Monthly data for each trust, aggregated over year											
Incident reporting													6-monthly for each trust			6-monthly for each trust			6-monthly for each trust			6-monthly for each trust																										
Hospital Mortality^c	Annual data for each trust												Annual data for each trust ^d												Annual data for each trust												Annual data for each trust											

^aAnnual NHS inpatient surveys carried out once per year, per trust.

^bAnnual NHS staff surveys carried out once per year, in October, per trust.

^cFrom annual SHMI data covering each calendar year, per trust.

^dUsed as the reference year in data analyses.

All routinely collected data are at trust level. The data structure for analyses is in the form of one row for each trust, for each of the years 2013 to 2016 inclusive. Therefore, each trust has four rows of data, with a small number of trusts having fewer than four rows if data are unavailable for particular years. As noted above the year 2014, in which PSCs were introduced, is used as the reference year. Analyses provide estimates of the change in outcome measures between the year 2013, when there were no PSCs, and 2014, as well as the change in measures between each of the years 2015 and 2016, when the PSCs were in place, and 2014. For each of the outcome measures from the NHS inpatient survey, NHS staff survey, classic safety thermometer and hospital mortality (SHMI) data, the main analysis is based on those trusts that have data reported for all four years. Sensitivity analysis uses all available data across all years, where some trusts have data reported for some but not all years. All analyses were carried out using R statistical software (version 3.4.1).²⁵⁹

4.d.i. NHS inpatient surveys

Analyses of NHS inpatient surveys focussed on a single question about the inpatient's overall satisfaction:

‘Overall...

‘I had a very poor experience [0]’to... ‘I had a very good experience [10].’

Possible scores for this question are from 0 to 10 in 1 point increments. This is question number 68 in the 2013 and 2014 surveys, question 72 in the 2015 survey and question number 74 in the 2016 survey.

Data are reported as the average score for each trust, for each year. Trust scores are summarised in terms of means and standard deviation. We fitted random effects linear regression models to the trust scores, with the fixed effect of year and random effects of trust. This allows for correlation between observations within the same trust. We report the mean difference between the average scores in 2014 (reference category) and each of the other three years; 2013, 2015 and 2016. Ninety-five percent confidence intervals and p-values are reported for the mean difference. Further analyses focus on each of the three AHSNs. In each case, we based the main analysis on those trusts that have data reported for all four years. We conducted sensitivity analysis using all available data across all years, where some trusts have data reported for some but not all years.

4.d.ii. NHS staff surveys

Some questions in the NHS staff survey are similar to questions in the SCORE survey. Our analyses of NHS staff surveys focussed on the published key findings, for each trust, for each of the years 2013 to 2016 inclusive, relating to:

- **Improvement:** staff feeling that they are able to contribute towards improvements in their area of work – reported as the percentage of staff who feel that they are able to do this, defined as those answering either ‘agree’ or ‘strongly agree’ across three questions from the ‘your job’ domain.
- **Managers:** support from immediate managers – reported as the mean score across five questions from the ‘your managers’ domain and one question, from the ‘your job’ domain, each scored on a 1 (very dissatisfied or strongly disagree) to 5 (very satisfied or strongly agree) with higher scores indicating that staff feel they have more support from their immediate managers.
- **Errors:** fairness and effectiveness of procedures for reporting errors, near misses and incidents – reported as the mean score across four questions from the ‘your health, well-being and safety at work’ domain, each scored on a 1 (strongly disagree) to 5 (strongly agree) with higher scores indicating a greater belief that procedures are fair and effective.
- **Recommendation:** staff recommendation of the organisation as a place to work or receive treatment – reported as the mean score across three questions from the ‘your organisation’ domain, each scored on a 1 (strongly disagree) to 5 (strongly agree) point scale, so that higher scores indicate a greater likelihood of recommendation.

To compare the key findings across the years we used random effects linear regression models fitted to the trust-level data, with the fixed effect of year and random effects of trust. This allows for correlation between observations within the same trust. We report the means and standard deviations of the outcomes (key findings) for each year and the mean difference between the outcomes in 2014 (reference category) and each of the other three years: 2013, 2015 and 2016. Ninety-five percent confidence intervals and p-values are reported for the mean difference. The main analysis is based on those trusts that have data reported for all years. Sensitivity analyses include all available data across all trusts within all AHSNs, where some trusts have data reported for some but not all years. Further analyses include trusts within each of the three focal AHSNs, with sensitivity analyses if there are any trusts within these AHSNs that do not report for all years.

4.d.iii. Classic safety thermometer

The Classic Safety Thermometer focuses on the four most commonly occurring harms in healthcare: pressure ulcers, falls, urinary tract infection (UTI) (in patients with a catheter) and VTEs. Data consist of the number of new harm events and the total number of patients, for each trust, for a single day of each month between January 2013 and December 2016 inclusive. There is a recommended day for each month, on which trusts should report on the safety thermometer but it is unclear whether this recommendation is followed and it is possible that data for different trusts will correspond to different days of the week, and possibly different weeks, within each month. For each trust, the numbers of new harm events and denominators were totalled across months within each calendar year, to give an annual total number of events and total denominator. The rate of new harm events per 100 person-days is reported for each year. This provides an estimate of the number of new harm events that would be expected to occur among 100 patients observed for a single day. To compare rates of new harm events across the years we used random effects Poisson regression models, fitted to the reported number of events, with the fixed effect of year and random effects of trust. We report the estimated rate ratio for each of the years 2013, 2015 and 2016, relative to 2014. Ninety-five percent confidence intervals and p-values are reported for the rate ratio. The main analysis is based on those trusts that have data reported for all years. Sensitivity analysis includes all available data across all trusts within all AHSNs, where some trusts have data reported for some but not all years. Further analyses include all trusts within each of the three focal AHSNs.

4.d.iv. Incident reporting

Trust level data on reported incidents within six-month periods, from April 2014 to March 2016 (categorised according to level of harm: none; low; moderate; severe or death), are summarised in terms of the percentage of all incidents reported that were either severe incidents or deaths.

4.d.v. Hospital mortality

Comparisons of hospital mortality rates over years use trust level published SHMI data for the years 2013 to 2016 inclusive. From these data we used:

1. The total number of finished spells for a trust, where a spell is a continuous period of time spent as a patient within a single trust. A spell may be composed of more than one episode (a single period of care under one consultant) and ends when the patient is discharged or dies;
2. The total number of observed deaths for a trust, which includes deaths in hospital or within 30 days of discharge.

The mortality rate per 100 spells is reported for each year. This provides an estimate of the number of deaths in hospital or within 30 days of discharge that would be expected to occur among 100 spells. To compare hospital mortality rates across the years we used random effects Poisson regression models, fitted to the total number of observed deaths, with the fixed effect of year and random effects of trust. We report the estimated rate ratio for each of the years 2013, 2015 and 2016, relative to 2014. Ninety-five percent confidence intervals and p-values are reported for the rate ratio. The main analysis is based on those trusts that have data reported for all years. Sensitivity analysis includes all available data across all trusts within all AHSNs, where some trusts have data reported for some but not all years. Further analyses include all trusts within each of the three AHSNs (PSCs) selected for fuller study, with sensitivity analyses if there are any trusts within these AHSNs that do not report for all years.

4.e. Synthesising the findings

Table 5 summarises the data we collected across the evaluation as a whole.

Table 5: Data collected

	Interviews	Other material
Implementation study: level 1	16	28 documents, 22 media reports, 364 free-text
Implementation study: level 2	14	SCORE responses, 15 PSC websites (for the
Implementation study: level 3	31	activities receiving resources) and the documents available in them.
SCORE survey data (both first	None	376 respondents, 6 sites.

and second round)		
Routine administrative data	N/A	NHS Digital datasets for: NHS Inpatient Survey; NHS Staff Survey; Classic Safety Thermometer; Incident Reporting; Hospital Mortality.
Secondary data	N/A	232 published papers, 18 research reports

Figures for the implementation study include the financial aspect.

To synthesise the findings from the three methods we used we carried out two framework analyses^{260,261}, reported in the Discussion (Chapter 9) below. The first framework analysis was conceptually equivalent to a tabulation in which each row was one of the research question and each column one of the three study methods described above. Table 1 shows which methods were relevant to which research questions. Each cell summarised the respective findings, and by collating them row by row (so to speak) we synthesised answers to all the research questions except one: what generalisable lessons might be drawn from our findings? To answer that question, we used a second framework analysis to compare the set of context-mechanism-outcome (C-M-O) assumptions for each mechanism in the policy-makers' programme theory for PSCs (see Chapter 2) with the combined data from all three methods outlined above. This framework analysis was conceptually equivalent to a tabulation in which each row was one of the eight mechanisms (and where specified, its context(s)) in the programme theory; see Table 6.

Table 6: Data Synthesis by PSC Mechanism

Mechanism	Context(s)	Findings from
1. Regional coordinating body and network make providers become more 'learning' organisations, assuming as context	1a. Central policy and organisations continue to support PSCs and their activities.	Implementation study
2. Each regional coordinating body establishes (a) cross-organisational network(s) of clinical teams	[None specified in programme theory]	Implementation study
3. Each regional coordinating body and network establishes cross-organisational	3a. Central policy and organisations continue to support PSCs and their	Implementation study

measurement systems	activities.	
4. The providers which have become learning organisations develop an organisational culture and climate more conducive to patient safety and quality improvement	4a. Staff training works [in changing workplace attitudes and skills]	Implementation study SCORE survey
5. Changed safety culture and climate help clinical working practices to change	[None specified in programme theory]	Implementation study SCORE survey Analysis of routine administrative data.
	5a. Staff training helps create or strengthen new working practices	Implementation study
	5b. The provider has sufficient staff	Implementation study
	5c. Contractual incentives align with the new working practices	Implementation study
6. The cross-organisational network(s) of clinical teams help clinical working practices to change	[None specified in programme theory]	Implementation study
7. The cross-organisation measurement systems help clinical working practices to change	[None specified in programme theory]	Implementation study
8. The changed working practices result in the <i>outcomes</i> of increased patient safety and quality improvement.	[None specified in programme theory]	Analysis of routine administrative data.

Our attempts to populate these frameworks exposed to us where data were missing, ambiguous or seemingly contradictory, prompting further data collection. This also exposed any dis-confirming evidence and counter-explanations for the programme theory outlined in Chapter 2. To minimise the risk of availability (of our own and each other's preconceptions) colouring the general findings and conclusions that we drew from this material, the two PIs first formulated their own conclusions separately, then compared and merged them. (In the event, their sets of conclusions were very similar.)

A potential limitation in such an approach to integrating qualitative and quantitative data by this method is that the analytic frameworks – which originated as much from policy as from scientific sources – might omit important contexts and co-determinants (‘confounders’) of PSCs’ QI work and its outcomes, might include extraneous contexts and co-determinants, or might do both. To minimise the likelihood of these errors we:

1. Supplemented the original (programme theory) analytic framework with further context-mechanism-outcome configurations derived inductively from our data, especially from the implementation study (see above).
2. Modified, or even removed from, the original (programme theory) analytic framework, those mechanism-outcome configurations for which our data gave only qualified evidential support, or none.

Furthermore, the routinely available administrative data were incomplete and in some cases questionable (see above) proxy measures for some of the intended PSC outcomes, or (for some variables including the SCORE survey, taken as a proxy for likely levels of harm to patients) for the processes by which policy makers expected PSCs to produce those outcomes. We have noted (Discussion, Chapter 9) how this limits the interpretation and conclusiveness of our findings.

4.e.i. Drawing general policy lessons

If the policy assumptions underlying policy makers’ programme theory of PSCs were valid we would expect to observe that:

1. The main elements of the PSC programme, i.e. its main mechanisms (see Chapter 2, Figure 1), were all established essentially as the policy intended, and;
2. Once established, these mechanisms each had their intended effects in triggering and reinforcing each other, thereby producing the intended effects (outcomes) of each mechanism and, together, of the PSC programme as a whole.

The latter observation, if it occurs, is what yields generalisable (‘shared’) ‘lessons’. The ‘mechanisms’ on which realist evaluation focuses are, by nature, of a general character and so are the contexts that moderate their effects. Findings about them are therefore generalisable, although (indeed, for that very reason) being corrigible in light of further research. Our method²⁶² for deriving lessons that might support improvement elsewhere was to compare our synthesised

empirical findings (Chapters 5-8) with the assumptions of the policy-makers' original programme theory for PSCs (Chapter 2). We used these comparisons as a method for qualitative, falsificationist testing²⁶³ of the policy-makers' initial assumptions about what the mechanisms and contexts are, through which PSC improve service quality and safety. Chapter 9 (Policy Relevance) reports these comparisons.

In light of these comparisons we then removed from the original PSC programme theory the assumed mechanisms for which our synthesised findings gave no supporting evidence for, or gave evidence against. For mechanisms or contexts that had only partial support in our synthesised evidence, we removed the un-evidenced elements. To the resulting truncated but more strongly evidence-based programme theory we then added statements, based on our synthesised findings, about:

1. Relevant causal links we found in this evaluation but which the policy-makers' initial programme theory of PSCs did not include.
2. Contexts which qualify (strengthen, weaken or mediate) the mechanisms for which we found evidence but which the policy-makers' initial programme theory of PSCs did not include.

In these ways we converted the initial programme theory into a revised, more strongly evidence-based logic model. These changes together constitute the general policy lessons drawn from this evaluation. We itemise these in Chapter 11.

4.f. Patient and public involvement

Patient involvement in this project ensured we dealt with questions that make sense to patients and members of the public; and helped us maximise the project's impact by guiding dissemination and translation of our findings. We sought and received expert PPI advice from our NIHR CLAHRC partners (CLAHRC for the South West Peninsula (PenCLAHRC); which is regarded as a national trailblazer in relation to PPI) It began at the preparatory stage for this study. Two expert patients (Rosamund Snow and Anya de Longa) were involved in the preparation of the research protocol. Rosamund Snow has extensive experience both as a patient and a PhD researcher in user focussed research. Another patient representative, Sarah Ross, joined as a member of the PiSCES steering

committee. By chance one of our research team was also undergoing orthopaedic treatment for all except the last four months of the study period. As fieldwork progressed it became evident that few if any effects of PSC activity would be immediately experienced by patients. First, as Chapters 5 and 7 report, it would take time (at least 18 months) for PSCs to start to influence working practices at clinical team level, and even longer to produce changes in patients' safety. Then, as Chapter 9 explains, these effects would probably be diluted by the lack of effects on services that had not yet engaged with QI and safety activity instigated by the PSCs. Lastly, safety work largely aims at (tertiary) prevention. To a large extent the intended outcomes (at the level of patient experience) were events that did *not* happen i.e. iatrogenic harm. From a research point of view there seemed little point in seeking patients' views about experiences which did not occur. We therefore changed the focus of PPI activity to focus on the dissemination phase of the project, as described in Chapter 12.

4.g. Equality and diversity

At PSC network level we studied all of England and were able to discover whether, and if so which, PSCs' strategies and activities deliberately and explicitly focussed on equality and diversity, and whether their strategies and activities differed in ways that reflected their regions' distinct socio-economic and ethnic profiles.

4.h. Ethics and research governance

The NHS Research Ethics Committee system approved the study (reference 15-NI-0235) subject to obtaining research governance approval from each NHS organisation involved, which we did, and maintaining informant anonymity. Accordingly all informants and study sites are pseudonymised in the following chapters, including (for consistency) those who waived their right to anonymity. The routine administrative data that we have analysed are all publicly available. The study was funded by the Department of Health (England) Policy Research Programme (see Acknowledgements). After the initial open and peer-reviewed competitive commissioning process the funder has until the time of writing (March 2018) played no further part in the study design, implementation, interpretation and publication.

Chapter 5: Key findings (1): PSCs as managed regional networks of providers

We present our findings by following the implementation ‘down’ the health system from the national level to the level of PSCs as managed regional networks of provider (this chapter) to the level of whole provider organisations (Chapter 6) and then to clinical team level (Chapter 7). This order corresponds to the sequence of events anticipated in the policy-makers’ PSCs programme theory (see Figure 1, Chapter 2). This chapter reports our findings on how the PSCs have been implemented in each of the 15 Academic Health Science Network (AHSN) regions (RQ1); how implementation varied across the PSCs (RQ6); and how resources were used for the PSC’s implementation activities (RQ3). Of our informants, network level PSC leads are labelled ‘PSCL’, organisational-level leads ‘PSCOL’ and front-line clinical team members ‘PSCFL’ (followed in each case by the relevant individual number).

5.a. Setting up the PSC coordinating body

In October 2014, PSCs were launched as a five-year national programme to support individuals, teams and organisations to build the necessary skills and knowledge to enhance patient safety and quality improvement in order to reduce the numbers of avoidable harm cases across England. PSCs had an estimated budget of £12 million per annum, although some was retained for national-level management and measurement activities, leaving £7 million for the regional PSC network coordinating bodies. PSCs were to be organised and delivered locally by 15 Academic Health Science Networks (AHSNs) in order to respond to local variation and need.

During the Collaboratives’ setup phase, PSC leads suggested that they needed more developed national structures to help support their local work; more local flexibility to respond to need, and more co-ordination of work across AHSNs so that "we don't reinvent the wheel" (PSCL7). Many PSC leads anticipated that their work would be challenging because of the “policy uncertainty and regulatory changes” (PSCL10) they were witnessing. They likened the impact of “organisational turbulence” and “ongoing churn in the system” to "tectonic plate shifts" (PSCL15) and felt these added to the already growing complexity of NHS funding streams, care pathways and methods of referral. They expressed concern as to how receptive provider organisations and their staff would be

to the launch of a new initiative in a system already buckling under operational pressures including workload, funding cuts, staffing pressures, and rising patient demand:

“The pressure in the system is just enormous and the pressure in the system is always there” (PSCL11).

Amidst these systemic pressures PSC leads needed to define, even justify, their new role and to determine their projected impact and output measures.

“I think there is always when you are a non-patient delivering organisation you know, a certain amount of cynicism about the value you know-is it a quango? Is it-what are you going to deliver? And because some of the stuff is not a tangible measurement you know, that’s quite challenging” (PSCL7).

PSCs were intended to be ‘working in partnership’²⁶⁴ with the ‘Sign up to Safety campaign’. Although we specifically asked about Sign up to Safety in our interviews, in our fieldwork we hardly came across it. Only one of the PSC leads we interviewed gave it much attention, as a parallel and fore-runner of something that PSCs do.

From the outset, a number of PSC leads were unsure about the branding of the new initiative. Some leads were adverse to the name “patient safety” collaborative, preferring the name “improvement” collaborative, as they felt member organisations may become: “Instantly wary of you. Instantly nervous, because the reality is there is a blame culture” (PSCL1). Indeed prior to their launch, some patient safety collaborative leads shared this concern:

“My slight concern was that the patient safety collaboratives were going to be a sort of a re-branded or a disguised version of Monitor and the TDA [Trust Development Authority], you know coming at it from a safety and quality initiative, but just sort of going in and trying to strong arm people into doing particular pieces of work.” (PSCL6).

In response to such concerns PSCs took steps to ensure their communication strategy, including their launch events, attempted not only to gain visibility, but to clarify their role.

Some PSC leads expressed an initial concern that PSCs might become “a cosy talking shop” with “not much delivery:”

"The planning phase was really important [...] because I think there is a danger with these types of projects that they just become a very cosy talking shop and there's not much delivery [...] because you're not necessarily as a regional improvement body, directly delivering improvement. You are assisting others to improve. So we were very careful about how we looked at implementation" (PSCL6).

Because senior endorsement and support were recognised as a vital and necessary prerequisite for any improvement to become fully embedded in the healthcare system, PSC time and resources were allocated to training key leaders and 'champions' of the Collaborative approach. By holding design days and engagement events in their local regions PSCs were able to engage with their member organisations during the setup phase of the Collaboratives rather than impose or be seen to be imposing a top down approach, and PSC leads reported how their facilitative role was a much-needed link in the system.

5.b. Variations between PSCs

PSCs varied in terms of their respective geographies, population size, quality of pre-existing network links, funding received, and improvement infrastructures. This led to three main types of variation in their dependency ('path dependency') on the history of QI in that region; their relationship to their host AHSN, and in the balance of implementation strategies that different PSCs adopted.

5.b.i. *Path dependency*

PSC differed in the extent to which QI activities within providers, inter-provider QI networks and other safety activities already existed. Due to this variation at regional and provider levels the PSCs were at different starting points when we commenced our evaluation.

"Unlike some of the other AHSNs who didn't have good improvement sort of access in their footprints, we are very fortunate, we've got AQuA and HALO and [region] Leadership Academy. So unlike some AHSNs we haven't set up ourselves as an improvement kind of body ourselves, it's already out there. We'd only end up competing with them which would be silly. It's about using the assets in the system" (PSCL15).

While some regions already benefited from having a whole quality improvement faculty within their AHSN other regions had to build a network and collaborative links from scratch.

“The *[region]* infrastructure was very, very light, non-existent so many of the other AHSNs had an existing quality improvement infrastructure largely a legacy of the Strategic Health Authorities [...] We had NONE of that. Absolutely none so the *[region]* as well as having currently a large number of challenged organisations, it had no infrastructure to enable those organisations to ask for help” (PSCL11, original emphasis).

As a result of this local variation the PSCs were at different starting points when we commenced our evaluation. Staff turnover delayed the setup phase for some PSCs and some experienced the loss of key leaders who had been advocates and champions of a more collaborative approach to improvement:

“I would have wished to have moved the programme plan for the PSC forward more quickly, but with a turnover of four MDs [medical directors]! You know you have to expect that any programme will fall behind its anticipated milestones if you have senior leadership changes. [...] We’ve lost several Chief Execs because of either CQC feedback or performance and pressures. You know some have been removed. Some have chosen to fall on their sword, but many of them were individuals that were also passionate advocates for our [improvement] work” (PSCL11).

When we went into the field some PSCs were at the early stages of building an improvement infrastructure and experiencing the challenges of trying to engage struggling and/or defensive organisations, or of managing what they termed “inherited reputational damage” (PSCL4). Others were at a more developmental stage, confronting challenges in gaining senior leadership support either within the AHSNs or within local NHS Trusts as they endeavoured to secure NHS Trust board representation and forge necessary links with member organisations. Most were at varying stages in setting up design days and holding engagement events to determine which work-streams to focus on from the national wall of priorities and balancing these with local variation and need. A few were at the delivery stage, already reporting a considerable amount of success with their learning events and levels of engagement, as well as through their infrastructure with good leadership and full NHS Trust board representation.

Some PSCs experienced setbacks during their launch due to the junior doctors’ strikes²⁶⁵ and this resulted in having to cancel scheduled learning and engagement events.

5.b.ii. Variable relationships between PSC and AHSN

The extent to which the PSCs were embedded in the AHSNs varied widely:

“It’s amazing how some of them [PSCs] have set themselves up as quite autonomous [...] ours is fully integrated, the health and implementation team adopted and includes patient safety Collaboratives, there isn’t a separate work-stream” (PSCL15).

For most PSC leads, being fully embedded within their regional AHSN was seen as highly beneficial, particularly in regions where this brought strong network links:

“Working within the AHSN is incredibly useful and very productive” (PSCL7).

“The AHSN was a very effective and useful place for it [PSCs] to be hosted” (PSCL6).

In contrast some PSC leads described encountering leadership challenges within their AHSN:

“Most of my challenge is internal within the AHSN. [...] Because the AHSNs weren’t originally set up to run Patient Safety Collaboratives, our original senior leadership team, they just didn’t get it at all and didn’t have any interest in it and now we have a different leadership team and they also don’t get it! So I spend a lot of my time justifying, explaining [...] I don’t think that people working in the AHSN recognise the size and complexity of this programme of work ” (PSCL1).

This particular PSC lead expressed concern that by being embedded within their AHSN, the PSC was inheriting “reputational damage” and therefore set at a disadvantage:

“I’ve got people in different places who have said “they’re a waste of space – that AHSNs are a waste of space!” You know, I’ve heard people say that. Now, they may well see patient safety as AHSN so therefore a waste of space...” (PSCL4).

In such cases the PSC needed more time to clarify and define its role within their AHSN and build better working relationships.

“I think initially some of our challenges were around understanding what the AHSN did. Let’s start right back at the basics, then understanding what the PSC is” (PSCL7).

5.b.iii. Strategy: hybrids and tensions

Collectively the PSCs used three main strategies to establishing and directing QI work. Adapting the PSCs' own terminologies, we label them the facilitative, the educative, and the 'national priorities' strategies. All PSCs used all three but as the differences reported above might lead one to expect, the balance of emphasis differed substantially between PSCs.

The facilitative strategy was for PSCs to support and develop existing patient safety activity. Absorbing existing activities produced rhetoric of 'not duplicate' but 'align [with providers' existing activities]'. PSC leads expressed from the outset that they did not want to "re-invent the wheel". This approach enabled re-badging of existing activities, at the cost of reducing the scope for attributing any successes to the PSCs and brought an emphasis on correcting system faults. One complication in the facilitative strategy was how to encourage local responsibility for improving service safety without at the same time reinforcing a 'blame culture'.

An essential element of this strategy was therefore to develop an infrastructure through which to use existing local (provider-level) projects:

“We see ourselves as facilitating networks, facilitating communities of practice, bringing collaborative groups of people together to work across boundaries to look at safety issues and being a bit of an honest broker [...] around some quite tough kind of challenging safety areas, bringing some people together [...] to look at things from multiple different lenses” (PSCL16).

To varying extents all PSCs did this. In regions with “less mature” improvement infrastructures, PSCs used their resources to directly fund bids for quality improvement initiatives. What varied at provider level was the providers' capacity to fully utilise improvement skills and effectively implement them in clinical practice, The form and extent of existing QI and safety activities and networks (see above) constrained the scope for adopting the facilitative strategy. A more general problem with facilitative strategy was that it muddied the branding of PSC work and their ability to attribute its development to (in part) the PSC/AHSN's own activity.

The educative strategy was to train and develop individual ‘change agents’ to introduce or implement changed working practices at clinic level, for example by training staff in QI methods. Wilson et al.¹⁹² list the varieties of relevant training. Some PSC leads described to us a transition from ‘Blame culture’ to ‘Just Culture’ to ‘Learning Culture’ to ‘Trusting Culture’ (see Chapter 7).

“I think there is a level of focus on patient safety that is having an influence [...] I think there is a culture change going on and I think the patient safety collaboratives definitely part of that and gives some support towards you know the direction of travel for that culture change” (PSCL10).

PSC informants tended to think that PSCs could contribute especially at the stage of developing a learning culture (Figure 2).

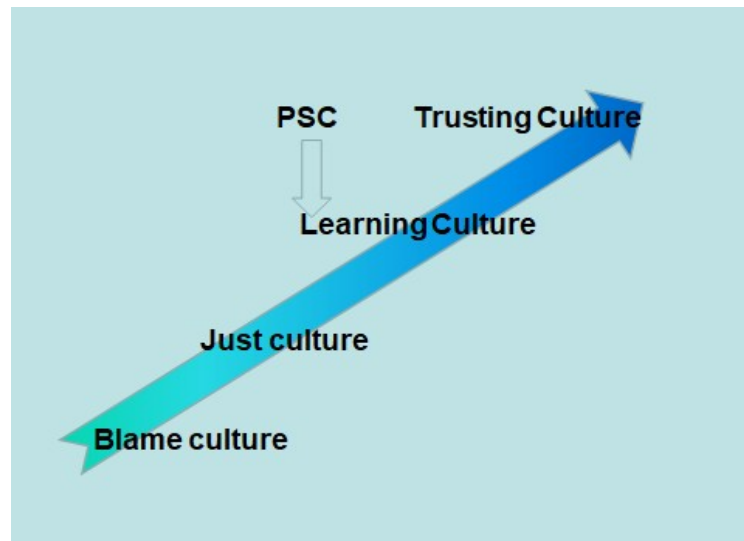


Figure 2: Culture changes and PSC role

An educative strategy had as its main elements:

1. Training: Some PSCs cited numbers trained as an outcome measure of success. For example one PSC lead reported having trained one hundred people in human factors in their first year with the aim and resources to train a further 2,500 people in the next 18 months in areas such as handover; communication; and team working.
2. Backfilling posts to enable training. Some PSCs offered backfill as well as paying for training - for example one PSC offered free human factor training from an external provider in order to help develop ‘Safety Champions’ for member organisations in their region. In other regions much innovation, drive and enthusiasm for quality improvement work was

already happening in pockets, due to passionate and enthusiastic people lending their time for free. In regions where sectors such as primary care were under represented or noticeably absent in terms of board representation, PSCs sought to fund backfill for staff to attend their learning events. However in some cases, workload and patient demand meant that despite financial support and incentives, many general practitioners (GP) were still unable to attend.

3. Advocating and facilitating the new appointments at provider level reported in Chapter 6. PSCs facilitating the recruitment of new roles and the more rapid recruitment of new roles for example through the score survey.

Typically, though not exclusively, both network and providers relied on training to produce the relevant 'learning'. This represented a narrower conception of 'learning organisation' than the PSC policy model (see Chapter 2) or the original models of how Collaboratives work (see Chapter 3) assumed. This approach tacitly assumed that training people to do QI work would lead to them implementing it, and in that way (not least, through the PDSA methods built into that QI work) providers would become more like learning organisations.

The 'National Priorities' or 'Work-streams' Strategy was for the PSC to focus on activities or care groups selected from the 'wall' of national priorities as work-streams to focus on and to try to balance these choices with local variations in services and healthcare needs. The PSCs tended to support new QI projects that had arisen from:

1. local attempts to implement national policy priorities (e.g. those in the Commissioning for Quality and Innovation (CQUIN) framework), and
2. National policy priorities to develop capacity, leadership and infrastructures at local level, including implementation of the new models of care.²⁶⁶

As a consequence of this national influence similar work streams (e.g. sepsis) developed across several PSCs. The PSC 'Guiding Principles'⁶⁰ had anticipated a division of labour among PSCs, with groups (not all) PSCs specialising on particular safety topics. When it became apparent that they were working on the same subject areas, such as sepsis, the PSCs formed 'clusters'²⁶⁴ to enable sharing of work and experiences. However NHSI did not see the five clusters as the most effective way to do this, and there was no collective understanding of what they were meant to do or achieve. The clusters were disbanded when NHSI promulgated its three national 'work-streams' for PSCs, doing so in order to be able to show that the PSCs had impact as a national programme.

PSC leads perceived a tension between the three strategies listed above, as NHS England had ‘tasked’ them with the challenge of balancing national priorities with more local needs:

“We were given quite a lot of width on selecting our local topic areas, but were given *very strong guidance* as to the under – you know the cross-cutting and under-pinning themes like capability, culture and leadership and measurement” (PSCL6).

Organisational leads and front-line staff perceived the same tension:

"That would be like a stick of rock running through my career [...]. There is definitely a tension there's always been a tension, although I've seen perhaps a little bit of change to that [performance driven culture] in the last two years” (PSCFL22).

One way in which PSC leads did not vary was in being clear from the outset that they wanted to shift from a performance-managed “command and control” culture, to a more facilitative educative approach:

“We've tried to definitively step away from anything that looks remotely like performance management. We think in terms of the role of PSCs and the value that PSCs can add, people are performance managed up to the eyeballs really and if performance management was the way forward to really deliver higher levels of safety, then we would probably be the safest healthcare system in the world” (PSCL16).

This tension and mixture of pressures also gave PSCs some leeway to develop different balances between the three strategies in response to their varying initial background conditions. Across England, however, we did not find any PSC whose strategies and activities deliberately and explicitly focussed on equality and diversity. The patterns of strategy variation reported above most of all reflected their inherited QI and safety activity, but those differences did not in any obvious way reflect or correspond to their regions’ distinct socio-economic and ethnic profiles.

5.c. Use of resources in PSC activities

As mentioned before the PSC programme had, an estimated budget of £12 million per annum of which some was retained for management and measurement at national level, with £7m going to the

regional PSC network coordinating bodies. In order to analyse the use of resources in PSC activities, we requested data from NHSI on budget allocation per PSC to specific activities. At the time of the request NHSI were not able to fulfil this request. We also reviewed each PSC website and the available annual reports in order to identify budget allocations to specific activities. We looked at our interview transcripts in order to identify opportunity costs. We received budget data at aggregate level from one PSC. From this information we were not able to make any meaningful evaluation of costs and, in financial terms, the health benefits for patients.

The information available in the websites across PSCs, with respect to the use of resources, was heterogeneous. For example some described using funds to set up and run network activities themselves, others released money to provide bursaries to conduct MScs and other training courses. Others have reported broad splits between priority programme activities (60-86% of annual budgets) and the remainder going to administration and supporting staff. It was also clear that some of the activities received funds from more than one funder. A clear pathway between money received, activities funded and outcomes was impossible to discover from publicly available sources including websites and annual reports.

In interviews some of the PSCs leads expressed the importance of having resources available for sending individuals to train in quality improvement but they also contrasted that with the fact that due to time pressures trained individuals were in some instances unable to put into practice what they had learnt. They saw the availability of such funds as an enabler. On the other hand, a PSC lead also pointed out that ASHNs were not originally established in order to run the collaboratives, and that AHSNs lacked understanding of the role of the PSCs, to the extent of seeing them as “cash cows”. This informant was also aware that the time required for people to come and participate in PSC activity "all costs something doesn't it?". This is an example of an opportunity cost and it is likely that these costs will be larger than the explicit budgets.

The level of funding available varied from PSC to PSC and from financial year to financial year. The aggregated data from one PSC illustrates the variation in funding showing a 10% increment in level of funding from 2015 to 2016 but a decrease of 30% from 2016 to 2017. PSCs received other resources that did not directly follow the flow from the central NHS. In one PSC the largest expenditure component within this PSC during 2015 to 2017 was the IHI Patient Safety Officer

Training. This training element was only partially funded by the PSC, the significant other proportion came from other, non-central NHS financial sources. Despite the uncertainty on the level of funding, expenditure on implementation initiatives increased from 28% in 2015 to 42% of the overall PSC budget in 2017; reflecting the initial start-up of costs of the collaboratives.. Among these activities, mental health received over 40% of the funding for implementation initiatives; these activities were already ongoing when the PSCs formed and the funding went directly from the PSC budgets' to continue these projects that had previously been funded from other NHS sources.

5.d. What did PSCs do to help providers become learning organisations?

PSCs' approach to helping providers become learning organisations was above all through the educative strategy noted above; and by attempting to shift providers', and within them clinical teams', safety climates over a 'long cycle'. But before PSCs could do either they first had to recruit providers into such a project. Because providers participated voluntarily, PSCs had actively to 'engage' potential member-organisations. Hence for a number of PSC leads, in order to solidify their place as a necessary link in a chain of inter-organisational networks concerned with quality improvement and patient safety, their main aim was to direct their resources towards securing high levels of engagement from member organisations:

“I think it's engage, engage, engage – you spend a lot of time trying to do as much face-to-face as possible and of course across the region, that's quite resource intensive” (PSCL9).

Policy guidance⁶⁰ had also emphasised the importance of such engagement.

5.e. Engaging the providers

Several PSC leads pointed to the importance of leadership support for the effective implementation of PSCs, i.e. that:

“the [Trust] Board supports the approach and the methodologies etc., and their readiness to adopt some innovation for example, it's got to be right through to the leadership” (PSCL15).

However some PSC leads encountered out-and-out resistance from senior NHS trust management in the early setup phase:

"One Chief Executive completely didn't support this vision. He literally said: 'Everyone in my organisation knows improvement [...]. This is a waste of money, we don't need to do it'" (PSCL1).

PSC leads were also mindful of the importance of securing a balance in their clinical representation:

"Most of the work that has been done to date with the AHSN improvement work [...] has been very much focussed on the acute trust sector, so trying to get a balance in our clinical representation was difficult" (PSCL6).

Several PSC leads described the challenges they faced in their attempts to make the PSC relevant to all types of provider and the importance of adapting their approach depending upon which sectors there were looking to engage:

"Our approach differs across sectors - so acute, care homes, [...] because in primary care we need different levers to pull people in and we might engage in different ways" (PSCL7).

Their approach also depended upon how developed or underdeveloped their improvement infrastructures were, particularly in primary care:

"At our CCG Primary Care they don't have the infrastructure that the acute providers have. So they don't have organisational development teams who take a strong leadership role in this area. So there's a bit of a disparity between primary and acute and their provision really that I think maybe that needs some attention" (PSCL15).

But the operationally-pressurised organisations identified as most likely to benefit from the PSCs were for the same reasons struggling to engage during their set up phase:

"The two [organisations] that hadn't responded were the two that genuinely needed to. But they're just so deep in trouble that they're drowning and so therefore they don't know how to engage. [...] Those stretched services don't release people to come to our events or they don't allow people who've come back from events that we're doing to actually implement their work [...], now that type of thing is hugely de-motivating and it's not uncommon sadly" (PSCL6).

Given the *de facto* historical emphasis of QI work on acute hospitals, a number of PSCs were keen to engage more community care organisations and care homes, general practice and mental health sectors during their implementation phase (PSCL16).

The fact that PSCs were launched within dynamic local contexts and were coexisting with multiple concurrent improvement initiatives, meant it was important to identify what developmental stage their member organisations were at and to adapt their implementation strategy accordingly:

“What is interesting is the different range of maturity between organisations. Some are very driven by quality improvement say for example [*name*] are a Trust who have really invested heavily in Lean methodology. [*Place*] have really invested in patient safety champions etc., so some were very skilled before they even came in [to the collaborative]” (PSCL15).

PSC leads were mindful of the importance of making PSCs relevant to the needs of their member organisations:

“Offering them [member organisations] the opportunity [...] if you think your weakness is measurement here’s some modules in measurement. If you think resilience or understanding your culture for safety in your organisation is something you’ve never explored you can tap into this. So we didn’t presume everybody could be in the collaborative and all came in as equals, we made sure there was a range of other opportunities to help their developments” (PSCL15).

Likewise at the level of leads within provider organisations, many of our interviewees emphasised the importance of having an iterative and evolving approach to PSC implementation:

“I wouldn’t say that we set aside objectives, what we constantly have to do is be very dynamic in our structures and how we support [...] the providers” (PSCOL1).

Although in practice PSCs each inherited very different conditions by being hosted by their regional AHSNs, most agreed that this structural arrangement meant PSCs were ideally placed to be “set apart from the NHS performance infra-structure” (PSCL11), while being supported to fulfil their facilitative and educative role.

5.f. Coordinating clinical teams' QI work across the member-organisations

The PSCs' early attempts at self-definition were broad, not focussed specifically on establishing cross-organisational network(s) of clinical teams. As described above, PSCs aimed initially to recruit providers to their QI and safety work, and then to recruit clinical teams through them rather than directly (and this is not inconsistent with practice in some of the original BSTs; see Chapter 3). Following this PSCs approached the task of coordinating clinical teams' QI work across providers by setting up a cross-provider, PSC-managed network of teams. Among those who had heard of PSCs, they acted as a vital focal point linking experts in academia with hospital staff in order to assist them in their QI projects with data collection, analysis, writing and publication. One PSC lead described a shift from organisation partners being:

“Tribalistic and reluctant to potentially share [to] now we are a new kind of team, we are developing really good relationships with these partners and accelerating progress” (PSCL4).

In relation to overcoming organisational barriers to QI work at provider level (see Chapter 7), PSC leads spoke about the importance of building trust and improving relationships through more face-to-face meetings; of site visits between learning events to understand barriers to patient safety and improvement work in context and to help provider organisations to identify any systemic barriers; of providing a collaborative learning space to share best practice; and of investing time and effort on NHS Trust “board development” in order to ensure good clinical representation, and expert leadership through training QI experts or “champions” of this approach.

Although such work tended to be focused on acute hospitals we found some examples of beneficial work in other settings. An example involving primary care teams related to prison health services. A clinical pharmacist working in mental health reported that the PSCs had helped to identify poor care and delayed care in prison settings and that the PSCs were beginning to facilitate more collaborative learning not only through providing network links between healthcare professionals, but through linking the NHS with academic expertise in the university sector:

“I think it's more joined up. It's more peer review so whereas in the past we probably all did little bits of project work, we all did our own thing and that may or may not have come to

anything. These do feel like there's more expertise within the actual network. People that come and lead the projects are often experts or are usually experts in the field and have a huge amount of international knowledge" (PSCOL6).

Through this collaborative network which linked the PSC, AHSN, university and community mental health sector, the clinical pharmacist was able to co-develop a medicines optimisation strategy with medicine safety as one of the elements; to complete a project around cardiac harm with antipsychotic drugs; and to look at rapid tranquilisation and its impact on physical health, as well as lessons learnt around high risk drugs.

In another region one of our interviewees reported that QI had become more embedded across mental health services and that the PSCs are helping to reduce violent incidents through facilitating sharing best practice:

"Using patient safety and QI methodology, they [*Trust*] developed something called the Four Steps to Safety, which is a care bundle, which is a package of interventions that, if used together and proactively, and with the person and their family or carers, can actually lead to a reduction in the levels of violence and aggression on inpatient unit wards" (PSCOL14).

Using the QI method of testing in one ward first before "scale up and spread", participants used this care bundle to share the learning from an inner city mental health hospital and test it a different organisation (PSCOL14). In this case implementing changes to policy and practice resulted in positive measurements for reducing violent incidents; in turn this was found to reduce the negative impact upon staff health.

5.g. Cross-organisational measurement systems

NHSE, and later NHSI, have recently attempted to establish and use cross-organisational measurement systems by 'procuring' a central measurement unit rather than developing ways for clinical teams to directly exploit existing NHS-wide datasets, including local data-sets, for QI purposes. Had the central measurement system materialised during the study period (it did so only towards the end) it would have provided an inter-PSC resource; as it was, the delay meant our respondents were uncertain how it would work. Some PSC leads described how they faced delays during the setup phase of the PSCs as they needed agreement that AHSNs could access Trust data:

“Measurements, data we’re still waiting for the central measurement unit to be procured. Well it’s expected to be completed and clearly we haven’t waited you know we’ve got on and done things, but actually its NHS data! Give me the data! As an AHSN you don’t have access to organisational data. I need to have that overview. How else do we work out what the priorities are?” (PSCL15).

In the meantime PSCs had to rely on Trusts for access to the data that PSCs’ work needed.

Increasingly during the study period PSCs also created or commissioned *ad hoc* measurement and data-sharing systems, developing for example on-line platforms (e.g. Life QI:

<https://www.swahsn.com/improvement/patient-safety-collaborative/collaborate-life-qi/>) for sharing project data between clinical teams.

In addition, and as Chapter 7 explains, many of the PSCs’ member-organisations were at the same time trying to surmount the technical barrier of how to measure the PSC’s impact on their own operations. Because their own safety measurement systems varied widely, trying to measure processes or outcomes in the same ways as the other participating clinical teams did was a recurrent challenge. Another barrier was that many clinical teams perceived measurement and data collection as being predominantly about a “performance culture” and took staff away from their primary role of caring for patients. In a community mental health setting a clinical pharmacist described how confidentiality was a major disabling factor when it came to sharing information across sectors:

“We don’t share information across sectors because there’s always confidentiality and difficulties and you know lots of barriers put up. So sometimes it does feel like we’ve got to get over another hurdle and another hurdle and another hurdle and you need a huge amount of drive and enthusiasm to get over all of those” (PSCOL6).

Others felt that, it was not so much a performance as a blame climate that was at the heart of much “organisational defensiveness” when it came to either a reluctance to share data, or an inability to effectively appraise or interrogate their own data. For example one PSC lead described how “struggling” organisations were seemingly reluctant to interrogate the data that made them “look OK or good”, while being quick to question or criticise the data that made them “look bad”:

“Some organisations get very uptight about their data making them look bad. Rather than saying ‘oh that’s interesting we’re not as good as everyone else I wonder why that is?’ They want to say ‘well that data can’t be right’ [...] every single piece of information that made them look bad, they would criticise and say ‘oh that can’t be right

because this or this can't be right because of that'. And yet every single piece of data that made them look OK or good, they never said anything about it at all" (PSCL6).

To overcome some of these provider level barriers PSC leads relied upon

1. building trust and improving relationships through more face-to-face meetings;
2. site visits between learning events so PSC staff could understand barriers to patient safety and improvement work in context and to help provider organisations to identify any systemic barriers;
3. providing a collaborative learning space to share best practice;
4. investing time and effort on Trust "board development" in order to ensure good clinical representation of Safety/QI work on Trust Boards,
5. developing expert leadership through training QI experts or "champions" of this approach.

5.h. Context: Central policy and organisations' support.

The policy makers' programme theory for the PSCs (see Chapter 2) explicitly stated two contextual conditions for PSC successes. One was continued political backing and available funding for the PSC initiative, in particular continued recognition through the system of the importance of the Berwick Report. During our study period this support (from NHSE then NHSI) did continue, although in the policy arena as well as within NHS provider management it was often, indeed increasingly, overshadowed by 'winter pressures' on demand for services, funding and staffing reported widely across the English NHS.

A second condition was that in the transfer of the patient safety function to NHS Improvement consistency of leadership should be maintained. That did appear to happen, though it came at the cost of some delay in setting up the measurement system (see above). However, staff turnover in AHSNs and NHS organisations more widely also delayed the setting up of some PSCs,

Our informants identified a third important condition: sufficient time. PSC leads reported that as well as the time needed for member organisations and their staff to engage in training and learning events where they could collaborate and share best practice, time was needed for providers' organisational climates to shift from competition, defensiveness and blame towards a culture of co-operation, collaboration and trust. Even when established QI activities were taking place, PSC-level informants acknowledged that time (18 months; see above) was needed in order for the PSC to gain traction:

"Driven from the bottom and enabled from the top, at a regional level between and across organisations, [... but] that's a 10 year vision not a 3.5 year vision" (PSCL6).

A poor follow-through to PSCs' work would risk losing the investment already made within the NHS towards building an improvement infrastructure, unless a longer-term investment of time and resources continued:

"How do we help to shift the NHS culturally? [...] how do you shift the thinking to a little bit more investment in the future, rather than this 'short term-ism' that is, you know, train and wave people goodbye..." (PSCL9).

According to PSC leads, such a change in thinking would mean recognising the length of improvement cycles:

"There's no point in us doing any of this if organisations in 5 years time, [...] aren't at the point of saying actually we're going to dedicate capacity you know time and effort to doing improvement and try and make it part of everybody's role" (PSCL1).

Chapter 6: Key findings (2): Organisational level activity in providers

We now report the organisational changes providers made in response to PSC activity (RQ2) and how they made them. Within the provider organisations recruited to participate in the Collaboratives during the study period, PSC activities in our study sites concentrated on the educative strategy mentioned in chapter 5, especially recruiting QI/Safety ‘champions’ and attempting culture change.

6.a. Obtaining managerial support

As we reported in Chapter 5 the preliminary step that PSCs had to take at provider level was to obtain senior leadership support because otherwise little would happen:

“Unless the Board supports the approach and the methodologies etc., and their readiness to adopt some innovation for example, it’s got to be right through to the leadership” (PSCL15).

According to PSC leads the PSCs’ work depended upon trust managers’ legitimation and the resources that trust managers controlled:

“The idea that you come up with the best process and product in the world that might be the absolute silver bullet to improving safety and quality and you might have THE best people within that organisation to implement it, but the organisation itself doesn’t give it space and endorse it to work so therefore it will fail, whereas in another organisation that’s UNBELIEVABLY ambitious but doesn’t have anyone there to implement the tool might fail, but for very different reasons” (PSCL6, original emphasis).

Senior managers’ support also helped legitimise the PSC’s intended activities:

“If you’ve got attention from your leaders and the policymakers, then people are more likely to take notice and think, ‘oh, this isn’t a fad, this isn’t going away, this isn’t just a couple of strange people over there that speak a different language that are just on the latest bandwagon. This is serious!’” (PSC0L14).

PSC leads regarded senior managers’ endorsement and support as a prerequisite for any quality improvement to become fully embedded in the healthcare system.

As we reported in Chapter 5 some senior managers were resistant to PSCs in the early setup phase. Even when obtained, endorsement by senior managers did not guarantee middle management support:

“People lack support, I think, from board to floor to implement this and we know the middle-layers are often quite difficult to shift their thinking around some of this. You know performance culture gets in the way of trying to enable people to take time and use a systematic and very rigorous approach to improvement” (PSCL9).

In some instances, chief executives and senior managers who had attended PSC learning events and been initially receptive and enthused by the training, were described as ‘reverting to type’ once they returned to their day-to-day roles; that is, switching their priorities and those of their staff as they again confronted day-to-day operational pressures.

Immediate working environment were seen to play a significant role in the uptake and receptivity of improvement work:

“We have this ‘lip service leadership support’ [...] The senior leaders engaged really well with the quality improvement training for themselves, but when they went back to have those conversations with their teams, they reverted to type in terms of ‘I’m an executive why are you working on this? Does that line up with our organisational priorities?’ [...] because the TDA are giving me a hard time about it” (PSCL1).

In some instances staff reported returning from PSC training sessions and being asked by their managers to focus on issues that the TDA were aware of rather than on any ottom-up improvement initiatives.

However PSCs also facilitated the appointment of new quality and safety roles within their member organisations (levels 2 and 3). The appointment of a “serious incident investigator” was cited in one case and in another, a “sepsis compliance assistant” role was created, whilst a falls specialist nurse described how “falls champions” were introduced in order to maintain momentum on a falls specific QI project. Through conducting SCORE surveys (see Chapter 7) PSCs facilitated the rapid recruitment of more staff within crowded hospital settings following the survey debriefing sessions.

6.b. Organisational changes

Our fieldwork lasted two years and during this period policy uncertainty, as well as regulatory and organisational changes, continued. In two of our three PSC regions that were our main study sites, for example, trust mergers took place over this period.

6.b.i. *General practice*

In another PSC the collapse and subsequent merger of four general practices across five sites provided a unique opportunity to rewrite all policy documents and protocols from scratch. Having attended a PSC funded “Patient Safety Officers’ course,” the senior practice partner and his colleagues used concepts and tools from this training to completely redesign their service:

“It [*PSC*] has totally rewritten it [*practice policy*] and again we’re very fortuitous [*sic.*], in the time that we’ve engaged with the patient safety collaborative, is the time that we’ve redesigned the service” (PSCOL4).

This group rewrote 160 practice policies on topics including infection control, prescribing methods, patient demand and flow, nursing registrations; appraisals, communication, leadership and teamwork. They did this with the PSC model in mind but adapted each policy to meet local needs:

“Every single one of those has been thought through, documented, educated the staff and embedded in the way that you work [...] The whole principle of building teams and gaining efficiencies and communicating between teams, which is at the core of the patient safety collaborative, is pretty much embedded in all of the new structures that we’ve created” (PSCOL4).

Nine months earlier the practice had carried out its first SCORE survey, at a time when staff were adapting to their new organisation. The initial survey results proved highly effective and timely in enabling this GP and colleagues “to identify groups that were in particular need of attention,” as well as areas that needed addressing, such as more regular appraisals and self-audit, taking the time to listen to staff; ensuring each staff member knew who his or her line manager was, and that they felt comfortable in approaching them should any problems arise, and bringing in new measurements and ensuring staff were confident and fully trained in their use:

“People are still going through that change cycle and some have got there. All the GPs on the first survey scored brilliantly because [...] they each had a project that they were driving

along and they were fully engaged. We've slowly brought the rest of the teams along by trying to explain why and what we're doing and they can actually be part of it and what would they like to do to make it better. I think the biggest hindering is just the pressure" (PSCOL4).

Following the merger, patient demand and communication across teams, as well as "leadership into the team" were identified as the biggest challenges:

"the only reason it's really worked is because the core group of 11 GPs are all young. They all get on and they have a very clear vision and there's no, there's no conflict at the top." (PSCOL4).

The PSC's ability to support organisational change in general practice was in this case related to the timing of the merger, which meant that everything aligned for the successful implementation of the PSC model.

In another general practice (this time in an inner-city setting), staff had taken part in a SCORE survey and completed two rounds and debriefs by the time we interviewed them. According to this practice partner:

"The staff got a chance to really think about the structure of the team here at [*general practice*], and with the amount of questions that they had to answer [...] Looking at the results, when they came along, when we did have our two sessions [debriefs] with the teams, everybody was pleasantly surprised [...] It was really nice to really analyse who we are in that much detail, and I think by the end of that exercise, it really boosted the morale of the team here" (PSCOL12).

Following the survey this practice implemented a handover booklet to record and date information that colleagues could check daily in order to improve communication among the senior team. They began recording data more fully and applying a greater depth of analysis to events judged to be significant events, either through a written report or a meeting with minutes, and a clear action plan. Although in this case the overall survey results were positive, the practice partner was nevertheless keen to ensure they continued:

"To look for ways to improve and we keep that open level of communication and the no blame culture going and the sense of one team going, because I think that is very important here, and it makes a huge difference." (PSCOL12).

Of these examples where PSCs influenced general practice organisation, one occurred when the conditions were ripe for change (a practice merger), and one in a high- performing practice that was already embracing innovation and might therefore be viewed as exceptional or exemplary rather than representative. According to a practice partner and CCG clinical chair from another region the overall impact of PSCs in primary care has yet to be seen:

“I’m not aware of any changes in outcomes for patients yet which is of course what we really want to be seeing, but the safety markers are improving in the right direction and patients are more safe in environments which they have to be in hospitals now” (PSCOL8).

Our CCG informants mostly felt that the Collaborative method might not translate from secondary to primary care settings:

“I think it’s had a massive impact on secondary care. I think the problem with primary care is that if you try and translate any of that into primary care, it doesn’t read across because all of the safety issues are not safety issues that they’re familiar with” (PSCOL2).

We were told that if there was to be significant impact in primary care from the PSCs, the operational pressures of rising patient demand and work load had to be surmounted. Despite this, our informants felt the will was there:

“One of the things that we need to have and practices would like, is the tools and the knowledge and the evidence-base and the facilitators to help them make further strides in quality improvement because actually they want to do it, it’s just creating the opportunity in the working week to put it into practise” (PSCOL8).

Provider leads reported that despite needing more time, PSCs were beginning to engage provider organisations, facilitate learning through networking groups and affect strategy. For example one participant from a CCG described: “seeing organisations willingly deciding to join the patient safety Collaboratives and embedding the care bundles into the way that they normally work” (PSCOL2).

6.b.ii. Hospitals

Changes were also reported in hospitals. As an example of changed clinical practice attributable to the PSCs one respondent said that “early warning scores to help identify deteriorating patients” (PSCOL7) were now being used throughout her hospital:

“The early warning scores and things like that that are all used now throughout the Trust and have become a big part of our work, I believe that they came from the PSC so yes, I would say that they have changed clinical practice. [...] From a safety point of view then you know that’s had quite an impact in terms of identifying these patients early and ultimately that saves lives” (PSCOL7).

We heard reports that “huge inroads” are being made in the collaborative work streams around acute kidney injury, are around sepsis through the implementation of more standardised procedures around diagnosis, treatment and teamwork:

“I’m not seeing from case note review’s deaths from sepsis in the way that I used to [...] If I look at the work that we’re doing around acute kidney injury, we’re not getting as many significant AKI flags as we were. It’s still work in progress. It’s not perfect. It’s not zero yet, but you know, we’ve made huge inroads” (PSCOL3).

6.b.iii. Community and mental health services

In community mental health services, one quality and safety programme lead was confident that PSCs were already changing culture and climates by embedding structured policies and procedures for safety and health delivery:

“In all of the work stream areas we’ve seen processes and systems become more reliable. We’ve seen changes in culture within organisations going from having no framework and quality improvement to it becoming business as usual [...] We’ve seen safety becoming a key priority of the board [...] we’ve seen reduction in harm in key areas, [...] building capability. You know we’ve got a little army of people that can talk about QI now and a will! A real will to keep coming in and learning how to do it.” (PSCOL1).

Another respondent, who worked as a community mental health manager, thought that PSCs had informed their clinical risk strategy but had yet to impact their front-line services.

A clinical pharmacist working in mental health reported that the PSCs had helped to identify poor care and delayed care in the context of prison settings and that they were beginning to facilitate collaborative learning not only by providing more network links between healthcare professionals but by linking the NHS with expertise from universities. This collaborative network developed the medicines optimisation strategy reported in Chapter 5.

The perception that the PSCs focus and work streams may not fit all care settings, led some to disengage and dismiss the PSCs as irrelevant. Others were keen to take the initiative and seize the opportunities which they saw represented in PSCs, adapting them to local need and different care settings:

“If you just keep speaking to people and try and harvest their ideas, you can come up with new things to do and offer to them and some people will run with it and some people won’t” (PSCOL2).

In one PSC region informants told us that the PSCs are helping to “forge a more holistic approach” to care in mental health services, through adapting the learning from the hospitals around the “physical health agenda” and applying it to mental health:

“We've been able to take some really tangible learning from the acute setting, but then apply it to our patient population and say, just because you happen to have a label that you've got a mental health condition, doesn't actually exclude the rest of you from suffering the same risks and issues as the general population [...] and actually trying to address that real inequality, we've got people actually, as I say, dying up to 20 years sooner than your average population” (PSCOL14).

Though it was still early in the period for which PSCs were funded, we were able to see evidence of PSC implementation and engagement, leading to tangible changes at the organisational level in healthcare providers. PSCs were providing a blueprint for organisational change and service redesign in general practice; sharing best practice across a number of health care settings leading to more standardised streamlined care; helping to facilitate learning and to build network links between the NHS and the universities leading to a number of QI projects and publications. PSCs were either directly funding improvement initiatives, or funding them indirectly by funding organisations to free up staff time to allow implementation, as in the case of the ED checklist. PSCs

implementing the SCORE safety culture survey as an intervention tool to help improve safety climate at clinical team level (see Chapter 7).

6.c. Developing safety culture and climate

As we described in Chapter 5, the tensions between the three parallel PSC strategies re-appeared within providers at both the whole-organisational and the clinical team (front-line staff) levels. Many informants saw a ‘performance culture’ as the main barrier to improvement work and as being in conflict with the PSC approach. However, leads within some provider organisations reported that the PSCs had begun to shift things away from a performance driven approach towards a facilitative and/or educational approach:

“Because the focus is around patient safety and improving outcomes and experience for people, it's really shifting, I suppose, from that ‘command and control’, everything being performance driven, to actually moving to a more kind of shared understanding of what that performance data is telling you” (PSCOL14).

Another description of this change was as a shift from a ‘blame’ to a ‘just’ culture:

“This whole idea about ‘blame’ versus ‘just culture’ I think is the thing that I’m watching the shift in. So it’s very difficult to say you’ve got no blame because at the end of the day either somebody or some process has gone wrong. So there is somebody to blame. So it might be the organisation or an individual that’s been let down by the organisation. But equally if the culture isn’t ‘Just’ enough, then sometimes when genuinely an individual has made a mistake, they don’t feel that they can step forward and say they’ve done wrong [...] the whole point is you’ve got to feel confident that you’re going to be treated appropriately when you do confess to something.” [...] “That’s a Just culture rather than a no-blame culture” (PSCL6).

In community mental health setting, a quality and safety programme lead was confident PSCs were already changing culture through embedding more structured policies and procedures for safety and health delivery (see above). In her account, cultures change was represented by concurrent learning, changes in working practices, and that people ‘can talk about QI now’.

6.d. Becoming learning organisations?

Policy statements about PSCs (Chapter 1) invoked the idea of each NHS provider becoming a 'learning organisation', implicitly drawing upon an underlying learning organisation literature (Chapter 2). What did this mean in practice?

6.d.i. Champions

PSCs saw QI experts - also referred to as "champions", or "change agents" - as vital for PSC implementation and necessary at every organisational level. Having clinical leaders in that role was especially valuable:

"I think champions are key [...] the seniors here, of doctors and nurses, helps the positive mind-set and culture, this is important work [...] having a champion among the HCA tier, a champion among the receptionists, among the band 7 nurses and several among the consultants and middle grades to permeate through is key" (PSCFL1).

Champions were important not just to engage, motivate and educate staff, but to help support and implement learning post-training. For example one interviewee described being funded to undertake fund quality and safety improvement training. Initially course participants would meet up

"once a month or once every 2 months to talk about all the great work we do. But it's kind of fizzled out" (PSCFL14).

By contrast, another respondent described how in her department:

"champions help keep the momentum going on the projects" (PSCFL12).

And another acknowledged this need for expert leadership:

"You need people continually pushing those changes, otherwise people just kind of, typically would resort back to the norm" (PSCFL15).

According to PSC leads, a key facilitator for PSC implementation was for QI to become embedded. In order to promote grass-roots change, it would be necessary for staff to take ownership of a given QI project, and this would mean educating them and engaging them more fully in QI activity. This

had been happening in pockets: over the last three years QI has become more formally embedded, being incorporated into more foundation year medical curricula:

“Quality improvement is now embedded into quite a few of the curriculums so trainees [...] have the experience of projects - both successful and unsuccessful projects [...] and it will embed itself, so there will be less of a need for a top-down approach” (PSCFL17).

Although some registrars and consultants are beginning to incorporate quality improvement as part of their appraisals and career progression, this is still patchy; a care home practitioner put it to use that QI could not be considered “fully embedded” until it was incorporated across more sectors and in specialisms such as nursing:

“I don’t think quality improvement is embedded until nurses need it, if that makes sense, but it’s not day-to-day. It’s not seen as part of our jobs, unfortunately”(PSCFL23).

One consistent finding for successfully embedding QI activity was having not just champions at every level, but champions with certain qualities of leadership:

“having really enthusiastic seniors has made a huge influence and created a massive impact” (PSCFL16).

Our informants emphasised that having passionate and committed leaders who could enable teams to feel valued and empowered to either speak up, or to suggest areas for change, was beneficial for QI activity.

6.d.ii. Training and its Aftermath

PSCs had aimed to support, facilitate and educate the staff in NHS providers in order to promote a more learning culture. PSCs interpreted their educative strategies as involving, above all, PSCs taking on an “educative” role of training leaders to become champions, change agents and QI experts. But this was not intended to stop with the champions: the PSCs also tended to equate ‘learning’ with ‘training courses’, or specifically **mass** training. In the early stages of the PSC implementation several PSC leads cited levels of engagement e.g. in learning events, as an important measure of their success.

“I think the success has been the engagement and the traction [...], raising awareness of the PSC -I think that’s been really good” (PSCL7).

Training was being provided but it was unclear what happened afterwards. PSC leads felt strongly that to engage member organisations and train staff in QI methodology without any support post training, was a "waste of clinical hearts" (PSCL9):

“When we ran our six days, people were so enthusiastic and all that energy, all that excitement around patient care and you can just lose it in a blink of an eye if there’s not support back in practice, because they go, they train and then they say: ‘this happens every time we get sent on things you know to learn new skills and knowledge and then we go back and there’s nobody to help us do it!’ [...] I think that is shocking for the Health Service” (PSCL9).

Several Patient Safety Collaborative leads emphasised that QI is a “developmental process” and that failing to understand this leads to a failure to implement:

“We have a lot of people who go onto courses and FAIL to implement because of a lack of understanding that it’s a developmental process quality improvement. You learn and learn by doing it [...] we still have this approach that if you go and train in it and then people can go out and do it and that for me is the most disappointing bit and the unintended consequence of that is it turns people off quality improvement” (PSCL9).

Without the necessary support in place post training, several PSC leads voiced their reluctance to engage in an “endless role of training:”

“We can’t just deliver a piece of training to a bunch of people and then send them off into the world, we’ve got to continue to provide a framework and a structure” (PSCL1).

Front-line staff needed support structures but were often hindered in their ability to implement improvement initiatives because their workload was too high or because of staff turnover and work schedules including the requirements of routine rotations. PSC leads recognised the various factors resulting in poor follow-through meant they would risk losing the investment made in the NHS towards building an improvement infrastructure. As we noted at the end of Chapter 5, they repeatedly voiced the need for a longer-term investment of time and resources (see also Section e.ii below). Nevertheless, according to some provider-level leads, the PSCs were beginning to have an impact on learning through their online sources as well as social media, in that when a person was unable to attend any learning event, they could still access it online, collaborate and share best

practice. However most felt it was still early days in terms of the PSCs overall impact, particularly in primary care:

“I mean really it’s [PSCs] an easy resource to tap into and I’m sure these improvement facilitators will start to make the difference. But for us [CCG] they only came on line probably in post, less than 6 months so you know, you can’t see any particular outcome from that as yet” (PSCOL8).

6.e. Contexts: Obstacles to PSC work at provider level

6.e.i. *Operational pressures*

Although they aspired to the Berwick vision of a system devoted to continual learning and improvement of patient care ‘*top to bottom and end to end*,’ PSC leads were equally mindful that, until such a system was in place, those on the front-line would be inevitably pulled in many directions. Informants at all levels in our study made this point:

“Operational pressures are so intense at the moment within emergency departments [...]. That really impacts upon our ability to innovate and deliver some of the things that we’d really love to be doing. [...] The department is constantly crowded, so [...] it seems like we’re just adding insult to injury by asking people to get involved in more to a degree of sort of innovative projects” (PSCFL1).

These operational pressures and time constraints were major disabling factors for PSC implementation:

“Whenever we go into a particularly tense or difficult period of time on a performance basis, so we might slip into these sort of high escalation black alert periods, all of the safety and quality meetings [...] are cancelled” (PSCL6).

“Smaller organisations say we’re only allowed to send one person because the organisation’s under so much pressure and it’s particularly evident if they are under the cosh of NHS England for their performance. So I would say that was a barrier” (PSCL5).

In order to see any significant impact from the PSCs, these pressures would have to be surmounted. Nevertheless, our informants felt that staff would be willing to do this:

“One of the things that we need to have and [general] practices would like, is the tools and the knowledge and the evidence-base and the facilitators to help them make further strides in quality improvement because actually they want to do it, it’s just creating the opportunity in the working week to put it into practise” (PSCOL8).

6.e.ii. Enough time

Within providers, as well as at inter-provider (PSC network) level, time was required for the learning to be put into practice and then to take effect. Our informants contrasted ‘short term-ism’ with the time needed for improvement cycles. Even when time was allocated and approved for staff to attend a learning event, many staff felt unable to leave their front-line duties:

“We had an event [...] there was a lot of interest and the pressure in the system is so intense that people were saying: “I can’t, I can’t come. I want to come. I’ve got approval to come, but I can’t do it to my colleagues. I can’t come out when I know there’s no backfill, there’s no agency” (PSCL11).

Indeed the time-stretched organisations identified as most likely to benefit from the PSCs were for those very reasons struggling to engage with PSCs initially. The challenge of how to free up staff time and capacity for engaging in improvement work was:

“hindered primarily about I think the perception that it’s an add-on, rather than improvement being you know, your day-to-day work. So we hear a lot of ‘I just have to go back to the day job’ ” (PSCL9).

Although PSC leads believed that QI work could in the long term free up capacity by enabling more efficient, streamlined working, they were equally clear that such a vision would require that QI become fully embedded across the health-care system, rather than added to already busy workloads:

“I guess it’s just time. Time for people on the ground to be able to dedicate to it. Time, I mean people are doing this sometimes as part of their existing day job and the demands on them are quite high” (PSCL12).

Nevertheless, both hospitals and general practices reported efforts to “ring fence” time for quality improvement and safety work:

“We’ve ring fenced every nurse which is about 40 people for one whole morning every 6 weeks - that’s a pattern that we are trying to embed into the way that we work. There’s regular appraisals, there’s regular feedback, there’s regular training and properly protected training for our staff” (PSCOL4).

Three different time requirements are implicit in the above accounts:

1. Allowing individual staff members enough time in their ‘day job’ to accommodate learning events and then the subsequent activities (see Chapter 7) necessary to put what they have learnt into QI and safety-management practice.
2. Continuing the Collaboratives long enough firstly for the providers to set themselves up to participate, and then for repeated cycles of PDSA and other QI activities to take place at clinical team level.
3. Continuing the Collaboratives long enough to enable them to recruit into their activities both the ‘early adopter’ parts of the providers who first joined the network, and the ‘late adopter’ organisations and services who were slower to.

6.e.iii. Staff turnover

Strengthening safety culture and climate was a key linkage in the policy-makers’ programme theory for PSCs (see chapter 1). Culture and climate, however, are embodied in the individuals working for an organisation. Staff turnover (‘natural wastage’) would therefore also have an effect on an organisation’s safety culture and climate, positive or adverse depending on whether it was resistant or supportive of staff who left. For leads within provider organisations, the size of the organisation or department, as well as the culture of the organisation – particularly in terms of leadership and engagement - were seen as critical in terms of the receptivity for change and the timescale needed for effective change to occur:

“The size of the organisation or department will depend on how quickly you can change. So I think the legacy of it [the PSCs] in five years, will depend on how much people have engaged and what the organisation was to start with. Because I know for example [hospital name], to try and change the culture there, even in one department, I reckon 20 years! Because you’re going to have to have certain key people who either move on, or there’s got

to be a wholesale change in the way the whole place is managed. A practice like ours, in the organisation with 32,000 people and 100 staff, I reckon in 2 years we'll have it 80% of the way to having a really good working environment. So it largely depends on how much people buy into it and how big the organisation is and how fruitful the ground is.”
(PSCOL4).

These contexts raise the question of what impact are PSCs having at the front-line of services. Next we report what changes there were to clinical teams' working practices.

Chapter 7: Key findings (3): Changed safety climate and working practices

Policy makers' programme theory for PSCs (Chapter 1) proposed that by becoming learning organisations, providers would strengthen the safety climate of clinical teams, and this would lead to changes in working practices on the front-line of services (see RQ5). Those changes would then make a detectable difference on rates of harm and adverse events involving patients as measured using routine data (see RQ4).

7.a. Safety culture or climate at clinical team level

We had three types of evidence available to indicate whether such changes in safety climate at clinical team level had occurred: the SCORE survey; secondary data from the NHS patient survey; and qualitative data.

7.a.i. SCORE survey

A first round of surveys was conducted across 72 sites, unevenly distributed across 6 PSCs. 36 sites were general practices, 13 were acute hospital wards (including maternity, paediatrics), and 9 were mental health wards. There were three ICUs, one emergency department, seven other hospital departments and one CCG. As noted, by the time of writing just six sites had completed a second-round survey: three general practices, a mental health trust pharmacy, an emergency department and a medical admission unit. The numbers of individual respondents in each site ranged from 9 to 151.

On the whole we found little evidence of a difference in safety climate scores between first and second SCORE surveys. Site by site there was little change in the learning environment, personal burnout, teamwork, safety climate and work-life balance domains; in all sites but one there was no significant change in the local leadership and burnout climate scores. The exception to this pattern was that in one general practice we found some evidence of a difference in the local leadership (table 7) and burnout climate (table 8) scores. In that site average local leadership scores were higher, and burnout climate scores lower, in the second survey compared to the first.

Table 7: Summary statistics for person-level scores on the local leadership domain of the SCORE survey.

LOCAL LEADERSHIP DOMAIN	First survey		Second survey		p-value
	Number completed	Mean (SD) score	Number completed	Mean (SD) score	
Hospital A: ED	110	57.5 (26.3)	150	52.3 (28.8)	0.1
Hospital A: MAU	83	59.4 (25.9)	95	59.7 (30.4)	0.9
General practice D	56	54.1 (27.9)	69	62.5 (26.4)	0.1
General practice E	13	65.6 (28.7)	9	78.6 (21.2)	0.2
General practice F	36	45.2 (26.3)	28	63.6 (31.2)	0.01
Pharmacy G	13	87.4 (16.2)	13	74.5 (23.4)	0.1

MAU = Medical Assessment Unit

Table 8: Summary statistics for person-level scores on the burnout climate domain of the SCORE survey.

BURNOUT CLIMATE DOMAIN	First survey		Second survey		p-value
	Number completed	Mean (SD) score	Number completed	Mean (SD) score	
Hospital A: ED	113	69.9 (21.7)	151	73.9 (20.3)	0.1
Hospital A: MAU	84	72.7 (19.4)	96	72.1 (20.9)	0.8
General practice D	59	70.8 (19.2)	69	66.0 (20.7)	0.2
General practice E	13	50.6 (26.3)	9	58.9 (21.0)	0.4
General practice F	36	67.1 (21.1)	29	52.2 (23.9)	0.01
Pharmacy G	13	67.3 (16.2)	13	57.3 (19.1)	0.2

Across all the sites and domains, only four of the mean person-level scores were in the first survey above eighty percent (see Appendix 7). The fact that most mean scores were below eighty percent whilst four were above suggests that it is unlikely that a ‘ceiling effect’ was the reason why scores in the second survey were, with the above exceptions, not significantly higher.

7.a.ii. NHS Staff Survey

For the period 2013-16 we analysed the four elements in the NHS staff survey relevant to some of the aspects of workplace safety climate that the PSCs were trying to influence, specifically:

1. Improvement: staff feeling able to contribute to improvements in their area of work.

2. Managers: support from immediate managers.
3. Errors: fairness and effectiveness of procedures for reporting errors, near misses and incidents.
4. Recommendation: staff recommendation of the organisation as a place to work or receive treatment.

Comparison of key findings across years, among all trusts, showed evidence of a small increase in mean response in 2015 and 2016, compared to 2014 (Table 9). The mean percentage of staff reporting that they felt able to contribute to improvements in their organisation was estimated to increase by 2.24% (95% confidence interval (CI) for increase 1.69% to 2.79%) from 2014 to 2016. Mean responses on the other key findings showed evidence of small improvements in 2015 and 2016, compared to 2014.

Table 9: Comparisons of key findings across years, across all AHSNs.

Outcome	Mean (SD)*	Mean difference**		
		estimate	95% CI	p-value
Percentage of staff able to contribute to improvements				
2013	68.30 (3.93)	-0.05	-0.60 to 0.50	
2014	68.35 (4.03)			
2015	70.25 (3.69)	1.90	1.36 to 2.45	<0.001
2016	70.59 (3.65)	2.24	1.69 to 2.79	
Mean level of support from immediate managers				
2013	3.65 (0.09)	-0.01	-0.02 to 0.003	
2014	3.66 (0.10)			
2015	3.72 (0.09)	0.06	0.04 to 0.07	<0.001
2016	3.74 (0.08)	0.08	0.07 to 0.10	
Mean level of fairness and effectiveness of procedures for reporting errors				
2013	3.52 (0.09)	-0.02	-0.03 to -0.01	
2014	3.54 (0.09)			
2015	3.71 (0.10)	0.17	0.16 to 0.18	<0.001
2016	3.73 (0.09)	0.19	0.18 to 0.20	
Mean level of recommendation as a place to work or receive treatment				
2013	3.71 (0.24)	0.004	-0.016 to 0.024	<0.001
2014	3.70 (0.24)			
2015	3.78 (0.20)	0.08	0.06 to 0.10	

2016	3.79 (0.19)	0.09	0.07 to 0.11
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*From raw data.

**Compared to 2014. From model including year of survey.

Results from sensitivity analyses, which included all trusts that reported for some or all of the four years, were very similar (Table 10). In general, from analyses based on trusts within all AHSNs, mean responses on key findings remained stable from 2013 to 2014, and then increased in 2015 and 2016. Because the key findings were stable across the first two years, we can be more confident that improvements in 2015 and 2016, compared to 2014 may be attributed to the PSCs.

Table 10: Comparisons of key findings across years: sensitivity analysis based on all trusts that reported for some or all years, across all AHSNs.

Outcome	Mean (SD)*	Mean difference**		
		estimate	95% CI	p-value
Percentage of staff able to contribute to improvements				
2013	68.34 (3.90)	-0.11	-0.65 to 0.43	<0.001
2014	68.44 (4.05)			
2015	70.26 (3.67)	1.84	1.30 to 2.38	
2016	70.59 (3.63)	2.17	1.62 to 2.71	
Mean level of support from immediate managers				
2013	3.65 (0.09)	-0.01	-0.02 to 0.002	<0.001
2014	3.66 (0.10)			
2015	3.72 (0.09)	0.06	0.04 to 0.07	
2016	3.74 (0.08)	0.08	0.07 to 0.09	
Mean level of fairness and effectiveness of procedures for reporting errors				
2013	3.52 (0.09)	-0.02	-0.03 to -0.01	<0.001
2014	3.54 (0.09)			
2015	3.71 (0.10)	0.17	0.16 to 0.18	
2016	3.73 (0.09)	0.19	0.18 to 0.20	
Mean level of recommendation as a place to work or receive treatment				
2013	3.70 (0.24)	0.003	-0.02 to 0.02	<0.001
2014	3.70 (0.24)			
2015	3.78 (0.20)	0.08	0.06 to 0.10	
2016	3.79 (0.19)	0.09	0.07 to 0.11	

*From raw data.

**Compared to 2014. From model including year of survey.

We repeated the analysis specifically for our case-study AHSNs. Comparisons of findings across years, among the trusts in AHSN Alpha similarly showed evidence of an increase in mean response in the years 2015 and 2016, compared to 2014, and indicated that responses were stable across 2013 and 2014. For example, the percentage of staff who felt able to contribute to improvements in their workplace was estimated to be 4.67% (95% CI for increase 2.03% to 7.30%) higher in 2015 and 5.33% (95% CI for increase 2.70% to 7.97%) higher in 2016, than in 2014 (Table 11).

Table 11: Comparisons of key findings across years, based on six trusts that reported for all years, within AHSN Alpha.

Outcome	Mean (SD)*	Mean difference**		
		estimate	95% CI	p-value
Percentage of staff able to contribute to improvements				
2013	66.50 (5.28)	0.33	-2.30 to 2.97	<0.001
2014	66.17 (6.21)			
2015	70.83 (4.92)	4.67	2.03 to 7.30	
2016	71.50 (5.39)	5.33	2.70 to 7.97	
Mean level of support from immediate managers				
2013	3.65 (0.10)	-0.01	-0.06 to 0.05	<0.001
2014	3.65 (0.13)			
2015	3.75 (0.10)	0.10	0.05 to 0.15	
2016	3.80 (0.09)	0.15	0.10 to 0.20	
Mean level of fairness and effectiveness of procedures for reporting errors				
2013	3.49 (0.09)	0.01	-0.04 to 0.06	<0.001
2014	3.48 (0.09)			
2015	3.65 (0.12)	0.17	0.12 to 0.22	
2016	3.68 (0.10)	0.20	0.15 to 0.26	
Mean level of recommendation as a place to work or receive treatment				
2013	3.66 (0.29)	0.06	-0.05 to 0.17	0.03
2014	3.60 (0.35)			
2015	3.75 (0.26)	0.15	0.04 to 0.26	
2016	3.76 (0.21)	0.15	0.04 to 0.26	

*From raw data.

**Compared to 2014. From model including year of survey.

AHSN Beta showed evidence of a difference in level of fairness and effectiveness of reporting errors across years. The mean response to this key finding was stable across 2013 and 2014, and was estimated to be 0.17 points higher (95% CI for increase 0.10 to 0.24) in 2015 and 2016, compared to 2014. There was some evidence of an increase in 2015 and 2016, compared to 2014, in the percentage of staff feeling able to contribute to improvements, but little evidence of differences in the other two key findings across the years (Table 12).

Table 12: Comparisons of key findings across years, based on nine trusts that reported for all years, within AHSN Beta.

Outcome	Mean (SD)*	Mean difference**		
		estimate	95% CI	p-value
Percentage of staff able to contribute to improvements				
2013	69.22 (4.06)	-0.78	-4.06 to 2.51	0.05
2014	70.00 (3.57)			
2015	73.67 (3.20)	3.67	0.38 to 6.95	
2016	71.44 (4.77)	1.44	-1.84 to 4.73	
Mean level of support from immediate managers				
2013	3.70 (0.10)	-0.03	-0.10 to 0.04	0.1
2014	3.73 (0.10)			
2015	3.76 (0.11)	0.03	-0.04 to 0.11	
2016	3.77 (0.09)	0.05	-0.02 to 0.12	
Mean level of fairness and effectiveness of procedures for reporting errors				
2013	3.56 (0.10)	-0.02	-0.09 to 0.05	<0.001
2014	3.58 (0.08)			
2015	3.75 (0.11)	0.17	0.10 to 0.24	
2016	3.75 (0.11)	0.17	0.10 to 0.24	
Mean level of recommendation as a place to work or receive treatment				
2013	3.78 (0.29)	-0.02	-0.14 to 0.10	0.8
2014	3.80 (0.26)			
2015	3.84 (0.21)	0.04	-0.08 to 0.16	
2016	3.81 (0.22)	0.02	-0.10 to 0.14	

*From raw data.

**Compared to 2014. From model including year of survey.

In AHSN Gamma there was evidence of an increase in level of support from immediate managers, fairness and effectiveness of procedures for reporting errors and recommendation as a place to work

or receive treatment, in 2015 and 2016, compared to 2014. These outcomes were stable across 2013 and 2014 (Table 13).

Table 13: Comparisons of key findings across years, based on 10 trusts that reported for all years, in AHSN Gamma.

Outcome	Mean (SD)*	Mean difference**		
		estimate	95% CI	p-value
Percentage of staff able to contribute to improvements				
2013	70.00 (3.06)	1.40	-0.67 to 3.47	0.4
2014	68.60 (3.95)			
2015	69.70 (2.63)	1.10	-0.97 to 3.17	
2016	70.10 (3.45)	1.50	-0.57 to 3.57	
Mean level of support from immediate managers				
2013	3.62 (0.11)	0.005	-0.05 to 0.06	0.004
2014	3.62 (0.09)			
2015	3.69 (0.06)	0.08	0.02 to 0.13	
2016	3.70 (0.08)	0.08	0.03 to 0.14	
Mean level of fairness and effectiveness of procedures for reporting errors				
2013	3.53 (0.10)	-0.003	-0.05 to 0.05	<0.001
2014	3.53 (0.10)			
2015	3.73 (0.06)	0.20	0.15 to 0.25	
2016	3.73 (0.07)	0.19	0.15 to 0.24	
Mean level of recommendation as a place to work or receive treatment				
2013	3.73 (0.24)	0.04	-0.04 to 0.12	0.001
2014	3.70 (0.25)			
2015	3.86 (0.18)	0.16	0.08 to 0.24	
2016	3.82 (0.16)	0.13	0.04 to 0.21	

*From raw data.

**Compared to 2014. From model including year of survey.

Results from sensitivity analyses of findings within each of these three AHSNs, which included trusts that reported for some or all of the four years, were very similar (Tables 14 to 16). Although our analyses based on trusts within all AHSNs show mean responses remaining stable from 2013 to 2014 and then increasing in 2015 and 2016, our qualitative data on the time needed to implement changes at clinical team level suggest it is unlikely that these changes can be attributed to PSCs.

Table 14: Comparisons of key findings across years: sensitivity analyses based on all trusts that reported for some or all years, within AHSN Alpha.

Outcome	Mean (SD)*	Mean difference**		
		estimate	95% CI	p-value
Percentage of staff able to contribute to improvements				
2013	66.86 (4.91)	0.30	-2.19 to 2.79	<0.001
2014	66.17 (6.21)			
2015	70.83 (4.92)	4.67	2.13 to 7.21	
2016	72.00 (5.10)	5.44	2.95 to 7.93	
Mean level of support from immediate managers				
2013	3.65 (0.09)	-0.01	-0.05 to 0.04	<0.001
2014	3.65 (0.13)			
2015	3.75 (0.10)	0.10	0.05 to 0.15	
2016	3.81 (0.08)	0.15	0.11 to 0.20	
Mean level of fairness and effectiveness of procedures for reporting errors				
2013	3.49 (0.08)	0.004	-0.05 to 0.06	<0.001
2014	3.48 (0.09)			
2015	3.65 (0.12)	0.17	0.11 to 0.23	
2016	3.70 (0.10)	0.21	0.16 to 0.27	
Mean level of recommendation as a place to work or receive treatment				
2013	3.68 (0.27)	0.05	-0.05 to 0.16	0.01
2014	3.60 (0.35)			
2015	3.75 (0.26)	0.15	0.04 to 0.26	
2016	3.79 (0.21)	0.16	0.06 to 0.27	

*From raw data.

**Compared to 2014. From model including year of survey.

Table 15: Comparisons of key findings across years: sensitivity analyses based on all trusts that reported for some or all years, within AHSN Beta.

Outcome	Mean (SD)*	Mean difference**		
		estimate	95% CI	p-value
Percentage of staff able to contribute to improvements				
2013	69.36 (3.75)	-0.95	-3.86 to 1.96	0.05
2014	70.30 (3.50)			
2015	73.40 (3.13)	3.12	0.13 to 6.11	
2016	71.55 (4.27)	1.23	-1.67 to 4.14	
Mean level of support from immediate managers				

2013	3.70 (0.09)	-0.03	-0.09 to 0.03	
2014	3.73 (0.09)			
2015	3.76 (0.10)	0.03	-0.03 to 0.10	0.05
2016	3.78 (0.08)	0.05	-0.01 to 0.11	
Mean level of fairness and effectiveness of procedures for reporting errors				
2013	3.56 (0.09)	-0.03	-0.09 to 0.03	
2014	3.59 (0.08)			
2015	3.75 (0.10)	0.17	0.10 to 0.23	<0.001
2016	3.77 (0.11)	0.18	0.12 to 0.25	
Mean level of recommendation as a place to work or receive treatment				
2013	3.73 (0.29)	-0.05	-0.16 to 0.06	
2014	3.78 (0.25)			
2015	3.83 (0.19)	0.05	-0.07 to 0.16	0.3
2016	3.82 (0.20)	0.04	-0.07 to 0.15	

*From raw data.

**Compared to 2014. From model including year of survey.

Table 16: Comparisons of key findings across years: sensitivity analyses based on all trusts that reported for some or all years, within AHSN Gamma.

Outcome	Mean (SD)*	Mean difference**		
		estimate	95% CI	p-value
Percentage of staff able to contribute to improvements				
2013	69.64 (3.14)	0.97	-1.24 to 3.18	
2014	68.60 (3.95)			
2015	69.91 (2.59)	1.24	-0.97 to 3.45	0.4
2016	70.55 (3.59)	1.88	-0.33 to 4.09	
Mean level of support from immediate managers				
2013	3.62 (0.10)	0.002	-0.05 to 0.05	
2014	3.62 (0.09)			
2015	3.69 (0.06)	0.08	0.02 to 0.13	0.001
2016	3.70 (0.08)	0.09	0.03 to 0.14	
Mean level of fairness and effectiveness of procedures for reporting errors				
2013	3.53 (0.09)	-0.002	-0.05 to 0.04	
2014	3.53 (0.10)			
2015	3.73 (0.06)	0.20	0.15 to 0.25	<0.001
2016	3.72 (0.07)	0.19	0.14 to 0.24	
Mean level of recommendation as a place to work or receive treatment				
2013	3.73 (0.23)	0.04	-0.04 to 0.12	<0.001
2014	3.70 (0.25)			

2015	3.85 (0.17)	0.15	0.08 to 0.23
2016	3.82 (0.16)	0.13	0.05 to 0.20

*From raw data.

**Compared to 2014. From model including year of survey.

Responses across 2013 and 2014 were stable, followed by increases in 2015 and 2016, at the level of these AHSNs. However, our qualitative data on the time needed for PSCs to implement changes at clinical team level again suggest that it is unlikely that the observed changes were due to PSC activities.

7.a.iii. *Qualitative accounts*

Qualitative findings about safety climate concerned: clinical teams' existing safety climate; patches of changes in that climate; and PSCs' contribution to those changes.

Some front-line staff informants thought that their hospital's existing safety climate was already 'blame free':

"I've always worked in a hospital which has always been fairly blame free... So, I don't think we've changed because I don't think we were bad before" (PSCFL28).

Similarly in a general practice setting we were also told that there existed a "no blame," "open" and "learning culture":

"When we come across complaints for example,[...] I don't see that as a negative thing, I see that as an external source looking in and saying, 'this can be improved', so then we try our best to improve it. And same with any significant events or adverse events that may have happened in the practice, [...] I see that as a learning exercise and so does everyone else in the practice. We very much have a no blame culture here, so if anything does go wrong [...] we have an open discussion about it and we move forward and we see how we can improve it and make it better for the future" (PSCOL12).

Responses elsewhere were more mixed, with some hospital informants describing efforts to move away from a blame culture:

“I think we’ve made a lot of effort in ensuring that the blame culture, sort of, you know is reduced markedly, I think. [...] I approached everybody when things went wrong to come and talk about it. And some people were very willing. Some people were absolutely not willing. When people were willing, I ensured that the focus was on the positive and not on the negative” (PSCFL29).

Nevertheless individuals could still come away from safety incidents feeling a sense of blame:

“People are more accepting of the fact that we have to look into these incidents and I think people recognise the importance of it. I don’t think it stops people from feeling that they might be under scrutiny or, that there might be a sense of blame somehow” (PSCFL27).

One indication of a change of safety climate was when informants reported that a more open “learning culture” had made team members more confident about the value of incident reporting. In some hospital settings that we accessed, informants were confident that this shift away from a blame culture towards a more learning culture had become more evident in the last eighteen months:

“I think definitely within the organisation I work, there is definitely a lot more of a safety culture and we definitely feel that we are going away from a blame culture to a, what can we improve[...] I would say within the last year to 18 months there seems like there's a change” (PSCFL31).

Some informants however initially interpreted such a shift toward a more learning culture as a new form of micro-management. Thus some consultants expressed a preference for a workplace shift towards a more “trusting culture” whereby they could be relied upon i.e. trusted to be more autonomous, less “micro managed,” and able to exercise their own professional judgement based on their technical knowledge and experiential learning and expertise:

“I think we also need actually to trust clinicians to try and...let them to do things,[...]most clinicians I talk to feel micro-managed and I think it's actually clinical empowerment probably would be more helpful and get rid of a lot of the red tape. We're addicted to rules and I think actually we just have to trust people and let them get on with it” (PSCFL28).

Although clinical teams' safety climate was reported to be changing in pockets, it was not happening in a clear linear fashion but dynamically, at times with different expressions of climate co-existing in different organisational layers, or with the safety climate changing in either direction at the level of organisation, team or individual agents (a similar pattern to that reported at network level: see Chapter 5 and Figure 2). On balance, more of our informants said that such changes were taking place than the opposite:

"I think there is a level of focus on patient safety that is having an influence [...] I think there is a culture change going on and I think the patient safety collaboratives definitely part of that and gives some support towards you know the direction of travel for that culture change" (PSCL10).

However some thought it was still early days and that more needed to be done nationally across the NHS to change workplace safety climate:

"I think to some extent there has been an improvement in the culture [...] You know, again, I don't think the NHS, as a huge organisation, has really done much to really walk the walk in terms of moving from a blame culture" (PSCFL30).

Another indication for a change of safety climate was when junior staff felt able to actively engage in or lead quality improvement initiatives. As one consultant commented:

"I think you really measure the ability of a department to innovate and embrace change and have that sort of positive culture when you look at the junior nurses and the junior doctors and see what they're doing. If they're involved in stuff, then that's pretty progressive" (PSCFL1).

This was reflected elsewhere, many junior doctors reported feeling more "empowered" when it came to initiating and carrying out improvement and safety work:

"I think that it [QI]'s empowering people to make changes, I think the days where people feel like they have to ask for permission to do small projects, has largely gone. [...] I know in our Trust, they're very happy for you to trial change without seeking approval first of all,

and then if it's a successful change, bringing that to the attention of the senior management" (PSCFL17).

A clinical pharmacist commented that the learning around QI methods had become more apparent, particularly among younger staff:

"People are becoming more aware of how to change stuff properly, rather than just making change for change sake. [...] So I think it is...culturally, people are a little bit more willing to try little changes, yeah, which is exactly what QI and PDSA cycles are all about, making a little change and observe the effect. There's definitely been a little bit of a shift. Early days still, I would argue, with some of our dinosaurs" (PSCFL14).

A care home practitioner described implementing an "urgent call communication tool" through the patient safety work they were doing on monitoring unplanned admissions and reported that:

"From the perspective of quality improvement within care homes, [...] there's been a significant shift in information people would share, in the collaborative working and the openness of what people want to do, definitely" (PSCFL25).

Similarly a matron in an emergency assessment unit reflected that quality improvement: "is changing the culture, because people are embracing and getting involved and feeling motivated" (PSCFL24).

Successful practical experiences of QI work reinforced such changes in clinical teams' safety climate. Where a new initiative or change process could be seen to improve efficiency and/or enhance patient care, then attitudes were more likely to change, even in those instances where morale had previously been low:

"There was quite low morale in staff [...] I think falls was quite low on their agenda and it's almost as if well, there's nothing we can do, you know 'old people will fall' [but through] doing workshops, talking and being proactive on the wards [they were] changing their [staff] mindset [...], over the last 3 years we've seen a reduction of 200 falls" (PSCFL12).

In some cases the PSCs were contributing to this change through introducing champions or QI experts to lead on quality and safety:

“I think the new people they've brought into our quality and safety team are very much leading from that point of view, so that it is open and transparent and people have the confidence to speak up. [...] the staff that they've brought in to start leading the quality and safety teams, they're very much...very passionate [...] they're very keen to spread the word and do various teaching sessions and everything to go through with people all about change and learning from things and changing what we do, as opposed to just sacking somebody or blaming somebody” (PSCFL31).

In our informants' ideational transition from blame culture to a just, learning and eventually trusting culture (or rather, climates), PSC intervention was especially relevant to reaching and developing the learning culture stage, as matched the PSC lead views described in Chapter 5.

One indication that PSCs were reaching different levels of the NHS was a subtle change in language use. For example when interviewing front-line staff we found some were using terms particular to the Institute of Health Improvement (IHI) model of improvement, such as using the term “champions” when describing leadership. In some instances, interview participants reported using QI methods such as Break Through Series (BTS) and Plan Do Study Act (PDSA) cycles, as well as applying small tests of change, while saying they had not heard of PSCs (see below); to us this implies that whether participants were directly aware of PSCs or not, by aligning with QI activity PSCs are reaching different levels of NHS activity. At the same time matters are confused by the fact that on the one hand adopting QI improvement methodology and engaging in QI activity may indicate that PSCs are becoming more embedded, but on the other hand QI activity was perceived by some as a parallel initiative that preceded the PSCs. In such instances, a distinction was made between “quality improvement” and “PSC quality improvement” (PSCOL5) and this raises the question of attribution, which we consider below.

7.b. Did changes in safety climate lead to changed clinical working practices?

We were able to trace several changes in practice. In acute hospitals we were told that the PSCs had facilitated a number of changes in the way people worked. One was a shift away from a *laissez-faire* attitude towards falls in older patients - “old people will fall” - towards active preventive measures. By using QI methods and carrying out “small tests of change,” staff were able to introduce more low-rise beds and red slipper socks to reduce the risk of falls. After studying fall

trends they altered the shift patterns of their staff and were able to achieve a reduction of 200 falls over a three-year period. Additionally staff were now “more open and more willing to report falls” (a change in safety climate) and the PSC had helped the team to work in a more multidisciplinary way:

“Over my time I've seen a very much more streamlined, efficient and patient... I think we are relying much more now on pathways and protocols to follow, with good effect. And I think people are being educated well and I see it through the junior doctors who come through. So I can tell that implementation of change has been widespread.” (PSCFL4).

In another hospital, morning “safety briefs” were introduced on the wards to review

“Things that are going well, things that could have gone better, whether there are any things that we need to highlight like safety alerts” (PSCFL2).

Staff reported changed attitudes towards breaches of admission times standards in the ED, breaches previously seen as “unavoidable”:

“Because it got so bad, people kind of desensitised to how long that patients been here and whether they are going to breach and if they breach, they breach! It's because you were busy. But now we realise yes we are busy, but we do know that we can avoid these breaches and we can do something about it” (PSCFL2).

In addition to the “inroads” being made in reducing acute kidney injury (see above), we were told of similar reductions in sepsis through implementing more standardised procedures around diagnosis, treatment and teamwork.

Another hospital modified a car industry technique. Should any patient care problem arise staff would

“‘Stop the Line’ and get very senior involvement very quickly so that we can resolve patient issues” (PSCFL24).

A fracture liaison nurse reported that the PSC activity in their organisation included falls and pressure sores and that they had introduced “intentional rounding” on their ward, as a pre-emptive and preventative approach to patient care:

“Every patient is checked on every hour to make sure A) would they like a drink, B) would they like to go to the loo and C) have they got any problems?” (PSCFL11).

Other hospital-based informants described how PSC-instigated QI work had yielded changes to discharge summaries and in triage, with the recruitment of more staff with new roles such as an ED “navigator”, which assisted patient flow. A head of nursing described how implementing new software for incident reporting had improved patient care:

“We moved to [*software A*] from something called [*software B*] and this gave us the ability to respond better to trends, to interrogate the data better” (PSCFL10).

In the general practices that we accessed, staff told us that within the preceding six months, more time has been built into the working week for regular meetings (PSCFL8) and one afternoon a month has been set aside to specifically discuss patient safety and quality improvement (PSCFL6). A receptionist told us:

“We had quite a lot of training about triaging calls [how to] prioritise workload and prioritise which patients need to be seen, it's just more managed now and patients are generally happier as a result, in my view anyway” (PSCFL7).

A respondent from a community mental health site reported that, due to the PSC, they were now using patient experiences more to evaluate their patient care qualitatively:

“We’ve done a huge amount of work at all levels, [...] including patients leading on the sort of shared decision making co-production agenda, we’ve done a huge amount on board development [...] we have patient stories at the beginning of each board meeting, again, to just ground people, to remind people why they’re there” (PSCFL22).

An important consideration for many was how to normalise QI work. In some regions our informants expressed the view that QI was yet to be incorporated fully into daily work across many sectors and specialisms such as nursing:

“I don’t think quality improvement is embedded until nurses need it, if that makes sense, but it's not day-to-day. It's not seen as part of our jobs, unfortunately”(PSCFL23).

Some registrars and consultants were beginning to incorporate quality improvement as part of their appraisals and career progression, but implementation of this remained patchy:

“Quality improvement is now embedded into quite a few of the curriculums so trainees [...] have the experience of projects - both successful and unsuccessful projects [...] and it will embed itself, so there will be less of a need for a top-down approach” (PSCFL17).

Three front line members of staff also told us that they had implemented safety initiatives either without training and/or by using *ad hoc* methods. Such initiatives must therefore be attributed to origins partly or wholly separate to any PSC.

7.b.i. SCORE surveys as a PSC intervention

Answers to the free text SCORE questions showed that clinical team members in those study sites more often reported the risks to patient safety shown in Table 17. (We have omitted risks mentioned fewer than ten times.) As previously explained some respondents mentioned risks in more than one category and the numbers in Table 17 include both surveys across all six sites.

Table 17: SCORE survey: Frequency of mentions of risks to patient safety

Safety Risk	Mentions
Overload: number of patients, over-crowding, not enough capacity	165
Understaffed (any category of staff)	165
Over-demands for work upon staff (tired, overloaded)	39
Pressure to move (or keep) patients inappropriately regardless of clinical context	30
Communication lacking	27
Handover / transfer poor or lacking	17
Appointments – too few, too late	17
Documentation (including electronic) - poor, late, laborious to complete	14
Tired or overworked staff make mistakes, cut corners	12
Prescribing errors / risks	11
Have to work when unwell or tired	11
Turnover, sickness, non-retention of staff	10
Lack of beds	10

A striking feature of Table 17 is that across workplaces, clinical team members who responded to this survey mentioned predominantly organisational rather than clinical risks to patient safety. In response to an open question, work overload (demand) and understaffing both received more than four times as many mentions as the next most frequently mentioned risk, ‘demands upon staff’ (and in fact this would appear to be a consequence of the first two risks). Handover or transfer, pressure

to move (or keep) patients inappropriately regardless of clinical context, and lack of beds applied to the three hospitals but not general practices. Appointment availability was mentioned only at two general practices.

An unforeseen finding was that the SCORE surveys themselves did not only measure clinical teams' safety climate but the post-survey de-briefing also motivated teams to review their everyday working practices and triggered what were, in effect, cycles of PDSA activity. The SCORE surveys were, rather than being a measurement tool, an almost immediately impactful PSC activity. For example a SCORE survey showed that one of the main problems in an ED was

“what a burned out environment we are working in and how close to the edge quite a lot of our staff groups were” (PSCFL1).

Being able to demonstrate this “numerically” and to explore the reasons why it occurred led to better communication within teams and between front-line staff and senior management:

“We were able to demonstrate the key issues are staffing, space and flow of patients i.e. you know, we have a crowded department [...] we were able to use the data and present it up the food chain to the executive directors. [...] Just having that numeric data available has enabled us to get more staff which is helpful. But unfortunately crowding and space is still a massive issue.” (PSCFL1).

In this case hospital staff reportedly felt listened to by senior management. Not only was safety information fed “up the food chain” to management, but following the SCORE survey and debrief sessions, senior executives were keen to know the results. This in turn led to quicker decision-making and tangible improvements such as the rapid recruitment of more staff to help with overcrowding in the department. The results were also used to inform the content of the hospital's safety days and smaller group work on areas such as “active listening and giving and receiving feedback,” (PSCFL1) as well as helping to inform, motivate and empower more staff to engage in quality improvement. The survey provided the space and time for staff to reflect upon their own attitudes, as well as the perspective of their colleagues:

“It highlighted individuals' perspectives that we had perhaps never even considered before and that [are] possibly very important in terms of delivering safe care to patients. So it highlighted the perspective of all different workers from the receptionist, three porters and all tiers of doctor and nurse and what they felt was important” (PSCFL1).

Given their usual size there is in most general practices little practical difference between the organisational and clinical team levels. In Chapter 6 we reported how PSC involvement in the merging of four general practices led to the practices rewriting all working policy documents and protocols from scratch. We also described the consequences of SCORE surveys for working practices in an inner-city general practice in another PSC. Other front-line staff to whom we spoke described other improvements including changes in management which facilitated improved communications, in particular with line managers; more regular feedback meetings; practice partners having an “open door policy” (PSCFL5); and “up-skilling” staff so that they are better able to support colleagues where necessary, including the training of receptionists to prioritise the needs of patients in order to improve safety.

In community mental health, the survey showed that some teams were productive and delivering to a high standard. Nevertheless there were underlying problems with communication, teamwork and burnout, all of which were negatively affecting staff well-being. This team considered the survey to have had a positive impact on them because it offered a framework and “safe space” to have potentially “difficult conversations” (PSCFL22).

Staff across community mental health, primary and acute care settings thought that conducting and responding to the SCORE survey enhanced multidisciplinary team working because it enabled those who had taken part in the survey to be involved in acknowledging problems and finding solutions, whether at a system or individual level. The survey showed where improvements were needed, for example in teamwork and communication, and highlighted the importance of developing a safe space for sharing feedback and the need for pre-emptive measures to offset the risk of staff burnout. Staff feedback on the SCORE survey included recommendations that the survey be relevant to all clinical groups; that the debrief sessions were essential but that it was not always possible to include all participants due to shift rotations and busy work schedules; and that regular email reminders to complete the survey were important to ensure a high response rate. A sufficiently large sample size was required to ensure confidentiality. Comparison between teams, for example in the community mental health sector, was not possible in cases where teams were so small that individual

respondents could be identified. Good leadership to facilitate changes post survey was essential as were support structures to sustain the proposed changes.

Although we used the SCORE survey, these findings would appear to apply to any survey (irrespective of the instrument) used as a means to assess and stimulate QI work. We were told that some AHSNs had used alternative tools (e.g. the Manchester Patient Safety Framework (MaPSaF)^{267,268}) for measuring safety climate in a similar way, as an important part of their work programme.

7.b.ii. Contexts: Operational pressures, pockets of resistance, time required

Clinical team informants mentioned contexts which strongly moderated, to the extent of creating barriers to, implementation of safety improvements, including PSC-instigated ones. Operational pressures (i.e. demand overload) meant clinical teams had insufficient time for QI work and this tended to strengthen pre-existing pockets of individual resistance.

Corroborating the SCORE survey participants' verbal responses, our interviewees repeatedly mentioned operational pressures as a substantial barrier to safety climate change and QI work. Besides the demands of direct patient care, one consultant commented,

“We are in a state of guideline and standard fatigue [...] There are nearly 200 NICE guidelines [...] One of my colleagues told me that a woman who breaks her hip and goes into hospital and has an operation and then is discharged has over, in some hospitals, 90 guidelines that apply to her care. [...] We have this vast, largely pointless, guideline industry that generates enormous amounts of standards and all it's doing, I think, is providing rope for clinicians to fail against, for them to hang themselves with” (PSCFL28).

Similarly in primary care, a practice manager commented:

“There seems to be a lot of unrealistic targets set and not all of them seem to feel like they have a quality of purpose behind them, and I think that does kind of put people off doing them” (PSCOL13).

Even when time was allocated and approved for staff to attend a learning event, many staff felt unable to leave their front-line duties. Providing direct patient care was the main priority and thus the main barrier to improvement work. Lack of time, not lack of motivation or ‘culture’, was for many informants the main barrier to engaging in QI work: .

“I love quality improvement work, but the difficulty is, if you work full time, having the time to do it.” (PSCFL17).

Nevertheless, besides being a practical barrier, operational pressures, workload and therefore lack of time could provoke expressions of ‘grass-roots’ cynicism:

“Actually so on grass-roots level, the people that deliver care in the emergency department are so overwhelmed with the pressure of delivering that care that you often get, you know, an eye roll or quite clear cynicism if you suggest that there is a quality improvement thing that they might like to be involved with [...]. So there are grass-root levels of cynicism” (PSCFL1).

The addition of any new initiative to the mix was in such instances likely to be viewed with suspicion and PSCs were no exception.

As well as time and workload pressures there remained other individual sources of resistance to QI programmes. Resistance to change appeared when proposed changes were interpreted as a direct, personal criticism of individual practice:

“A lot of people I've found in health-care are incredibly scared of change [...] they don't see it that the system could be improved, they see it that they need to be improved [...] a lot of the greatness of QI work is you can do stuff as a test of change, it's kind of easier to sell it to people [...] But still there's always a lot of apprehension with some of certainly my older colleagues in work, some of the dinosaurs are a bit scared of change” (PSCOL6).

As a consultant anaesthetist commented:

“Sceptics abound actually I think in the NHS. I don't think people are willing to change practice. So we have a phrase which we use very commonly, ‘change happens one funeral at a time’” (PSCFL29).

Hospital staff described encountering resistance when they tried to introduce a change process without educating and fully explaining to their colleagues or team why they were introducing a change:

“It used to be a little bit hit and miss. You would try to introduce something and it wouldn’t work because people didn’t want to get involved and they just thought well, what’s the point? It’s not going to make it any better” (PSCFL2).

Any quality improvement or safety initiative was more likely to fail if those who might be affected by the change had not been consulted and engaged.

Some critics outside the hospital argued that the PSC’s focus and work streams did not fit all care settings, leading them to disengage and dismiss the PSCs as irrelevant:

“I have found others in mental health settings you know in similar roles as myself, have just not bothered with the collaboratives and have sort of walked away saying ‘they don’t suit us. They don’t do what we need’ [...] but actually we can use the Collaboratives such as the medicines one that we had last year and make it fit for us” (PSCOL6).

One way to meet these pockets of resistance to change was to educate and train local champions. According to PSC leads, another facilitator for PSC implementation was for QI to become embedded and in order to promote grass-roots change, it would be necessary for staff to take ownership of a given project or change process: which would mean educating them and engaging them more fully in QI activity.

Armed with the Berwick vision of a system devoted to continual learning and improvement of patient care, ‘*top to bottom* and *end to end*,’ PSC leads were mindful that until such a system existed, *front-line* staff would be inevitably pulled in many often opposing directions:

“There’s a capacity issue definitely. Because what happens at the moment is it [QI and safety work] just gets added to already busy work lives and you know all you end up with is people who’ve learnt new skills and are desperate to use them and have become frustrated and disillusioned with the whole thing” (PSCL1).

For other reasons, middle managers were also susceptible to these operational pressures, as noted in Chapter 6. We noted in Chapter 5 how PSCs gave support outside participating NHS trusts in an attempt to address these barriers.

Not only was time needed to free up individual staff to engage in QI, it was needed at organisational level to educate and train local champions to meet pockets of resistance to change; to build in the necessary support structures for QI to become more fully embedded post training; to carry out the necessary “tests of change”, and to build the structures needed to sustain the proposed change:

“I think sometimes there's a misconception about how much time is required to actually start making a change to get those PDSA balls rolling. And certainly, with the outside external pressures from our clinical commissioning group, from the CQC, from NHSI, it has... particularly our sepsis work in ED, it has taken us a year to get where we are now!”
(PSCFL24).

A hard but necessary task following such changes was to remind clinical team members from time to time why they had changed their working routines and why it was important to sustain the changes.

As we described in Chapter 6, organisational or departmental size was another factor determining its receptivity to change and the timescale needed for PSC activity to take traction. The ideal conditions for PSC implementation included having champions that could maintain momentum on projects and help QI become fully embedded across the healthcare system, adapt QI initiatives to local need - ideally born out of a grass-roots initiative - and enable clinical teams to take ownership of QI project or change process, so as to promote staff engagement and motivation. But even if all these factors were in place, unless enough time and resources were built in for QI activity, as well as the capacity for sufficient staffing relative to workload, any QI initiative would more likely fail. PSC leads were clear that QI work could in the long term free up capacity through the establishment of more efficient, streamlined approaches, but they were equally clear that such a vision would require that QI become fully embedded across the health-care system.

7.c. Inter-organisational networks of clinical teams and clinical working practices within providers

We found instances of inter-organisational network(s) of clinical teams helping clinical working practices to change within the providers that participated in the PSC networks. One reason was that such meetings stimulated idea-sharing:

"Going to the collaborative meetings gives you fresh ideas [...] Seeing how other trusts have turned things around and using that as an example" (PSCFL12).

Clinical teams saw PSC activities as providing a "collaborative learning space" and focal point:

"It's useful just having a point of contact [...] that has its sort of tentacles going out into lots of other organisations" (PSCOL7).

These activities also helped disseminate better practice and boosted clinical team members' morale and confidence:

"Patient Safety Collaboratives, [...] you get such a lot out of it, actually it inspires you, gives you ideas. And you hope that [...] your organisation benefits from you getting exposed to that and the energy that it gives you to come on and swim through treacle, as it often feels. And so I go because I'm scared if I stop going, I won't feel that energy commitment from anywhere else. But [...] I'm still not sure I've got enough energy in my own organisation to maintain the momentum that we need to see us through this longer journey. And I think the Patient Safety Collaboratives give you the energy to keep doing what you know you need to do" (PSCFL22).

7.c.i. In what ways did collaboration with clinical teams in other providers help the clinical team within each provider to change its clinical working practices?

At various levels of the NHS, those who had heard of PSCs saw them as a legitimising agent with national backing that could justify time out from the front-line in order to engage in QI and improvement work. PSCs were also seen as a focal point that could provide what respondents termed a: "learning space"; "collaborative space"; "enabling space" or "sharing space"; that is, as somewhere where they could network and share ideas and best practice, as well as learning from things that may not have worked. Among those who had attended a training or collaborative learning event, the feedback was positive as these comments relating to a "sharing best practice day" event held by one PSC illustrate:

"Patient Safety Collaboratives are all about being that "open learning sharing culture," so that if you happen to be near a specialist centre in London and have access to all the great evidence based medicine and interventions, [...] if you live in [*city*], through PSCs, that learning and that improvement to patient care should spread wider than just the 20 mile radius of your specialist hospital" (PSCFL22).

By attending these events and learning from the experience of other organisations, respondent reported, PSCs were helping to facilitate organisations to shift away from "working in silos":

"It was useful to hear the successful initiatives that are going on elsewhere and to share ideas, but also to share things that have gone perhaps not so well" (PSCFL1).

Although the majority of our front-line staff informants who had attended learning and training events reported feeling highly motivated post training, a few were more sceptical:

"I think it's almost like echo chambers. You know, [...] you don't get new people in. It's the same people [...] what happens is that you go for a meeting [...] you meet some people and then everybody goes back and, you know, sort of, gets busy with their work. And it doesn't actually make any progress" (PSCFL29).

7.d. Inter-organisational measurement and comparison

Scope for inter-organisational measurement systems and comparisons to help clinical teams within each provider to change their clinical working practices was constrained by the lack of established measurement systems at the time of our fieldwork (see chapter 5) and by the inherent difficulties of measurement. PSC leads and provider leads alike wondered how to measure their impact:

"I think the measuring bit is the bit that people are struggling with. So there have been some discussions about metrics and what do we measure that's meaningful and from my recollection it's ongoing work and there isn't an answer – there isn't a sort of working model at the moment. And certainly within my organisation as a CCG, what we are looking at are outcome measures at the impact of services that we commission. There's a lot of time goes into trying to refine the metrics to measure outcome as opposed to not just process to get an outcome and then as you say, it's a quality outcome not just yes this person left and went back to independent living. So more work nationally I think on that" (PSCOL8).

At the time of our fieldwork, there remained substantial local variation in measurement systems across organisations:

“[measurement] will be variable across organisations because that will vary on how the measurement systems are set up in organisations. So, some organisations may be under a system where everything is very RAG [red-amber-green] rated so it’s either good or it’s bad or it’s improved or it’s fallen, which is very much an old way of thinking about safety, whereas some of the more mature organisations that have had a longer history with the collaboratives, they are now starting to [...] use their SPC [statistical process control] charts in board reporting so think about improvement over time and look for actual significant changes in data as opposed to one number’s higher than another therefore someone’s either good or bad” (PSCOL1).

Another barrier some organisational leads were encountering at project level, was the perception that measurement and data collection are predominantly about “performance culture” and takes staff away from their primary role - that of caring for patients:

“On the project teams, we do an awful lot of work around collecting measurement for improvement because there’s a real culture around I’m a nurse or I’m a clinician and I don’t do the counting [...] that’s what you know, the performance team do.” (PSCOL1).

7.d.i. In what ways did PSC-wide measurement, data-sharing and comparisons help change clinical practice?

As we noted in Chapter 5, getting trusts to share data was a major challenge in some regions and this applied to community mental health as well as hospitals. A clinical pharmacist described how confidentiality was a major disabling factor when it came to sharing information across sectors:

“We don’t share information across sectors because there’s always confidentiality and difficulties and you know lots of barriers put up. So sometimes it does feel like we’ve got to get over another hurdle and another hurdle and another hurdle and you need a huge amount of drive and enthusiasm to get over all of those” (PSCOL6).

Some informants also wondered whether their performance data, if released, might be used more for performance management than as a learning tool:

“I think mostly our kind of regulators and people who judge us on whether we're doing a good job or not, they are definitely in that framework of information for judgement [rather than] performance data, [being] information for improvement, which is kind of where I think the PSCs are trying to get us to go to culturally” (PSCOL14).

Until data-sharing occurred, the question of how it affected clinical practice could hardly arise.

7.e. Attributing changed working practices to the PSC s

To ensure maximum variation at organisational and front-line staff levels we studied regions and study sites with contrasting contexts of pre-existing improvement infrastructure and network links, so we expected PSC activity and visibility would vary. Out of 31 front-line staff that we accessed across three regions, 18 had heard of PSCs although their familiarity and involvement with PSCs varied; five were unsure or had little knowledge of PSCs and eight had not heard of PSCs though they may have been involved in quality improvement and/or safety work, some of which may have been linked to PSCs.

In some regions and healthcare sectors PSCs lacked visibility, particularly in terms of their improvement activity. One GP to whom we spoke was aware of PSCs but thought quality improvement opportunities and initiatives focussed more on hospitals:

“It [PSC]’s not really impacted at all! I mean I know it’s happening, and we talk about it and the quality teams know and therefore they’re the sort of conduit into primary care, but in all honesty the resource available for making quality improvements in primary care is very scarce. It’s all been focussed at the acute sector” (PSCOL8).

Such local variation was in some cases due to the lack of any improvement infrastructure, as we reported in Chapter 5. In other cases poor communications support or branding was a factor. For example one consultant when asked if he had heard of patient safety collaboratives, responded:

“No, unless that...unless you're talking about the Academic Health Science Networks?” (PSCFL28).

Consultants elsewhere made similar comments. In one case a junior doctor who had heard of PSCs, was less sure about their impact:

“I’m sure they have things which have been introduced which I now do, I just don’t know it’s directly from a Patient Safety Collaborative, if that makes sense? [...] Or even if they [PSCs] have done something and they say the change is this, I have been told this is the change and I do make that, but it doesn’t necessarily mean I know who it has come from” (PSCFL15).

Another felt the PSCs were useful in raising awareness about “issues within the National Health Service” but still lacked visibility and impact particularly among junior doctors.

In community mental healthcare, a clinical pharmacist felt that poor marketing or branding of PSCs meant it was difficult to understand how the aims of the AHSN would fit in with existing trust policies:

“From an introduction point of view, I’m not sure that they [PSCs] really came with a big bang that people would know that it had happened, or that they [PSCs] were something that were actually there to support organisations and Trusts to deliver safer services or better services or to use evidence more quickly in all the areas that they were initially set out to do” (PSCOL6).

As reported above participants were positive about how PSC learning events generated and shared ideas.

Nonetheless some felt they could not yet comment on the visibility or impact of PSCs and their outcomes:

“I think it’s too early. I think we haven’t got enough projects going on that are visible to me for me to be able to say that I can see that” (PSCFL10).

Others reported a more positive impact from the PSCs in that front-line staff are now more aware of safety issues and more willing to report any incidents, but that any impact is difficult to quantify. Informants in the acute hospitals and mental health sectors thought that the PSCs were helping to foster more awareness of the patient journey and of staff well-being, with the PSCs helping to facilitate a shift in staff attitude and morale. Hence, as one PSC lead described, that their work may

be likened to a “party planner”. If the party has gone well, then they have succeeded in their role but such a role risks going unnoticed or unacknowledged:

“It’s a bit like being a massive party planner really! We organise the venue, we organise the agenda. We get them all together. We make them work really hard when they’re there so they don’t just come for a jolly. We provide them with network space when they’re there as well so that they can all talk to each other and learn things from each other” (PSCL3).

Whether their involvement was acknowledged or not, PSC leads hoped that their facilitative role would enable collaboration to take place that would otherwise not have done:

“You do need something as a focus. And I’d like to think that the Patient Safety Collaboratives are creating the focus for those kind of conversations or certainly allow a home for some of those conversations. And if they weren’t there would those conversations happen on this scale? I’d like to think not, but I suppose really you know, only time will tell and then we’ll have to do what all good facilitators do which is stand at the back and allow everyone to bathe in their own glory rather than us going ‘yeah that’s all down to us’” (PSCL6).

As mentioned above, one indication that PSCs are reaching different levels of the NHS was clinical teams’ subtle changes in language use, even among those who said they had not heard of PSCs. But some informants also perceived (with some historical justification) QI improvement and activity as a parallel, pre-PSC initiative.

Despite PSCs needing more time to take traction, some organisational leads reported that PSCs were beginning to engage organisations, facilitate learning through networking groups and to affect policy level strategy. For example one participant from a CCG described: “seeing organisations willingly deciding to join the patient safety Collaboratives and embedding the care bundles into the way that they normally work” (PSCOL2), while another participant cited the “early warning scores” mentioned in Chapter 6 as an example of changed clinical practice attributable to the PSCs.

The general picture therefore was that although not all the front-line staff that we met had heard of them, PSCs were becoming more visible to front-line staff involved in QI.

7.f. Concurrent non-PSC influences on clinical teams' working practices

PSCs were not the only thing driving changes in working practices. Events such as a disappointing CQC inspection, being in special measures, or Trusts undergoing mergers each occurred in some regions and lay alongside PSCs as potential triggers for a given change process or improvement initiative. For example one head of nursing described how a disappointing CQC inspection led to the Trust reviewing its systems for incident reporting:

“We completely restructured the way that we utilise the data that came from incident reporting so that we started to understand in some detail the early indicators of something starting to go wrong, so that we can actually intervene and improve something prior to a big incident or a big event that ended in a patient safety incident” (PSCFL10).

A number of nursing staff reflected that Mid Staffordshire crises and the reports that followed (including but not limited to Berwick's: see Chapter 2) acted like a “shock tactic” to shift staff “complacency” and refocus their minds on quality improvement and safer patient care:

“I do think it's palpable through organisations, and I think that it was so shocking to people, that everybody got on board with it; and you shouldn't need a shock tactic, but it certainly worked if you did need a shock tactic, and made people recognise that actually you can't be complaisant, it's too easy for complacency to get in the way. And so I think it refocused people's minds. And definitely I've seen people getting on board more since then.” (PSCFL10).

7.f.i. *Front-line clinical team level: Overview*

Regarding safety climate in NHS hospitals during the PSC period we found, in summary, that:

1. Qualitative evidence showing, on balance, safety climate change in the intended direction.
2. There were changes in the intended direction in the relevant NHS staff survey data domains.

3. No significant change by early 2018 on most of the SCORE survey domains.

This paradoxical pattern requires some explanation and interpretation, which we give in Chapter 9. We found evidence of changes in working practices, in the sites we studied, across hospital, general practice and community and mental services. They had been achieved, in some cases, despite difficult circumstances for NHS providers. The changes arose from QI work which PSCs had supported, indeed in the case of (at least) the SCORE surveys initiated.

Chapter 8: Key findings (4): Consequences for patient safety

If we presume the changes in working practice reported in Chapter 7 were based on good evidence, we might assume that they would improve the quality and safety of patient care. It was impracticable for us to review such a large and disparate body of evidence for this study but we did examine whether PSCs (England-wide) appeared to have made a detectable difference to rates of harm and adverse events involving patients, as measured using routine administrative data.

8.a.i. NHS inpatient surveys

As we explained in Chapter 4 we focussed on the question of where inpatients' experience scores were on the 10-point scale from 'very poor' to 'very good experience'. Analysis of data across all AHSNs showed a difference in overall experience scores across the years studied, with a small increase in trust scores in 2015 and 2016, compared to 2014 and small reduction in scores in 2013, compared to 2014 (see Table 18). This small year-on-year increase in scores, across all four years, suggests that the changes observed in 2015 and 2016, compared to 2014, may be due to a secular change over time rather than due to the introduction of the PSCs.

Table 18: Comparisons of trust scores of overall experience across years, across all AHSNs.

Outcome	Mean (SD)*	Mean difference**		
		estimate	95% CI	p-value
Overall experience score				
2013	8.03 (0.33)	-0.05	-0.08 to -0.02	<0.001
2014	8.08 (0.33)			
2015	8.13 (0.29)	0.05	0.02 to 0.09	
2016	8.14 (0.30)	0.06	0.03 to 0.09	

*From raw data.

**Compared to 2014. From model including year of survey.

Sensitivity analysis, in which we included data on all trusts reporting for some or all four years were included, showed similar results (Table 19).

Table 19: Comparisons of trust scores of overall experience across years: sensitivity analysis based on all trusts that reported for all or some years, across all AHSNs.

Outcome	Mean (SD)*	Mean difference**		
		estimate	95% CI	p-value
Overall experience score				
2013	8.02 (0.35)	-0.05	-0.08 to -0.02	<0.001
2014	8.06 (0.34)			
2015	8.13 (0.30)	0.06	0.03 to 0.09	
2016	8.14 (0.32)	0.07	0.04 to 0.10	

*From raw data.

**Compared to 2014. From model including year of survey.

We repeated the analysis specifically for the trusts in the three AHSNs which were our case study sites. Within AHSN Alpha there was little evidence of a difference in overall experience scores across the years (Table 20) and this remained the case when a further trust, which only reported for two of the years, was included in a sensitivity analysis (Table 21).

Table 20: Comparisons of trust scores of overall experience across years, based on six trusts that reported for all years, within AHSN Alpha.

Outcome	Mean (SD)*	Mean difference**		
		estimate	95% CI	p-value
Overall experience score				
2013	8.18 (0.27)	0.02	-0.14 to 0.17	0.8
2014	8.17 (0.22)			
2015	8.22 (0.21)	0.05	-0.11 to 0.21	
2016	8.23 (0.16)	0.07	-0.09 to 0.22	

*From raw data.

**Compared to 2014. From model including year of survey.

Table 21: Comparisons of trust scores of overall experience across years: sensitivity analysis, based on all seven trusts that reported for some or all years, within AHSN Alpha.

Outcome	Mean (SD)*	Mean difference**		
		estimate	95% CI	p-value
Overall experience score				
2013	8.21 (0.26)	0.01	-0.14 to 0.16	0.6

2014	8.17 (0.22)		
2015	8.22 (0.21)	0.05	-0.10 to 0.20
2016	8.29 (0.20)	0.08	-0.07 to 0.24

*From raw data.

**Compared to 2014. From model including year of survey.

We found little evidence of a difference in scores across the years for AHSN Beta (Tables 22 and 23) and AHSN Gamma (Tables 24 and 25), although there was some suggestion (results approaching significance) of an increase in scores in 2015 and 2016, compared to 2014, within AHSN Gamma.

Table 22: Comparisons of trust scores of overall experience across years, based on nine trusts that reported for all years, within AHSN Beta.

Outcome	Mean (SD)*	Mean difference**		
		estimate	95% CI	p-value
Overall experience score				
2013	8.08 (0.37)	-0.06	-0.20 to 0.09	
2014	8.13 (0.39)			
2015	8.16 (0.33)	0.02	-0.12 to 0.17	0.7
2016	8.12 (0.32)	-0.01	-0.16 to 0.13	

*From raw data.

**Compared to 2014. From model including year of survey.

Table 23: Comparisons of trust scores of overall experience across years: sensitivity analysis based on all 11 trusts that reported for some or all years, within AHSN Beta.

Outcome	Mean (SD)*	Mean difference**		
		estimate	95% CI	p-value
Overall experience score				
2013	8.04 (0.40)	-0.07	-0.21 to 0.07	0.4
2014	8.14 (0.37)			
2015	8.14 (0.32)	0.04	-0.10 to 0.19	
2016	8.09 (0.30)	-0.02	-0.16 to	

0.13

*From raw data.

**Compared to 2014. From model including year of survey.

Table 24: Comparisons of trust scores of overall experience across years, based on 10 trusts that reported for all years, within AHSN Gamma.

Outcome	Mean (SD)*	Mean difference**		
		estimate	95% CI	p-value
Overall experience score				
2013	8.16 (0.34)	0.02	-0.10 to 0.14	0.06
2014	8.14 (0.35)			
2015	8.27 (0.29)	0.13	0.01 to 0.25	
2016	8.27 (0.27)	0.13	0.01 to 0.25	

*From raw data.

**Compared to 2014. From model including year of survey.

Table 25: Comparisons of trust scores of overall experience across years: sensitivity analysis based on all 11 trusts that reported for some or all years, within AHSN Gamma.

Outcome	Mean (SD)*	Mean difference**		
		estimate	95% CI	p-value
Overall experience score				
2013	8.13 (0.34)	0.03	-0.09 to 0.15	0.1
2014	8.14 (0.35)			
2015	8.21 (0.34)	0.11	-0.01 to 0.23	
2016	8.23 (0.29)	0.13	0.01 to 0.25	

*From raw data.

**Compared to 2014. From model including year of survey.

The overall trends we found across England as a whole were not detected in the AHSNs and Trusts that we took as case studies. This may be because the effect size was too small to detect at that level from these data.

8.a.ii. *Classic Safety Thermometer*

As previously described we concentrated on the four most commonly occurring harms in healthcare: pressure ulcers, falls, UTIs (in patients with a catheter) and VTEs. Routinely reported data include: number of new harm events and total number of patients, for each trust, for a single day each month between January 2013 and December 2016 inclusive. The rate of new harm events per 100 person-days gives us an estimate of the number of new harm events expected to occur among 100 patients observed for a single day.

Analysis of safety thermometer data across all AHSNs showed evidence of a reduction in the rate of new harm events over time. Relative to 2014, we estimated the rate to be 10% lower in 2015 and 16% lower in 2016. The rate of new harm events we estimated to be 26% higher in 2013, relative to 2014 (Table 26).

Table 26: Comparisons of rates of new harm events across years, across all AHSNs.

Outcome	Rate per 100 person- days*	estimate	Rate ratio** 95% CI	p-value
New harm events				
2013	3.03	1.26	1.24 to 1.28	
2014	2.40			
2015	2.16	0.90	0.88 to 0.91	<0.001
2016	2.04	0.84	0.83 to 0.85	

*From raw data. The number of new harm events that would be expected to occur among 100 patients observed for a single day.

**Relative to 2014. From model including year.

Results from sensitivity analysis, including all trusts that report for all or some of the four years, were similar (Table 27).

Table 27: Comparisons of rates of new harm events across years: sensitivity analysis based on all trusts that reported for all or some years, across all AHSNs.

Outcome	Rate per 100 person-days*	estimate	Rate ratio** 95% CI	p-value
New harm events				
2013	3.01	1.26	1.24 to 1.28	
2014	2.40			
2015	2.16	0.89	0.88 to 0.91	<0.001
2016	2.05	0.84	0.83 to 0.85	

*From raw data. The number of new harm events that would be expected to occur among 100 patients observed for a single day.

**Relative to 2014. From model including year.

These year-on-year reductions in rates of new harm events, across all four years, suggest that the changes observed in 2015 and 2016, compared to 2014, may relate to a general reduction occurring over time, rather than to the introduction of the PSCs. Comparisons of rates of new harm events over time, within AHSN Alpha, showed little evidence of a change in rate of events in the years 2015 and 2016, relative to 2014, but the rate was estimated to be 61% higher in 2013, relative to 2014 (Table 28). Such an extraordinary decline is in our view more likely to reflect changes in data definitions, data collection methods or data analysis than in clinical practice.

Table 28: Comparisons of rates of new harm events across years, based on all seven trusts within AHSN Alpha.

Outcome	Rate per 100 person-days*	estimate	Rate ratio** 95% CI	p-value
New harm events				
2013	3.35	1.61	1.50 to 1.73	
2014	2.08			
2015	2.19	1.04	0.96 to 1.12	<0.001
2016	2.21	1.01	0.93 to 1.09	

*From raw data. The number of new harm events that would be expected to occur among 100 patients observed for a single day.

**Relative to 2014. From model including year.

Analyses of the safety thermometer data across trusts within each of the AHSNs Beta and Gamma showed evidence of a reduction in the rate of new harm events across the four years (Tables 29 and 30), suggesting that reductions in rates after 2014 may be due to secular trends rather than an effect of the PSCs. All trusts within these three AHSNs reported data for all four years, so we did not carry out any sensitivity analyses in this case.

Table 29: Comparisons of rates of new harm events across years, based on all 11 trusts within AHSN Beta.

Outcome	Rate per 100 person-days*	estimate	Rate ratio** 95% CI	p-value
New harm events				
2013	2.51	1.39	1.32 to 1.47	<0.001
2014	1.77			
2015	1.74	0.98	0.93 to 1.04	
2016	1.64	0.92	0.87 to 0.98	

*From raw data. The number of new harm events that would be expected to occur among 100 patients observed for a single day.

**Relative to 2014. From model including year.

Table 30: Comparisons of rates of new harm events across years, based on all 11 trusts within AHSN Gamma.

Outcome	Rate per 100 person-days*	estimate	Rate ratio** 95% CI	p-value
New harm events				
2013	2.39	1.10	1.03 to 1.18	<0.001
2014	2.17			
2015	2.09	0.97	0.90 to 1.04	
2016	1.86	0.86	0.80 to 0.92	

*From raw data. The number of new harm events that would be expected to occur among 100 patients observed for a single day.

**Relative to 2014. From model including year.

8.a.iii. *Incident reporting*

Table 31 summarises trust level data on reported incidents within six-month periods, from April 2014 to March 2016 (categorised according to level of harm: none; low; moderate; severe or death) in terms of the percentage of all incidents reported that were either severe incidents or deaths.

Table 31: Proportions of severe incidents or deaths among those reported by NHS trusts

Reporting period	Number of trusts reporting	Percentage of all incidents reported that were either severe incidents or deaths	
		Overall	Median (lower quartile, upper quartile)
April 2014 to September 2014	123	0.48	0.40 (0.27, 0.64)
October 2014 to March 2015	126	0.49	0.37 (0.23, 0.67)
April 2015 to September 2015	122	0.41	0.38 (0.21, 0.56)
October 2015 to March 2016	118	0.41	0.36 (0.21, 0.52)

These findings are ambiguous. A falling percentage of severe or fatal incidents might reflect safer care, lower reporting thresholds, more effective data collection or some combination of these and we have no means by which to determine which of these applies here. .

8.a.iv. *Hospital mortality*

Table 32 compares trust-level mortality data for the years 2013 to 2016. These data include for each trust the total numbers of:

1. Finished spells, where a spell is a continuous period of time spent as a patient within a single trust; and
2. Total number of observed deaths for a trust, including deaths in hospital or within 30 days of discharge.

The mortality rate per 100 spells provides an estimate of the number of deaths in hospital or within 30 days of discharge that would be expected to occur among 100 spells.

Comparisons of hospital deaths across all AHSNs showed evidence of a difference in mortality between the years. Relative to 2014, we estimated the rate to be 3.4% higher in 2013; 3.8% higher in 2015 and 4.1% higher in 2016 (Table 32).

Table 32: Comparisons of mortality rates across years, across all AHSNs.

Outcome	Rate per 100 spells*	Rate ratio**		
		estimate	95% CI	p-value
Hospital mortality				
2013	3.27	1.034	1.028 to 1.039	<0.001
2014	3.15			
2015	3.27	1.038	1.033 to 1.044	
2016	3.28	1.041	1.035 to 1.046	

* From raw data.

** Relative to 2014. From model including year.

Results are similar when those trusts not reporting for all four years are included in the analysis (Table 33).

Table 33: Comparisons of mortality rates across years: sensitivity analysis based on all trusts that reported for some or all years, across all AHSNs

Outcome	Rate per 100 spells*	Rate ratio**		
		estimate	95% CI	p-value
Hospital mortality				
2013	3.25	1.034	1.029 to 1.040	<0.001
2014	3.14			
2015	3.26	1.039	1.034 to 1.045	
2016	3.27	1.041	1.036 to 1.047	

*From raw data.

**Relative to 2014. From model including year.

Analyses of data from each of our three focal AHSNs showed evidence of a difference in mortality between the years, with estimated small increases in mortality in 2015 and 2016, relative to 2014 (Tables 34 to 37). (In these cases, the figure for 2014 was lowest.)

Table 34: Comparisons of mortality rates across years, using all available data from all seven trusts within AHSN Alpha.

Outcome	Rate per 100 spells*	estimate	Rate ratio** 95% CI	p-value
Hospital mortality				
2013	3.42	1.017	0.991 to 1.043	<0.001
2014	3.37			
2015	3.56	1.055	1.029 to 1.082	
2016	3.50	1.037	1.011 to 1.063	

*From raw data.

**Relative to 2014. From model including year.

Table 35: Comparisons of mortality rates across years, using all available data from all 10 trusts within AHSN Beta.

Outcome	Rate per 100 spells*	estimate	Rate ratio** 95% CI	p-value
Hospital mortality				
2013	3.01	1.017	0.997 to 1.037	<0.001
2014	2.95			
2015	3.10	1.052	1.031 to 1.073	
2016	3.13	1.064	1.043 to 1.086	

*From raw data.

**Relative to 2014. From model including year.

Table 36: Comparisons of mortality rates across years, within AHSN Gamma.

Outcome	Rate per 100 spells*	estimate	Rate ratio** 95% CI	p-value
Hospital mortality				
2013	3.72	1.043	1.022 to 1.065	<0.001
2014	3.56			
2015	3.62	1.019	0.998 to 1.040	
2016	3.72	1.045	1.024 to 1.066	

*From raw data.

**Relative to 2014. From model including year.

Table 37: Comparisons of mortality rates across years: sensitivity analysis based on all trusts that reported for some or all years, within AHSN Gamma

Outcome	Rate per 100 spells*	estimate	Rate ratio** 95% CI	p-value
Hospital mortality				
2013	3.72	1.047	1.026 to 1.068	
2014	3.55			
2015	3.61	1.023	1.002 to 1.044	<0.001
2016	3.72	1.048	1.027 to 1.069	

*From raw data.

**Relative to 2014. From model including year.

A more likely explanation than a harmful effect of PSCs is an increasingly complex case mix²⁶⁹, and we have presented evidence of increased workload pressures, overcrowding (possibly reflecting falling hospital bed numbers²⁷⁰) and staff shortages in our study sites. As Chapter 4 noted the validity of SHMI as a measure of hospital safety is itself contested.

In summary the pattern of evidence on the PSC-relevant safety outcomes was that:

1. Chapter 7 reports qualitative evidence of changed working practices which one would expect (on the basis of the relevant supporting evidence) to improve patient safety and service quality.
2. The quantitative analysis of these data sets showed no significant change by early 2018 that could plausibly be attributed to PSCs alone.
3. Despite this, overall changes in the intended direction were occurring.

This is a second paradoxical pattern requiring explanation and interpretation.

Chapter 9: Discussion

9.a. Paradoxical findings

Our qualitative data (and therefore findings) included participants' descriptions of ways in which PSC activities had changed safety climate at clinical- team level and as well as changing clinical teams' working practices (see Chapter 7). However, the outcomes of SCORE measures of workplace safety climate did not change over the study period (see Chapter 7) nor did the available relevant quantitative measures of impacts upon service outcomes (see Chapter 8).

To begin with safety culture and climates, we found (Chapter 7) no significant change by early 2018 on most of the SCORE safety survey domains. Over the same period, scores on the relevant NHS Staff Survey data domains did change in the intended direction. We also found some qualitative evidence suggesting, on balance, positive changes in safety climate. All this presents an interpretive challenge: how to reconcile these paradoxical findings?

We should note at this stage that NHS Staff Survey findings relate to whole trusts rather than clinical teams. In our view the most plausible inference from this combination of findings is that progress towards the PSCs' aims of a stronger safety culture and climates was reinforced by secular trends that led NHS hospitals in the same direction. PSCs contributed to that wider movement but their contribution was more modest because of the limited scale (at the time of this study) of providers' participation in PSC activities, and the later onset of PSC activities compared to other activities and policies whose effects were also to strengthen safety climates and clinical quality of care. This inference is consistent with two other studies that reported significant quality improvements in services without a corresponding change in safety culture.^{235,236} We infer that in the circumstances faced by PSCs the most relevant reinforcing factors included:

1. At national level the evidence-based medicine movement. PSCs can be seen as a part of and a contributor to this, but this movement has also (and for longer) been implemented through guidelines and guidance from NICE, financial incentives to providers (e.g. QOF, CQUIN), publication of data (down to provider and sometimes consultant level) on the quality and

safety of each provider's services, performance indicators, and clinician and managerial training and appraisal.

2. The concurrent political and media salience of patient safety (including reactions to the Francis report itself).

At clinical team level, staff turnover would adversely affect measures of the safety climate of clinical teams and thus reduce PSC impacts. It seems unlikely that departing staff would be replaced by others from services in which PSCs had been active but we do not have data on this.

If there were time-lags between initiating culture change activities and observing or measuring their effects in workplace safety climate, then the later start and small scale of SCORE surveys, and especially the repeat surveys, means they would not easily capture change. Other studies^{94,126,131} (see Chapter 3) report that changing workplace 'culture' (sc. climate) is a long-term process occurring in a succession of stages over repeated QI cycles (e.g. PDSA cycles). Another question is whether the SCORE survey showed little evidence of safety climate change in the clinical teams because the mechanisms for changing that climate were too remote, not just in time but also in terms of intermediate causal links, from the variables which SCORE surveys mostly measure. That is, PSC attempts to make healthcare providers more like learning organisations may meantime have had other intermediate effects that will eventually help change safety climate in clinical teams in ways and to the extent that future SCORE surveys will eventually detect; or perhaps have other effects that increase patient safety; or both. Chapter 6 Section d and Chapter 7 Section a report what intermediate effects we found during the study period but the longer-term effects remain of course to be seen.

Turning to service outcomes (Chapter 8), studies²⁷¹⁻²⁷³ of policies unrelated to PSCs have reported similarly mixed findings, that is qualitative reports of change. There were some significant changes in findings from routine administrative data, but they cannot be attributed to PSCs. Such studies suggest potential reasons for the pattern of our findings about PSCs' impacts on service outcomes.

1. Dilution of any effects of PSCs upon service outcomes. The available datasets combine data about localised activities that PSCs may have influenced with data from other, often larger-scale, activities which PSCs did not immediately influence. This is typical, for example, of

data provided by NHS Digital. This dilution occurs in two ways, each of which assume that little or no effect spilled over from PSC activities into services unaffected by PSCs when:

- (a) Data relating to intervention and non-intervention services are combined but the former are only a small proportion of the total.
- (b) Within a given service, a PSC's intervention was implemented for only part of the care pathway, in which case the non-intervention stages will dilute any effect of PSC activity. (This explanation only applies to measures relevant to all stages of the pathway, such as infection rates and patient-reported outcomes.)

In each of these cases, if PSCs had succeeded in delivering some of their intended effects, these would be too localised to change the larger data-sets perceptibly. Lilford and Provonost¹¹⁴ argue that only small-scale, i.e. localised, datasets are likely to detect any change of this type.

2. Countervailing mechanisms and/or contexts: these can outweigh the effects of PSCs; those reported by our informants were:
 - (a) Demand overloads (such as persistent 'black alerts' during the winter) that divert staff from QI activities.
 - (b) The problem of insufficient staffing, which in one general practice, not even additional finance could resolve. These conditions also divert staff from QI activities, as other studies^{107,209,231} corroborate (see Chapter 3).
 - (c) Staff turnover (again as other studies^{130,204} corroborate: see Chapter 3): Staff transfers may cancel out across the health system as a whole but for an individual clinical team they mean the loss of trainees and their knowledge (both formal and tacit), undoing attempts at safety climate change and producing discontinuities in QI work.
 - (d) Financial constraints preventing initial PSC set-up, training and/or changes of workplace practice afterwards.

3. Time lags: since 2015 there has been time to start implementing PSC's quality improvement work, but not to do so universally (see 'dilution' above) and not for long enough to feed through to the end of the chain of mechanisms outlined in Chapter 2. In these circumstances

we might observe the earlier links in the programme theory being implemented but not (yet) the later links. The period when PSC activity began to yield changes in working practices (at most a year before the end of this study) began too late for routine administrative data available within the study period to be able to capture the changes.

4. Reductionist measures of safety climate: the absence of significant change on the measures available to us leaves open the question of whether a change in safety climate at clinical team level might have been observed had other measures been used for measuring or recording safety climate.
5. Reporting bias: people tend to give exaggerated or inflated reports of their own activity and its effects. The greater the proportion of data gained from non-participant observers and ‘third party’ documents, the more this bias can be dealt with through triangulation.
6. If any of the above countervailing mechanisms were at work, observing the effects of the PSCs might require using a different counterfactual since the apparently unchanged outcomes in the data we analysed would have been worse without PSCs.

To summarise: PSC activity had the effects reported above (Chapters 5-8) but they were too localised and too heavily exposed to and diluted by the confounding contexts (both favourable and unfavourable) described above to be measurable in the routinely-reported administrative data. PSCs have made a difference in how things work but one can only observe this when viewing through the correct lens, that of localised qualitative enquiry.

9.b. Limitations and strengths of the findings

9.b.i. *Implementation study*

At national and regional levels, the implementation study was a census, so had no selection bias nor, in this study, participation bias. We interviewed PSC leads during the early set up phase of the collaboratives and did not repeat the interviews later to determine any subsequent changes in activity or attitudes as implementation went on. Therefore our findings capture, among other things,

what might prove to be early teething problems, especially in relation to how AHSNs hosted the PSCs. At provider and clinical team levels, a study of mechanisms had to select sites where the mechanisms were present (even if not implemented as policy-makers intended), and informants. Our findings suggest PSCs had only pockets of impact. The NHS is a massive system and it is extremely unlikely PSCs could influence the whole system in what was effectively a three year period. In PiSCES we have, with the exception of the census of PSC leads interviews and the routine data, specifically targeted the areas first involved in the PSCs rather than focusing on the wider impact of the Collaboratives on sites that began participating later. This means that generalisations from our findings may be biased towards overstating the effects of PSCs and under-reporting implementation deficits and barriers to implementation. A similar study conducted later would be able to produce a more complete picture of PSC impact. As for costs, any analysis including ours is always context specific and the breadth of analysis is limited by the availability of data. In this study the main limitation was the difficulty in obtaining detailed data around PSC funding and budgets, and the opportunity costs. As such we were not able to make any meaningful comment on the cost effectiveness of the PSC programme. Over time it is likely that the data regarding expenditure will become more easily accessible but it would require significant research effort and resource to estimate the opportunity costs of both managerial and clinical activity that was not undertaken as a result of PSC activity.

9.b.ii. SCORE survey

The sites in our sample had a response rate of more than 60% of staff so they reached the threshold declared in advance as the minimum ensuring valid findings. The SCORE study sites were self-selected (volunteers) and the study relied upon NHS organisations, through their participation in the PSCs' QI work, to help implement the survey. Uptake in the first round, and still more the second round, was small compared with the study protocol and this is likely to reflect the extent and pace at which additional QI activities were introduced at clinical team and general practice level during the study period. This low uptake places significant limitations on the interpretations we can make in the safety culture work package. In addition the six sites were all in one PSC and this introduces further potential for bias in that our findings are based on sites advanced in implementing QI activity in general (including PSC-initiated activity), and supportive of it. The consequence of this bias is likely to be towards presenting a more positive view of PSC activity and impact than would be found in NHS organisations more generally. Mental and community health service participation

in the SCORE survey was low but use of the SCORE survey appears to be spreading so this is likely to change over the remainder of the currently funded PSC activity. More than 40 sites plan to have completed their second round of surveys by the end of 2018 and a subsequent evaluation would lead to a better understanding of how and why safety climate has changed over this period.

Although we found no significant observable change in safety climate in the six sites we examined it might be premature to conclude that the PSCs were not changing safety climate. It may take longer for the survey data to change. A Dutch study¹⁷² described successive stages (hence a gradual process) of safety climate change and a US study found statistically significant increases in safety culture scores over a five year period with the surveys repeated on average three times.²⁷⁴ Finally, safety climate change may be a *consequence* of changed working practices, not (or not only) a prior condition for them.

9.b.iii. Analysis of routine administrative data

An empirical limitation of our analysis is that NHS routine administrative data are not necessarily exhaustive regarding the main aspects of patient safety (e.g. avoidable deaths). Hospital mortality data were used but there is little evidence to directly link these data to actual harm events. One study published in the BMJ compared standardised mortality ratios (SMR) with case note reviews of death and found no evidence of an association. The authors concluded that overall SMR data do not reflect the quality of hospital care²⁷⁵, something also found in subsequent studies.²¹²

In estimating differences in outcome measures in 2013, 2015 and 2016 against a 2014 benchmark we used a short post-PSC implementation period (albeit the whole such period for which data were available at the time of this study) and a short pre-PSC period. Previous studies assessing the implementation of safety Collaboratives have suggested it takes a mean of 17 months from start to tangible improvement.⁶⁶ From a practical perspective the PSCs did not commence activity until the start of 2015 and our implementation study suggests it took not less than 18 months for the effects to begin to reach clinical teams. In practice we might expect the PSCs to need a longer run-in time than previous, less complicated collaboratives before they began producing substantial effects. For this reason, and based on the observations of a comparable Dutch study¹⁷², it would be surprising for the PSCs to have had measurable impact before mid-2016. As the majority of the routine data we

analysed were from 2016 or earlier, we would be surprised to see any signal within routine data even if PSC activity was having an impact.

We also considered whether any policy events in 2012-13 might have made the 2013 data exceptional (off-trend) and therefore bias (under- or over-state) the changes observed in 2015-16. We identified no obvious grounds for thinking that the demand pressures facing NHS hospitals in 2012-13 deviated from the longer-term trend. Within the limitations of the published data we also allowed for this possibility by testing (see Chapter 4) how stable the relevant measures were across these years. The Health and Social Care Act (2012) led to NHS re-structuring that affected regional bodies and commissioning organisations but not provider organisations. During 2016-17 NHS providers began to run significant financial deficits that could affect the 2016 data by pushing measured activity levels downwards and drowning out any effect of PSCs but we have limited qualitative, and no quantitative, data to indicate that this occurred.

The dilution mentioned above means comparisons of outcomes at NHS trust level, and still more at regional or whole system level, are likely to reveal only large, widespread impacts of any policy initiative, including those resulting from PSCs. They are not necessarily a test of the policy makers' programme theory about how PSCs would impact upon clinical teams' working practices. To test that would require data specific to the clinical teams that participated in PSC-initiated QI activity and in the current NHS those data would have to be collected specifically for this purpose.

9.b.iv. Policy lessons

The limitation in the lessons for policy we have drawn reflect the limitations both of our own findings and of published research on collaboratives generally (see Chapter 3), since they were the sources we used to revise and update the policy-makers' original programme theory into a more evidence-based logic model.

9.c. Generalisability of the findings

Our findings from the three different work packages have different levels of generalisability which will be described in turn below. We think the implementation study has the most useful lessons for policy makers (see Chapter 11). The routine data on safety outcomes were not likely to, and did not, demonstrate any change attributable to the PSCs, although they did demonstrate a gradual improvement over time in all of the metrics that we analysed and this finding is certainly relevant to the outcomes that the PSCs were (also) trying to achieve. As we have noted at length the safety climate data were too limited and analysed too early in the PSCs' life-cycle to yield generalisable findings at this stage, but this may change over time. One learning point from this is how long it takes to set up safety culture surveys within providers.

1) The implementation study. In this study we looked at the impact of a significant policy change in a centralised state funded and delivered health service, the English NHS. As such the closest comparisons would be the wider NHS in Northern Ireland, Scotland and Wales, and other health systems modelled in part on the NHS (e.g. those of Australia, Greece, Italy, New Zealand or Spain). Although there will be some contextual differences the lessons learnt from the study will be transferable.

In the English NHS further policy changes within the broader scope of healthcare (i.e. not specifically patient safety and quality improvement) are very likely to face the same barriers to implementation as was observed in the PSCs. Beyond healthcare, policy changes in state run and funded services (such as education in England) are also likely to encounter the same problems if they are implemented in a similar manner, that is with interruptions to their leadership (e.g. restructuring), unclear timelines and uncertain funding.

In systems that are not state-managed (and largely state-delivered) the contexts will be sufficiently different that many of the findings will have limited use or have to be interpreted with caution. The English NHS does not have any effective competition between providers and so any system that does have competition would have to implement initiatives such as the Patient Safety Collaboratives in a very different way. It is comparatively easy for leaders of healthcare in state-

delivered systems to mandate policy but less so in systems that rely on private companies and the open market.

2) The analysis of routinely collected administrative data. Due to the timing issues discussed above little sign of the effect of PSCs appear in metrics collected routinely and thus there are no real lessons to be learned from this. The most interesting finding was the gradual and often statistically significant improvement in the metrics collected for this study: staff surveys, patient surveys, incident reports and the monthly safety thermometer. This has important implications as it demonstrates that the analysis of interventions and initiatives always has to have a control group, in the absence of which any effect may be falsely attributed to those interventions when in fact improvement would have happened without them. This has also been demonstrated in a large, randomised team training study in operating theatres.²⁷⁴ Both the control group and the study group showed a significant reduction in the major adverse event rate but no difference between the two groups. This awareness should always influence study design and creates significant problems when analysing data on interventions designed to change whole healthcare systems such as the PSCs.

Because proportionately more acute hospitals than other kinds of provider engaged with the PSCs, more caution may be required when generalising from our findings about the effects of PSCs in other settings than when generalising our findings about acute hospitals. A more general empirical limitation is that our findings about non-GP services only concern NHS providers, not services commissioned from non-NHS providers. Among NHS providers, community health services and mental health services were under-represented in this study, reflecting the general pattern of PSC implementation.

9.d. Comparison with other studies

One other study among those commissioned alongside this one reported during the study period. Of relevance to PiSCES, the authors of the study of NHS acute hospital trust boards²⁷⁶ reported that, following the Francis report, the NHS trust boards they studied began to prioritise safety and quality above financial objectives, though they noted this change might have been temporary. In terms of the PSC programme theory (Chapter 2), the trusts only temporarily met the prioritisation condition for 'Providers become learning organisations' and the corresponding activities did not necessarily

extend into middle management so the QI activity and safety climates remained very variable. As for context, regulation has had a massive negative impact on trusts' ability to respond to the Francis Report. Boards had more idea of what regulators want than of what patients do – 'the regulators are the customers of health care rather than the patients'²⁷⁶. Despite this, the responsibilities of Chief Nursing Officers did increase significantly following the Francis Report, and the Duty of Candour was broadly fulfilled.

These findings corroborate our own regarding the variability of QI and safety climate. Indirectly (by inference from the uneven pattern of PSC and QI implementation at provider and clinical team levels) they corroborate our finding that implementation of these activities by middle management is inconsistent.

Kent and Surrey AHSN carried out a realist evaluation²⁷⁷ of its local PSC (which was not one of our in-depth study sites). They found

1. Quality of clinical leadership was the most influential factor for strengthening safety climate in clinical teams. High quality leadership achieves this through enabling teamwork, a shared direction and values, safety behaviours, and by creating a psychologically safe environment and an approach to improvement driven by asking 'What works?' Staff members found this type of leadership more credible when senior managers practice what they preach.
2. Observation of practice helps engage staff by recognising success as well as any mismatches between stated values and actions.
3. 'Safety huddles' of front-line teams promote interdisciplinary collaboration and teamwork, and help in adapting QI activity to clinical teams' settings and needs.
4. Ensuring the engagement and participation of key stakeholders, and making QI activity meaningful to them, are the most important activities for promoting learning, improvement and service development. Facilitators are an important resource in doing this.
5. Managerial support for facilitators and clinical teams, and for safety and QI activities, generally helped promote a safety climate, as did coordinated, organisation-wide systems for managing patients, storing records, and holding protocols and standards.

6. Climate surveys can be the foundation for practical safety improvement activities, as can ‘action learning’ (by which the authors meant: ‘Building networks. Learning from others in other organisations’²⁷⁷), which the Kent and Surrey PSC facilitated.

The evaluators found that the value of PSCs more generally was in focusing attention upon and developing the activities described. They also reminded managers of the danger of ‘overload’ and ‘paralysis’ when already-busy staff confront over-ambitious projects. This point, and points 1, 2, 4, 5 and 6 corroborate our findings.

Chapter 10: Results

As study results we recapitulate summary answers to the five empirical research questions, RQ1 to RQ5. The generalisable lessons from these results, which answer RQ6, are directly relevant to policy but are more clearly presented as a separate chapter, which follows this one.

Overall, the qualitative data (of all kinds, taken together) showed a positive impact of the PSCs. The quantitative data were more ambiguous.

10.a. How PSC implementation varied across the 15 AHSNs (RQ1)

10.a.i. Differences

There were significant historical differences in a variety of factors between the AHSN regions. Therefore each PSC inherited different geographies, population size and quality of pre-existing network links and infrastructure. Several PSCs had a long history of region wide safety and quality programmes, whilst others were starting almost from scratch with little or no existing quality and safety networks. This inheritance of different starting points, understandably, influenced how the PSCs were implemented. Where there were existing programmes and networks the PSCs supported these networks rather than creating new structures and programmes. PSCs with little prior systematic knowledge of quality and safety had to begin by creating networks by running regional events and allowing the creation of emerging collaborations between provider organisations.

The relationship between the hosting AHSNs and the PSCs also varied. Some brought the PSCs ‘in house’ and simply combined them with the AHSNs pre-existing quality and safety programmes and from a practical perspective merged the budgets. Others kept the PSCs as separate organisations that they only provided administrative support for. This divergence correlated with the inherited conditions. The AHSNs with significant previous QI experience held the PSCs ‘in house’ and *vice versa*.

Other things varied both within and between PSCs:

- 1) The uptake of the SCORE surveys (at the time of writing, still only by minority of providers) was uneven across the PSCs, again linked with previous QI experience.
- 2) The extent of recognition, at clinical team level, of PSC activity and ‘branding’ (see Chapter 7). Where PSCs supported existing QI and safety work, it became harder to attribute any changes in working practices and outcomes unequivocally to PSC activities.
- 3) The more rural PSCs faced geographical boundaries and barriers to providers’ participation in cross-organisational networking activities.
- 4) The effects of junior doctors’ strikes in hindering PSC activity varied considerably between our case study PSCs.

The contextual differences between PSCs demonstrate that the PSCs were performe all complex adaptive systems reacting and responding to the local situations in varied manners.

10.a.ii. Similarities

Although the contexts were very different, the three main strategies the PSCs applied for attempting to improve patient quality and safety at provider level were the same:

1. A facilitative strategy. This built where possible on existing QI and safety work in healthcare providers. Existing networks were supported, often financially, and new networks were created by running workshops, seminars and conferences.
2. An educative strategy of educating, training and developing individual ‘change agents’. This took the form of a variety of small to large scale training programmes in the techniques of quality improvement and human factors. These ranged from a half day workshops to full weeks of training.
3. The work-stream approach. This resulted in several PSCs developing similar work-streams, which were initially called ‘clusters’; sepsis, deteriorating patients and culture. These clusters morphed into three national work-streams; maternity, management of the deteriorating patient and culture.

Because of the ‘national priority’ approach, certain care groups or conditions were prioritised among most if not all PSCs. Although all PSCs used facilitative and educative approaches to improvement, there were some tensions between the facilitative and the national priority focus, as

the latter seemed to our informants closer to a performance management approach which could distort the effect of the facilitative strategy with its collaborative approach. If too much emphasis is placed on the measures relating to work-streams, these measures become targets and the collaborative features of these networks collapses. This effect has been seen before in other safety Collaboratives. The mere perception of data being used for performance management, even when it is not, distorts behaviour negatively as was seen in the ‘Matching Michigan’ project.^{24,136}

In general, across and within PSCs, NHS staff appeared to favour a shift from a ‘blame’ culture to learning culture focused on service development as the type of culture most conducive to activities to improve patient safety.

We found a common acceptance of, and adherence to, the Collaborative model across all the PSCs. Implicitly they all accepted the policy model and programme theory outlined in chapter one. What differed was the ways in which different PSCs emphasised different components and elaborated some mechanisms rather than others; some, for example, focused heavily on climate or on ‘huddles’.²⁷⁷ Partly because PSCs were promoted in response to problems in hospital services (Francis Report) and partly because, looking internationally, Collaboratives were first devised for hospitals, providers’ participation was *proportionately* greater among acute hospitals than general practices. Only a minority of general practices were involved at this stage. Mental and community health services participated in at least two PSCs to our knowledge; and probably in others. This reflected in part the technical challenges in making the collaborative models relevant to non-hospital services. General practices apart, we found no instances of non-NHS owned providers other than a small number of care homes and pharmacies participating in the PSCs’ work.

Where they were used (which was increasingly, albeit starting from a small base), the SCORE surveys were implemented much the same way everywhere, since their design and use is highly formalised and standardised. SCORE had a relatively quick impact upon working practices.

10.b. Organisational changes that providers made and what they learned from the PSCs (RQ2)

A precondition for any such changes and learning was that the provider's senior management be willing to participate in PSC activity, but as Chapter 5 reported NHS trusts were disparate in that respect and when they were willing organisational upheaval, including senior leadership changes, made trusts' engagement harder to sustain. The consequence was lack of engagement or 'ownership' of PSCs' QI and safety improvement work at senior management ('whole-organisation') level in some NHS trusts. For general practice the senior management was synonymous with GP partners.

In the providers that did participate, the main organisational factors reported to aid PSC implementation were:

- Providing front-line clinical and managerial staff with time in their normal working pattern to undertake improvement work. This required initial prior expenditure from the organisations which was often lacking. Senior leadership support for improvement activity was critical as only the senior leaders can create 'time' for this work to be done. Of all the factors this creating of 'capacity' was most crucial.
- Recruiting trained QI and safety experts or 'champions' at all levels in the managerial structure, most critically at Board and at clinical team levels. This approach was general across our case study sites (and elsewhere), and evidently learnt from the PSCs (see Chapter 5, Section c and Chapter 6 Section d).
- Ensuring that these champions had the leadership skills to motivate and empower teams, and to create psychological safety for staff to either speak up or suggest areas for change.
- 'Bottom-up' approaches to safety improvement (a facilitative strategy) which promoted provider-level engagement and enhanced motivation by adapting fully to local needs the activities that PSCs were promoting, and enabled staff to take ownership of a given project/or change process
- Initial prior expenditure for start-up training and the early introduction of measurement systems, or alternatively adaptation of existing management information systems to serve (also) as a measurement system for clinical teams participating in the PSC.

- Build structures and processes, at both whole-organisation and at clinical team levels, to promote sustainability when introducing a change to working practices. That is, by making sure that QI is fully embedded at all levels and tiers within healthcare providers.

Two organisational changes that the policy-makers' programme theory had anticipated (see Chapter 2) had not yet materialised at the time of our fieldwork. One was the development and use of formal measurement, hence information, systems to support these activities (see Chapter 5). The planned central measurement unit had not started at the end of our fieldwork but by the time of writing was beginning work. The initial tendering for it began in 2015 from NHS England; the substantial time taken to set this up was partly due to the pace of work of any large bureaucracy, compounded by the transition from NHSE to NHSI. The other expected but not observed change was in safety climate, in particular at clinical team level. Although PSC activity, including the SCORE surveys, had impact upon clinical teams' working practices in the sites we studied (see Chapter 7), these changes appear to have occurred in the absence of measurable changes in workplace safety culture and climate. In summary, we found:

1. Qualitative evidence of safety climate change in the intended direction, in particular high levels of staff engagement and a shift away from a blame culture towards a more 'open learning culture'.
2. No significant change safety climate, in our survey sites, by early 2018 on most of the SCORE survey domains (and with no reason to suspect a ceiling effect).
3. Change in the intended direction in the relevant NHS staff survey data domains (some questions in the NHS staff survey are similar to questions in the SCORE survey), but the trend began before PSCs.

To suggest that any safety climate changes at clinical team are diluted within much larger data-sets might be valid for the NHS Staff Survey but not for the SCORE survey results, which are precisely localised to the relevant clinical teams. Another possible explanation is that any culture or climate changes are as much the *consequence* as the cause of changes in working practices, in a virtuous circle of mutual reinforcement. In that case, safety climate changes would follow changes that made clinical work safer by PDSA-like methods. If the SCORE surveys were repeated (i.e. a third round of surveys were made) this circle may result in a demonstrable change in safety climate. The problem then would be separating this effect from the secular trend as we have observed from the

climate questions from the NHS staff survey which have improved over the recent past, before the widespread adoption of PSCs and safety culture surveys.

Three main contextual constraints on organisational change and learning in response to PSC activity were also evident. Sufficient time is required to implement a complex set of activities across all levels of the NHS, and needed on three different time-scales.

1. At least 18 months were needed for the Collaboratives working with the providers to set themselves up to participate and then start to change working practices through the Collaboratives' methods. They included allowing individual staff members enough time at work for learning events and the subsequent activities putting what they learnt into practice.
2. Continuing the Collaboratives long enough to enable them to recruit 'late adopter' providers into their work. In our study sites, this would appear to require at least three years and in practice much longer to really effect change ('This is a 10 year vision' (PSCL6)).
3. Time for cycles of QI activities to repeat, to become and remain institutionalised; and allowing individual staff members enough time at work for putting what they learnt into practice

In short the "improvement cycle is a long cycle", indeed open-ended. Healthcare and the English NHS in particular is littered with previous attempts at improvement and safety Collaboratives and national programmes that were stopped within a few years before they had a chance to develop real traction. Examples include Safer Care South West, the NHS Institute, NHS Improving Quality, the Safety Patient Initiative and the National Patient Safety Agency.

No less constraining were the concurrent operational pressures, creating competing pressures and priorities for front-line staff, and the concomitant resource and financial constraints, staff shortages and turnover. During the fieldwork we observed safety and quality meetings being cancelled when operational pressure increased. At an individual level the barriers included difficulties utilising expertise post training due to number of factors including performance culture (i.e. conflicting priorities in work place, pulling in opposing directions); lack of time and support within member organisations; high staff turnover (and even shift rotations or moves between work locations); and individual resistance to change.

10.c. Resource use, costs of participation and implementation (RQ3)

Our study PSCs provided broad information how spending on PSCs had been allocated at AHSN level (to which programmes, and to broad categories such as allocation to support staff, training etc.). More detailed accounts of monetary flows from PSCs to provider level were either unavailable or, at least, not available to us. We heard say of one NHS trust attempting to monitor how the availability of these extra resources contributed to changes in working practices (and by implication produced, or helped produce, health benefits for patients), but this was a single instance, news of which came to us at the very end of the research. We found no organisation estimating the monetary value of whatever impacts changed working practices had upon care outcomes for patients. Any such data would have to be collected specially, a large and complex task.

10.d. Have the PSCs made a detectable difference to rates of harm and adverse events involving patients as measured using routine data? (RQ4)

For the PSC-relevant safety outcomes which we analysed, we found:

1. Qualitative evidence of changed working practices which one would expect (given *their* supporting evidence) to improve patient safety and service quality
2. The quantitative analysis of the relevant routinely-collected data sets showed no significant change by early 2018 that could plausibly be attributed *to PSCs alone*. This applies alike to the indicator which deteriorated slightly (hospital mortality), the indicator about which the findings were ambiguous (incident reporting) and the three which improved slightly (safety thermometer, staff survey, patient experience).
3. Nevertheless longer-term changes in the intended direction were occurring in two, and perhaps three, of the four relevant routinely-collected data sets.

The reasons for this paradoxical pattern of findings appear in our judgement to be:

1. Time lag: At the time of our fieldwork, PSCs were about half-way through their initially-planned life-span. Chapters 5-7 present evidence on the time-scale required for their work to have any prospect of impact on the intended policy outcomes. Hence the period during which the administrative systems could collect any data related to PSC activity data was under a year.

2. Dilution: the PSCs' activity, hence any impact from it, was not universal across the NHS and the available datasets combined data about activities in which PSCs were involved with data about the larger areas in which PSCs were not yet involved.
3. Other secular factors: The effects of PSCs could have been outweighed by countervailing mechanisms and changing contexts across the NHS: increasing demand; insufficient staffing relative to demand; staff turnover; and financial constraints.

We infer that PSC activity had many of the effects intended for it (Chapters 5-7) but they were so localised and so diluted by the confounding contexts as to be undetectable in the routinely-reported administrative data; not least because they had very little time to impact upon those data.

10.e. Change in practice on the front-line of services (RQ5)

We found evidence of changes in practice in the front-line services (i.e. clinical team level) in our case study sites. In organisational terms these were not so much changes in formal accountabilities or hierarchies as in the routinisation and standardisation of certain working practices. In practice, inter-professional working had been strengthened, the clinical teams had become more like *multidisciplinary* teams, and a more open climate developed that was more focused on patients and their care rather than on the hierarchical managerial structures, for example the safety governance (assurance) system which appeared to have little effect on the quality and safety of care

Clinical teams developed and were developing skills that allowed them to adapt and improve the reliability and therefore safety of patient care. This was mostly achieved by using quality improvement methodology; including 'The Model for Improvement' and 'Lean'.²⁷⁸ These processes involve setting clear patient orientated goals, locally measuring before testing changes judged against the aim and the initial measurement.

The SCORE survey, and its practical impacts, can be understood as a special case of such activity. Chapter 7 reported how SCORE surveys developed into a practical intervention on the part of PSCs. We emphasise that the post-survey debriefing sessions were the essential step through which data (survey findings) triggered practical revisions of working practices and changes in working relationships.

Changes in working practices were both clinical (e.g. falls reduction) and organisational (e.g. pathway and service re-design). At that level, the reported impact of PSCs included, in hospitals: new staff roles e.g. within triage; sepsis work; incident reporting; and standards and protocols becoming more efficient and streamlined. In general practice they included: more time built into working week for regular meetings; setting aside one afternoon a month to discuss patient safety and QI; and new prescribing software as well as changes to the way blood results are actioned. The SCORE surveys and other PSC activity allowed the development of better care and safety management systems and processes but also of improving individual and team resilience. This resilience the best defence against rare and infrequent events where the systems and process are not realistically standardisable.

Chapter 11: Policy relevance

Our findings are relevant to policy in two ways. First, they suggest revisions to some of the specific assumptions underlying the ‘programme theory’ about how Patient Safety Collaboratives would work, and with what effects (Chapter 2). These revisions consist of generalisable practical knowledge arising from this study and they help answer RQ6 (‘What generalisable knowledge can be shared about this?’ - that is, about PSCs). They take the form of a revised, more evidence-based logic model for PSCs, based on our key findings (Chapters 5-8). Second, we believe some wider policy and managerial implications also follow from our findings.

11.a. Generalisable knowledge arising (RQ6): How policy makers’ assumptions compared with our findings

As we set out in Chapter 4, the answers to our other research questions yield generalisable (hence shareable) knowledge by allowing an evidence-based revision of policy makers’ original assumptions (‘programme theory’) about the effects PSCs would produce, how, for whom and in what contexts. We revised these original assumptions (Chapter 2) in light of our empirical findings (Chapters 5-8) and existing research (Chapter 3), and report the revisions mechanism by mechanism, including where applicable any context(s) which moderated (facilitated or obstructed) these effects. First, in the remainder of this Section, we review what our findings show about the evidential status of policy makers’ original assumptions about how PSCs would work. Then, in Section b of this Chapter, we outline the changes to those assumptions that our findings suggest.

11.a.i. The regional coordinating body and network make providers become more ‘learning’ organisations (Mechanism 1)

In our study regions (and at least one other²⁷⁷) the PSCs recruited providers to participate in their network. The providers that volunteered were more often (but not exclusively) hospitals and general practices than other services. Community, and especially mental, health services were less represented. General practices made up a substantial proportion of providers participating in our study PSCs but nationally they represented only a small proportion of general practices as a whole. This inclusion of general practice in safety collaboratives is relatively unusual; previous safety collaboratives had focussed far more on secondary care, possibly due to the US healthcare system

having a very different primary care system. This means that **this mechanism was partially established in terms of service coverage, but more fully established in terms of its range of activities** (see below). The PSCs we studied appeared willing and able to expand their coverage in the future.

The PSCs and their participating providers undertook activities intended to enable these providers to become more like learning organisations in respect of patient safety. Both network and providers often equated ‘learning organisation’ with ‘training courses’ and so they focused more on training in QI methods and sharing experiences than on double- and triple-loop learning (see Chapters 2-3) with their implications for providers’ internal managerial structures and control. These activities were more specific than the broad ideal type¹⁹⁷, or some^{67,279} might say managerial fashion, of the ‘Learning Organisation’. The PSC regional coordinating bodies that we studied did help their member-providers become learning organisations in the former, narrower sense.

Policy documents explicitly assumed (Chapter 2) a context:of central policy and NHS organisations, especially national organisations, continuing to support PSCs and their activities. In the event, overt policy support for PSCs was consistent, although during the study period responsibility for the PSCs transferred from NHSE to NHSI, and the latter attempted to link separate PSCs’ activities into national sets of networks. However we also found (Chapters 6-7) that other concurrent policies, especially the financial and therefore overload constraints on NHS providers, severely limited, and in some instances practically obstructed, providers’ attempts to initiate or maintain the QI activities that PSCs were promoting. This meant the assumed context was only partly present, a conclusion that corroborates other studies’ findings (see Chapter 3) as to which kinds of policy contexts support Collaboratives and which are inimical.

11.a.ii. Each regional coordinating body establishes cross-organisational networks of clinical teams

Across their recruited providers, the PSCs that we studied were able to establish this mechanism. Clinical teams from the providers that participated in the PSCs’ met and exchanged data, experiences, knowledge and lessons learnt. As we reported in Chapter 7 these activities helped sustain QI activity by the participating clinical teams in their own workplaces. **To that extent, this mechanism also had its intended effects.**

Policy documents did not make explicit what contexts would favour or impede such activities. We found that the important contextual factor was the availability of staff to participate, i.e. that the providers had sufficient staff relative to their workload to allow individuals to meet others in these networks, collect the necessary data, then share and implement what they had learned back in their own workplaces. Sufficient staff time was a *physical* requirement. Financial support was no substitute if sufficient, or backfill, staff were simply not to be found. Providers seemed able to free staff to attend regional training events but much less able to give staff specific time to undertake QI work once they returned to their normal roles. Very often, in such situations, we heard that organisational pressures took over and QI and safety work was not prioritised.

11.a.iii. Each regional coordinating body and network establishes cross-organisational measurement systems (Mechanism 3)

This mechanism was not fully established in our PSC study sites nor indeed nationally because NHSE then NHSI were slow to set up the proposed NHS-wide central measurement unit and it was not fully operational during the study period. Procurement started at the end of 2015 and took around two years. At the time of writing this measurement unit has now formed and early impressions are positive about its potential effect. Our study PSCs regarded this hiatus as placing a ‘planning blight’ on regional or local efforts to develop ways clinical teams could directly exploit the existing NHS-wide datasets, or indeed even local data-sets, for QI purposes (see Chapter 5). PSCs and clinical teams therefore had to adopt – either make or buy - more localised, *ad hoc* approaches to measurement (e.g. the on-line platforms mentioned in Chapter 5). Such approaches may serve the purpose of monitoring QI practices and their impacts within a single workplace (for a single clinical team). At least one (the Life QI system: see <https://www.swahsn.com/improvement/patient-safety-collaborative/collaborate-life-qi/>) was also designed to give clinical teams the capacity to compare themselves with counterparts in other provider organisations. There is also an important difference between data for improvement, which are local and used by small clinical units and data for assurance, which are used across organisations, in that assurance data have the potential to (and in fact often are) used for performance management.

Because of its absence during our study period we could not observe whether this mechanism, a cross-organisational measuring system, had or would have had its intended effects.

National policy statements presupposed (see Chapter 2) that a similar context was required for this mechanism to work as for mechanism 1, so our conclusions about that context also apply here.

11.a.iv. The providers which have become learning organisations develop an organisational culture and climate more conducive to patient safety and quality improvement (Mechanism 4)

The providers we studied did attempt to become more like learning organisations within the narrower sense noted above, and in doing so attempted to promote a culture and climate more conducive to patient safety and quality improvement. In Chapters 6 and 7 we reported their expressions of support for such a culture and how our informants thought it might be strengthened. Nevertheless the evidence we gathered about the effects of this effort and support was, we noted, hard to interpret. We heard qualitative reports (Chapters 6-7) of instances of changes in safety climate at clinical team (although also a few to the contrary) and NHS Staff Surveys showed changes in the intended direction but we found little SCORE survey evidence of safety climate change. Chapter 9 considered some reasons for these paradoxical findings, including the early stage and so far limited geographical spread of PSC-instigated QI activities, the countervailing pressures of service overload, and above all the presence of other influences (besides PSCs) co-producing the intended changes in workplace safety climate. On balance the **evidence from this study for the presence of this PSC mechanism is at best equivocal.**

As listed above there are many other explanations for the gradual improvement in routine administrative data relating to safety which are likely to outweigh the impact of the PSCs, certainly during the early stages. These include: the impact of the Francis Report (separately from the establishment of PSCs); the legacy of (25%) budget increases from 2006-2010; increased awareness of guidelines linking to the evidence based medicine movement; improved research and technology and improved training of students and junior staff in quality and safety issues. If anything counts as a culture change, then the spread of evidence-based medicine does, involving as it has the promulgation of new norms of clinical practice, service evaluation and clinical education; new working practices; supporting scientific and knowledge-mobilisation structures; and reinforcement

of each of these things with official guidance, regulation, monitoring, rewards and penalties. Taking Cochrane's work²⁸⁰ as foundational, both NHS and external agents have sustained, indeed strengthened, these forces for culture change for forty years or more. Pending further findings from SCORE or similar surveys, a more evidence-based logic model of PSCs would therefore supplement PSC-instigated activities with the evidence-based medicine movement as the stronger prime mechanism – or more precisely complex of mechanisms - that strengthened safety climate at clinical team level.

The policy makers' programme theory of PSCs assumed (Chapter 2) that **staff training works in changing workplace attitudes and skills. We found some qualitative evidence** that this was indeed the case, a finding which corroborates the balance of (but not all) previously-published studies (see Chapter 2 section e.iii).

We therefore infer that whilst this assumed context for the operation of mechanism 4 did exist, other contexts not accounted for in the policy-makers' original programme theory of PSCs acted against it. Our findings (Chapters 6-7) suggested that these countervailing factors were:

1. Workplace conditions which prevented trained staff from applying what they had learnt. Such conditions included service overload (such as black alerts) and staff shortages.
2. Insufficient 'organisational' support from higher management and/or resistance from key staff or managers (see Chapter 6).
3. Policy and guidance overload (over-management).

In some cases these conditions then led to fatigue and cynicism but it is important to add that we nevertheless found **no evidence of staff resisting or rejecting the norms of a patient safety culture.**

11.a.v. Changed safety culture and climate help clinical working practices to change (Mechanism 5)

The **uncertainty over whether safety culture changed due to PSC activity** in the workplaces we studied means we have to be cautious in concluding that any cultural changes *caused by PSCs* motivated and produced the reported changes in clinical work practices. Previous studies (see

Chapter 3) have been equally equivocal about the premise that improving safety culture leads to safer care for patients. There is reasonable evidence that safety culture scores are correlated to safer care^{170,281,282} but this is not a consistent finding as other studies have not shown a change.^{235,283} A systematic review in 2015 demonstrated a trend linking culture and outcome, but only a few studies found statistically significant correlations.^{236,284,285}

Clinical team members described to us **changes in working practices** (Chapter 7), whose implementation was accomplished through quality improvement activities including team re-design of parts of care pathways. In our study sites the feeding back of climate survey (e.g. SCORE) results created new links between safety climate change (in this case, the measurement, feed-back and self-evaluation of that change) and changed working practices. Nevertheless routine administrative data showed (Chapter 8) no evidence of resulting changes in in-patients' overall experience scores, occurrence rates for the four most common hospital harms, incident reporting or hospital mortality rates per 100 patient spells attributable to PSCs or indeed to any other cause. This may be explained (see Chapter 9) mostly by the dilution of the effects of local, small-scale work changes when they are combined with the (absence of) effects on the greater, unchanged parts of care pathways.

Policy documents about PSCs assumed that three contexts moderated the culture-safety relationship (mechanism 5).

1. Staff training helps create or strengthen new working practices: As noted above, the qualitative evidence that we found lends **limited support to this assumption**.
2. The provider has sufficient staff: We found **evidential support for this assumption**, or more precisely clear evidence for its converse: low staffing levels relative to workload (Chapter 7) caused QI work to be postponed at times of high demand on services which by 2016 were becoming increasingly frequent and prolonged.
3. Contractual incentives align with the new working practices. At the time of this study NHS providers faced a range of incentives, not limited to contractual cash payments. Although we asked our informants about them, financial incentives to providers (health resource groups (HRG), CQUIN for hospitals and QOF payments for general practices) did not figure much in our qualitative evidence (Chapters 6,7) and this suggests that whilst these incentives did not positively 'align' with the new working practices, they did not inhibit them either. They

acted neither as incentives nor as disincentives to the kinds of QI work that PSCs were created to promote. Instead, **the relevant incentives were those that operated through performance targets**. Notwithstanding NHS foundation trusts' nominal organisational independence or the inclusion of these targets in service contracts, performance targets operated for all practical purposes as line-management-like incentives on senior managers to meet financial and service access requirements. (An earlier commentator²⁸⁶ described them as management by 'targets and terror'.) As we reported in Chapter 7 these incentives were in practice often 'unaligned' with the QI work that PSCs intended clinical teams to carry out, in the sense of creating an unaccommodating context for it at clinical team level.

As we noted in Chapter 3, earlier studies mention additional contextual factors favouring changes in working practices: that the clinical team be already familiar with ideas and working practices similar to the proposed new ones²⁸⁷; and the new working practices be simple² and compatible (or easily made compatible) with the remaining unaltered work practices.^{124,182,184}

11.a.vi. The cross-organisational network(s) of clinical teams help clinical working practices to change (Mechanism 6)

In Chapters 5 and 7 we reported that our study PSCs did establish cross-organisational networks of clinical teams, at least across providers that participated in the Collaboratives. **Where it existed this inter-organisational collaboration between clinical teams had its intended effects** in that some clinical teams learnt from one another what changes in working practices were feasible (had been achieved elsewhere) and how they had been introduced (see Chapter 7). This finding about PSCs therefore corroborates the more sanguine findings of earlier studies into the relationship between inter-organisational networks of clinical teams and changes to clinical working practices *within* the networked provider organisations. In many cases (although very variably across the different PSCs) these networks already existed and the PSCs chose to support what already existed rather than creating new networks.

11.a.vii. The cross-organisation measurement systems help clinical working practices to change (Mechanism 7)

As noted, at the time of this study cross-organisational measurement systems of the type foreseen in policy-makers' original programme theory of PSCs had not yet been widely established, making it

impossible to report yet whether, within PSCs, cross-organisational measurement systems had (or would have) their intended effect in practice.

11.a.viii. The changed working practices result in the outcomes of increased patient safety and quality improvement. (Mechanism 8).

In relation to this mechanism **the evidence we gathered (Chapter 8) was again ambiguous.** Qualitative reports of changed patient outcomes contrasted with the absence of change in routine administrative data. Among the possible reasons for this we described, in Chapter 9, the ‘dilution’ of PSC impacts upon clinical safety and quality. In realist terms, the dilution of the effects of PSC activity by services or by parts of a care pathway without that activity is an additional ‘context’, not foreseen in policy-makers’ original programme theory for PSCs (see Chapter 2). This means that contextual requirement for PSC impact at whole care-group level is for QI activity to take place across most of the care pathways for that care group; and the same applies to a whole trust, a whole region or a whole health system.

The changes to working practices were accomplished through quality improvement cycles including team re-design of parts of care pathways, as we elaborated in Chapter 7. This finding contrasts with the policy-makers’ initial programme theory (Chapter 2) but aligns with previously published studies (see Chapter 3) in suggesting that **two distinct and sequential mechanisms, not just one, connect changed safety climate to changed working practices:**

1. Shifts in organisational culture and climate legitimate and motivate learning by clinical teams. Clinical teams learn how to identify, measure, critique and improve the ways in which their working practices impact upon patient safety and quality of care. Ways to bring about these changes in clinical teams’ skills, knowledge and attitudes to other professions, can be taught and learned.
2. That learning leads, in turn, to changes in the teams’ everyday working practices. Insofar as the teams learn partly through cycles of QI activity, changing their working practices then extends and reinforces their learning.

This means the assumed mechanism, Mechanism 8, unpacks into these two separate mechanisms, which implies that clinical team learning could take place without much, or any, change in everyday working practices. We found evidence (see Chapters 6-7) that because of the clinical teams’

workload and staffing pressures, this separation between learning and changed working practices had to some extent happened in our study sites. Our findings also suggest that requirement for ‘sufficient staff with enough time’ is a context that moderates the link between team learning and changed working practices rather than to the link between changed working practices and increased safety or clinical quality. A causal separation between clinical team learning and changes in working practice would also help explain why changed safety climate is sometimes but not always associated (in this study and in others, see Chapter 3) with changed working practices and therefore with increased safety and quality.

11.b. A revised PSC logic model

Our findings suggest that the programme theory assumptions (Chapter 2, Figure 3) implicit in the policy statements of NHS Collaboratives were not fully realised.

Comparing how PSC implementation occurred with our other findings and with earlier research allows us to move towards a more evidence-based logic model for PSCs. Presented graphically it would resemble Figure 3 in Chapter 2 but unlike the policy-makers’ original programme theory and PSCs as in fact implemented (Chapters 5-8) it would have the following characteristics (presented at they appear in the revised logic model, not in order of importance).

1. Recognition of the wider, older EBM movement as a safety culture-making mechanism predating and underlying the work of PSCs’ network-level coordinating organisations (AHSNs).
2. In practice local cross-provider measurement systems would suffice for Collaborative purposes, i.e. to enable clinical teams in different provider organisations to compare activities and learn from another. A national system would obviously enable wider comparisons and may have other policy considerations in its favour (e.g. public accountability, transparency, assisting research) but has a potential pitfall. The value in feeding back SCORE Survey results to clinical teams was that they could use the results formatively, as data whose only repercussions were to guide their selection of working practices to change and inform their selection of methods for doing so. This is different to making SCORE (or any other) measures into obligatory, summative quality measurements, in effect another performance indicator (especially one that triggers penalties or rewards).

Our informants thought that use of measurements as potential performance indicators was difficult to reconcile with using measurements to motivate safer working practices.

3. Incorporation of our finding that culture change does not change working practices directly but does so through two sequential links:
 - (a) A culture of EBM and ‘learning’ encourages clinical teams to learn QI methods. Then,
 - (b) Team learning of QI methods leads to changes in working practices (SPC, PDSA cycles etc.).

We found instances (Chapter 7) where clinical teams’ experience of making working practices safer or of higher quality for patients had a reinforcing effect on safety climate. ‘Culture’ change may be as much an effect as a cause of QI activity and safer working practices, in a ‘virtuous circle’. Team learning only changes working practices provided the context – i.e. time, staffing, workload, budgets - allows. This has implications for what kind of ‘staff training’ context is required. Its necessary kernel is quality improvement skills, especially PDSA and measurement, skills; the wider ‘learning organisation’ aspect (i.e. what Senge¹⁹⁷ and others²⁸⁸ describe as a ‘Learning Organisation’) is elaboration. Clinical teams are the critical audience for this training, and were for PSCs’ developmental activities.

4. Concomitantly, if provider organisations are to become ‘learning organisations’ for PSC purposes, ‘bottom-up’ approaches to safety management are required. One aspect is for a clinical team’s ‘home’ organisation to adapt its managerial structures to allow QI-trained staff the discretion and resources to implement what they have learnt. That helps sustain the changes in management, climate and work practices that Collaboratives’ activity, especially at the level of clinical teams, is intended to produce. Another requirement is that the provider’s managers allow clinical teams discretion to adapt QI activities to their local needs, and let clinical teams take ownership of a given project or change in work processes (our findings suggest this also promotes staff engagement and motivation). We found evidence of the necessity, for PSC work, of recruiting expert leadership ‘champions’ at every level (network, whole-provider, clinical team) and of ensuring that managers and the champions normalise, hence fully embed, QI and safety improvement at each of these levels.
5. Ensuring that provider-level conditions do not severely constrain clinical teams’ ability to translate Collaboratives’ activity into practice. That is:

- (a) Providing sufficient clinical staff relative to workload, enabling staff to undertake QI work consistently.
- (b) Doing one or both of two things that have the potential to counteract the dilution of PSC impact, i.e. to make PSC impacts more salient:
 - i. Extend the scope of PSC work (hence its resources including projected life-span) so that it covers whole services, care groups, even whole NHS trusts or integrated care organisations.

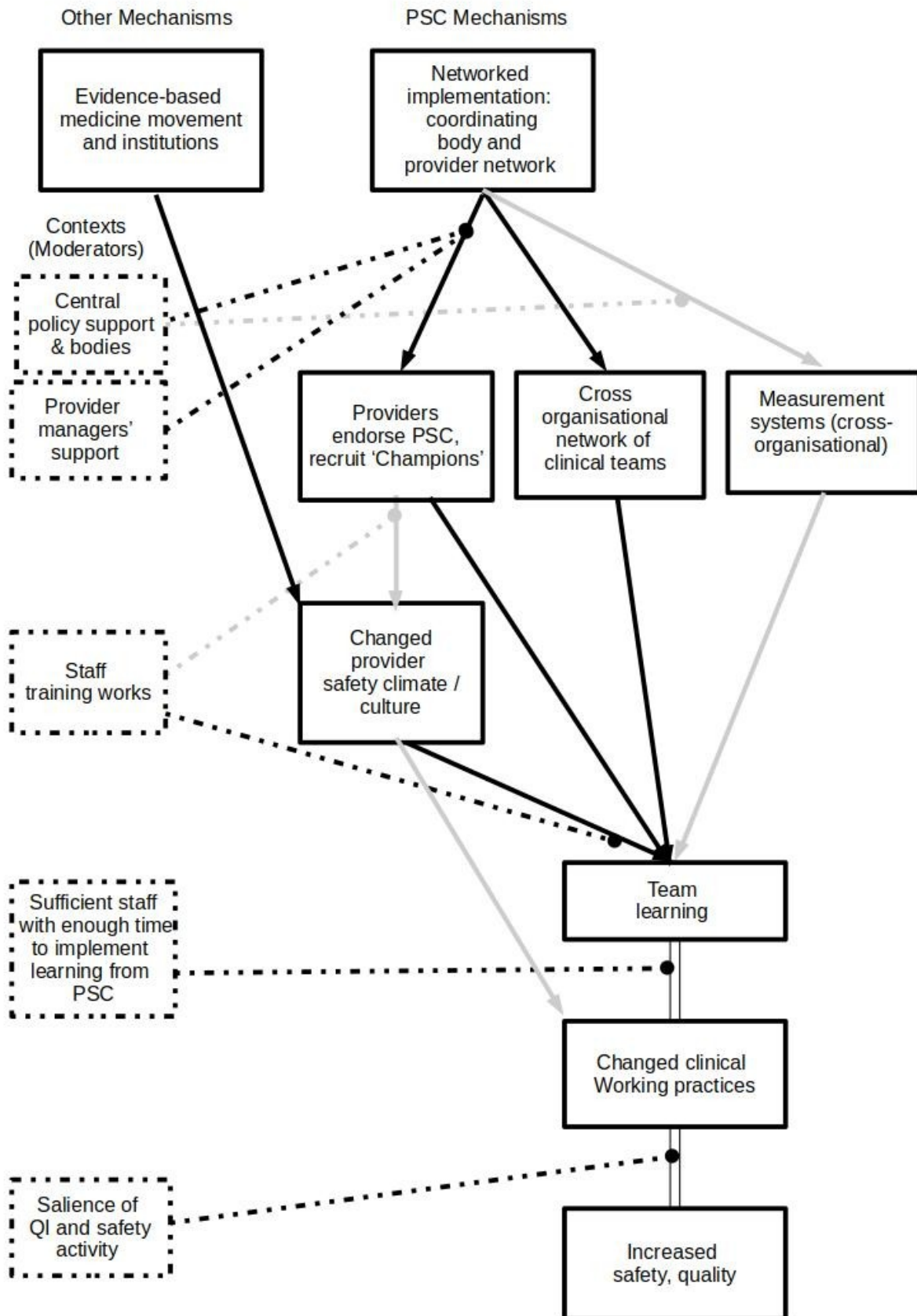
and/or

- ii. focus PSC activity on specified services, care groups or safety problems, preferably along the whole care pathway.

Either or both of (b)i and (b)ii are also necessary for there to be a prospect of improvements in patient safety and quality becoming detectable in changes in the routine administrative data sets that we analysed.

The revised logic model retains the other aspects of the policy makers' original programme theory essentially as they were and is shown in Figure 3 below. Grey lines show missing mechanisms which the policy documents anticipated but which at the time of this study PSCs had not set up; and grey dotted lines indicate the corresponding but in practice inoperative required contexts. The mechanisms that were set up but whose effects were compromised by contextual factors are shown as hollow lines. Dotted boxes and lines again indicate contexts in the realist sense of moderators i.e. conditions which strengthen or weaken the causal link. As Chapter 10 explained the wider evidence-based medicine movement and institutions (NICE etc.) now appear as an additional national-level initiating mechanism, in parallel with PSCs themselves, that contribute to changing workplace safety climate. As another context we add non-dilution or, putting it in more positive terms, sufficient 'Salience of QI and safety activity', meaning how far that activity extends along each care pathway. To prevent confusion with the corresponding figure in Chapter 2, Figure 3 below does not number or re-number the mechanisms.

Figure 3: PSC Implementation: A Revised Logic Model



While (as Figure 3 shows) many of the PSC programme mechanisms were set up, it was (as earlier chapters noted) with limited coverage across services. A graphic can show that the mechanisms did operate in a temporal sequence, but not how long that took nor how many providers and services they influenced. In practice at least 18 months were required for the effects of PSC activity to ‘trickle down’ to clinical team level. This time-scale applied in PSCs that inherited sophisticated QI and safety systems; others needed longer, with some PSC leads citing three and a half years as the minimum time needed. Upper-level organisational changes within the NHS during the start-up period lengthened the time required by most PSCs.

11.c. Wider policy and management relevance

The findings reported above suggest a number of wider policy and managerial implications that would increase the likelihood and extent of PSC impacts on the safety and quality of NHS, and NHS-funded, care. Summarise below, these concern giving PSCs sufficient time to produce their intended impacts; a context of organisational stability; scope for facilitative rather than performance-management strategies; small data; the salience of PSC activity; and ameliorating the providers’ circumstances.

11.c.i. Giving PSCs sufficient time

In Chapters 5-7 we reported, and in Chapter 10 we analysed, the timescales required for PSCs to establish and sustain the clinical team-level safety improvement activities and outcomes that current policy intends (see Chapter 2). In NHS settings at least, but also elsewhere (see Chapter 3), some years are required to:

1. Set up coordinating networks and ‘engage’ and recruit provider organisations to participate (see Chapter 5).
2. Recruit and prepare the safety ‘champions’ (Chapter 5).
3. Establish the necessary measurement systems at clinical team and inter-organisational levels (which has so far taken two years: see Chapter 5).
4. Enable repeated cycles of improvement (e.g. by means of repeated SCORE or similar surveys) to occur. In NHS practice a cycle of survey, debriefing, corrective action and re-

survey, together with *ad hoc* outcome measurement and re-measurement, takes at least a year (Chapter 7). Repeated cycles are required to sustain and normalise QI and safety work.

5. Overcome the dilution of PSC impact by subsequently adding ‘late adopter’ providers and services into QI and safety activity.

Our informants thought that altogether the above implied a five to ten year timescale, at the level of a whole PSC. The requirement for time and continuity incidentally implies that there is sometimes a sound rationale for 're-badging' existing, still-developing QI and safety activities in order to accommodate and continue them within later policy initiatives.

11.c.ii. Organisational stability

In Chapter 5 we reported how the formation and initial work of PSCs were made more difficult by organisational instabilities at national and at clinical team levels. At national level, the transition from NHSE to NHSI disrupted oversight of the PSC programme. It left leaders of the individual PSCs unsure of their position, particularly their financial position: budgets were not confirmed until well after the PSCs had to start spending money. This resulted in significant inertia, but to different extents across different PSCs. Those PSCs that inherited more extensive QI work were prepared to take more risks and just get on with their programmes. Those with less experience and inheritance practically stalled waiting for more coherent higher authority. Recently an NHSI review of the PSCs has been mooted. NHS managers have had experience of ‘reviews’ turning into programme abolition. A review that creates uncertainty as to how long PSCs will continue would restrict their ability to create the conditions to allow providers and front line staff to improve the care of patients because as explained above the Collaborative methods have to be applied consistently over a medium- or long-term time-scale. The transition from NHSE to NHSI resulted in a degree of perceived chaos and managerial inertia, especially in the PSCs which inherited less mature quality and safety improvement infrastructures. For that reason and because of the time-scales required to produce safer working practices at clinical team level, it would in our view be ill-advised to reorganise the PSCs just when some are beginning to achieve practical impacts.

11.c.iii. Facilitative rather than performance management strategies

Our findings also highlighted (Chapter 7) the centrality of clinical teams in PSCs' (indeed, any) safety and QI work. In our view this is an argument in favour of PSCs pursuing the Facilitative strategy (see Chapter 5) where possible, building on existing QI and safety activity so that the latter becomes, so far as possible, emergent 'from below'. The value in feeding back SCORE survey results to clinical teams was that the teams could use the results formatively to select working practices to change and methods for doing so. This is an argument against using the results of such surveys summatively as another performance indicator (especially one associated with penalties or rewards), which could be expected to reduce the psychological safety of QI work at clinical team level, tend to inhibit criticism and revision of existing working practices and relationships, and so be counter-productive of the policy objectives set for PSCs (Chapter 2). Whilst the PSCs used the SCORE survey to review and revise working practices and relationships (see Chapter 7), any equally valid instrument with similar psychometric properties would in our view probably have similar impacts if it was used for debriefings in a psychologically safe climate (not for performance management) and to trigger cycles of improvement activity. Because the PSCs were complex adaptive systems reacting and responding to local situations in varied ways, any attempt to manage PSCs uniformly and force them in one particular direction would risk hampering their ability to promote and allow the locally-originating work to occur that will ultimately lead to better patient care. In our opinion it would be useful for NHSI to study the emergent behaviours of each PSC, support positive behaviour, dampen negative behaviour and resist the temptation to apply a 'one size fits all' managerial approach. Alongside this, if provider organisations are to become 'learning organisations' for PSC purposes, a 'bottom-up' approach to safety management will be needed.

By now the cultural influence of EBM may seem well established but it is uneven, EBM is more prominent in general medicine for example than in much of mental health. This means start-up support for Collaboratives may be especially important in domains where EBM remains less developed and embedded. Furthermore, learning by clinical teams is a discrete step linking changes in safety climate to changed working practices. This has implications for what kind of training is required; the essential core of this must be QI and measurement skills, especially in relation to PDSA. Clinical teams are the critical audience for this training and this is reflected in existing PSC activity.

11.c.iv. Small data

NHSI is now addressing the absence of cross-provider measurement systems for PSC purposes (to enable clinical teams within different provider organisations to compare activities and learn from one another). However the ‘dilution’ of PSCs’ impact within larger data-sets (Chapter 8) underlines¹¹⁴ that the measurement systems required for QI work need to collect and compare data at the level of the particular clinical team (or other work-group) that is undertaking QI and safety work. For psychological safety these local measurement systems should be disconnected from systems that reward or penalise individuals. In our view, the development of measurement systems to support PSC activity should accommodate, indeed focus upon, this small data as much as on the ‘big data’ that compare whole NHS trusts.

11.c.v. Increasing the salience of QI and safety work

To reduce the dilution of PSCs’ impact sufficiently for that impact to become perceptible in changes in routine administrative data, it would be necessary to extend the scope of PSC work to cover whole services, care groups or provider organisations. Proportionately, PSCs’ work was concentrated in acute hospitals. Whilst general practices were strongly represented among the providers engaging with PSCs, the number of general practices at large is so much higher that these participants still represented only a small minority of general practices overall, including the ‘new models’ of ‘at scale’ general practices, multi-speciality community providers and primary and acute care systems. Community health services and mental health services were also less represented than acute hospitals. General practices apart, the non-NHS owned providers which engaged with PSCs were few and small (e.g. pharmacies, nursing homes). So far as we are aware, the large corporate and non-for-profit private providers did not participate.

11.c.vi. Ameliorating providers’ circumstances

We found clear evidence (see Chapters 5-7) that demand overloads, staff shortages and budget constraints were the biggest practical obstacle to providers, especially clinical teams, being able to do QI and safety work, and therefore to realising the intended impacts of PSC activity. Although there seems little immediate prospect of these circumstances improving, the more that policy opportunities arise to ameliorate these problems, the greater the likelihood of creating enough of the

‘organisational slack’ that, according to existing research findings^{207,289}, creates the leeway for innovation in general, and in this case to enable clinical teams to undertake safety and QI improvements consistently.

Chapter 12: Conclusions and further research

12.a. Conclusions

PSCs have had an impact on working practices in some clinical teams in some providers, hospitals and general practices among others. They have done so in a challenging context of provider overload, shortages of clinical staff, budget constraints and organisational instability. In light of these circumstances, of the small scale of PSCs in comparison with the NHS as a whole, and of the timescales required to change the working practices that impact upon quality and safety in healthcare, it would be unreasonable to expect these impacts to be visible even in the latest available relevant routine administrative data-sets, and this is supported by our observations.

We conclude that changes in safety climate at clinical team level do not necessarily change working practices directly. Rather, changes in organisational culture legitimate and motivate clinical teams' learning of new working practices, of quality improvement methods, and of safety measurement. When they have done this, members of clinical teams then attempt to put what they have learnt into practice at work. Whether they can do so depends upon their having the necessary permission to do so, as well as sufficient time, staff and other resources. None of this, however, requires safety climate at team level to change *before* working practices can change. Climate is not motivation. Working practices can be changed without prior changes in safety climate, and in our study sites they were. Our finding that PSC activity did not swiftly change the safety climate in the clinical teams for which we had data may tell us more about policy-makers' and others' assumptions about 'culture change' in the clinical workplace than about the practical impacts of PSCs. Rather, PSCs applied, benefited from and reinforced the background influence of the whole EBM movement, which represents culture change on a broader scale than PSCs at their current scale could produce alone. Rather than wait for culture change, a strategy more likely to produce organisational learning at clinical team level is the facilitative one of building, where possible, on existing local QI and safety work, and stimulating it in a psychologically safe setting where it does not yet exist. This approach is somewhat in tension with approaches that might be taken (or mistaken) for another form of performance monitoring and management. It may well then influence measurable safety culture positively.

An unexpected conclusion is that the SCORE Survey acted as a PSC intervention that proved capable of stimulating clinical teams to undertake QI and safety improvement activities, and change working practices. In effect it gave clinical team members permission to identify, discuss and address issues within existing working practices and relationships. The SCORE Survey – and others of its kind – produce ‘small data’ specific to the clinical team addressing a particular QI project which for QI purposes is much more useful than (say) trust-wide datasets. For measurement systems the practical question, for QI and safety purposes, is how to combine the small data with the larger, comparative cross-site datasets.

At the time of writing (early 2018) we conclude that a period of stability in which PSCs can sustain their work and extended it to further providers and services is more likely to promote changes that favour clinical quality and safety than would another re-organisation of their work.

12.b. Dissemination plans

Some dissemination of the PiSCES project’s work has already occurred:

1. Presentation of emerging findings to South West AHSN and PSC managing directors, Exeter, 18th April 2017.
2. Invited presentation to Health Services Research UK conference on policy responses to Francis Report, Nottingham, 6th July 2017.
3. Invited presentation to dissemination launch event of study of NHS Boards’ response to the Francis report, London, 23rd January 2018.
4. Presentation of emerging findings to AHSN and PSC directors, London, 25th January 2018.
5. Presentation of emerging findings to AHSN and PSC directors, London, 20th March 2018.
6. Presentation of findings to CQC, London, 23rd April 2018.
7. Presentation of findings to Patient Safety Measurement Unit, London, 14th February 2019.
8. Paper, International Quality and Safety Forum, Improvement Science and Research Symposium, Glasgow, 27th March 2019.

Subject to the relevant bodies' acceptance, our dissemination plans include:

1. Consultation with PPI groups about what parts of the findings are likely to be of most interest to patients, and the best dissemination channels for that purpose.
2. Offering feedback sessions to our study sites, and circulating electronic copies of publications from the project (see below) to our informants, to the Department of Health and to other relevant bodies.
3. Submission of journal articles, at least and provisionally one overview paper (for a health services research or health policy journal) and another presenting our findings on organisational culture and safety climate (for an organisational research journal).
4. Further collaboration with AHSNs as SCORE surveys continue, laying the basis for a later publication about the findings and uses of such surveys.
5. Scientific, academic and professional conferences, probably including the BMJ International Forum on Quality and Safety in Healthcare, the European Health Management Association, and Organisational Behaviour in Health Care.

We are currently working with PenPIG (SW Peninsula CLAHRC patient involvement group) to consult them about which of the project findings are likely to be of most interest to patients, how to present and communicate them.

As a more innovative and ambitious dissemination plan however we propose that greater impact from this study would be achieved by combining PiSCES dissemination activity with that of the other projects concurrently researching the consequences of and responses to the Francis Report. The idea would be to produce materials, combining findings from all the studies and tailored for specific audiences (managers, policy-makers, patients, researchers etc.): that is, an extended joint dissemination project on similar lines to that of the NIHR Health Service Delivery Research programme's extended dissemination of the research studies it has sponsored on the new models of primary care and on the re-structuring of stroke services in London and Manchester.

12.c. Further research

We list the needs for further research arising from this study in what we judge to be descending order of importance.

1. Policy-makers originally intended PSCs to have a five-year life span, presumably on the assumption that five years was and sufficient for PSCs to produce their intended effects. That is a *prima facie* argument for extending, or replicating, the present study to cover the PSCs' full initially-intended life-span; in particular, for continuing (repeating) and widening (across more sites) the before-and-after comparisons of SCORE survey results in order to obtain more robust findings as to whether the impact of PSC and provider managers' activity upon safety climate at clinical team level does indeed take at least three years to materialise (perhaps as much a consequence as a cause of safety improvement).
2. Because the revised logic model is formulated in terms of mechanisms and contexts, it is applicable to other settings than our study sites. To apply it in this way would expose it to further empirical testing, and no doubt further empirical refinement and correction. One such refinement would be to build on our findings about contrasting PSC strategies (Chapter 5) to construct a typology of PSCs, informed by different theories of collaborations and of networks.
3. Evaluate the effects of PSCs or PSC-like initiatives more widely across community health services, mental health service and residential care, to explore whether these settings, where EBM is less developed, require specific adaptations for Collaboratives.
4. Evaluate and understand more fully any causal relationship between changing safety culture (and climate) and changing outcomes. Only a few studies have been conducted. One²³⁵ showed that safety climate did not change during the intervention period of a collaborative, but that service safety improved anyway (significantly reducing catheter associated urinary tract infections)⁶. Another²³⁶ showed that implementing the safe surgery checklist did not affect mortality and morbidity but did improve safety culture scores. More generally, further research into the relationships between implementation processes and outcomes in PSCs and other QI initiatives is still needed even now.
5. Social network analysis (SNA) based on repeated network mapping of PSCs over time would be a methodologically strong way of showing the patterns of engagement, the clustering of relationships around different priorities, and the connections between PSCs as a network of networks. (The foreseeable difficulty however is data collection: such studies

would almost certainly require collecting new primary data, for which high response rates (>70%) are required to populate sufficiently the square data matrices which SNA requires. Whilst using existing data such as e-mail traffic would be technically simple and give full data, getting ethical approval for it is, in our view rightly, not straightforward.)

6. Explore which forms of measurement system (i.e. the corresponding management information systems) are best-adapted for PSCs' safety and QI purposes, in particular the ways in which existing NHS management information systems (e.g. those which NHS Digital harvests) might be exploited for those purposes; and what adaptations they would consequently require.
7. Develop and use more localised measurement systems, including new primary data if necessary, to evaluate the relationships between clinical team learning, changes to working practices and safety/quality outcome changes. Such a study would involve examining the mechanisms by which clinical teams use such information, and other sources of information, for QI and safety purposes.
8. Evaluate which forms of training, especially for clinical teams, are most practicable and effective for PSCs' safety and QI purposes.
9. In the current state of PSC financial flows, the lack of PSC-attributable changes in routine administrative data, and the absence of detailed financial data it remains unfeasible to evaluate (and hence to compare) the resources received by PSCs and the economic consequences (value) of their health outcomes for patients. A further, more comprehensive, study would be able to estimate the direct and probably larger indirect opportunity costs relating to PSC activity; thus allowing policy makers to make more informed financial decisions.
10. Previous research has shown that people in more deprived material circumstances are less likely to receive appropriate diagnoses and treatments than people from less deprived backgrounds.²⁹⁰ Little is known about whether this pattern also applies to healthcare safety.

Finally, this study examined just one of several policy responses to the Francis Report. A study integrating the findings from this study with those from the other concurrent studies would produce a more rounded view of what has been done, how, and to what effect to increase the safety of NHS services.

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Appendices

Appendix 1: How the PiSCES study enacted the SQUIRE reporting standards.

Table 38: Standards for *Q*uality Improvement Reporting Excellence (*SQUIRE*) items

SQUIRE Item	See report section
1. Title: Did you provide clear and accurate information for finding, indexing, and scanning your paper?	Yes, see title page
(a) Indicates the article concerns the improvement of quality (broadly defined to include the safety, effectiveness, patient-centredness, timeliness, efficiency and equity of care)	Yes, see title page
(b) States the specific aim of the intervention	Yes, see long form of title
(c) Specifies the study method used (for example, “A qualitative study,” or “A randomised cluster trial”)	Yes, see long form of title
2. Abstract: Summarises precisely all key information from various sections of the text using the abstract format of the intended publication	Abstract
Introduction: Why did you start?	Chapter 1
3. Background knowledge: Provides a brief, non-selective summary of current knowledge of the care problem being addressed, and characteristics of organisations in which it occurs	Chapter 3
4 Local problem: Describes the nature and severity of the specific local problem or system dysfunction that was addressed	Chapter 2
5 Intended improvement: (a) Describes the specific aim (changes/improvements in care processes and patient outcomes) of the proposed intervention (b) Specifies who (champions, supporters) and what (events, observations) triggered the decision to make changes, and why now (timing)	Chapter 2
6 Study question: States precisely the primary improvement-related question and any secondary questions that the study of the intervention was designed to answer.	Chapter 1

Methods: What did you do?	Chapter 4
7 Ethical issues: Describes ethical aspects of implementing and studying the improvement, such as privacy concerns, protection of participants' physical wellbeing and potential author conflicts of interest, and how ethical concerns were addressed.	Chapter 4, section1 (research design) and Chapter 4, final section
8 Setting: Specifies how elements of the local care environment considered most likely to influence change/improvement in the involved site or sites were identified and characterised.	Chapters 2,3,9,10,11,12
<p>9 Planning the intervention:</p> <p>(a) Describes the intervention and its component parts in sufficient detail that others could reproduce it</p> <p>(b) Indicates main factors that contributed to choice of the specific intervention (for example, analysis of causes of dysfunction; matching relevant improvement experience of others with the local situation)</p> <p>(c) Outlines initial plans for how the intervention was to be implemented—for example, what was to be done (initial steps; functions to be accomplished by those steps; how tests of change would be used to modify intervention) and by whom (intended roles, qualifications, and training of staff).</p>	<p>(a) Chapter 2</p> <p>(b) Chapter 2</p> <p>(c) Chapter 2</p>
<p>10 Planning the study of the intervention:</p> <p>(a) Outlines plans for assessing how well the intervention was implemented (dose or intensity of exposure)</p> <p>(b) Describes mechanisms by which intervention components were expected to cause changes, and plans for testing whether those mechanisms were effective</p> <p>(c) Identifies the study design (for example, observational, quasi-experimental, experimental) chosen for measuring impact of the intervention on primary and secondary outcomes, if applicable</p> <p>(d) Explains plans for implementing essential aspects of the chosen study design, as described in publication guidelines for specific designs, if applicable (see, for example, www.equator-network.org)</p> <p>(e) Describes aspects of the study design that</p>	<p>(a) Chapters 5-7</p> <p>(b) Chapter 2</p> <p>(c) Chapter 4, section 1.</p> <p>(d) Chapter 4, <i>passim</i>.</p> <p>(e) Chapter 4, section e.</p>

specifically concerned internal validity (integrity of the data) and external validity (generalisability).	
<p>11 Methods of evaluation:</p> <p>(a) Describes instruments and procedures (qualitative, quantitative or mixed) used to assess (i) the effectiveness of implementation, (ii) the contributions of intervention components and context factors to effectiveness of the intervention and (iii) primary and secondary outcomes</p> <p>(b) Reports efforts to validate and test reliability of assessment instruments</p> <p>(c) Explains methods used to assure data quality and adequacy (for example, blinding; repeating measurements and data extraction; training in data collection; collection of sufficient baseline measurements).</p>	<p>(a) Chapter 4, sections b,c,d and Appendix 3 (Interview Schedule).</p> <p>(a)(i) Chapter 4, section d.</p> <p>(a)(ii) Chapter 4, sections a,e.</p> <p>(b) Chapter 4, sections b,c,d.</p> <p>(c) Chapter 4, section d. (Blinding; repeating measurements and data extraction; training in data collection not relevant to this study design.)</p>
<p>12 Analysis:</p> <p>(a) Provides details of qualitative and quantitative (statistical) methods used to draw inferences from the data</p> <p>(b) Aligns unit of analysis with level at which the intervention was implemented, if applicable</p> <p>(c) Specifies degree of variability expected in implementation, change expected in primary outcome (effect size) and ability of study design (including size) to detect such effects.</p> <p>(d) Describes analytical methods used to demonstrate effects of time as a variable (for example, statistical process control).</p>	<p>(a) Chapter 4, sections b,c,d,e.</p> <p>(b) Chapter 4, sections b,c,d,</p> <p>(c) This observational study was designed to measure only the effect direction post facto, not its expected (predicted) size.</p> <p>(d) Chapter 4, sections c,d.</p>
Results: What did you find?	Chapters 5-8,10.
<p>13 Outcomes:</p> <p>(a) Nature of setting and improvement intervention</p> <p>(i) Characterises relevant elements of setting or settings (for example, geography, physical resources, organisational culture, history of change efforts) and structures and patterns of care (for example, staffing, leadership) that provided context for the intervention</p> <p>(ii) Explains the actual course of the intervention (for example, sequence of steps, events or phases; type and number of participants at key points), preferably using a time-line diagram or flow chart</p> <p>(iii) Documents degree of success in</p>	<p>(a) Chapters 5-8.</p> <p>(a)(i) Chapters 5-8.</p> <p>(a)(ii) Chapters 5-8.</p> <p>(a)(iii) Chapter 9</p> <p>(a)(iv) Chapters 5-8.</p> <p>(b) Chapters 5-8.</p> <p>(b)(i) Chapters 5-8.</p> <p>(b)(ii) Chapters 5-8.</p> <p>(b)(iii) Chapters 5ff.</p> <p>(b)(iv) Chapter 4 section a, Chapters 5-8.</p> <p>(b)(v) Chapter 9.</p>

<p>implementing intervention components</p> <p>(iv) Describes how and why the initial plan evolved, and the most important lessons learned from that evolution, particularly the effects of internal feedback from tests of change (reflexiveness)</p> <p>(b) Changes in processes of care and patient outcomes associated with the intervention</p> <p>(i) Presents data on changes observed in the care delivery process</p> <p>(ii) Presents data on changes observed in measures of patient outcome (for example, morbidity, mortality, function, patient/staff satisfaction, service utilisation, cost, care disparities)</p> <p>(iii) Considers benefits, harms, unexpected results, problems, failures</p> <p>(iv) Presents evidence regarding the strength of association between observed changes/improvements and intervention components/context factors</p> <p>(v) Includes summary of missing data for intervention and outcomes.</p>	
<p>Discussion: What do the findings mean?</p>	<p>Chapter 9</p>
<p>14 Summary</p> <p>(a) Summarises the most important successes and difficulties in implementing intervention components, and main changes observed in care delivery and clinical outcomes</p> <p>(b) Highlights the study's particular strengths.</p>	<p>(a) Chapter 12</p> <p>(b) Chapter 9</p>
<p>15 Relation to other evidence: Compares and contrasts study results with relevant findings of others, drawing on broad review of the literature; use of a summary table may be helpful in building on existing evidence.</p>	<p>Chapters 3,9.</p>
<p>16 Limitations:</p> <p>(a) Considers possible sources of confounding, bias or imprecision in design, measurement, and analysis that might have affected study outcomes (internal validity)</p> <p>(b) Explores factors that could affect generalisability (external validity)—for example, representativeness of participants; effectiveness of implementation; dose-response effects; features of local care setting</p> <p>(c) Addresses likelihood that observed gains may weaken over time, and describes plans, if any, for monitoring and maintaining</p>	<p>(a) Chapter 9</p> <p>(b) Chapter 9</p> <p>(c) Chapters 5-9</p> <p>(d) Chapter 4.</p> <p>(e) Chapter 9</p>

<p>improvement; explicitly states if such planning was not done</p> <p>(d) Reviews efforts made to minimise and adjust for study limitations</p> <p>(e) Assesses the effect of study limitations on interpretation and application of results.</p>	
<p>17 Interpretation:</p> <p>(a) Explores possible reasons for differences between observed and expected outcomes</p> <p>(b) Draws inferences consistent with the strength of the data about causal mechanisms and size of observed changes, paying particular attention to components of the intervention and context factors that helped determine the intervention's effectiveness (or lack thereof) and types of settings in which this intervention is most likely to be effective</p> <p>(c) Suggests steps that might be modified to improve future performance</p> <p>(d) Reviews issues of opportunity cost and actual financial cost of the intervention.</p>	<p>(a) Chapter 9</p> <p>(b) Chapters 9,12</p> <p>(c) Chapter 11</p> <p>(d) Chapters 5-8.</p>
<p>18 Conclusions:</p> <p>(a) Considers overall practical usefulness of the intervention</p> <p>(b) Suggests implications of this report for further studies of improvement interventions.</p>	<p>(a) Chapters 11-12</p> <p>(b) Chapters 11-12</p>
<p>Other information: Were there other factors relevant to the conduct and interpretation of the study?</p>	Chapter 9
<p>19 Funding: Describes funding sources, if any, and role of funding organisation in design, implementation, interpretation and publication of study.</p>	Chapter 4, section 4; Acknowledgements section.

Appendix 2: Informants' job titles.Level 1: PSC network

1. PSC lead (AHSN1) (AHSN Alpha)
2. PSC lead (AHSN2)
3. PSC lead (AHSN3)
4. PSC lead (AHSN4)
5. PSC lead (AHSN5)
6. PSC lead (AHSN6)
7. PSC lead (AHSN7)
8. PSC lead (AHSN8)
9. PSC lead (AHSN9) (AHSN Beta)
10. PSC lead (AHSN10)
11. PSC lead (AHSN11)
12. PSC lead (AHSN12)
13. PSC lead (AHSN13) (AHSN Gamma)
14. PSC lead (AHSN14)
15. PSC lead (AHSN15)

Level 2: Provider management

1. Acute trust deputy pharmacist
2. Mental health/community pharmacist

3. GP practice manager
4. Senior Manager Innovation & Research, CCG
5. Programme Lead, Mental Health Quality and Patient Safety Improvement Collaborative
6. Head of Safety, Risk & Patient Experience (acute hospital)
7. GP partner
8. Head of Patient Safety and Governance, CCG
9. Associate director, medicines optimisation/CD Accountable Officer
10. Patient Safety Collaborative Programme Manager
11. Chief Nurse and Director of Quality, Strategy and Innovation, CCG
12. Director of Nursing, acute hospital
13. Patient Safety Manager, acute hospital
14. GP & CCG Chair
15. Director of Nursing and Quality, CCG

Level 3: Front-line clinical teams

1. Consultant Emergency Medicine
2. Senior Sister & Lead Practitioner Emergency Department
3. ACCS Acute Medicine CT1
4. Senior physiotherapy practitioner
5. General practice manager
6. GP
7. Lead receptionist GP surgery
8. Office Supervisor GP surgery

9. Receptionist GP surgery (also trained phlebotomist)
10. Divisional Head of Nursing (Surgery)
11. Specialist Nurse Practitioner (Osteoporosis)
12. Specialist Nurse Practitioner (Falls & Fracture)
13. Healthcare Assistant (previously receptionist)
14. Clinical pharmacist, intensive care and cardiology
15. F2 doctor
16. Quality improvement fellow for surgery
17. Core Trainee Year 2B of Anaesthetic Acute Care, (F1, F2, CT1, CT2A, now CT2B)
18. Registrar (Colorectal surgery)
19. F2 doctor
20. SC7 (colorectal surgery)
21. Post CCT Fellow
22. Associate director for medicines optimisation/CD Accountable Officer
23. Care home practitioner
24. Matron for emergency assessment unit/lead nurse for clinical audit and effectiveness
25. Care home practitioner
26. Discharge to assess programme manager
27. Consultant – medicine for elderly
28. Consultant - emergency Department
29. Consultant – anaesthetist
30. Consultant - emergency Department
31. Lead nurse/senior sister ICU

Appendix 3: Participant information sheet and consent form



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**South West
Academic Health
Science Network**
Connecting needs with solutions

Invitation to take part in a research study

PROJECT TITLE

PiSCES – The Patient Safety Collaborative Evaluation Study

SUMMARY

Fifteen Patient Safety Collaboratives (PSCs) have been launched across England with the aim of improving NHS patient safety and quality. The object of this project is to understand how best PSCs can achieve that aim.

RESEARCH QUESTION

In this project we will address four research questions:

- How have Patient Safety Collaboratives been implemented?
- What are the costs (in terms of staffing, administration, and non-financial factors)?
- What have been the intended and unintended outcomes (including patient safety, sharing best practice, and patient/public views)?
- What are the barriers and facilitators and what lessons can we learn (in relation to participation, engagement, outcomes, and perceptions)?

BACKGROUND/CONTEXT TO PROJECT

Safe health care is a basic expectation for patients and the public and a core responsibility for healthcare organisations, but healthcare systems sometimes fail to provide safe care to all patients. The findings of the Francis Report demonstrated that the major changes required to reliably deliver safe health care in the NHS have not yet taken place. The Government's response to the Francis Report included a policy to implement 15 PSCs covering the whole of England. The PSCs are networks of NHS service providers, whose role is to help implement central government policy for improving patient safety, but whose implementation activities are adapted to reflect a local ownership model; each will last for a minimum of five years.

Our team, made up of people from the South West Academic Health Science Network (SW AHSN) and the universities of Exeter and Plymouth (through PenCLAHRC), has been funded for two years by the Department of Health to evaluate PSCs.

PROJECT AIMS

Our aim in this research project is to evaluate the progress of the 15 PSCs in the first two years to determine what difference they are making and how their impact can be maximised in the remainder of the programme. We are taking a realist approach; that is, we want to find out what parts of the PSCs work, for whom and in what respects, to what extent and how? This approach is increasingly used for evaluations of complex multifactorial interventions in favour to the blunter but less nuanced traditional research question “did it work?”

We will address these questions:-

- How have the PSCs been implemented in each of the 15 Academic Health Science Network (AHSN) regions?
- What organizational changes have providers made? How have they done this and what have they learned from the PSCs?
- What are the costs of participation and implementation?
- Have the PSCs made a detectable difference on rates of harm and adverse events involving patients as measured using routine data?
- Has change in practice taken place on the front-line of services?
- How has implementation varied across PSCs and what generalisable knowledge can be shared about this?

CURRENT ACTIVITY

Our mixed methods study has three strands that will run side by side, each addressing a different aspect of the work of the PSCs.

Implementation study: qualitative methods

We will identify interview subjects based on their involvement in the implementation of PSCs at each system level, following the flow of information and finance as it cascades through the system. We estimate we will need to conduct up to seventy five semi-structured interviews, aiming to reach theoretical saturation. We will carry out high-level interviews across all AHSNs and then more detailed interviews within two specific AHSN geographies (one largely urban and one largely rural). The interviewees will include AHSN Patient Safety Leads, executive and patient safety leads within provider organisations, and front-line staff.

Safety culture: specialised survey

Safety-culture surveys will be conducted at the start of the evaluation period and repeated at the end. There is a significant body of evidence linking safety culture to improved patient safety and many argue that this is one of the most sensitive ways to detect improvement in outcomes for patients. We will work with an international company, Safe and Reliable Health Care, that has extensive experience of safety culture surveys and has successfully administered its survey in 28 healthcare systems across North America.

Service and patient outcomes: re-analysis of routine administrative data

We will triangulate data from available systems (HED database, SHMI, patient and staff surveys, ICD10 coding) across all AHSNs 18 months before the implementation of PSCs, at baseline, and then again after 24 months. This will enable us to detect any differences in overall mortality and morbidity resulting from the PSCs

ANTICIPATED OUTPUTS

The expected outcome of this research is a thorough evaluation of the impact of the PSCs. The realist approach will demonstrate what parts of this complex social intervention work and for whom they work. Potential impacts are expected to include:-

- Enabling NHS England to demonstrate the return on investment of PSC funding
- Informing the ongoing running of the PSCs, showing what has worked and what has not worked so well
- Guiding future central policy in terms of patient safety.

KEY CONTACT(S)

For SW AHSN: Mr Rob Bethune, email rob.bethune@nhs.net

For PenCLAHRC: Prof Rod Sheaff, email R.Sheaff@plymouth.ac.uk or Dr Iain Lang, email I.Lang@exeter.ac.uk

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CONSENT FORM

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Title of project: PiSCES – The Patient Safety Collaborative Evaluation Study

Name of researcher(s): Natasha Doran; Sue Child; Iain Lang; Susan Ball; Antonieta Medina-Lara; Rod Sheaff; Rob Bethune.

	Tick in this column or type "yes"
I understand that the interview will be recorded and that This information will subsequently be transcribed.	
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
I would like to have the opportunity to review and agree the transcribed interview before it is used in the research. (If "yes", please return the approved transcript within 1 week of receiving it.)	

I agree to take part in the above qualitative study:
 Signature..... Name.....Date.....

Name of researcher taking consent:

Appendix 4: Interview schedules

Semi-Structured Interview Schedule

1st Level Interviews PSC Leads

Open ended Question	Prompts (if not covered by initial response)
<p>Background questions</p> <p>Age Current job title(s) When took up current post Previous posts</p>	
<p>Purpose and intended outcomes of the PSC</p>	
<p>What are the main aims of your PSC? Who selected them? What type of safety topics and interventions are you focusing on and why? How does the PSC accommodate local initiatives and local practices with the national vision?</p>	<p>Probe: Balance between 'guiding principles' and local aims.</p>
<p>History/origins of this PSC</p>	
<p>How was this PSC established Whose aims predominated in it implicitly What are they trying to do/achieve? (What are the outcomes that they are looking for?) Who co-ordinates the PSC? Who runs it in practice?</p>	<p>Prompt</p> <p>Probe: Role of AHSN vs. CLAHRC, CCGs, others (who?) Balance of clinician vs. managerial.</p>
<p>Process/implementation</p>	
<p>How have you planned to achieve the PSCs intended outcomes?</p> <p>Have the collaboratives produced or changed department-level policies for quality management in the participating hospitals?</p> <p>To what extent is your PSC following pre-existing activities or introducing new ones?</p> <p>How far have your activities been achieved by sharing good practice between the sites within the PSC?</p> <p>Who are the main actors in the network of organisations in the PSC?</p>	<p>Prompt</p> <p>Probes: How will it influence practitioners? How will it influence: NHS Foundation Trusts? General practices? Other service providers?</p> <p>Probe: Is it a ready-made model or is it one that you have come up with?</p> <p>Who does what, who has what roles?</p>

<p>How do you motivate or empower various groups within the collaborative?</p> <p>How does your approach to involving and motivating actors differ between different groups: i.e. managers, QI experts, doctors, patients (other groups?)</p> <p>What contextual factors are likely to be important in its implementation? /What could possibly hinder or stop your progress with the implementation process</p>	<p>(PROBE what assumptions (critical conditions) do the implementation processes depend on?)</p>
Experience in practice	Prompt
At the current stage in its implementation, how does it work/how far has it been made to work?	(Insofar as it has been implemented, how has this worked in practice?)
What successes have you encountered?	
What barriers have you encountered?	Vested interests/unforeseen consequences - good or bad?
Have you had to deal with any uncontrollable or initially unforeseen factors or constraints?	Probe Have your activities run up against the so-called 'Blame culture'? Have you needed to take any steps to confront or weaken it?
How has the implementation activity evolved as you have developed it?	Probe: Have you modified your implementation process in the light of experience? If so how/to what extent?
Can you identify any sites where the PSC activity is going well or is likely to go well?	Probe Why select those sites? (or providers)
Are you able to identify any sites where you think it is likely to be difficult or problematic to implement PSC activity?	Probes Why? What are the perceived problems and difficulties? Why do you think they have arisen? Do you know what the possible barriers are?
What methods or resources do you anticipate having to use in order to counter or circumvent or work around these problems? (or barriers)	
Reflexivity measures	
What do (did) you hope to achieve?	
What impact or outcomes were you expecting? How has this borne out in practice so far?	
How is the PSC going about identifying or checking whether it is achieving its objectives?	What measures it is using?
Are there any new or innovative approaches to your data collection being introduced for these purposes?	

In what ways is it trying to share learning both within and across other PSCs?	
How is the PSC evaluating itself?	How well is it doing this?
PSC leads/managers in charge of finances	Prompts
Where do the PSC budgets come from?	Have the PSC's replaced anything? What was in place before/what resources and programmes have you inherited? To what extent is it a reworking of earlier activity and what activities have been started from scratch?
What help in kind do PSC's get?	For example do they get consultant time, administrative support?
Can and do the PSCs offer any financial or material incentives to organisations or individuals to implement their ideas?	
If the PSC was to be closed down tomorrow, what would the PSC resources be used for instead?	
General questions	
It is fairly early days, but do you think there's any sense of a culture change going on with this activity?	
Is there anything important we have not asked about, or you'd like to add?	

Semi-Structured Interview Schedule

2nd level Interviews

Patient Safety Leads within provider organisations

Open ended Question	Prompts (if not covered by initial response)
Background questions: Age Current job title(s) When took up current post Previous posts	
Prior experience of QI and safety work	
Prior to the patient safety collaboratives, what quality improvement and safety work were you	Prompt - what sort of safety topics and interventions did you focus on and why?

involved in within your organisation?	
Pre-existing networks/infrastructure	Prompt
Prior to PSCs what experience have you had of external bodies involving you in this type of work?	What experience did you have of other external bodies supporting this type of work within this organisation? (Check role of earlier clinical networks, national professional organisations, other local collaborations etc)
Prior to the PSC, what quality improvement work did your Strategic Health Authority involve you in?	
How does this compare or how has this changed since the introduction of PSCs?	
Impact of PSCs	Prompt
What aims or objectives is the PSC trying to pursue?	
What local objectives of your own have you added (if any)?	
Have you set aside any of the PSCs objectives?	Prompt: Which objectives? Why did you do (choose) that?
What impacts has the PSC had?	Has it had much impact?
Has the PSC been useful? If so why? Where has it worked?	For whom and in what context
Are you aware of any negative impacts?	Why, in what context and for whom?
(If so,) How has this happened and what can be learnt from it?	
Can you tell me about any positive impacts?	Why do you think it has worked in this context? What do you think are the main facilitators?
What more useful things could the PSCs do?	
Experience of PSC	Prompt
Have you attended any networking meetings?	Have they been useful?
Has the collaborative produced or changed department level policies for quality management within your organisation?	Which department(s)? Are there any (which one(s)?) that you think are important for patient safety but the PSC has not affected?
Have the PSCs done anything or are they doing anything to change clinical practice?	Could you tell me about your views as to what the PSCs have done or are doing to change clinical practice?
What activities has it led to?	Can you give any examples?
To what extent have the PSCs changed your ways of measuring and improving patient safety?	Who gets to see the measurement data?
QI methods The national language includes terms such as "scale up and spread" with pressures to provide results. In your	

organisation, how does this fit with the QI methodology being that of testing in a small area first, before building up to scale?	
Have you encountered pressures to prove outcomes of your PSC activity?	Probe: can you tell me a bit about your views and experience regarding this - what kinds of pressure? From whom? Why are they exerting this pressure? Etc
Have staff within your organisation been allocated time within their job plan to engage in QI activity?	If so, how much time? Whose? If not, why...
Within your organisation, what circumstances have helped you in carrying out PSC work?	Probes: what contextual factors are likely to be important e.g. resources; people - advocates or champions; information; facilities; knowledge; other conditions Probes: in terms of motivation what drives PSC activity and what tends to hinder momentum?
Within your organisation, what circumstances have hindered you in carrying out PSC work?	Probes: people - sceptics, rivals or opponents; competing priorities and tasks; lack of resources - information, facilities, knowledge; other conditions
Have you had to deal with any uncontrollable or initially unforeseen factors or constraints?	Probe: Have any of your activities run up against the so-called 'Blame culture'? Have you needed to take any steps to confront or weaken it?
Overall perception of PSCs	Probes
What are your views on the introduction of PSCs?	Do you think they are a useful initiative? Do you think they should continue?
How do you perceive the PSCs role and implications for how this organisation is managed?	
In this organisation, how have the patient safety collaboratives been connected with the Q initiative and Sign up to Safety?	Probe: have these initiatives had much impact? Have they been useful?
Have the PSCs connected these two initiatives up, or are they still perceived as three parallel initiatives?	Do they seem to be consistent with each other?
If the PSCs were to be closed down tomorrow what impact would this have on your organisation?	How would you feel? What resources would be freed, and what do you think would happen to them then?
Projecting forward 5 years what do you hope their legacy would be?	
General questions	
It is early days, but do you think there's any sense in which this type of activity (which you've described to me in answering earlier questions) is changing the culture in this organisation?	What kind(s) of culture change?
Is there anything important we have not asked about or that you'd like to add?	

Semi-structured interview schedule

3rd Level Interviews Front line staff

Open ended Question	Prompts (if not covered by initial response)
Background questions: Age Current job title(s) When took up current post Previous posts	
Prior experience of QI and safety work	(Before 2015)
What quality improvement (QI) work have you done before?	Prompt In particular before 2015?
What activities has that work led to?	Prompt Can you give any examples? Because of what or whom? Whether and what role has the PSC played in this?
Have there been any changes in your working practices as a result of that activity?	Prompt Because of what or whom? Whether and what role has the PSC played in this?
Has that activity led to any change in occupational roles? How were those changes borne out in working practice?	Prompt Because of what or whom? Whether and what role has the PSC played in this?
Current experience of QI and safety work	
Have you been allocated time within your job plan to engage in QI and safety work? Or are you doing this as extra-curricular?	Prompt Because of what or whom? Whether and what role has the PSC played in this?
Have you attended any networking meetings? In what ways were they useful?	Prompt Because of what or whom? Whether and what role has the PSC played in this?
Can you identify any factors which may hinder or have hindered you in carrying out quality improvement and safety work?	Prompt e.g. People, sceptics, rivals or opponents, competing priorities and tasks, time, lack of resources, information, facilities, knowledge, other conditions
What circumstances have helped you to carry out quality improvement and safety work?	Prompt Can you identify any factors which may help or have helped you? E.g. time, resources, people, advocates or champions of this type of work, additional information
Impact of PSCs	
Have you heard of the patient safety	Prompt

collaboratives (PSCs)?	when were you first aware of the patient safety collaboratives and PSC activity?
Have you heard of the Academic Health Science Network?	Prompt AHSNs?
Are you aware of ‘Sign Up to Safety’; ‘Q initiative’; The SCORE patient safety culture survey?	
Have these initiatives (Sign Up to Safety, Q initiative, PSCs) been connected up so far as you can tell, or are they in practice three parallel initiatives?	
Have these initiatives had much impact?	Prompt Have they been useful?
Has the PSC led to any changes in clinical/medical practice?	Prompt What are your and your colleagues’ views about what the PSC has done/is doing to change clinical practice?
Are you aware of any negative impacts (from PSC activity)?	Prompt E.g. increased workload with no perceivable benefits? Have you been to a workshop, taken a day off work and found it hasn't been useful or not added anything of value to you?
(If so), how has this happened and what can be learnt?	Prompt What changes could be made?
Are you aware of any positive impacts (from PSC activity)?	Prompt E.g. within your work role and your area, being able to use the learning you have had from the PSC?
Measurement	
How do you currently measure patient safety and/or patient quality care?	
Has PSC activity led to any changes to your ways of measuring and improving patient safety?	
SCORE patient safety culture Survey	
Have you taken part in a safety culture survey?	Prompt Who carried out and provided (funded) the survey?
Have you had extra time within your job plan to do this work?	
What was your overall experience?	
How did you find the survey?	Prompt Was it helpful?
What changes, if any, has it led to?	Prompt Positive? Negative?
Did these changes result from the debriefing?	Prompt If so, how? If not, what did produce them?
Could anything be improved with either	

the process or survey content?	
Is there anything important we have not asked about or that you'd like to add?	

Appendix 5: Example inductive thematic interview summary (level 1)

Thematic Summary PSCL15

Page	Text	Coding: Preliminary theme/sub- themes	Notes
2	“They’ve [stakeholders] progressively become more involved. I would be honest and say that in the first instance when we started the national launch in October 14 we had a business plan that we still needed to deliver [...]. We proposed this and got support for it rather than listened in the first instance” later more locally driven.	Selecting safety topics	Contrast with other PSC's
2	Medicines optimisation: "I just wanted something in the first instance that got [region name] members in the room together" [...] “there was a real strong sense of wanting to find something that unified all our member organisations. Medicine’s is in all their work who wouldn’t want to improve their patient safety in terms of efficiency and effectiveness of medicines in what people are taking?”	PSC aims /selection criteria	
3	"It's amazing how some of them [PSCs] have set themselves up as quite autonomous" [...] “Ours is fully integrated and the health and implementation team adopted and includes patient safety collaboratives, there isn't a separate WorkStream”	PSC fully embedded in AHSN	
3	“the AHSN has wealth and industry as one, research and informatics as a second and the third is health and implementation which includes the PSC”.	PSC structure/ WorkStreams	
4	“We’ve got [...] to think about capability building so [...] skills in measurement, human factors, resilience, culture and safety [...], but then we ran a one year IHI breakthrough series collaborative for our member organisations and we had 9 teams complete the whole year. And when I say teams they were health economy teams.”	Implementation process/training	
4	“We had an expert group consider where were the opportunities for improvement in [region name] medicine’s safety and that was local, national and international experts that did	Infra-structure/ linking into pre-existing networks/collaboratin	

	<p>that. We commissioned the quality improvement group called HALO which is based at [place name] to be our partners to deliver this. Unlike some of the other AHSNs who didn't have good improvement sort of access in their footprints we're very fortunate we've got AQuA and HALO and [Region] Leadership Academy. So unlike some AHSNs we haven't set up ourselves as an improvement kind of body ourselves, it's already out there. We'd only end up competing with them which would be silly. It's about using the assets in the system so HALO were our partners on this."</p>	<p>g with other experts</p> <p>Comparison with other AHSNs</p>	
4	<p>"We did a launch and then we did 3 face to face learning sessions over the 1 year period and shared the learning between the teams and as I say out of the 9 teams there's probably about 3 maybe 3-4 which now have something that's ready to go at scale you know being mindful about sustainability and where they've made significant changes in either service specifications, workforce or models of care"</p>	<p>Implementation process/scale-up/impact</p>	
4 & 5	<p>"things have as a result changed and of course we capture the measurement throughout the whole programme. If I don't do myself a disservice we saw a 42% increase in the bundle of measures for medicines safety that they capture the data on over the year. [...] I have to be honest though, we did start at quite a low point [laughs] so it sounds like we've had great improvement but I think we started at something like 23% in the bundle of measures, but one of the things we said at the end if we had that overall driver statement that we wanted to make [city] the safest place to take medicine's and on the last day I said so do you think you know looking at the run charts etc. have we made [city] the safest place to take medicines? And the answer was no! But what we all agreed was we had made it A safer place to take medicines."</p>	<p>Impact/measurement</p>	
5	<p>"We were doing the ramping up of the PDSAs and sharing the learning as it happened."</p>	<p>Sharing best practice</p>	
5 & 6	<p>"We had patients on our expert panel. We had patients at EVERY learning event taking part in the presenting programme and every group had a patient rep in their team. One group took it so far she was so integrated in their</p>	<p>PPI/patient involvement/representation</p>	

	<p>team that she actually participated in the collection of data. She made some telephone calls / follow-up that we were doing about confidence of taking medicines post-discharge. She participated in that which was really good. So for some teams that was quite different. They hadn't always had full patient engagement in their groups so there was a lot of learning around that and we produced some tools for them in how best to support their patient reps and that wasn't a learning that we were expecting to see actually, but it did really help some of the teams."</p>	<p>Learning around patient engagement</p>	
6	<p>"What is interesting is the different range of maturity between all those organisations. Some are very driven by quality improvement say for example [place name], then [place name] are a Trust who have really invested heavily in LEAN methodology. [place name] have really invested in patient safety champions etc., so some were very skilled before they even came in" [for other member organisations it was new] "offering them the opportunity [...] if you think your weakness is measurement here's some modules in measurement. If you think resilience or understanding your culture for safety in your organisation is something you've never explored you can tap into this. So we didn't presume everybody could be in the collaborative and all came in as equals really. We made sure there was a range of other opportunities to help their developments."</p>	<p>Organisational "readiness"</p> <p>Differences between member organisations/ contrasting stages of development</p> <p>PSC as supportive/facilitative role to organisations new to QI</p>	
6 & 7	<p>"We've paid attention to Board developments as well, because you can send teams into these programmes, but unless the Board supports the approach and the methodologies etc, and their readiness to adopt some innovation for example it's got to be right through to the leadership. So they need a different kind of programme. A different focus and attention for them to understand what their role is in leading improvement in their organisations. So yes, a range of approaches definitely. [...] I think where you've got organisations that have got a maturity around improvement and innovation you can sense a permissiveness almost for their staff to be able to try things. To have a go and fail. Fail quickly and learn etc. There</p>	<p>Leadership support/board level support</p> <p>Comparisons between member organisations in terms of leadership/control/ organisational readiness</p>	<p>Adapting approach, needing Boards on board.</p>

	are a couple of organisations I'd say who've sent people to the group who I remember seeing one day that their team leader wasn't there and we asked them to say what's the 2 things you'll do when you go back next week or something and they couldn't say because their leader wasn't there! And so that was a really interesting thing to see that the level of command and control was tighter in some organisations than it is in those who were open-minded to learning I guess."	Impact of absent leadership/Over reliance on leader	
7	"Measurements, data we're still waiting for the central measurement unit to be procured. Well it's expected to be completed and clearly we haven't waited you know we've got on and done things, but actually its NHS data! Give me the data! As an AHSN you don't have access to organisational data. I need to have that overview. How else do we work out what the priorities are? And so I'd say that is to some extent hindering the PSC currently."	Implementation process/contextual factors hindering PSC activity Barriers to PSC implementation	
8	"There's quite a lot of data out there that's publically available, but then for me almost to aggregate and anonymise all those you know if it's big data then you kind of need that analyst sort of support to be able to do that. It isn't about pointing you know to the North or the East and saying there's an issue you know. You need to be able to present that back in a – you know in a story that says we are where we are, but there is an opportunity to improve."	Accessing data/using data to inform positive change	
8 & 9	"There's nobody saying we don't need to do any better. Everybody's actually – there's quite an open and honest culture. It was interesting – one of our – at one of the first meetings we had for the collaboratives one of the patient reps in the room actually became quite un-nerved by the openness that people had around what can go wrong, what does go wrong and he said "oh gosh we trust the NHS to be you know secure and now I'm wondering whether I need to you know be more concerned about some of these things?" So they've been very open and honest really."	Experience in practice/open and honest culture/honest about the deficiencies and areas for improvement in the system	Culture change in pockets, beginning to see more of an open and honest culture. Impact on patient perspective: more aware of the risks, impact on placing trust in the system
9	"When you ask people about how things could be better here [...] there's usually kind of 2 to 3 things they think we come along with and one's money. Give me more money	How PSC perceived by member organisations	According to

	<p>and I'll do it differently and the other one is I haven't the time and neither wash with me really at all [laughs]. We just need to use our time better and the money? Well £6.2M spent in [city] I don't think we need to spend anymore I think we just need to spend it on the right things. So I kind of always put those aside but I have to say to be honest to do something on a regional footprint, time does seem to becoming increasingly difficult and by that I mean actually just getting people away from their organisation to a central location for a day so how we work with that because that was clearly becoming an issue over the year. We're doing far more site visits in between all the learning events and actually going out to people and actually seeing they can report at a meeting, but actually seeing the difficulty they have to deliver change in the context of the setting that they're trying to do it in, has really, really been useful and so in the work we're commissioning going forward this year under the collaborative we have put that in so we had one programme of work called Advance Team Training for Patient Safety and teams come in and they work through a project that they want to do fully supported, capability building we absolutely put site visits in after each scheduled face-to-face meeting with them. The value just seems to be 1) from the learning but 2) not just always expecting people to come to you. Go to them. Yeah, so we're definitely taking that as a strong approach."</p>	<p>Perceived barriers to improvement within member organisations</p> <ul style="list-style-type: none"> - Time - Money <p>Time as a barrier to PSC activity/barrier to effective engagement</p> <p>Importance of site visits/able to witness contextual barriers to QI work</p>	<p>PSC lead: The need to spend time and money differently</p> <p>Challenges i.e. How to free up time to coordinate busy professionals</p>
9	<p>Not encountered blame culture "No, no I've not seen that at all. Maybe because they are a self-selecting group who choose to come and do these things (PSC activity). They have a very glass half full positive approach"</p>	<p>Blame culture</p>	
9 & 10	<p>"North-west ambulance came in on one of our projects and they were owning a whole problem themselves. They'd looked at the journey of an ambulance over the span of its shift, which I think was about 12 hours and they were concerned that their first break wasn't till about seven hours and the second break was about an hour later" [...] "If anything it wasn't a blame culture, they were owning too much of it [the problem]"</p>	<p>Example of people fully "owning" the problems e.g. ambulance service PSC lead helped them to reflect that there were a number of other systemic factors at play impacting their</p>	

	themselves"	ability to take more regular much-needed breaks.	
10	"Reflecting on the site visits, all I saw was a pride and people were so pleased that we'd gone to them, keen to show you where they worked and how they worked [...] It was really heartening"	PSC experience RE site visits	
11	"A couple of teams have found it more difficult" PSC lead identified more struggling organisations. "We haven't taken any action, we're just reflecting and thinking how do we help those organisations move into the space where coming into a one-year collaborative for example, is do-able and possible because they've got the right infrastructure"	Areas where problematic to implement PSC activity The need to tackle more "systemic" barriers. Difficulties freeing up time to engage.	
11	"for example at our CCG Primary Care they don't have the infrastructure that the acute providers have. So they don't have organisational development teams who take a strong leadership role in this area. So there's a bit of a disparity between primary and acute and their provision really that I think maybe that needs some attention."	Comparison acute and primary care sector	
12	"There is a range and there are a couple that do struggle [...] they have no mandate to work with us and we've got to make a compelling offer that they want to take up and that's where one size doesn't fit all and we may have to tailor something differently to those organisations. And that's not about blame. That's – there'll always be a range won't there and some of that end of the range will need something different."	Engaging organisations	
12	"It is early days [...] It's really only 18 months if you take it from the national launch" [...] "I think that it's a journey [...] even the best organisations that we have in the patch, there is always room for improvement, so I would see a success is that [Beta] work together and that the learning is shared, the learning is rapid and we as a region improve and improve and improve"	Measurement/legacy	
12 & 13	"We need to get more agile as PSCs to understanding what we're doing in each of our organisations and sharing the learning wider than our regions" [...] "That's a mark of success, that people have adopted and spread things that have grown in [city]"	Sharing best practice	

13	<p>“from a capability building point of view we do evaluate obviously the modules that are offered or the short project span. We use the Kirkpatrick evaluation model”</p> <p>“we just need to understand the impact better and to follow the impact whether on an individual or team basis or an organisation basis.”</p>	Evaluation/ understanding impact	Also using AQuA to help with measurements see page 13
14	<p>“I guess you articulate your objectives and your ambitions and aims and self-check against that. We have on this occasion as patient safety leads in this first quarter now started to map that out in a shared approach because we were all using different ways I guess of demonstrating what we were doing. So we’ve kind of drawn from the logic model trying to articulate in those sort of 6 spaces of the logic model where we’re delivering what we’re delivering and what the impact might be.”</p>	<p>How PSC is evaluating itself.</p> <p>The logic model</p> <p>Collaborating with other PSC leads</p>	
14	<p>“We’ve now started to have a development session prior to what is the kind of operational PSCs meeting. So we have a dedicated slot pre-meeting to focussing on a topic. So that’s a space where we can do a lot more sharing. We shared simple things like plans on a page and dot matrixes of where we’re working so we can [...] recognise where someone’s doing something similar. [...] just do that old fashioned thing and pick up the phone but we have now developed and brought forward a number of cluster groups.”</p>	PSC lead meetings/clusters	
15	<p>Clusters were formed through sharing best practice and recognising that e.g. a number were already working on discharges: "We just organised ourselves and these are strong people these patient safety leads. We don't wait to get given permission, so the cluster groups just emerged. People organised themselves. You know leads, they are natural leaders really who were taking those groups forward."</p> <p>"Some of them are beginning to be so active that they may need secretarial support etc these can be really effective models you know improvement labs for want of a better word, that have got themselves organised already"</p>	Clusters how formed/becoming more organised/professionalised	
15	Plan on a page: organised by "the Chair of the group"	‘Plan on a page’ developed as ‘marketing tool’ to	For patient safety congress planned for

		explain AHSN and PSC	July 2016
16	“We haven’t any money yet which is causing difficulties certainly here for us to do that planning for what the activities this year will be. All the noise and the mood music is patient safety collaborative money will come out of NHSI which is where it reports to Mike Durkin’s team. That money will be sent to NHS England and NHS England will then send it to the AHSN but we’re almost at the end of quarter one and we have no money yet.”	Finances/ barriers to PSC activity	Funding flow: DH ↓ NHS I ↓ NHS England ↓ AHSN
17	“So if you think about commissioning the medicines safety collaborative – the one year collaborative that was £210,000.00 to deliver over a year. So I can’t start anything of that volume and size until I know about the money so that’s a real issue. Some of the PSCs – so the share from NHS Improvement is equal for all AHSNs but some of your AHSN finances have a small amount of patient safety money in as well. Now that’s because AHSNs are given different amounts of money depending on whether they were Phase 1 or Phase 2 and depending on their size means there will be some variation in what comes through from core budget.”	Delay in accessing funds/barrier to PSC activity	Comparison with other PSCs: funding is equal from NHS improvement "but from the core AHSN budget, that's where there'll be subtle differences"
17	“early adopted AHSNs there was like a Phase 1 and a Phase 2 and some got a lot more money in Phase 1 to get them off the ground quickly and then in the second year they got less and the Phase 2 people got more in the second year so it’s quite complicated [laughs].”	Funding distribution for PSCs	
18	“approaches we may take this year is offering teams an opportunity to join an improvement science for patient safety group and to deliver this it would normally cost £15,000.00 per team. So what we might do is put that out as a bursary so people could see I’m getting that free, the AHSN are going to pay it and they’re paying £50,000.00” [...] “grants, bursaries [to] broker opportunities so we’re working with one of our CCGs who want to do some identification of atrial fibulation using a new innovation that they’ve had to purchase so we wrote a bid with them for the access to innovation fund”	Grants/bursaries New approach to team learning and engagement	
19	“It’s a bit of a bold and brave decision but we	Delaying activity	

	<p>have not pressed the go on anything until we get that money.”</p> <p>“Some of them [other PSCs] have gone at risk and gone ahead. So we’ve still got activities. We’ve got evaluation and publication work going on. We’ve got scoping exercises being undertaken. But as I say, as to triggering something with a high finance factor value that’s not going to be done until we know we’ve got the money in the bank!”</p>	<p>until funds are secured/contrast with other PSCs</p>	
19	<p>“We would just shrink our operational – our business plan for the year! That’s because of that integral function with the AHSN. I would look at the portfolio of work and I’d have to reduce what our ambitions and aims were.”</p> <p>“We’re pretty under-resourced and we’re pretty under-powered, but it would just shrink us even further”</p>	<p>Embedded in pre-existing AHSN/ Benefits: more protected if PSC funding stopped</p>	
19 & 20	<p>“Our PSC work, I see that as an umbrella which also includes Signup to Safety and the Q initiative" [...] "When you bring those three together, that's where I feel there's been more power and more movement and a sense of change"</p>	<p>Culture change comparison across PSCs</p>	<p>All three announced by Jeremy Hunt in response to the Berwick report</p>
20 & 21	<p>Q initiative: 10 places for each region "we've surfaced people across the system who obviously are part of this wider, national network, but what does that mean locally as a network of improvement leaders? And what return to [Beta] does that give us and how do the AHSN and the patient safety collaborative in particular, support those to deliver improvement in the wider footprint than just their organisation" [...] “This is where you get the connectivity across the system that actually means [Beta] works together to move us forwards. It's very exciting I think" Recruitment to Q initiative "it's limitless now"</p>	<p>National networks/ impact on local regional structures/ Q initiative</p>	<p>The AHSNs were involved in the recruitment to Q initiative in their region: “the glue in the area was the AHSN really [...] The Health Foundation and NHS England offer opportunities and a national view, but locally it’s the AHSN that’s the glue”</p>
21	<p>All organisations in [Beta] have signed up "apart from six CCGs" Learning events were held to help this process: "now we’re looking at the spread and so care homes for example would perhaps be an opportunity to widen that cohort"</p>	<p>Sign up to Safety</p>	

	"On Signup to Safety, it was a little bit difficult for them [CCG's] because the language used is you know very sort of acute trust focused"		
22	"One thing that we mull over a lot really at the patient safety leads meetings is the metrics and demonstrating impact and some of it's not a number crunching thing. Some of it is a cultural shift as opposed to you know reducing mortality rates. There needs to be space for both really. So I think we are struggling to understand or we're evolving our thinking really around how we might best demonstrate that. You know we don't want to be a hostage to fortunes but you know there is that grand ambition of reaching 5000 lives saved. [...] there isn't necessarily absolute clear lines to: "I did this; we made it better" because the system's learning and evolving all the time. Hopefully there's a correlation but yeah, how best to demonstrate that I think is a challenge for them at the moment."	Measurement and impact current stage in process	
22 & 23	"it's just one of those tectonic plate shifts isn't it? It's always moving really" [...] "So really it's just keeping up with those moving plates to see can we be the thread that no matter what changes we make, patient safety shouldn't be the thing that suffers or loses the momentum."	Organisational changes/churn in the system/impact on PSCs/ PSCs role	
23	"We have had a change of Managing Director – just one change. Our first Managing Director had been in a year and so our second's been with us now 15 – 16 months but hasn't really had I would say any impact or change in our vision and approach. So that's not been disruptive. We've been a fairly stable organisation all the way through to be honest. There's not much turnover in our workforce."	Staff turnover/changes in leadership/impact	Contrasts with other PSCs eg East of England
24	"I think we're just starting to pay more attention to that now which is probably reasonable in the journey we've been on" "We made a commitment that we will put a call out to each patient safety lead in each patient safety collaborative and in a way very similar to the way the AHSNs did last year to just name the top 2/3 things that they think's ready for adoption wider than the footprint that they have." [...]where there [is] enough information, enough change and enough	Culture change Adoption and spread	

	improvement to say we shouldn't wait any longer we should all be going with this now [...] let's tell each other what's ready to share. Let's give the evidence. Let's make the recommendations and then let's take something to scale."		
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Appendix 6: SCORE survey questionnaire

SCORE - Safety, Communication, Operational Reliability, and Engagement.						
Please answer the following items with respect to your specific unit or clinical area.						
1. In this work setting, the learning environment (ability to learn and improve)...						
	Disagree Strongly	Disagree Slightly	Neutral	Agree Slightly	Agree Strongly	Not Applicable
...is observable by the way we treat each other with respect.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...utilizes input/suggestions from the people that work here.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...integrates lessons learned from other work settings.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...effectively fixes defects to improve the quality of what we do.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...allows us to gain important insights into what we do well.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...allows us to pause and reflect on what we do well.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...is protected by our local management.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...is valued by the people that work here.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. In this work setting, local management...						
	Disagree Strongly	Disagree Slightly	Neutral	Agree Slightly	Agree Strongly	Not Applicable
...is available at predictable times.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...regularly makes time to provide positive feedback to me about how I am doing.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...regularly makes time to pause and reflect with me about my work.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...provides frequent feedback about my performance.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...provides useful feedback about my performance.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...provides meaningful feedback to people about their performance.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...communicates their expectations to me about my performance.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. In this work setting, people are...						
	Disagree Strongly	Disagree Slightly	Neutral	Agree Slightly	Agree Strongly	Not Applicable
...affected by events here in an emotionally unhealthy way.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...burned out from their work.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...exhausted from their work.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...frustrated by their jobs.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
...working too hard on their jobs.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

SCORE - Safety, Communication, Operational Reliability, and Engagement.

4. Communication and Safety Norms

	Disagree Strongly	Disagree Slightly	Neutral	Agree Slightly	Agree Strongly	Not Applicable
Disagreements in this work setting are appropriately resolved (i.e., not who is right but what is best for the patient).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In this work setting, it is difficult to speak up if I perceive a problem with patient care.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It is easy for personnel here to ask questions when there is something that they do not understand.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The people here from different disciplines/backgrounds work together as a well-coordinated team.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dealing with difficult colleagues is consistently a challenging part of my job.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My suggestions about quality would be acted upon if I expressed them to management.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Errors are handled appropriately in this work setting.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I receive appropriate feedback about my performance.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The culture in this work setting makes it easy to learn from the errors of others.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I would feel safe being treated here as a patient.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In this work setting, it is difficult to discuss errors.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Communication breakdowns are common in this work setting.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Communication breakdowns are common when this work setting interacts with other work settings.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The values of facility leadership are the same values that people in this work-setting think are important.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In the past month, my activities have been restricted due to illness.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
In the past month, I have missed work (for any reason).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

5. During the past week, how often did this occur?

	Rarely or none of the time (less than 1 day)	Some or a little of the time (1-2 days)	Occasionally or a moderate amount of time (3-4 days)	All of the time (5-7 days)	Not Applicable
Skipped a meal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Ate a poorly balanced meal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Worked through a day/shift without any breaks	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Arrived home late from work	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Had difficulty sleeping	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Slept less than 5 hours in a night	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Changed personal/family plans because of work	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

SCORE - Safety, Communication, Operational Reliability, and Engagement.

6. Does your clinical area use patient safety Leadership Rounds to discuss with senior leaders any issues that could harm patients, reduce reliability, or undermine the safe delivery of care?

- Yes
- No
- Not Sure

7. How often do you participate in these patient safety Leadership Rounds?

- Never
- Weekly
- Monthly
- Quarterly
- Yearly
- Not sure

8. Do you receive feedback about issues that were discussed as a result of patient safety Leadership Rounds?

- Yes
- No
- Not Sure

9. Have you completed this survey before?

- Yes
- No
- Not Sure

SCORE - Safety, Communication, Operational Reliability, and Engagement.

13. If you are a physician, what is your specialty?

- | | |
|---|--|
| <input type="radio"/> Anesthesiologist | <input type="radio"/> Oncologist |
| <input type="radio"/> Cardiologist | <input type="radio"/> Ophthalmologist |
| <input type="radio"/> Emergency Medicine | <input type="radio"/> Otolaryngologist |
| <input type="radio"/> Endocrinologist | <input type="radio"/> Pathologist |
| <input type="radio"/> Gastroenterologist | <input type="radio"/> Pediatrician |
| <input type="radio"/> Hematologist | <input type="radio"/> Perinatologist |
| <input type="radio"/> Hematologist | <input type="radio"/> Podiatrist |
| <input type="radio"/> Hospitalist | <input type="radio"/> Psychiatrist |
| <input type="radio"/> Infectious Disease Specialist | <input type="radio"/> Pulmonologist |
| <input type="radio"/> Intensivist | <input type="radio"/> Radiologist |
| <input type="radio"/> Internist | <input type="radio"/> Rheumatologist |
| <input type="radio"/> Neonatologist | <input type="radio"/> Sports Medicine |
| <input type="radio"/> Nephrologist | <input type="radio"/> Surgeon |
| <input type="radio"/> Neurologist | <input type="radio"/> Urologist |
| <input type="radio"/> Obstetrician | |

Other (please specify)

14. Years in Speciality

- Less than 6 months
- 6 to 11 months
- 1 to 2 years
- 3 to 4 years
- 5 to 10 years
- 11 to 20 years
- 21 years or more

15. Do you have any other comments, questions, or concerns?

Appendix 7: SCORE survey results

Tables 39 to 45 below show summaries of first and second survey person-level domain scores from each unit, for each of the seven domains of the SCORE survey. On the whole, there was little evidence of a difference in participants' domain scores between first and second SCORE surveys. In one of the six units (general practice F) there was some evidence of a difference in scores on the local leadership and burnout climate domains ($p = 0.01$ for each, Tables 40 and 41). On average, local leadership scores were higher, and burnout climate scores were lower in the second survey, compared to the first.

Table 39: Summary statistics for person-level scores on the learning environment domain of the SCORE survey.

LEARNING ENVIRONMENT DOMAIN	First survey		Second survey		p-value*
	Number completed (% response rate)	Mean (SD) score	Number completed (% response rate)	Mean (SD) score	
Hospital A: ED	111 (58)	73.6 (20.4)	150 (66)	71.2 (22.2)	0.4
Hospital A: MAU	83 (58)	66.8 (22.5)	96 (61)	70.0 (24.0)	0.3
General practice D	57 (62)	67.8 (21.9)	67 (61)	67.9 (20.3)	0.99
General practice E	13 (100)	83.4 (13.4)	9 (69)	83.3 (15.5)	0.99
General practice F	36 (82)	69.6 (20.9)	29 (94)	75.7 (16.5)	0.2
Pharmacy G	13 (72)	78.2 (15.5)	13 (81)	85.6 (8.8)	0.2

*From two sample t test.

Table 40: Summary statistics for person-level scores on the local leadership domain of the SCORE survey.

LOCAL	First survey	Second survey	p-
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LEADERSHIP DOMAIN	Number completed (% response rate)	Mean (SD) score	Number completed (% response rate)	Mean (SD) score	value*
Hospital A: ED	110 (57)	57.5 (26.3)	150 (66)	52.3 (28.8)	0.1
Hospital A: MAU	83 (58)	59.4 (25.9)	95 (62)	59.7 (30.4)	0.9
General practice D	56 (61)	54.1 (27.9)	69 (63)	62.5 (26.4)	0.1
General practice E	13 (100)	65.6 (28.7)	9 (69)	78.6 (21.2)	0.2
General practice F	36 (82)	45.2 (26.3)	28 (90)	63.6 (31.2)	0.01
Pharmacy G	13 (72)	87.4 (16.2)	13 (81)	74.5 (23.4)	0.1

*From two sample t test.

Table 41: Summary statistics for person-level scores on the burnout climate domain of the SCORE survey.

BURNOUT CLIMATE DOMAIN	First survey		Second survey		p-value*
	Number completed (% response rate)	Mean (SD) score	Number completed (% response rate)	Mean (SD) score	
Hospital A: ED	113 (59)	69.9 (21.7)	151 (67)	73.9 (20.3)	0.1
Hospital A: MAU	84 (58)	72.7 (19.4)	96 (61)	72.1 (20.9)	0.8
General practice D	59 (64)	70.8 (19.2)	69 (63)	66.0 (20.7)	0.2
General practice E	13 (100)	50.6 (26.3)	9 (69)	58.9 (21.0)	0.4
General practice F	36 (82)	67.1 (21.1)	29 (94)	52.2 (23.9)	0.01*
Pharmacy G	13 (72)	67.3 (16.2)	13 (81)	57.3 (19.1)	0.2

*From two sample t test.

Table 42: Summary statistics for person-level scores on the personal burnout domain of the SCORE survey.

PERSONAL BURNOUT DOMAIN	First survey		Second survey		p- value*
	Number completed (% response rate)	Mean (SD) score	Number completed (% response rate)	Mean (SD) score	
Hospital A: ED	113 (59)	58.3 (26.0)	151 (67)	57.5 (26.7)	0.8
Hospital A: MAU	85 (59)	59.2 (24.5)	97 (62)	56.0 (30.1)	0.4
General practice D	59 (64)	53.3 (28.9)	69 (63)	52.0 (26.6)	0.8
General practice E	13 (100)	40.6 (31.4)	9 (69)	47.8 (34.9)	0.6
General practice F	36 (82)	44.7 (29.8)	29 (94)	40.6 (29.7)	0.6
Pharmacy G	13 (72)	45.8 (26.6)	13 (81)	43.8 (22.4)	0.8

*From two sample t test.

Table 43: Summary statistics for person-level scores on the teamwork domain of the SCORE survey.

TEAMWORK DOMAIN	First survey		Second survey		p- value*
	Number completed (% response rate)	Mean (SD) score	Number completed (% response rate)	Mean (SD) score	
Hospital A: ED	113 (59)	66.0 (16.3)	150 (66)	63.4 (16.4)	0.2
Hospital A: MAU	84 (58)	63.9 (19.1)	97 (62)	65.1 (20.5)	0.7
General practice D	58 (63)	65.8 (17.8)	69 (63)	62.8 (20.9)	0.4
General practice E	13 (100)	83.0 (17.6)	9 (69)	85.8 (9.9)	0.6
General practice F	35 (80)	67.2 (17.5)	29 (94)	68.2 (15.7)	0.8
Pharmacy G	13 (72)	59.9 (17.5)	13 (81)	73.2 (15.5)	0.05

*From two sample t test.

Table 44: Summary statistics for person-level scores on the safety climate domain of the SCORE survey.

SAFETY CLIMATE DOMAIN	First survey		Second survey		P-value*
	Number completed (% response rate)	Mean (SD) score	Number completed (% response rate)	Mean (SD) score	
Hospital A: ED	113 (59)	66.4 (17.8)	151 (67)	64.5 (18.3)	0.4
Hospital A: MAU	84 (58)	62.8 (17.3)	97 (62)	67.6 (20.8)	0.09
General practice D	58 (63)	67.2 (21.1)	69 (63)	66.0 (19.0)	0.7
General practice E	13 (100)	84.1 (16.7)	9 (69)	93.7 (7.3)	0.08
General practice F	36 (82)	66.9 (18.9)	29 (94)	75.6 (21.1)	0.09
Pharmacy G	13 (72)	76.4 (17.8)	13 (81)	81.3 (13.1)	0.4

*From two sample t test.

Table 45: Summary statistics for person-level scores on the work-life balance domain of the SCORE survey.

WORK-LIFE BALANCE DOMAIN	First survey		Second survey		P-value*
	Number completed (% response rate)	Mean (SD) score	Number completed (% response rate)	Mean (SD) score	
Hospital A: ED	112 (58)	2.1 (0.7)	149 (66)	2.1 (0.7)	0.6
Hospital A: MAU	82 (57)	2.2 (0.7)	95 (61)	2.2 (0.9)	0.6
General practice D	57 (62)	2.0 (0.8)	69 (63)	2.0 (0.7)	0.6
General practice E	13 (100)	2.1 (0.9)	9 (69)	2.0 (0.9)	0.9
General practice F	36 (82)	1.7 (0.5)	27 (87)	1.5 (0.5)	0.1
Pharmacy G	13 (72)	1.8 (0.5)	13 (81)	1.7 (0.6)	0.6

*From two sample t test.