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What influences improvement processes in healthcare?

A rapid evidence review

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Preface

RAND Europe was commissioned by The Healthcare Improvement Studies (THIS) Institute at the University of Cambridge to conduct a rapid review of academic reviews and grey literature covering the influences on improvement processes in healthcare, with the aim of identifying themes and issues relevant to future research in this space.

The report is structured as follows:

- Section 1 provides the background and context to this study and outlines its aims.
- Section 2 briefly describes the study methodology (with further information provided in Annex A).
- Section 3 describes the profile of the reviewed literature.
- Section 4 presents key lessons learnt from the rapid evidence assessment, as they relate to the nature of and influences on improvement processes.
- Section 5 reflects on the learning and discusses implications for future research.
- Annex A elaborates on the study design and methods.
- Annex B provides a summary table of the reviewed publications.

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Summary

Background and context

Poor-quality healthcare has significant health-related and economic consequences for patients and the wider health system [1, 2]. Although many healthcare organisations are now engaging with improvement activity, the challenges of improving care quality remain considerable [3, 4].

The field of improvement research has significant potential to contribute to a better understanding of how improvements in patient care can be achieved and sustained. It is an interdisciplinary academic field, and although the literature on quality improvement is broad and diverse, it is also fragmented. Many studies look at individual improvement models, approaches and interventions, and focus on understanding what works in relation to specific improvement aims. However, there is less consolidated and curated evidence on learning about the process of doing improvement and from the experiences of those involved. A better understanding of the nature of improvement processes and influences on them could inform both ongoing and future practice, by drawing out practical insights such as those related to the challenges faced by improvers and the strategies used to overcome them. Against this context, THIS Institute commissioned RAND Europe to conduct a rapid scoping exercise to draw out initial learning from a subset of the literature, with a view to also informing potential themes to explore in future research.

Research aims and methods

The scoping research conducted for this report aimed to identify and share learning about the influences on quality improvement processes and to identify potential themes and issues to explore in future research in this space. Although we adopted a relatively broad view of quality improvement, the scope of our work excluded improvement efforts related to productivity or broader efforts to improve the social determinants of health. We built on the definition of quality improvement proposed by Batalden et al. [5], referring to quality improvement as ‘the combined and unceasing efforts of everyone – healthcare professionals, patients and their families, researchers, payers, planners and educators – to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning).’ We see this definition as compatible with a view of safety and patient experience as dimensions of quality of care [6]. Within this, we considered ‘changes’ to include not only changes in management and governance, but also in behaviours, cultures and relationships. The study was primarily conducted using a rapid evidence assessment (REA) approach (further detail is available in Section 2 and Annex A).

There are some caveats to bear in mind when interpreting the findings. For example, the research focused on academic literature from reviews and systematic reviews as well as selected grey literature reports, and it is possible that primary studies might contain more detail on the processes of doing improvement.

In addition, the quality improvement field is broad and lacks a clear classification system for what constitutes quality improvement, which can present challenges in establishing inclusion and exclusion criteria for a study of this nature. Together with THIS Institute, RAND Europe adopted an inclusive approach to decide on the criteria for and final list of included publications, but we cannot claim to have covered all relevant reviews on the topic. Related to this, our methods dictated the focus of our findings and the way that they are presented. As we conducted our analysis, the plurality of literature on quality improvement became all the more apparent: the literature varied widely in terms of what it understood to fall within the scope of quality improvement activity. It is beyond the scope and remit of this work to explore issues of boundaries and classification in the quality improvement field or to critically appraise its meaning to different stakeholder communities. We included literature that was aligned with the general approach to defining the concept, as we have outlined above. Whereas much of the literature covered explicitly referred to quality improvement, some of the papers we identified through our search adopted a broad view on quality within the wider concept of improvement, and use the term improvement as part of discussions that are relevant to quality. We use both the terms ‘improvement’ and ‘quality improvement’ in this report.

Despite these caveats (and others that are elaborated in Section 2.2) this scoping exercise aims to offer a rounded account of key lessons about influences on quality improvement processes across a broad range of contexts. It also identifies a range of themes, concepts and ideas to build on in future research.

Profile of the reviewed literature

Key features of the body of literature included in this review are summarised below (further detail is available in Section 3 of the report):

- *Types of publications and sources of evidence.* We identified 54 information sources that were eligible for inclusion, comprising 38 academic publications and 16 grey literature publications.
- *Geographical context.* The majority of the literature drew on evidence from international contexts and provided learning of international relevance. Some academic and grey literature publications applied learning from an international evidence base or from specific countries to a particular country context that was of interest to the authors. The majority of the selected grey literature publications focused on UK-relevant learning (drawing on insights from either international or UK evidence).
- *Clinical and disease areas.* The vast majority of sources had no explicit focus on any particular clinical and/or disease area (although they do refer to different clinical areas in their underlying evidence base). Only eight academic reviews had a specific disease or clinical area focus.
- *Healthcare settings.* Most of the literature included evidence from a range of healthcare settings and did not explicitly focus on a specific part of the healthcare system. Approximately one third of the academic reviews did have a specific focus, predominantly secondary and/or tertiary care settings.

- *The nature of improvement activities covered.* The reviewed literature varied widely in terms of the types of activities it saw as falling within the scope of quality improvement. Some examples of improvement approaches and activities included Six Sigma approaches, Lean, Business Process Reengineering, Plan-Do-Study-Act, clinical audits and feedback, quality improvement collaboratives and peer-learning communities, various training and education interventions, patient engagement and feedback, as well as approaches to improve patient flow and hospital accreditation programmes that were directly related to quality improvement aims in the reviewed publications. Some publications had a primary interest in contextual factors influencing improvement processes and/or outcomes (e.g. leadership, skills, resources), and not in any specific quality improvement approach or intervention.
- *Aims.* An emphasis on learning about or from the process of improvement was an explicitly stated aim in half of the reviewed publications. In just over a third, the desire to learn about or from improvement processes was a more implicit aim. Often, these publications aimed to identify influences that contributed to the *success of an improvement effort,* but it was not clear from the way in which the reviews reported their conclusions whether or not they drew on qualitative learning about the *process of carrying out improvement* or whether they arrived at their conclusions in some other way. For example, some of the reviews we analysed were informed by source studies which seemed to focus more on analysing outcomes data to draw out correlations between the outcomes of quality improvement efforts and the nature of implemented interventions, rather than studying the process of improvement. For seven publications, the papers' objectives did not include any explicit or implicit reference to learning from improvement processes, but the papers nonetheless reported on such learning.
- *Stakeholders involved.* The vast majority of the literature discussed stakeholder involvement in the context of implementing interventions, with a few publications also looking at stakeholder roles in intervention design or assessment and evaluation. The literature considered the involvement of diverse healthcare professionals (e.g. nurses, consultants, junior doctors, general practitioners, pharmacists) across different levels and hierarchies in organisations, although there was substantial emphasis on the role of senior leadership (including clinical and non-clinical leaders and managers) in setting direction, mobilising engagement and steering quality improvement efforts. Some publications also looked at how external stakeholders (such as commissioners and suppliers of national clinical audits) contributed to the design or implementation of improvement interventions; this tended to be through various implementation support functions or in evaluation and assessment roles. Patient engagement was often highlighted and acknowledged as important, although only a few publications discussed the active involvement of patients and/or their carers and families in the design or implementation of improvement efforts. It is important to note that the reviewed literature was not always clear on whose perspectives it reflected when reporting on lessons learnt (e.g. whether it was the perspective of improvers themselves or of academics or evaluators).

Influences affecting the implementation of improvement processes in healthcare: key learning points

This rapid evidence assessment has systematised learning on some of the influences affecting the implementation of improvement efforts. Based on the reviewed literature, the key influences relate to:

- Leadership.
- Relationships and interactions that support an improvement culture.
- Skills and competencies.
- Using data for improvement purposes.
- Patient and public involvement, engagement and participation.
- Working as an interconnected system of individuals and organisations, influenced by internal and external contexts.

The rapid evidence review has attempted to go beyond identifying the high-level, general influences only, to explain what specific aspects of the influencing factors outlined above are particularly important for quality improvement. Boxes 1 to 6 summarise the key insights gained and reflect the issues that appear to receive the most attention in the reviewed literature.

Box 1: What matters: key messages and insights related to leadership support of improvement efforts

- Involving different types of leaders and improvement champions: (i) clinical and managerial; (ii) from different specialties in areas of healthcare that depend on multi-professional teams; (iii) from different levels in an organisational hierarchy; (iv) experienced in managing complex patient conditions; (v) from different components of a healthcare system (e.g. primary, acute, community care); (vi) from outside provider organisations, such as in policy, funding and regulator communities.
- Clearly articulated roles and responsibilities for leaders (as well as for those who are being led).
- A long-term view on improvement (with milestones built in), supported by consistent and coherent strategies.
- Integrating improvement activity into wider organisational strategies, and to the extent possible, into everyday individual roles and responsibilities.
- Realistic goal-setting that balances ambition with what is feasible.
- Sustained and continuous engagement from leaders and managers over time (and not just at set- up or completion phases).
- Staff trust in the values, vision and expertise of leadership.
- A compelling narrative from leadership on the value of improvement activity and on how and why leadership will support it.
- Ensuring that practical enabling mechanisms for staff to engage with improvement activity are built into the design of improvement initiatives (e.g. freeing-up clinical, managerial and administrative staff time, financial resources, IT infrastructure, facilities and equipment).
- Variation and adaptation in leadership styles (ranging from those rooted firmly in social relationships to more hierarchical leadership approaches) to ensure appropriateness to specific social contexts, improvement interventions and points in time.

Box 2: What matters: key messages and insights related to relationships and interactions that support an improvement culture

- Relationship-building that can establish and communicate the alignment of the improvement intervention with the values and perceived roles and responsibilities of implementers.
- Creating both personal and collective benefits from collaborative improvement efforts, in support of sustainable improvement cultures.
- Environments that support open discussion and transparency about improvement needs, opportunities and challenges (for collective sense-making and to build improvement cultures).
- Environments where frequent communications and regular interactions can take place between those involved in improvement activity, in order to sustain engagement and buy-in, support collective learning and reflection and inform ongoing actions (e.g. through meetings, regular newsletters).
- Relationships that embrace feedback as a way of supporting continual learning.
- Cultures that value diversity, voluntary participation and inclusiveness (which may be facilitated through structures such as collaboratives, clinical communities and networks, and experience-based co-design initiatives).
- Exchanging learning about the experience of doing improvement between different organisations and creating a shared understanding of the benefits that can accrue, the challenges that can be experienced along the way and how they might be addressed.
- A clear communication and dissemination strategy related to improvement efforts that considers what to communicate, to whom, how and when.

Box 3: What matters: key messages and insights related to skills and competencies for improvement

- Appropriately resourced staff training in requisite skills and knowledge, including training for both those at the coalface of improvement, and leadership and senior executives (albeit to varying degrees and in potentially different ways).
- Understanding the types of skills that need to be built to ensure that appropriate training is pursued (i.e. skills gaps are not always easy to identify and the skills needed for effective quality improvement span technical and social skills).
- Potential integration of educational components into improvement intervention design and implementation (e.g. through workshops, lectures, guidelines and protocols, simulations, scenarios, role play, experiential learning, feedback and online materials).
- Reinforcing and/or refreshing training through time (e.g. through on-the-job coaching).

Box 4: What matters: key messages and insights related to the use of data for improvement purposes

- Data serves multiple purposes in an improving healthcare system: data can help identify improvement needs, inform the design of improvement interventions and implementation strategies, and support monitoring and evaluation activity.
- Some improvement approaches (e.g. clinical audits) depend on data availability as a core enabler of improvement activity.
- Good evaluation is central to improvement, but is not possible without access to accurate and relevant data on the quality of care.
- Staff are not always aware of what data exists and how it can be accessed. Leadership has an important role to play in (formally and informally) raising awareness about access to data and about the implications of data use for improvement opportunities and activities.
- Organisational culture and staff attitudes towards data and evidence influence the extent to which they are used in improvement. This includes whether staff believe that data can help them improve and succeed; see data as relevant, meaningful and valid in their context; trust data quality and accuracy; and see the source of the data as credible.
- The effectiveness of data in guiding improvement activity is also influenced by when it is provided, to whom and how. Feedback must be timely in order for it to have traction. Data needs to be presented, interpreted and communicated in user-friendly and engaging ways tailored to the purpose and audience: there is no one-size-fits-all way of communicating findings.
- Engagement with data needs to be ‘kept alive’ throughout an ongoing improvement initiative to support implementation, and to document and reflect on progress (e.g. as part of meetings, training, newsletters or emails).
- Tools and guidance can help with data gathering, analysis and interpretation for improvement purposes.
- Quality improvement that is driven by access to and use of data needs to secure a supportive IT infrastructure and technical support in resource planning.

Box 5: What matters: key messages and insights related to patient and public involvement, engagement and participation in improving healthcare quality

- Patients, carers and members of the public can contribute to improvement in diverse ways – in patient and public involvement roles (e.g. actively contributing to and advising on initiative design, implementation or evaluation and coproducing the effort); in patient engagement roles (where information and knowledge about improvement efforts is provided and disseminated to patients); or as participants in the delivery of an improvement study or improvement initiative.

- Enabling meaningful contributions from patients and the public requires clear communication about when and how service users can add value to improvement efforts; clear roles and responsibilities, feedback and ways of recognising contributions are also important.

- Involving patients and/or carers early in the process of establishing an improvement intervention and supporting informal and frequent interactions can help build and nurture relationships of trust, and can support effective involvement and engagement.

- A series of practical issues need to be considered in the design of patient and public involvement, engagement and participation strategies (e.g. health literacy, language barriers, costs of travel to engagement events, general resourcing).

- The approaches used to enable patients and the public to contribute need to be carefully thought through to ensure that they are feasible and engaging.

- Patient and public involvement can have both positive and unintended negative consequences (the latter potentially related to instances of tokenistic practice and when patient and public involvement is not carefully considered or relevant). Better evaluation evidence is needed on both patient and public involvement (PPI) processes and outcomes relating to improvement in order to learn about what works best, when and how.

Box 6: What matters: key messages and insights related to the importance of working as an interconnected system, influenced by the internal and external context

- Taking account of local histories and local contexts when planning for future improvement activities can enable more effective intervention design and implementation and can support efforts to build adaptive capacities into an intervention.
- Interaction between different components of the healthcare system (primary, acute, community and social care) is sometimes needed for the effective implementation of quality improvement efforts, for example when the clinical conditions and quality improvement issues that are being tackled are relevant and depend on the actions of different organisations and take place in different components of the healthcare system.
- Factors internal to an organisation's management and governance approach (e.g. clear goals for improvement, enabling resources and infrastructure, inspiring leadership) and in the external context (e.g. policy mandates, payment regimes, reporting structures in the health system) can influence how committed clinicians are to quality improvement.
- Building in sustained support for implementing quality improvement interventions over time matters for success: components that reinforce specific skills or practices over time in a given context can help (e.g. peer-based support, on the job coaching, feedback, reward and recognition).
- Interventions that seem sensible in principle can fail if implementation criteria and requirements are not carefully thought through prior to roll out.
- The evidence base on the impact of having previous experience of doing improvement on the ability to build and nurture improvement cultures is inconclusive.
- Critical mass is important for a thriving and sustainable improvement culture, but what constitutes critical mass and how it can be achieved merits further research.

Implications for future research

We offer some reflections here on the insights gained from the rapid evidence review, in the context of their implications for further research. In particular, we consider the need for research that focuses on understanding how the challenges to implementing quality improvement and ensuring a supportive environment can be addressed in practice. We consider the need for research that digs deeper into the interactions between different influences on improvement efforts and the need for more contextualised learning. We discuss how such learning could be of practical value for those designing, implementing and evaluating quality improvement efforts and how it could contribute to the field of improvement research. We also highlight the need for further research on the unintended consequences of quality improvement efforts. Finally, we offer some brief reflections on the design of future studies.

Further research is needed to understand how challenges to implementing improvement can be addressed in practice

There is a need to strengthen the evidence base on how the influences on improvement processes that we have identified can be incorporated into the design and implementation of quality improvement interventions. At present, there is limited detail on the operational processes associated with implementing quality improvement. Thus, even some relatively well-researched or 'obvious' needs can be difficult to meet in the practice of quality improvement. Implementation challenges relate not only to lack of resources and capabilities but also to the absence of tailored, nuanced and context-specific recommendations that can ensure that general insights about what it takes to do quality improvement well can be made practical and actionable in a given context.

Future research also needs to consider the interactions and interdependencies between different influences on improvement

This rapid evidence assessment has identified a range of influences on quality improvement processes, but it is the interactions between them that ultimately are likely to determine the nature of an improvement process and its outcomes. For example, there is need to understand how influences related to the design of an intervention, to the fidelity of its implementation, and to the organisational context (e.g. leadership, skills, data availability) and external context (e.g. policy and regulatory environment), interact with each other. Sometimes they may reinforce one another, sometimes they may undermine each other. There is also a need to pay more explicit attention to understanding what is modifiable and what is not in the organisational and external context (i.e. at micro, meso and macro levels).

The same types of influences on improvement initiatives can play out very differently in different contexts. Future primary research needs to focus on attaining practical and actionable, nuanced and contextualised understanding of how the influences on improvement that we discuss in this report manifest themselves in specific clinical and disease areas, healthcare settings or parts of an improvement pathway.

It is important to stress that leadership, relationships, skills and competencies, data, patient and public involvement and engagement, and working as a connected system of individuals and organisations all matter. This may not be particularly surprising, but the seemingly 'obvious' can sometimes be deceptively difficult to embrace and internalise into the social, cultural and organisational context, and activity flows of a specific environment. Sometimes the difficulty in implementing the recognised requirements for success relates to a lack of financial and staff resources or implementation capability. It can also relate to challenges in understanding how the recognised requirements for success can actually be realised in a specific context. For example, it can be difficult to know what the precise steps involved are and in what order they should happen; who the specific relevant points of contact are in organisations; and what risks are involved and how they might be mitigated or managed in a specific context. These difficulties may stem from implementation requirements not being specified clearly enough and without sufficient detail to make them appropriately actionable.

There is a need to study how the relatively generic influences that are known to be important in improvement at an abstract level play out in reality. In other words, there is a need to understand how influences on improvement can be translated into specific roles, behaviours, norms, interactions, structures and institutions that govern healthcare practice across different contexts.

Further research – targeted at learning from the experience of improvers directly and building on the insights presented in this report – could have practical value for the healthcare system and help to advance improvement research as an academic field

Further learning could help refine insights on the influences on improvement discussed in this report and could potentially help establish a profiling approach or tool to assess the readiness of organisations to embark on improvement activity. This could in turn help inform national and local investments into quality improvement capability building and into establishing and spreading improvement cultures in the health system. However, any such tool to assess organisational readiness for improvement would need to be robustly evaluated, to ensure that it can effectively support efforts to gain a better and more granular understanding of bottlenecks and gaps in capability in specific parts of health and care pathways, in particular disease and clinical areas, or for particular patient profiles. This is important because the degree to which different issues are bottlenecks differs depending on the context. Furthermore, any effort to develop an organisational readiness assessment tool or to inform new national capability-building efforts would need to integrate learning from prior experiences, as we elaborate on in the report.

There is also scope for gaining further *comparative* learning about improvement capability-building needs across different clinical areas (e.g. oncology versus orthopaedics), different parts of a healthcare pathway (e.g. prevention, diagnosis, treatment) and healthcare system (e.g. primary care, acute care and community care in mental health), and across different parts of the improvement pathway (e.g. supply chains issues, decommissioning-related quality improvement issues). Exposing and characterising the differences in improvement conditions, capabilities and capacities across the healthcare system could lead to a better coordinated and more systematic evidence base, help shed light on how capability changes over time and is sustained or lost, and facilitate better-targeted policy responses.

Further research on the unintended consequences of improvement efforts is also needed to ensure that any new improvement efforts can manage such risks

Existing studies point to a range of potential unintended consequences from quality improvement efforts. Some of these include unintended effects on healthcare staff morale associated with a very crowded improvement landscape. The demands on staff time to engage with myriad quality improvement efforts can also detract from day-to-day patient care activities. Some examples of other unintended consequences discussed in the literature relate to fixation behaviour (e.g. measurement fixation), gains in quality as a result of improvement efforts in one area happening at the expense of care quality in another area, and negative financial consequences. Further research is needed to better understand the risks associated with quality improvement efforts and the diversity of both intended and unintended consequences that can materialise, and to identify mitigation and risk management strategies for particular types of unintended consequences.

In order to avoid simply uncovering 'more of the same', the design of future primary research needs to carefully consider different aspects of the improving healthcare system

Learning from existing literature that reports on primary studies in specific fields could help contribute more granular insights on improvement processes. However, we hypothesise that the practically relevant and detailed information that is needed to inform – for example – the development of a profiling tool of organisational readiness for improvement or a system-wide improvement intervention (that is modular and that can be tailored and adapted to specific contexts) is most likely to accrue from direct engagement with stakeholders in improvement activity. This could be pursued through primary research using methods such as interviews, surveys, ethnography and citizen science approaches. It is likely that both longitudinal and cross-sectional study designs would be needed to develop a more comprehensive evidence base. Insights from primary studies would need to be combined with a synthesising review to draw out generalisable learning from an accumulation of studies of improvement activities in different clinical and geographical contexts.

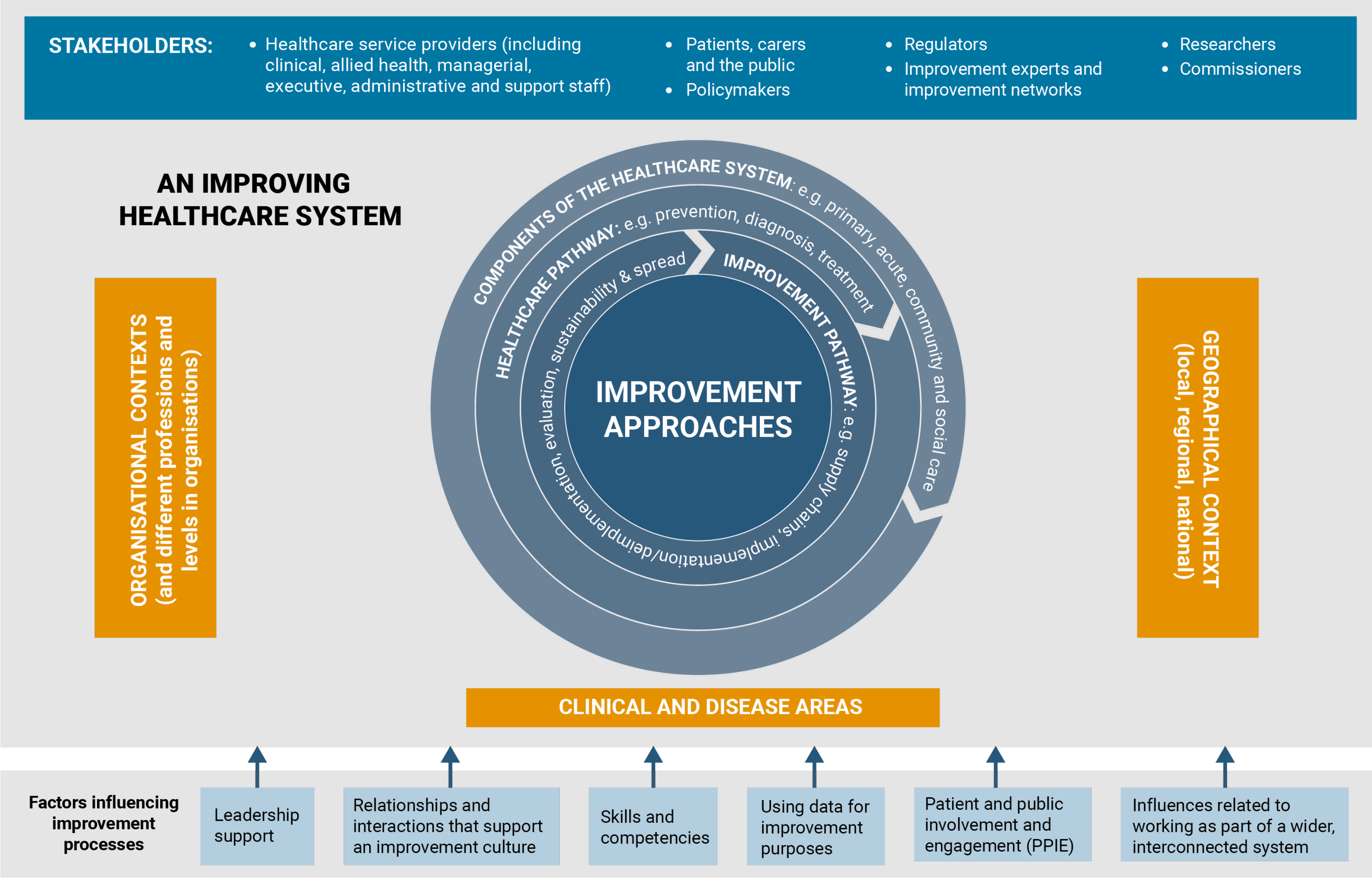
The focus of research studies could be on answering the following types of research questions:

1. How do the key influences on improvement (as outlined in Boxes 1–6) play out in practice in a given context? Research designs would need to focus on capturing rich narratives on the process and experience of improvement, paying attention to the language and discourse used in different professional communities.
2. What can we learn about the process and from the experience of doing improvement through longitudinal research and historical analyses? Learning from the past and from in-depth longitudinal studies of improvement processes and directly from the experiences of improvers could inform meaningful learning about how improvement capability can be built, sustained and lost in a system. Speaking to frontline staff (clinical, operational and administrative) can help expose nuanced insights and detail associated with their practical experiences and operational realities. Frontline staff can also sometimes provide insights on the less obvious challenges to implementing quality improvement. In addition, they can be a source of fresh and outside-the-box thinking about new opportunities and ways of managing challenges. Given that much of the current literature focuses on learning targeted and senior managers and leadership, integrating the frontline more prominently into research studies, and developing recommendations geared at frontline staff, seems to be an area in need of particular attention. Similarly, there is a need for research that can distil recommendations for policymakers and in doing so support national-level improvement efforts.
3. How are different stakeholders addressing challenges in the social, organisational and cultural context locally (and nationally) as they relate to the diversity of factors influencing improvement? This could in the longer term inform potential improvement interventions or evaluations.

Sampling for such research would need to consider the different elements of an improving healthcare system (see Figure 1 for further detail). This is not to suggest that any one study could address all of the relevant issues, but a conceptualisation of the improving healthcare system, such as the one we outline below, could help guide coordinated approaches to research on this topic, and the phasing of research activities. Indeed, one of the challenges in improvement research rests in better coordinating improvement studies to build a more comprehensive evidence base, where context-specific learning accumulates over time to inform generalisable knowledge.

As conceptualised in Figure 1, an improving healthcare system refers to the configuration of improvement activities, stakeholders and settings in which improvement processes unfold. More specifically, understanding improvement processes requires gaining insights into how specific improvement interventions (e.g. models, approaches and tools) unfold in relation to the parts of the improvement pathway they involve (e.g. supply chains, implementation, decommissioning/de-implementation, evaluation, sustainability and spread); the parts of the healthcare pathway they target (e.g. prevention, diagnosis, treatment); and the components of the health and care system in which they take place (e.g. primary, acute, community or social care). It also requires an understanding of the way in which different stakeholders interact with improvement activities in specific organisational, geographical, clinical and disease area contexts.

Figure 1: An improving healthcare system



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Acronyms and abbreviations

BPR	Business Process Re-engineering
CCG	Clinical Commissioning Group
CPD	Continuing Professional Development
CQC	Care Quality Commission
CQI	Continuous Quality Improvement
DESI	Decision Support Intervention
eGFR	Estimated Glomerular Filtration Rate
ELC	Experience-Led Commissioning
GDE	Global Digital Exemplar
GP	General Practitioner
EBCD	Experience-Based Co-Design
HDC	Health Disparities Collaboratives
HQIP	Healthcare Quality Improvement Partnership
LMS	Lean Management System
LST	Large-System Transformation
LTC	Long-Term Care
MatNeoSIP	Maternity and Neonatal Safety Improvement Programme
ORCA	Organizational Readiness to Change Assessment
ORIC	Organisational Readiness for Implementing Change
NICE	National Institute for Health and Care Excellence
P4P	Pay-for-Performance

PDSA	Plan-Do-Study-Act
PERT	Programme Evaluation and Review Technique
PORC	Perceived Organisational Readiness for Change
PPI	Patient and Public Involvement
PREM	Patient-Reported Experience Measure
PROM	Patient-Reported Outcome Measure
PROMPT	Practical Obstetric Multi-Professional Training
QI	Quality Improvement
RCT	Randomised Controlled Trial
REA	Rapid Evidence Assessment
RPIW	Rapid Process Improvement Workshop
THIS Institute	The Healthcare Improvement Studies Institute
TQM	Total Quality Management

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1 Background and context

1.1. Learning about the process of doing improvement in healthcare is important for informing future practice

The healthcare system in the United Kingdom (UK) has been paying increasing attention to quality improvement in recent years. Diverse stakeholders – healthcare service providers, researchers and research networks, funding bodies and charities, peer communities, professional organisations (such as the royal colleges and medical societies), commissioners, policymaking and arm's-length bodies – have been involved with improvement through a variety of local initiatives or large-scale coordinated improvement efforts at a national level [7-10].

As we illustrate later in this report, the improvement approaches that have been used are very diverse and the literature on quality improvement is broad and varied. There are many (albeit relatively fragmented) studies and reviews of 'what works' in relation to specific types of improvement interventions. But there is much less consolidated and curated evidence on learning about the process of doing improvement itself, in terms of what influences the implementation of quality improvement efforts. Such learning could help inform both ongoing and future improvement efforts, by drawing out practical insights, for example based on the challenges improvers encounter and the strategies used to overcome them.

THIS Institute commissioned RAND Europe to conduct a rapid scoping exercise to draw out initial learning from a subset of the literature, with a view to also informing themes to explore in potential future research. The scope and focus was on reviews and systematic reviews as well as selected grey literature reports. Primary studies were not in the scope of this work.

1.2. This report aims to draw out initial learning, based on a focused review of the academic and grey literature

1.2.1. Aims

The rapid evidence assessment aimed to identify and share learning about the influences on quality improvement processes. It also aimed to identify potential themes and issues to explore in future research in this space. The key questions that were explored were:

- What are the key themes discussed in the reviewed literature?
- Related to the above, what are the key messages that can be pulled out from

the literature on what influences quality improvement processes and how?

- What is the profile of the reviewed literature in terms of clinical areas and healthcare settings, geographical contexts and types of improvement approaches?
- What sources of evidence, study designs/methods and types of data does the literature draw learning from?

2 Methodology

2.1. A brief overview of the methods used

This scoping research included three core tasks:

- **Task 1: A rapid evidence assessment (REA) of academic literature (reviews and systematic reviews only) and grey literature that discusses learning about the process of doing quality improvement in healthcare.** An REA follows the principles of a systematic review in terms of specified research questions and a replicable search strategy, but is less exhaustive. It limits aspects of the search strategy, such as the search terms, the timespan of eligible studies, the types of studies included, the databases searched and the languages of the publications, and sometimes also includes other trade-offs such as limited assessments of the quality of underlying evidence [11]. Academic literature was identified through a systematic search approach. Grey literature supplemented insights from the academic literature. Grey literature was identified through a combination of searching the websites of organisations that are known to the research team to be active in quality improvement (based on the research team's experience), Google searches and snowballing from the academic literature. The detailed methodological annex (Annex A) includes full inclusion/exclusion criteria and a PRISMA flow diagram setting out how we identified papers for inclusion in the REA.

  The literature was analysed using a narrative synthesis approach [11-13]. The researchers conducted a full-text review of the included publications. Information from the reviews was extracted and coded into a coding frame which was based on the study aims, but which also allowed for emerging themes to be included (see Table A.3 in Annex A for the analytical framework). Insights relating to the influences on improvement processes were then categorised into overarching themes, which were arrived at inductively based on the nature of the learning discussed in the literature.

- **Task 2: Identifying themes that could be relevant to explore in future research, including an initial conceptual framework that could help in designing future studies.** This was done through team-based discussion and reflection on the findings from the literature review to help draw out key learning points and wider themes in need of further research. We supplemented insights from this project with wider relevant knowledge and experience that researchers in the team hold from working on other projects.

- **Task 3: Synthesis and reporting.** This task focused on bringing together and reporting on the findings and analysis conducted as part of Tasks 1 and 2.

Further detail on the methodology associated with each of these tasks is provided in Annex A.

2.2. Caveats

There are some methodological caveats to bear in mind when interpreting the results presented in this report:

- This study was a scoping exercise. The REA focused specifically on review or systematic review document types reported in the academic literature, and did not look into the primary studies covered in the reviews. Given the nature of reviews and systematic reviews, there was *relatively* limited nuance on learning about the processes of doing improvement.
- There may be additional grey literature that speaks to relevant issues, but that was not within the scope and approach adopted in this rapid review.
- Given the nature of this scoping exercise and the resources available, a formal quality assessment of the publications reviewed was not conducted. However, the research team did note key quality-related issues (see Section 3.6 for further detail). Thus, we can reflect on but not make definitive claims about the quality of the evidence presented in the academic literature. The types of issues we considered in our assessment included the clarity of the question(s) the publication seeks to answer, information about the populations/settings, comprehensiveness of and nature of the evidence base of the publication, and the appropriateness and clarity of inclusion/exclusion criteria.
- Some of the academic publications included in the reviewed literature were classified as systematic reviews in the searched databases and may have adopted a systematic search strategy, but did not always meet established systematic review criteria such as those defined by the PRISMA Statement [14]. In this report, we classified self-proclaimed systematic reviews that did not include some important elements of the evidence-based PRISMA Statement as reviews (specifying that this group of papers employed systematic search strategies but did not meet enough additional elements of the PRISMA Statement for us to accurately classify them as systematic reviews).
- The field of quality improvement in healthcare is broad and there is no clear classification system for what constitutes quality improvement and where its boundaries lie. In light of this, we adopted an inclusive approach and the criteria for and list of included publications were determined jointly by THIS Institute and RAND Europe. Although we adopted a relatively broad view of quality improvement, we were not interested in improvement efforts related to productivity or efforts to improve the social determinants of health. Our methods determined the focus of our findings and the way that they are presented. The literature we analysed reflects a plurality in the field, in terms of what is understood to fall within the scope of quality improvement activity. We do not within the remit of this work explore issues of boundaries and classification in the quality improvement field and its meaning to different stakeholders. We included literature that was aligned with the general approach to defining the concept, as introduced earlier in this report.

- Similarly, much of the literature covered explicitly referred to quality improvement rather than improvement more broadly (and indeed our search terms identified documents where the word 'improvement' or related permutations of the term appeared near the terms 'quality' or 'safety'). However, some of the papers we identified through our search adopted a broad view on quality within the wider concept of improvement, and use the term improvement as part of discussions that are relevant to quality. We use both the terms 'improvement' and 'quality improvement' in this report. This is because the term 'quality improvement' is used narrowly in some of the literature to refer to a very specific set of methods and techniques, rather than the full range of activities oriented towards improving healthcare and its quality that are of interest to us in this research, and that are aligned with the definition we built on.
- Our search uncovered literature considering quality improvement programmes at different levels in the healthcare system (e.g. within parts of organisations, organisation-wide, and at regional levels). The influences on improvement processes we identified are likely to manifest themselves differently at different levels in the healthcare system, but we were not able to explore this issue at depth within this research and based on the included literature. This is partially because the literature we assessed often drew evidence from many different settings and levels in the system.
- The conceptual framework and learning themes identified in this study serve to inform thinking about issues of importance for future studies and could be enriched through further research (e.g. expert consultation, reviews of primary studies).

Despite these caveats, we think that this rapid evidence assessment gives a rounded picture of key lessons from doing improvement based on the nature of the reviewed literature, and identifies a range of themes, questions, concepts and ideas to build on in potential future research. It also considers key influences affecting improvement processes at a more granular level than we have come across in much of the reviewed literature.

3 Profile of the reviewed literature

3.1. The basic profile of the reviewed publications

The sections below provide a brief overview of the literature in terms of the number of publications and document types reviewed, the geographical context they cover, and the clinical and/or disease areas and healthcare settings they relate to.

3.1.1. Number of publications and document types

This review identified 54 information sources that were eligible for inclusion: 38 academic and 16 grey literature publications. A summary table setting out each included publication's geographical and healthcare setting, type of improvement activity and key relevant findings is provided in Annex B.

Of the 38 academic articles:

- There were 11 systematic reviews [15-25] that closely adhered to the PRISMA Statement and fulfilled the majority of the Statement's evidence-based reporting guidelines [14]. Some authors explicitly stated that they followed the PRISMA Statement, while in other cases this was deduced by the research team based on knowledge of the PRISMA Statement's guidelines. These included systematic reviews that identified as realist reviews, but that employed clearly described systematic review methods with realist synthesis.
- A further 13 academic articles employed systematic search strategies and some additional elements of a systematic review (such as clear inclusion criteria and a systematic study selection process based on title and abstract screening followed by full-text review). In some cases these were presented as systematic reviews but did not meet enough of the PRISMA Statement's systematic review guidelines to be classed as such by the research team [26-38]. The elements that were most commonly missing were quality appraisal of the included literature and double screening/review by two independent reviewers.
- Nine academic articles were non-systematic literature reviews [39-47].
- The five remaining academic articles were all reviews of reviews: they included three systematic reviews of systematic reviews [48-50], one non-systematic review of systematic reviews [51], and one systematic review of (systematic and non-systematic) reviews [52].

Of the 16 grey literature publications:

- Three were research reports informed by literature identified through a systematic search strategy and with some additional elements of a systematic review, but not adequately fulfilling the guidelines set out in the PRISMA Statement [53-55], [14].

- A further five were research reports were informed by a combination of non-systematic literature review and stakeholder consultation conducted through interviews, roundtable discussions and/or other qualitative research methods [7-9, 56, 57].
- One additional research report was based only on insights from interviewing organisational and stakeholder representatives [58].
- Three grey literature publications reported insights from the work of a health charity (namely The Health Foundation) [10, 59], one of which also provides insights from the literature [60].
- The remaining four grey literature publications, which fall under the category 'other' (see Table 1), included two briefings for NHS leaders [61, 62], one guide to using quality improvement tools that reflects on lessons from doing quality improvement [63], and one blog article [64].

Table 1: Summary of publication types

Academic journal publications		**Grey literature publications**	
• Systematic review	11	• Research report, informed by:	9
• Review that employed a systematic search strategy and some additional elements of a systematic review, but did not fulfil other important elements of the PRISMA Statement [14]	13	- *(Review that employed a systematic search strategy and some additional elements of a systematic review, but did not fulfil other important elements of the PRISMA Statement [14])*	*(3)*
• Non-systematic review	9	- *(Non-systematic review and stakeholder consultation)*	*(5)*
• Review of reviews:	5	- *(Organisation and stakeholder interviews)*	*(1)*
- *(Systematic review of systematic reviews)*	*(3)*	• Reflective organisational learning report:	3
- *(Non-systematic review of systematic reviews)*	*(1)*	- *(Organisation's experiences only)*	*(2)*
- *(Systematic review of reviews)*	*(1)*	- *(Organisation's experiences and literature review)*	*(1)*
		• Other:	4
		- *(Briefing for NHS boards and leaders)*	*(2)*
		- *(Guide to using quality improvement tools)*	*(1)*
		- *(Blog article)*	*(1)*
Total (academic journal publications)	**38**	**Total (grey literature publications)**	**16**

Note: The text in italics and in brackets indicates subsets of a classification category.

3.2.1. Geographical context

The academic and grey literature included a mix of publications that:

- Drew on evidence from international contexts and provided learning of international relevance, i.e. learning that is not geography-specific (23 academic reviews, 6 grey literature sources).
- Drew on evidence from international contexts and applied that learning to a particular country or regional context (4 academic reviews, 4 grey literature sources).
- Drew on evidence from improvement efforts in a particular country, and applied the learning to the local country or regional context (2 academic reviews, 6 grey literature sources).
- Were not clear about whether evidence was drawn from one or multiple countries, but applied learning to a particular country (4 academic reviews).
- Did not provide any information about the geographical context informing the learning they present (5 academic reviews).

Further detail is provided in the subsections below.

Academic literature

The majority of the academic reviews (27 out of 38) drew on learning from international contexts (thus falling under one of the first two categories in the bullet points set out above). We categorised a review as international if eligible evidence was not restricted to any particular country context (beyond country restrictions in our search strategy, see Section A.1.1. in Annex A) and if the review's conclusions drew on evidence from at least two countries (though more often these reviews identified and included evidence from a variety of countries).

23 of the 27 international reviews drew on evidence from international contexts and provided learning of international relevance. Of these, 18 provided clear details about the geographical context of the included literature (i.e. which countries the evidence used came from); 15 included evidence from the UK among other countries [15-17, 21, 24, 27-31, 35, 37, 39, 41, 48]; and three did not include any evidence from UK contexts [19, 20, 25]. The remaining five international reviews that drew evidence from international contexts and provided learning of international relevance did not provide clarity on all of the countries from which they drew evidence [22, 34, 36, 38, 50].

Four of the 27 international reviews drew on evidence from international contexts and applied that learning to a particular country or regional context. Of these, two applied the learning from international contexts to focus on lessons for the UK context [23, 40], one applied international evidence to the Norwegian context [52] and one to the US context [18]. These reviews either implied or explicitly stated that they drew mostly but not exclusively on insights from the country of key interest, but complemented it with evidence from elsewhere.

Two academic reviews clearly focused on just one country, and only reviewed literature from the country of interest. Of these, one focused on Australia [33] and one on the UK [46].

Four further academic reviews were particularly interested in learning that is of relevance to a specific country context – namely the UK [45, 51] or the US [42, 47] – but did not make clear whether they drew only on insights from this country or also from elsewhere.

Finally, five reviews provided no information relating to the geographical context of the evidence that informed the learning presented [26, 32, 43, 44, 49].

Grey Literature

The majority of the grey literature publications selected for review by THIS Institute and RAND Europe focused on UK-relevant learning, drawing on insights from either international or UK evidence (see Section A.1.2 in Annex A for further details):

- Ten of the 16 grey literature publications drew on learning from international contexts, all of which also included lessons from the UK as part of a wider mix of countries. Of these ten publications, two provided a clear overview of the countries from which evidence had been derived [9, 55]. It was not possible to identify every country included in the remaining eight publications in this category, although all stated that the UK accounted for some of the evidence. Four of the ten papers did not seek to apply the international learning to any particular country context, while six focused their discussion on the relevance of the findings to the UK context.
- The remaining six grey literature publications only drew on learning from UK contexts, and sought to apply this learning only to a local, regional or national context in the UK. Of these, three drew on insights from England only [7, 57, 61], two from UK-wide insights [10, 59], and one did not make clear whether lessons learned were from just England or also the other UK regions [58].

Table 2 presents an overview of the geographical coverage of the reviewed literature.

Table 2:Geographical context of the sources of evidence informing the reviewed literature

Sources of included insights	Academic literature	Grey literature
Draws from an international evidence base (total)	***27***	***10***
International – including UK	17	10
International – not including UK	3	0
International – unclear whether including UK	7	0
Draws evidence from a single country (total)	***2***	***6***
Single country – not UK	1	0
Single country – UK-wide	1	2
Single country – England only	0	1
Single country – unclear whether UK-wide or England only	0	3
Geographical origin of source evidence not reported or unclear (total)	***9***	***0***
Unclear whether international or single country	4	0
Not reported	5	0

3.1.3. Clinical and disease areas

We extracted information on the clinical and disease areas of interest for each publication. By clinical area, we mean clinical disciplines such as oncology, anaesthesia and surgery. By disease area, we mean diseases or medical conditions such as dementia or specific types of cancers. Given that the boundaries between clinical and disease areas can be blurred (e.g. some clinical areas such as oncology are clearly linked to a particular disease such as breast cancer or cervical cancer, whereas others such as surgery are not), and given that the literature does not always distinguish between the two, we report on clinical and disease areas together.

The majority of the literature sources we reviewed did not focus on any specific clinical or disease area. For example, only 8 of the 38 academic reviews focused on healthcare improvement in a specific clinical discipline or disease, and none of the grey literature sources was clinical area- or disease-specific. That said, some of the academic reviews, while not having an explicit aim to learn about a specific area, tended to draw learning that was particularly relevant for a specific area (perhaps as a consequence of the evidence base used). Further detail is provided below.

Academic literature

The majority of the academic reviews (30 out of 38) had no explicit focus on any particular clinical or disease area (but this is not to say they do not refer to different clinical areas when reporting on the evidence base). Of these:

- Some 25 reviews identified relevant quality improvement initiatives implemented in a range of clinical and disease areas, without drawing a majority of evidence from any one area [15, 16, 18, 19, 21-27, 29, 30, 33-39, 43, 45, 46, 48, 52]. For example, a systematic review of the impact of clinical networks on improving quality of care and patient outcomes included studies of clinical networks in cancer, cardiac services, neonatal services, diabetes and end-stage renal disease [16].
- Four of the academic reviews did not have an explicit focus on a particular clinical or disease area built into their research aims, but produced results that emphasised a particular clinical or disease area due to a significant proportion of their included evidence coming from that area. For example, the majority of evidence included in a review of interventions in long-term care settings focused on dementia care, even though the study aims did not explicitly focus on learning about dementia [41]. Surgery [28], diabetes [42] and breast/prostate cancer [31] were the other clinical and disease areas from which reviews that did not explicitly set out to study a particular clinical or disease area identified a large proportion of their evidence. Although speculative, this could be an artefact of the design of our REA, but may also indicate areas in which quality improvement activity is more common.
- One academic review was, by nature of the intervention of interest, concerned with all clinical and disease areas [17]. This review explored large-scale hospital- and system-wide initiatives, and studies were therefore only eligible if the associated intervention was implemented across clinical and disease areas.

Eight of the academic reviews had an explicit focus on one clinical or disease area. Of these, one review focused its research question on the impact of feeding back data on quality indicators to improve care in anaesthesia [51], but drew on lessons about feeding back data to improve care processes from a broad range of clinical and disease areas. The remaining seven reviews focused on a particular clinical or disease area, and only reviewed learning from that area of interest. These reviews covered palliative and end-of-life care [40], paediatrics [20], surgery [32], radiology [47], psychiatry for severe mental illness [49], maternal health (gynaecology and obstetrics) [44], and maternal and child health (obstetrics and paediatrics) [50].

Grey literature

None of the grey literature sources had an explicit focus on any clinical or disease area. The majority (14 out of 16) drew on insights from any area [8-10, 53-57, 59-64]. The remaining two grey literature reports explored cross-cutting improvement initiatives that spanned all clinical and disease areas - for example, strategies to improve quality across all clinical and disease areas within an NHS trust [58], or to embed a culture of improvement across all clinical and disease areas delivered by an NHS provider organisation [7].

3.1.4. Healthcare settings: components of the healthcare system

We extracted information on the healthcare setting of interest for each publication (to the extent that such insights were available). By healthcare settings, we mean specific components of the healthcare system such as primary care, secondary/acute care, tertiary care, community care as well as more specific details about the type of care provided in the setting of interest, e.g. acute care hospital settings.

Most of the academic and grey literature we reviewed included evidence from a range of healthcare settings and did not explicitly focus on a specific part of the healthcare system (25 out of 38 academic papers; 14 out of 16 grey literature sources). Approximately one third of the academic reviews (13 out of 38) focused on a specific part of the healthcare system, with secondary and/or tertiary care settings being the predominant focus.

Academic literature

The majority of the included academic literature (25 out of 38 papers) was not setting-specific in its focus, and often tended to include evidence from a diverse range of healthcare settings (components of the healthcare system). Of these 25:

- 21 reviews identified quality improvement initiatives implemented in a range of healthcare settings, without identifying a majority of evidence from any one setting or part of the healthcare system [15, 16, 19-21, 23-26, 29, 31, 36, 38, 39, 43-46, 49-51]. For example, a review of the sustainability of Lean in paediatric healthcare identified studies conducted in paediatric radiology and neuro-radiology, paediatric intensive care units, emergency service departments, a paediatric emergency unit, a paediatric eye clinic, new-born centres, hospitals and primary care departments [20].
- Two reviews, although not setting-specific, included a majority of evidence from a particular type of setting, though not to the intentional exclusion of others. One of these had a slight emphasis on primary care [28], while the other drew mostly on empirical evidence from hospital settings [30].
- A further two reviews explored quality improvement collaboratives, which are improvement initiatives that may span across different healthcare settings [34, 52].

The remaining 13 academic reviews focused on a specific healthcare setting. Of these, one focused on community care [42], two on primary care [27, 33], and ten on secondary and/or tertiary care [17, 18, 22, 32, 35, 37, 40, 41, 47, 48]. Of the ten studies focusing on secondary and/or tertiary care, two drew on insights from a wide range of hospital settings [18, 35]; five on particular areas, such as radiology centres [47], operating rooms [32], palliative and end-of-life care [40] and acute care settings [17, 48]; and three did not further specify the area [22, 37, 42].

Grey literature

Most of the included grey literature (14 out of 16 papers) did not refer to a specific healthcare setting or part of the healthcare system [7-10, 53-56, 59-64]. Of these 14, one mainly focused on hospitals/trusts, though not to the exclusion of other healthcare settings/components of the healthcare system [8].

Of the remaining two grey literature reports, one focused on hospital settings [58] and one on primary care referrals to secondary, tertiary and specialist care [57].

3.2. The nature of improvement interventions covered in the literature

The reviewed literature varied widely in terms of the types of improvement activities it considered and what it understood to fall within the scope of quality improvement activity. To illustrate this diversity, the literature we reviewed focused on approaches including (but not limited to):

- Lean [20, 30, 47, 48, 54], such as a systematic review of the use of Lean in paediatric healthcare [20] or a non-systematic review of Lean in radiology [47].
- Six Sigma [48, 54], such as a systematic review of reviews of Six Sigma (and Lean Thinking) in acute care [48].
- Business Process Reengineering (BPR) [46, 54], such as a non-systematic literature review discussing UK-specific BPR efforts [46].
- Total Quality Management (TQM) and Continuous Quality Improvement (CQI) [33, 54], such as a review focusing on the implementation of quality improvement in aboriginal and Torres Strait Islander primary care settings [33].
- Experience-Based Co-Design, discussed in a non-systematic literature review in the context of palliative and end-of-life care [40].
- Rapid Cycle Change and Plan-Do-Study-Act (PDSA), discussed in a Healthcare Improvement Scotland review of key quality improvement models [54].
- Quality improvement collaboratives and networked quality improvement approaches (including peer-learning communities) [9, 16, 26, 34, 42, 52, 64], such as a part-systematic review aiming to identify determinants of success for quality improvement collaboratives [34].
- Clinical audits and feedback [8, 24, 63], such as a grey literature report discussing how engaging clinicians can help scale up the use of national clinical audits for quality improvement [8].
- The use of various quality indicators and performance measures for quality improvement purposes [21, 23, 51].
- Training and education to improve various aspects of care quality or safety such as handover quality [22, 43].
- The use of patient engagement and feedback as an improvement tool in the design, delivery and evaluation of healthcare services [15, 21, 27, 35, 45].
- Approaches to improve patient flow through referral management from general practitioners (GPs) to other healthcare

organisations or professionals (e.g. through referral management centres, clinical triage and assessment, peer review and feedback, financial incentives, use of clinical guidelines and other tools), and through this improve the quality of care [57].

- The use of medical registry data to provide feedback to healthcare providers, which should help inform improvement efforts [38].
- Hospital accreditation programmes and their links to quality improvement in areas such as organisational culture, safety, patient-centredness, patient satisfaction and clinical quality of care [37].
- Implementation tools to support uptake of clinical guidelines [19].
- The use of patient decision-making tools to improve patient experiences [31].

Some of these interventions can simultaneously serve improvement agendas and other aspects of service delivery. For example, tools to support the implementation of clinical guidelines can be targeted at improvement in the quality or safety of care, but also at compliance with national policy.

Similarly, not all of the reviews we analysed were focused only on quality improvement. For example, a review by Best et al. [28] discussed large-system transformation more widely – in this review, quality improvement was considered as part of a broader set of transformation efforts (such as efforts to improve the efficiency of healthcare delivery and population-level outcomes [28].

In addition, some publications emphasised contextual factors over the nature of an improvement intervention itself: their interest was in explaining the role and effect of various influences on the quality improvement processes and/or outcomes and on the sustainability of quality improvement, and less in a specific improvement intervention or set of interventions. These publications, to give some examples, examined the impact of influences such as leadership [7, 53, 55, 56, 58-62], staff knowledge and skills [36] or the availability of resources [36] on quality improvement more generally.

Whereas many of the publications we reviewed (33 out of 54) centred their aims and analysis around specific quality improvement models, approaches, tools or interventions (or combinations thereof) [8, 9, 15, 16, 19-24, 26-28, 30, 31, 33-35, 37, 38, 40, 42, 43, 45-48, 51, 52, 54, 57, 63, 64], not all did. We also identified a number of publications that did not focus on a specific intervention or set of interventions: rather, their analysis was focused on explaining improvement in a specific clinical or disease area of care or a specific healthcare setting, and they tended to draw learning from a very broad array of improvement approaches and tools [18, 25, 32, 39, 41, 49, 50]. One example was a review focused on learning about how to change practice in long-term care settings with a view to improving the quality of care and lives of long-term facility residents [41]. Other examples included reviews of efforts to improve the quality of care for pregnant women, neonates and/or children [50], intraoperative efficiency [32] and the quality of care and outcomes for patients with severe mental illnesses [49].

Some papers also considered improving safety of care or improving patient experiences, or a combination of these dimensions [10, 17, 27, 43, 44] – which as discussed earlier are considered as dimensions of quality improvement in our review [6]. For example, Clay-Williams et al. [17] reviewed studies that focused on patient safety interventions implemented in hospital settings, such as interventions to improve hand hygiene or multi-component interventions that aim to reduce adverse events, improve patient monitoring and/or improve safety culture and care quality; Illingworth discussed lessons learned from Health Foundation projects and efforts to improve patient safety [10]; Mann & Pratt [44] reported on the role of clinician involvement in patient safety activities; Issenberg et al. [43] looked at studies that focused on the use of training simulations to address patient safety issues; and Baldie et al. [27] focused on how patient feedback in general practices can improve the quality of care experiences.

3.3. Which stakeholders are involved in healthcare improvement efforts and whose experiences and perspectives are reflected in the evidence base?

3.3.1. Stakeholders involved in improvement efforts

Although many of the reviewed publications mentioned the stakeholder groups associated with the design or implementation of an improvement effort, not all did. The lack of clear information on stakeholder involvement seemed to be particularly common in reviews that included a variety of different interventions [24, 25, 46, 50] or that focused on more general learning about quality improvement and not on any particular intervention or approach [9, 36, 53, 55, 56, 59].

Some publications provided limited information about stakeholder involvement but did not go into much detail. For example, they tended to refer vaguely to healthcare professionals' involvement without specifying which healthcare professional group was involved in implementing an improvement effort or how they actually contributed [7, 10, 15, 17, 19, 29, 34, 37, 38, 40, 45, 48, 52, 54, 58, 64].

In addition, some publications focused on the involvement of a particular subset of a stakeholder group, such as leadership in healthcare provider organisations [53, 61, 62]. However, this does not imply that other groups were not involved with the design or implementation of an intervention; they may simply not be mentioned in the publication as they were not its core focus.

Despite these limitations in the evidence base, some key insights on the nature of stakeholder involvement in improvement efforts can be inferred.

The majority of the analysed literature discussed stakeholder involvement in the context of intervention *delivery/implementation* [18, 19, 22, 25, 28, 32, 33, 35, 36, 41, 44-50, 54, 57, 61, 62]. Some of the literature also looked at stakeholder roles in contributing to the *design* of improvement interventions [10, 18, 34, 40, 44, 53, 61] or to their *assessment and evaluation* [15, 29, 37]. In terms of assessment and evaluation, we refer to stakeholder roles in evaluating improvement interventions, rather than in the design of interventions which are themselves evaluative in nature (e.g. audits). (However, it is worth noting that there may well be a greater level of stakeholder involvement in design or evaluation than is explicitly discussed in the literature, as the literature may not look at this issue as a key focus: i.e., the fact that it is not discussed cannot be inferred to mean that it does not happen.)

The key stakeholder group that was considered in the reviewed literature was healthcare professionals internal to the organisation in which the intervention was unfolding [7, 8, 10, 15-52, 54, 57, 58, 61-64]. The types of healthcare professionals involved are diverse, reflective of the diversity of clinical and disease areas and healthcare settings in which improvement activities take place. Examples include nurses, nurse assistants and nurse practitioners [18, 19, 22, 24, 25, 30-33, 36, 41, 44, 49, 50, 61]; diverse consultants [22, 30, 32, 57, 61], junior doctors [63], GPs [23, 27, 33, 49, 57, 61] and other not-further-specified types of doctors [33, 36, 62, 63], pharmacists [24, 41, 61] and midwives [18, 50, 61].

The involvement of healthcare professionals also spans different levels and hierarchies in organisations. However, although the literature recognised this and the importance of frontline staff engagement, it tended to place much more substantial emphasis on the role of senior leadership in steering improvement efforts [7, 10, 15, 16, 20, 21, 25, 26, 33, 35, 36, 39, 42, 44, 46-48, 51-54, 57, 58, 61-63]. One exception is a publication on the implementation of new ambulatory heart failure clinic at the City General Hospital Stoke as part of a quality improvement initiative, which was led by nurses and supported by cardiologist consultants [61]. Frequently mentioned (mainly senior) leadership activities included providing a vision for quality improvement [53, 58, 60, 62]; creating strategies or plans for an improvement intervention [10, 51, 53, 58, 60, 62]; showing commitment to the improvement intervention [47, 62]; and providing support, guidance and supervision of staff [44, 47, 48, 53, 58, 60-62]. Further information on the role of leadership is discussed in Section 4.1 of this report.

The involvement of both clinical and non-clinical leaders and managers of improvement efforts was also discussed in various reviews and in the grey literature [7, 10, 15, 16, 20, 25, 26, 33, 35, 36, 39, 42, 44, 46-48, 51-54, 57, 58, 60-63], Examples include clinical leads in a specific care setting [16, 20, 44, 48, 61, 63]; executive, non-executive and medical directors; managers as well as board members [7, 10, 15, 16, 20, 25, 26, 33, 35, 36, 39, 42, 44, 46-48, 51-54, 57, 58, 60, 62].

As highlighted above, the reviewed literature mainly referred to the involvement of stakeholders internal to a healthcare setting, but some publications (although relatively few) also stated how external stakeholders were involved in the design or implementation of improvement interventions [8, 19, 20, 37]. This tended to be through mainly support functions or in evaluation and assessment roles. For example, Ng et al. [37] discussed an accreditation programme in hospitals and mentioned that external accreditors engaged with healthcare staff as part of the accreditation process, for example through interviewing them or asking them to fill in a survey, and reviewing documents and clinical and organisational data. As an alternative example, a publication discussing clinicians' involvement in the National Clinical Audit and Patient Outcomes Programme in England and Wales noted that external auditors typically visited the audited healthcare organisations and engaged with staff through interviews [8]. Some publications also referred to external trainers delivering training sessions or workshops on quality improvement skills to healthcare staff [19, 61], or experts on specific improvement methodologies supporting intervention implementation (for example Lean experts supporting the implementation of Lean Thinking in paediatric healthcare [20]).

Patient engagement is often highlighted as important, and although many of the publications we reviewed acknowledged this, only a few discussed the active involvement of patients and/or their carers and families in the design or implementation of improvement efforts [e.g. 15, 20, 35, 45]. Examples included patient roles in multidisciplinary improvement or pathway redevelopment implementation teams [20], or as advisors to or members of governance bodies in hospitals, contributing to the design of improvement strategies and initiatives [35, 45]. Patient engagement, when described, was most often relatively limited – for example through providing feedback and data to healthcare organisations and professionals [7, 8, 10, 21, 23, 27, 35, 40, 45, 51].

Although collaboration is central to the implementation of many (indeed most) improvement initiatives, some models of stakeholder engagement are fundamentally premised on the principle of collaboration. For example, several publications [7, 9, 26, 34, 35, 42, 52, 61, 64] focused on or provided examples of collaborative and networked quality improvement approaches (e.g. quality collaboratives, peer networks or clinical communities for quality improvement), which often involved quality improvement experts, leaders and/or managers in healthcare provider organisations across all levels, different healthcare professionals, commissioners, and sometimes patients and carers. For example, in a case study described by Alderwick et al. [61], a core project team of a clinical commissioning group (CCG) was involved in improving dementia care through developing a new pathway, which actively engaged and collaborated with partners across the health and social care system, including senior leads from different clinical areas and implementation settings (primary care, acute care, community care and social care), representatives of voluntary organisations, patients and carers.

3.3.2. Whose experiences and perspectives are reflected in the reviewed literature?

Although some of the reviewed literature clearly specified which stakeholders were involved in the delivery of an improvement effort, the literature was not always clear on whether the evidence and learning reported stems directly from the perspectives and experiences of those involved in improvement activities or not. For example, it is possible that some of the learning and evidence reflects the perspectives of others, such as academics studying the improvement effort or evaluators [e.g. 17, 18-20, 24, 28-30, 32, 34, 37, 41, 44, 45, 48-51, 55, 56, 60, 61, 63]. This was inevitably a result of the sources for our study being mainly reviews and systematic reviews, and not primary studies. It was not possible in the scope of our work to go back to the primary studies and identify which sources of evidence they were informed by.

Several publications did make clear that they were reflecting the experiences of specific stakeholders, most frequently healthcare professionals involved with intervention implementation [9, 26, 27, 35, 37, 38, 42, 45, 52, 55, 56], leaders of the quality improvement initiatives in organisations [7, 8, 20, 33, 36, 37, 42, 47, 53, 57, 58, 62] or alternatively external stakeholders [7, 8, 10, 15-18, 23, 25, 31, 33-35, 37, 40, 45, 50, 56, 59] (such as national leads of clinical audits and members of the National Advisory Group for Clinical Audit & Enquiries [8]; patients [15-18, 23, 25, 31, 35, 40, 45, 50]; patients' families [18, 25, 50]; community workers [33, 50]; or representatives of quality improvement organisations such as the Healthcare Quality Improvement Partnership (HQIP) or the Health Foundation [7, 8, 10, 34, 59]).

3.4. The aims of the reviewed literature

Learning about and from quality improvement processes tended to be to various degrees explicit or implicit in the aims of the publications we reviewed. In some instances, such learning was not a stated aim, but was nonetheless available in the publication. More specifically:

Learning about or from the process of improvement was explicitly stated as an aim in 27 of the 54 reviewed publications [7, 10, 15, 16, 21, 26-31, 35, 40-42, 46, 48, 49, 52-54, 56, 58-61, 64].

A more implicit focus on learning from improvement was present in 20 of the 54 publications [8, 17, 18, 20, 22-24, 32-34, 36-39, 43, 45, 47, 50, 51, 55]. Often, these publications aimed to identify influences that contributed to the *success of an improvement effort*, but it was not clear from the way in which the reviews reported their conclusions whether or not they drew on qualitative learning about the *process of carrying out improvement* or whether they arrived at their conclusions in some other way. For example, some of the reviews we analysed were informed by source studies which focused more on analysing outcomes data to draw out correlations between the outcomes of quality improvement efforts and the nature of the interventions that are implemented, rather than studying the process of improvement. For example, Clay-Williams et al.'s [17] systematic review of the impact of hospital- and system-wide interventions on patient outcomes explored the relationship between patient safety interventions and organisational and cultural factors. They focused on understanding which organisational and cultural factors were associated with improved patient outcomes, and drew on quantitative findings from empirical studies. By reviewing studies that focused on organisational and cultural determinants and provided patient outcome data before and after implementation, the review authors sought to infer which factors influence intervention success and patient outcomes. Seven publications did not state an *aim* to learn about or from the processes of improvement initiatives, but did report on such learning [9, 19, 25, 44, 57, 62, 63].

Publications with an explicit aim to learn about and from the processes of doing improvement in healthcare

Nine of the 27 publications with an explicit aim to share lessons about or from the processes doing improvement had this as their primary or core aim [7, 10, 26, 40, 53, 58, 60, 61, 64]. To illustrate with a few examples: one grey literature report's main aim was to share learning from quality improvement processes in trusts [58]; another review had the core aim to draw out practical lessons for how the clinical communities approach can be used for quality improvement [26]; and a grey literature report analysed improvement literature and examples from within the NHS to provide quality improvement lessons for senior NHS boards and leaders [61]. In the other 18 publications, the explicit aim to share learning from doing quality improvement was accompanied by other prominent aims [15, 16, 21, 27-31, 35, 41, 42, 46, 48, 49, 52, 54, 56, 58, 59], for example to learn about 'what works' intervention-wise and to report on the impact or effectiveness of interventions [15, 16, 29, 41, 42, 48], or to provide a comprehensive descriptive overview of how an intervention works [21, 30, 46, 54].

Some of the reviews and grey literature which explicitly focused on drawing out lessons from the process of doing improvement shared insights very descriptively and/or at a high level only, while other publications went a step further to provide more formative and directly actionable learning (e.g. to produce guidance) [e.g. 7, 26, 53, 59, 61, 63]. For example, Dixon & Pearce [63] provided practical guidance on using quality improvement tools to drive clinical audits, and a Health Foundation report discussed and suggested how to effectively share quality improvement ideas using communication approaches, based on lessons learned from previous Health Foundation quality improvement programmes [59]. It delved into the specifics of how to plan communications, who to engage with, how to sustain interest and how to effectively celebrate and share achievements and with whom.

Publications where the aim of learning about or from improvement processes was implicit

Some publications did not explicitly state a core aim to learn about or from the process of doing improvement (20 out of 54), but more implicitly sought such insights and reported on them in their findings [8, 17, 18, 20, 22-24, 32-34, 36-39, 43, 45, 47, 50, 51, 55]. For example, such publications tended to have other issues as their core and primary concern, such as providing an overview of quality improvement interventions [18, 23, 33, 38, 43] or identifying influences affecting quality improvement but where it is unclear whether this aim will be pursued through studying the process of improvement or some other means (as discussed earlier in this section) [17, 20, 23, 24, 33, 34, 37, 38, 47, 50]. Identifying such influences was also often a key aim of those reviews with an explicit focus on learning from the process of improvement [15, 21, 27, 28, 52, 56].

Other general points on the aims of publications we reviewed

Across all 54 publications, other overarching aims included – to give some examples – evaluating the effectiveness or the impacts of quality improvement efforts [15, 16, 19, 24, 29, 31, 35, 38, 42, 48, 51, 52, 54, 57], focusing on specific influences as a primary concern, such as leadership, patient and public involvement (PPI), engagement and participation or stakeholder engagement in quality improvement [7, 8, 44, 45, 53, 61, 62], and providing or developing a theoretical framework to characterise quality improvement efforts [23, 36].

3.5. The sources of evidence informing the literature

The academic literature included in this review was identified through a search strategy designed to pick up literature reviews classified as either reviews or systematic reviews in the search databases (please see Section A.1.1 in Annex A for further detail). Most of the 38 academic publications included in our analysis reviewed primary studies, while others reviewed reviews of primary studies, and some reviewed a combination of primary studies and systematic reviews (the nature of information provided in the source documents is not amenable to quantification as not all sources provided such information). The source primary studies spanned a mix of qualitative, quantitative and mixed-method research. Study designs through which improvement initiatives were tested or evaluated included randomised controlled trials (RCTs), non-randomised controlled trials (quasi-experimental studies), time series cohorts, controlled pre-post studies, pre-post studies and observational studies. Across the 38 academic publications, and based on the information we could access, less than a third specifically referred to RCTs as part of the evidence base they reported on [17-19, 21, 23, 27, 32, 33, 35, 38, 42, 49]; however, in most of these publications the number of included RCTs was only a small fraction of the overall evidence base (less than 20 per cent of all included studies, in most cases less than 10 per cent) [18, 21, 27, 32, 33, 42] or was not further specified [17, 23, 35]. (That said, the relatively low number of RCTs cannot in and of itself be seen as an indicator of poor quality as RCTs are not appropriate for every intervention and evaluation context.) There appeared to be relatively few large-scale and coordinated evaluations, although we cannot make any definitive claims about that given the nature of reporting on the source evidence, and this would require further investigation. Frequently mentioned methods used to gather data on the process of implementing improvement initiatives were surveys, interviews and focus groups. Case studies, commentaries and opinion pieces were also occasionally drawn upon, as was in some cases more theoretical and conceptual literature. Less commonly, the academic reviews were also part-informed by consultation with relevant experts [28, 42].

The majority of the grey literature publications also drew on published evidence identified through some form of literature review, but here this was usually supplemented with additional sources of evidence in the form of case studies, interviews, reviews of secondary data sources such as outpatient data and audit outputs, and/or author reflections on organisational or personal experiences. Overall, the sources of evidence (including the nature of the primary studies included) were less clear than those of the reviewed academic papers.

3.6. General reflections on the quality of the reviewed literature

A full quality assessment was outside the scope of this review and commissioning brief, but the research team noted key quality-related issues as part of the literature coding process (i.e. particularly notable strengths or weaknesses associated with a particular publication. In doing so, we were sensitised by considerations related to the clarity of the question(s) the publication sought to answer, information about the populations/settings, comprehensiveness of and evidence base of the publication, and the appropriateness and clarity of inclusion/exclusion criteria.

The research team found that the quality of the overall sample of publications varied quite significantly, but tended towards moderate quality contributions overall. The academic and grey literature publications ranged from relatively low-quality publications drawing on a narrow range of experiences and perspectives, to high-quality systematic reviews synthesising a broad sample of relevant evidence identified through a replicable search strategy with minimal selection bias. However, across the sample of 54 included information sources, the research team judged that only 15 academic journal articles (and no grey literature sources) fulfilled enough of the established systematic review guidelines set out in the PRISMA statement [14] to be accurately identified as systematic reviews. The quality of the academic literature is assessed slightly differently to that of the grey literature, so the discussion below summarises key information on the quality of the academic and grey literature separately.

Quality of the academic literature

Of the 38 academic reviews included in our sample of publications (as discussed in Section 3.1.1), 11 were systematic reviews, 13 were reviews that employed a systematic search strategy but did not meet enough of the PRISMA Statement's systematic review guidelines to be classed as such, five were reviews of reviews (four of which were systematic reviews of reviews and one a non-systematic review of systematic reviews), and nine were non-systematic reviews.

Eleven of the 38 academic reviews were identified as adhering closely enough to the PRISMA Statement [14] to be identified as systematic reviews, and can therefore be considered to be of relatively high quality. Aspects of their methodology that contributed to quality included a systematic and replicable search strategy designed to identify an unbiased and close-to-comprehensive sample of the relevant literature; pre-defined inclusion and exclusion criteria to guard against selection bias; a clearly described and replicable strategy for data extraction, usually in the form of pre-designed and piloted data extraction tables; a quality appraisal process that assesses the risk of bias in each included study and takes the results of this process into account during data synthesis; and completion of each phase (title and abstract screening, full-text review, data extraction and quality appraisal) by two independent reviewers, with a third reviewer available to resolve any disagreements. Although these 11 systematic reviews were of high quality, they all reported that the average quality of their included studies was low to moderate.

There were 13 academic reviews that fulfilled some but not all of the characteristics of a systematic review. These employed systematic search strategies, sometimes supplemented by additional iterative searches, but missed several important criteria as set out in the PRISMA Statement [14]. The elements that were most commonly missing were completion of each review phase by two independent reviewers, and quality appraisal of the included literature. These reviews were considered moderate to high quality in consideration of their scope and aims, but most did not assess the quality of their included studies so we cannot comment on the quality of the evidence that informed the reviews.

Of the five reviews of reviews, four were systematic reviews that we considered to be of moderate to high quality, although akin to the 11 systematic reviews mentioned earlier these reported that the evidence they drew on suffered some significant weaknesses, both in terms of the reviews they reviewed and the evidence included within them. The remaining non-systematic review of reviews employed a low-quality approach to identifying relevant literature, but due to it including only systematic reviews it was judged to be of moderate quality.

Finally, we judged the nine non-systematic reviews to be of low to moderate quality. All reviews employing a non-systematic approach were by default considered to be of low quality. However, if their quality was considered in the context of their not being systematic reviews (i.e. in the context of their stated methods and scope), some could be considered moderate quality.

Quality of the grey literature

The quality of the grey literature publications was broadly assessed according to the comprehensiveness of information sources they drew upon, the methods employed to identify these sources, and the clarity and quality of the analysis presented.

Overall, we reviewed 16 grey literature sources spanning research reports, health organisation reports and briefings for NHS leaders, a guide to using quality improvement tools and a blog article, as discussed in Section 3.

Three of the grey literature research reports were informed by structured reviews, and were judged to be of moderate quality because they were not fully clear about issues such as the search strategy used and/or the evidence included in the review.

A further five research reports were based on a combination of non-systematic literature review and stakeholder consultation. The quality of these was judged in part using the same criteria used to assess the non-systematic academic reviews. The quality of the stakeholder consultation elements that often accompanied literature review components in the grey literature was also considered, particularly taking into account the number and relevance of consulted stakeholders. These reports were considered to be of moderate quality if they employed appropriately rigorous qualitative research methods (in terms of numbers or nature of stakeholders consulted, clarity of the analytical process and evidence-based backing of claims being made), and described these methods in appropriate detail.

The remaining eight grey literature reports were judged to be of low to moderate quality. Four were judged to be of low quality because they drew on a very limited range of experiences and perspectives (especially from the literature) and four were assessed as being of moderate quality because they appeared to synthesise lessons from a wider body of evidence.

4

Learning about the influences on improvement processes

In this section, we discuss the key lessons learned from this rapid evidence assessment, as they relate to the nature of and influences on improvement processes.

More specifically, the section shares learning pertaining to six key influences:

- Leadership
- Relationships and interactions that support an improvement culture
- Skills and competencies
- Using data for improvement purposes
- Patient and public involvement, engagement and participation in quality improvement
- Influences related to working as a system.

Case examples in support of key learning points are provided where appropriate. At the end of this section, we also briefly reflect on the evidence-base as it relates to the links between the processes of improvement and reported outcomes.

4.1. Leadership

It is widely accepted that leadership support for improvement efforts is critical for their implementation and that it increases the chances of achieving an intended impact [8, 16, 20, 44, 52, 53, 58, 60-62]. However, leadership is somewhat of an umbrella term and it is useful to reflect on what it means in practice and what the dimensions of effective leadership of improvement processes are. Based on the literature reviewed for this REA, effective improvement activity requires different elements of leadership to be manifested in both the design and implementation of improvement initiatives.

Leaders from diverse professional communities, both clinical and managerial, need to be involved in steering and overseeing improvement efforts [17, 20, 28, 30, 44, 52, 54, 55, 58, 60-62]. Although the engagement and buy-in of both clinical staff and managers is important, it can be challenging to secure. Clinical leadership and hospital managers can experience conflicting priorities or loyalties and values, and this can hinder the successful implementation of improvement efforts [20]. Mitigating this requires upfront investment into the alignment of goals and into creating a shared vision prior to the roll-out of an improvement intervention. It also requires nurturing such a shared vision throughout the implementation of improvement activities [58]. A Health Foundation report [55] focusing on communications that can support the spread of improvement emphasised the importance of paying particular attention and listening to those who have doubts and to their concerns, and considering how adaptations in an

Box 7: The importance of multi-professional leadership support and the need for practical actions to demonstrate leadership commitment to improvement efforts: Practical Obstetric Multi-Professional Training (PROMPT) in Southmead Hospital, Bristol

In a briefing for senior NHS Leaders, Alderwick et al. [61] discussed the case of the development and implementation of Practical Obstetric Multi-Professional Training (PROMPT) in Southmead Hospital in Bristol. The training was developed by a group of healthcare professionals from maternity units in southwest England, and it was first introduced at North Bristol NHS Trust in 2000. The support of midwifery, obstetric and maternity leads was identified as key for successful implementation. According to the authors, the manifestation of leadership support in practical actions (e.g. time to attend the training, ensuring that enough trainers are available to deliver the training) as well as leaders' long-term commitment helped with successful intervention implementation. Reported achievements include a 50 per cent reduction in injuries to babies due to lack of oxygen and a 100 per cent reduction in permanent brachial plexus injuries, as well as a reduction in litigation claims from £25 million to £3 million in the first ten years after PROMPT's introduction. Many other maternity units have now implemented PROMPT.

envisaged improvement approach can help secure their buy-in.

Collaboration between multiple clinical and allied health specialties is particularly important for areas of clinical care that strongly depend on multi-professional teams for care delivery, and securing effective collaboration requires leaders from different specialties to commit to a shared vision. The importance of multidisciplinary collaboration and of a strong teamwork ethos was flagged in numerous reviews and reports on the topic of quality improvement, including for example in Conry et al.'s systematic review [18] of quality improvement interventions in hospitals; a Healthcare Improvement Scotland report [56] on building sustainable improvement cultures; Franx et al.'s [49] review of organisational changes to improve quality and outcomes for patients with severe mental illness; and in Alderwick et al.'s [61] briefing for senior NHS leaders (supported by an example of quality improvement in maternity care – see Box 7).

Involving leaders across different components of the healthcare system is important for improvement efforts in some clinical areas [60, 61] and for complex conditions where patients are followed by multiple components of the healthcare system. It is also integral to some collaborative networks for quality improvement [9, 16]. This includes leadership in the healthcare provider sector, but is not confined to it. For example, Øvretveit [53] identified political leaders, leaders from the regulatory sector, purchase sector leaders, board leaders, chief executives and top management from provider organisations, general operational management, senior medical leaders, other medical and nurse leaders and support from administrators, students and medical assistants as all being important for a healthcare system committed to continuous improvement (see Box 8 for examples of actions that different types of leaders can take). Similarly, Alderwick et al. [61] emphasised the importance of leadership support and collaboration across the healthcare system (see Box 9). The Health Foundation too has highlighted the importance of creating a culture of 'distributed leadership' when implementing organisation-wide improvement [60].

Box 8: Examples of actions that different types of leaders can carry out to support an improving healthcare system (adapted from Øvretveit [53])

Øvretveit [53] acknowledged that any leadership actions are situation-dependent, but highlighted the general role that different types of leaders can play in efforts to improve healthcare:

- **Political leaders** can communicate the vision for improved healthcare quality as well as their long-term commitment and support through dedicated improvement programmes.
- **Regulatory leaders** can take action by, for example, defining what is expected (and of whom) in terms of quality and safety, as well as through providing feedback about the degree to which improvement goals are being achieved in provider organisations.
- **Purchase leaders** can ensure that provider organisations who pursue and achieve improvement goals are not financially penalised and can consider value-based instead of cost-based purchasing.
- **Board leaders** can develop and track quality and safety indicators, systems and processes in provider organisations.
- **CEOs and top managers** can communicate and demonstrate why improvement is important; have and share an improvement vision and improvement aims; motivate and incentivise staff; change the system and processes in a way that improvements can be made; and provide resources and capabilities necessary for improvement.
- **General operational managers** can contribute to improvement through discovering poor quality and taking actions to address issues, including through priority-setting, training, the adoption of improvement methods and the management of conflicting demands on healthcare professional time.
- **Senior medical leaders** can involve doctors in quality improvement, provide information and incentives to staff as well as provide training tailored to doctors' needs.
- **Medical leaders** can point out areas for improvement based on evidence from research and practice and be role models in their behaviours, in support of improvement cultures and practices.
- **Nurse leaders** can learn safety and quality improvement methods and then use them in practice: this can encourage others to improve quality and help spread improvement cultures and associated behaviours.

Box 9: The importance of leadership support and collaboration across different components of the healthcare system in improvement efforts: whole-pathway improvement for dementia care at NHS High Weald Lewes Havens CCG

Alderwick et al. [61] discussed the impact of securing buy-in and support from senior leaders from across primary, acute, community, social care and the voluntary sector in Sussex and the involvement of different professions (e.g. GPs, commissioners of care) in a collaborative whole-pathway improvement programme for dementia care. In 2013, a local clinical review of dementia care in Sussex – the region with the highest share of people living with dementia across England – found poor care experiences. This was partially related to a lack of access to information and a lack of adequate post-diagnosis support. Based on these findings, a project team at NHS High Weald Lewes Havens CCG consisting of people from across the health and social care system, as well as patients and carers, developed a new care model. The pathway was successfully piloted in a GP practice in Buxted in Sussex in 2015 and then rolled out across other organisations. According to the authors, the new pathway had a positive impact on the emotional and physical wellbeing and quality of life of patients with dementia, and also contributed to a reduction in GP consultations, acute care attendances and admissions.

Sustainable quality improvement is not a top-down activity and support from leaders at different levels in organisational hierarchies, with clearly articulated responsibilities for implementing improvement, matters greatly [16, 17, 20, 26, 28, 36, 40, 47, 48, 57, 58, 60, 61]. Champions and opinion leaders for improvement initiatives, who are critical for mobilising and sustaining wide-scale buy-in and commitments, need to be drawn from executive leadership, management and frontline staff communities in order to create a 'habit of improvement' [16, 17, 20, 36, 40, 48, 59, 60]. Aveling et al. [26] highlighted that the quality improvement efforts of clinical communities can fail if they are seen as too burdensome and if buy-in from managers is seen as weak. Lipworth et al. [36] flagged the importance of social influences – if a whole team believes in an intervention it is more likely to be taken up than if views on its value are divided.

A long-term view on improvement is needed from leadership, especially in light of the complexity of many quality improvement efforts [7, 61, 62]. A long-term view mitigates the risk of putting excessive pressure on staff to achieve quick fixes, which is important as many quality improvement efforts require time to accrue benefits. This is not to say that shorter-term milestones cannot be built into a longer-term vision and strategy. However, a report by the Care Quality Commission [58] identified that impatience at non-executive director and board levels can compromise the implementation of a long-term oriented strategy, although the authors also implied that this may in part be mitigated through training and education on quality improvement at non-executive director and board member levels. Alderwick et al. [61], Jones et al. [60] and West et al. [62] have also flagged the importance of efforts to ensure long-term board-level support and buy-in.

A consistent, coherent and realistic strategy for leading and implementing quality improvement efforts can support a long-term vision and needs to be accompanied by a clear delegation of roles and responsibilities for improvement, and trust in the leaders of improvement initiatives [7, 10, 33, 36, 44, 58, 61]. By contrast, the pursuit and promotion of ad hoc, piecemeal interventions and a lack of planning are signs of weak leadership and can threaten the sustainability and impact of quality improvement efforts, as Bakke et al. [52] have highlighted in the context of improvement collaboratives. Realistic goal setting – that balances ambition with what is feasible – needs to be part of any effective strategy. For example, Bibby [64] has stressed that improvement collaboratives can sometimes have unclear or excessively ambitious goals which can lead to frustration amongst all those involved. Improvement activity also requires sustained and continuous engagement from leaders and managers over time [37, 48, 60] and trust in those promoting and leading quality improvement efforts [36]. In this context, staff turnover or staff shortages, especially at senior leadership levels, can compromise the implementation of a consistent long-term vision and strategy [33, 58]. Given that senior leadership turnover is not uncommon in the healthcare system in the UK, West et al. [62] have highlighted the importance of integrating newly recruited leaders into an improvement culture.

Leadership support can be demonstrated in a variety of concrete ways and requires a multipronged approach. As one example, Jones et al. [60] provided illustrations of the diverse ways through which leadership can effectively support improvement initiatives, through both strategic direction and practical enabling mechanisms (see Boxes 10 and 11).

Box 10: The importance of a long-term leadership vision and a multipronged strategy for improvement: transformation at Western Sussex Hospitals NHS Foundation Trust (adapted from Jones et al. [60])

Jones et al. [60] discussed how Western Sussex Hospitals NHS Foundation Trust implemented a trust-wide transformation programme (Patient First) to embed a culture of continuous improvement into the trust and embed improvement into everyday staff roles. The programme built on the Lean quality improvement approach. The leadership deployed a multipronged approach to steering the transformation effort – providing both strategic direction and ensuring practical support. For example, the trust's leadership established an improvement 'Kaizen' office to oversee and support the implementation of a long-term sustainable improvement strategy, including to ensure alignment between improvement and workforce strategy in the trust. Practical enabling mechanisms – such as training staff in Lean methods, giving clear improvement roles and responsibilities to middle and senior managers, and the introduction of improvement huddles that enabled all staff to contribute views and ideas – supported implementation needs. A Care Quality Commission (CQC) inspection report also highlighted the importance of a culture of respect, good team working and leadership that could motivate staff to buy into the improvement vision and strategy. The improvement efforts contributed to improved CQC ratings (from inadequate to good for the Brighton and Sussex University Hospitals Trust, which was taken over by Western Sussex Hospitals NHS Foundation Trust in 2016).

Box 11: A capability-building programme in Northumbria Health NHS Foundation Trust: the importance of embedding quality improvement capability building into wider organisational strategies and of adopting a multipronged approach (adapted from Jones et al. [60])

The Northumbria Health NHS Foundation Trust established an improvement capability-building programme that has been implemented across all levels of the trust for clinical and non-clinical staff. In their report, Jones et al. [60] explained that the trust was given an outstanding rating by the CQC in part as a result of the quality improvement capabilities it had established. Jones et al. [60] highlighted how the trust combined clear roles for capability building (e.g. a quality improvement executive lead supported by Q community members, flow coaches and quality improvement-trained clinicians and managers) with a consistent and coherent quality strategy (that is aligned to the wider strategic vision of the trust and focuses on a relatively limited number of core quality priorities), an implementation and monitoring forum (Quality Lab) with members from different professional communities and levels in organisational hierarchies, and an improvement training programme that is rolled out to clinical and non-clinical staff.

The nature of communications from leadership plays a strong role in any effort to build a shared vision and buy-in for improvement activity. A compelling narrative that clearly conveys the value of an improvement initiative, leadership support for it, and how the implementation process will work and be made feasible is essential [8, 9, 56]. For example, in a report on engaging clinicians in national clinical audits, Allwood [8] highlighted that a lack of clarity on the purpose behind some national clinical audits and on an audit's relevance to clinical practice, as well as mistrust in the perceived benefits of audit activity, can act as a barrier to mobilising staff engagement with them. Lipworth et al. [36] found that upfront beliefs influence the likelihood of ensuring commitment and staff support for improvement. For example, they refer to hospital and primary care clinicians' use of recommendations in clinical practice guidelines for chronic obstructive pulmonary disease. The clinicians strongly believed in the effectiveness of a recommendation to talk to patients about smoking cessation, and this facilitated implementation; by contrast, the clinicians were less convinced by a recommendation to communicate with their patients about medication self-management, and were therefore less likely to act on this recommendation. Messages from leadership may need to be targeted differently for different audiences to ensure they clearly communicate how an improvement initiative aligns with the priorities of specific stakeholder groups [55].

Leadership also has a role to play in awareness-raising about improvement activities and about the evidence base behind them [47, 55]. For example, Schultz et al. [47] addressed Lean management systems in radiology and argued that for improvement efforts to be successful, leaders have to make their employees aware of changes and encourage them to adopt new practices. They use the experiences of leaders at ThedaCare Medical Center in Appleton, Wisconsin as an example. These leaders were able to address employee concerns and communicate the need for change and where it fits within existing practice in regular newsletters (i.e. sharing that Lean did not replace critical thinking and explaining its importance) [47]. Similarly, Clay-Williams et al. [17] reviewed diverse large-scale hospital and system-wide interventions and found that awareness-raising about the intervention among healthcare workers was a key factor contributing to sustained cultural change. They referred to a hand-hygiene intervention at the University of Geneva teaching hospital in Switzerland, where strategies to raise awareness of the importance of hand hygiene among healthcare workers included multiple promotional activities (such as giveaways), social functions, slogan competitions, quizzes, pay slip notices, internal newsletters and screen savers [65]; cf. [17].

Practical enabling mechanisms for staff to engage with improvement activity need to be built into the design of improvement initiatives. Such mechanisms need to address financial requirements, human resource capacity and capabilities, and issues related to securing requisite technical resources [8, 16, 36, 53, 60, 61, 64]. More specifically:

- Many publications highlighted the importance of freeing up staff time [7, 8, 40, 42, 53, 61], including for example through buying out their time from the delivery of everyday clinical activities in order to engage with improvement initiatives. Integrating quality improvement activity into the everyday roles and responsibilities of staff and aligning improvement with the organisation's wider strategic goals can support sustainable improvement cultures [54, 60]. However, such integration (without ring-fenced time for improvement activity) may be challenging to achieve in a healthcare system with already extreme pressures on staff time. Brown et al. [16], Mann & Pratt [44] and Conry et al. [18] have also flagged that administrative support is needed for the efficient and effective delivery of improvement activities, and its lack can be a major challenge to implementing interventions. Jabbal's [7] report on embedding quality improvement into organisational cultures highlighted the importance of backfilling the time of individuals who are 'released' from regular day-to-day activities, and communicating the importance of what they are doing to colleagues who are 'continuing as normal' in their absence.
- Staff skills and competencies are also critical for the effective implementation of improvement aims and training is a key element of many improvement efforts [7, 8, 16, 20, 22, 36, 39, 41, 43, 48, 50, 53-55, 58, 60, 61, 64]. This is discussed further in Section 4.3.
- Supportive IT infrastructure is also needed for many improvement efforts, especially data intensive ones such as audits [8, 16, 42, 54].
- All improvement activity needs to be appropriately resourced financially and the lack of appropriate funding can be a significant barrier to implementing improvement [8, 16, 42, 60-62]. In the context of efforts to meet quality targets under pay-for-performance schemes, Christianson et al. [29] highlighted that financial rewards for successful implementation must be sufficient to justify the required investment by implementing organisations. Reward-based schemes that do not cover the upfront costs of implementation are challenging for organisations to engage with and are thus unlikely to stimulate change [29].

The reviewed literature considers many different leadership styles, some of which are based on more relational approaches, others more on hierarchy. For example, Aveling et al. [26] described the role of relational leadership in nurturing a connected clinical community with shared norms and values (see Box 12). The social contexts for quality improvement efforts are likely to vary in terms of the extent to which they rely on social relationships as a driver of activity versus the extent to which they are led through hierarchy. In this light, the mix of tactics needed to keep the initiatives functioning well will vary across contexts and across time [16]. Overly top-down approaches to improvement efforts are thought to limit the buy-in and engagement of clinical staff [9, 46, 60, 62]. Coordinators may help in developing and managing effective quality improvement networks and in providing sufficient structure and oversight, while mitigating the unintended consequences that overly top-down, hierarchical management can have [9].

Austin & Pronovost [39] highlighted that effective oversight of improvement activity by health boards should be built on mutual trust between board members and staff, and that board members must be alert to the needs of both patients and staff. There can be tensions in balancing the exercise of authority that is sometimes needed to overcome resistance to change or inertia, and relationship-based leadership within the same setting, and leaders sometimes need to be able to adapt their leadership style to the circumstances at play [58].

4.2. Relationships and interactions that support an improvement culture

The notion that relationships and culture underpin the ability for improvement and change is not new, and relationships and culture are also closely linked to other influences such as leadership [20, 25, 26, 56, 61, 64]. By improvement culture we mean a set of shared values, norms and behaviours that underpin improvement activities. But what aspects of culture are important for improvement, and how can relationships be nurtured to support an improvement culture, especially given that so much improvement activity is collaboration- and cooperation-dependent? Based on the reviewed literature, we identify below a series of aspects of relationships that matter in effective quality improvement processes and cultures.

Many types of quality improvement efforts benefit from cultures that actively value diversity and harness voluntary participation and inclusiveness [9, 17, 56, 60, 64], and some are fundamentally rooted in the concepts of inclusiveness and participation. This includes (but is not confined to) collaboratives and various clinical communities and networks [16, 26, 52, 64], and initiatives pursuing Experience-Based Co-Design (EBCD) of services for improvement purposes [40]. Bibby [64] has highlighted that collaboratives (which are premised in the context of multidisciplinary teams of clinical and quality improvement experts working in structured processes and activities with clear and measurable goals and targets) are more likely to be successful if they involve staff from various disciplines and also patients. Hulscher et al. [34] reported that collaboratives are more likely to succeed if the teams that are interacting get to know each other well and know each other's strengths and weaknesses, and Borgstrom & Barclay [40] describe how the use of inclusive EBCD methods can support improved commissioning of services (see Box 13).

Box 12: The role of relational leadership in nurturing a connected clinical community with shared norms and practices

Aveling et al. [26] discussed clinical communities for quality improvement, which are networks of interdependent members brought together by their shared focus on action and learning and by their collaborative commitment to shared quality improvement goals, rather than by direction from hierarchical leadership. Although these networks are not open to everyone, the flexible boundaries that define them cut across the typical segmentation of organisations, professions and disciplines, resulting in a diverse but collaborative membership [26]. Clinical communities for quality improvement focus on quality improvement-related learning and action. In clinical communities, buy-in to quality improvement behaviours and interventions strongly depends on the ability to establish and sustain shared norms. Aveling et al. [26] highlighted that unlike quality improvement collaboratives, which are often recognisable by their commitment to a specific quality improvement methodology, clinical communities are distinguished by how the network is structured and organised.

The network is held together by both vertical and lateral structures. A vertical core of leaders is responsible for identifying evidence-based interventions, and it is this core that leads, organises and mobilises quality improvement activity. Lateral links between members in the community facilitate local adoption and adaptation. The spread and adoption of quality improvement activities takes place due to social norms rather than hierarchical or legal structures (clinicians tend to learn from experience and from their peers rather than through hierarchies). The controls in the community are partially informal and social, and thus depend on social norms that influence behaviours.

However, Aveling et al. [26] also argued that overreliance on voluntary social linkages can put clinical quality improvement communities at risk of disintegration, as sustained cohesion, integration and coordination typically rely on some degree of hierarchical leadership. Despite their intentions in terms of design, clinical communities can sometimes be fragmented, with individual members having a mix of shared and conflicting interests. Some members may not even believe there is a need to improve.

The risk of disintegration can to some extent be addressed by developing and supporting a strong vertical core comprising credible leaders, ideally drawn from the community. The role of this vertical core is to lead and organise quality improvement activities, and to mobilise participation. It is an important feature for facilitating development of a united vision across the community, and for establishing community cohesion.

Aveling et al. [26] also highlighted that different styles of leadership and decision making are more important at different stages of implementation; for example, ‘moral entrepreneurs’ are required to engage staff consciousness and challenge the status quo during the establishment of a clinical community, while leaders with deep and practical ‘know-how’ are more important later on (although the two types of leaders are not necessarily mutually exclusive). These leaders need to balance the exercise of authority and relationship management, although the authority they command is likely to be influenced by community trust in their credibility and experience, which can also serve to support good relationships. Regular interaction, communication and informal socialising within the community, and the collection and sharing of both process and outcome data, can also help to establish shared norms in clinical communities for quality improvement, and can assist in setting and sustaining common goals.

Box 13: Using the principles of inclusive and participatory EBCD methods to support experience-led commissioning of end-of-life care services

Experience-Based Co-Design (EBCD) focuses on collaboration between service users and healthcare professionals in the design of services (with a view to improving care quality, safety and/or patient experience). EBCD is a specific form of a participatory approach that, like others, seeks to engage a variety of stakeholders to collaboratively work with each other, but it is somewhat unique in its focus on using experience as a motivator for change. This is achieved by using narratives captured through in-depth interviews, observations and shadowing of service delivery activities, as well as co-design events to emotionally connect healthcare providers with patient experiences, leading them to reflect on potential improvement needs and options [40]. EBCD can be costly and time-intensive and sustaining EBCD-based improvement approaches requires senior leadership support. Borgstrom & Barclay [40] also identify the importance of good facilitation skills to support EBCD processes.

In their review of EBCD in end-of-life care, Borgstrom & Barclay [40] discussed the case of experience-led commissioning (ELC) by the Healthworks CCG (now a locality group within Sandwell and West Birmingham CCG) in Birmingham in 2011, which was delivered to improve end-of-life care services. The CCG drew on EBDC and participatory models to hold five local events to cooperatively design end-of-life care services with stakeholders ranging from commissioners, service providers and other health professionals to users and user representatives. Using a so-called ‘trigger’ film, researchers at the University of Oxford tried to initiate first discussions and connect healthcare providers’ views with patient experiences; the trigger film was developed using national archive videos. In addition, the ELC effort included a workshop for service design and co-design; a needs assessment for the service; monitoring and review; contracting; and change champions for implementation support. Borgstrom & Barclay [40] reported on a formal evaluation of ELC which found that participants felt that ELC-enabled commissioning is more reflective of the ‘real world’. At the end of the process, commissioning resources were produced, including a strategy document for end-of-life commissioning, an online interactive case study and electronic resources.

A culture that promotes relationships based on open discussion and transparency is important for effective quality improvement and for collective sense-making about an improvement approach [10, 20, 61]. This is often linked to cultures promoting teamwork and focused on creating improvement communities [9, 60]. It is also linked to cultures that identify and promptly and proactively deal with problems, conflict or marginalisation of traditionally less powerful groups such as patients and nurses [26, 64] and seek consensus on solutions [64].

The alignment of an improvement intervention to the values and perceived responsibilities of different individuals and professions involved in improvement activity matters [20, 36, 58], ***and achieving such alignment requires investment in communications and relationship building.*** Congruence is vital and improvement approaches that work against the established norms of an organisation are unlikely to have much traction. For example, Flynn et al. [20], in the context of examining the sustainability of Lean in paediatric healthcare, highlighted that the success and sustainability of improvement activity is likely to depend on the alignment of the values intrinsic to Lean (e.g. achieving efficiency and eliminating waste) with those of staff in the improving organisation. An alignment of values is likely to support collective sense-making, buy-in and engagement. This alignment needs to start at organisational level: for example, institutional goals need to be in line with Lean aims, and this requires leadership to fully understand the Lean philosophy and integrate it into their organisation's strategy [20]. Moreover, if staff 'make sense of' Lean Thinking as a way to improve patient care, then they are more likely to engage with it. By contrast, if healthcare staff think that a quality improvement activity is introduced just for the sake of cutting costs, they might see it as a burden to their job ([66], cf. [20]).

An improvement culture is more likely to be embedded into the daily function of healthcare teams and organisations, when the importance of quality improvement is supported by investments into enabling regular interactions, communication and information exchange between those involved in improvement [26, 32, 52, 61, 64]. Regular interactions can support common values and shared sense-making on the need for improvement, as well as shape collective learning and reflection on progress with improvement activities. Practical actions, such as clearly outlining and standardising interventions and accompanying procedural requirements can also help support effective communication and interactions related to implementing improvement efforts [32]. Jabbal [7] also highlighted that transparency and openness pertaining to the implementation of quality improvement is important. The same is true of regular communications to ensure that staff are aware of improvement opportunities and activities. For example, Jabbal [7] illustrated how regular weekly newsletters helped to improve staff engagement and create a quality improvement-supportive culture in a healthcare organisation. Schultz et al. [47], reporting on Lean management systems in radiology, referred to huddles as a key element of Lean management systems: these regular meetings (e.g. every morning) enable all staff to meet and communicate quality improvement efforts.

Sharing and disseminating learning between different organisations engaging in their respective quality improvement efforts can be helpful in building quality improvement cultures in organisations [58] ***and in the healthcare system more widely, and lessons can be learnt both from improvement efforts within the health sector and in other sectors*** [8, 10, 58]. Engaging with a target audience and sharing evidence in an accessible format is important in any such communication and dissemination activity, including getting the input of a target audience and not just sharing information with them as passive recipients [59]. A clear communication and dissemination strategy needs to consider what to communicate, to whom, how and when [59], as not all mechanisms are appropriate to all contexts. Learning and exchange can be facilitated through diverse means, including face-to-face events and meetings, newsletters and weekly publications, social media, emails and flyers [7, 8, 55]. A Health Foundation report [55] provided the example of midwives who organised annual online events ('e-vents') to share learning and strengthen international networking among midwives. They used various social media services to raise awareness of the events and to invite other midwives to participate. Participation in the events increased over time, and social media was thought to have contributed to the increase. However, the authors also noted that there is very little evidence on the impact of social media and campaigning in influencing improvement cultures [55]. As detailed in Box 14, Allwood [8] identified regular communication, feedback and close relationships as important drivers of an improvement culture.

Box 14: The importance of regular communication, feedback and interactions to support and sustain an improvement culture: learning from national clinical audits

Based on literature review and stakeholder consultation, Allwood [8] considered ways to improve and scale up the use of national clinical audit for local improvement, and in particular how to engage clinicians with audit activity. As part of this research, Allwood reported on interviews with diverse stakeholders involved in clinical audits (e.g. clinicians, clinical audit leads, medical directors, members and managers of clinical audit and clinical effectiveness teams, audit suppliers, HQIP Quality Improvement and Development team members, and members of the National Advisory Group for Clinical Audit & Enquiries).

Allwood identified engagement and communication activities as a key determinant of staff engagement with clinical audits. This includes communication across different levels and stakeholders – for example between clinical audit leads and clinical teams, between clinical audit leads and local audit teams, and between audit suppliers and trusts. Interviewees specifically referred to the value of feedback between clinical audit leads and clinical teams. According to one interviewee, providing frequent feedback helped ensure that ‘people knew what a difference they were making’ [8: p. 53].

Close relationships and communication between clinical audit leads and local audit teams were found to be particularly important, including to support shared learning across an organisation. Similarly, some interviewees highlighted the importance of medical directors in helping drive and keep alive communication between clinical audit leads and local audit teams.

Interviewees also referred to the importance of good communication between audit suppliers and trusts, highlighting a few cases where communication did not work that well due to staff turnover, lack of clear contact points in organisations, or audit reports being sent to the wrong people. An interviewee thought that audit suppliers should have at least two contacts per trust to ensure that reports are received. However, sending audit results was not perceived as sufficient: interviewees also felt that additional support from suppliers, for example to analyse audit data, improves the experience of doing a clinical audit.

A culture of improvement is more likely to be sustained if individuals who are involved in improvement activity can feel personal benefit from the improvement efforts as well as collective, organisational benefit. These benefits can include both personal development [40, 42] and mutual learning, as well as benefits in relation to the ease and quality of job performance [9, 24]. Recognition and reward of individual contributions and commitment to an improvement culture is also important [7, 30, 36, 40-42, 59] and can take many different forms. Some examples from the literature included celebrating success through awards and celebratory events [58] (see also Box 15), embedding recognition in career and promotion pathways for staff, Continuing Professional Development (CPD) points, and sharing success via social media and other means [40, 55, 59, 62, 67]. Another example was provided by Bakke et al. [52]: in their review of quality collaboratives for quality improvement that aim to facilitate mutual learning between professionals working in different departments, organisations and clinical communities, the authors highlighted that a sense of shared learning and personal and mutual development, and a better understanding of the roles and needs of different individuals and groups, can help drive commitment to implementing quality improvement activities.

Box 15: Creating an improvement culture: celebrating learning and success at Midlands Partnership NHS Foundation Trust

A report published by the CQC [58] provided the example of regular meetings at Midlands Partnership NHS Foundation Trust, which have an emphasis on sharing as well as celebrating learning and success. These meetings also help foster a quality improvement-supportive culture. On Friday afternoons, the trust organises meetings, for example in the form of a Rapid Process Improvement Workshop (RPIW) (a type of meeting used in Lean Thinking) or a Kaizen event (a shortened version of a RPIW) [68]. Before a RPIW takes place, the quality improvement team shares an improvement report with the staff at Friday lunchtime, which includes updates on quality improvement projects and monitoring and metrics data. All staff are invited to attend the meetings, which are also filmed and streamed live within the organisation. The trust has also created stories about their quality improvement work and shares them on the trust's screensavers and through newsletters to disseminate quality improvement-related information organisation wide. In addition, staff are encouraged to think about quality improvement efforts that could be communicated more widely across the trust [58].

4.3. Skills and competencies for improvement

Although not surprising, much of the reviewed literature highlighted that training staff involved in quality improvement in requisite skills and knowledge is beneficial in supporting the quality improvement process [7, 8, 16, 20, 22, 36, 39, 41, 43, 48, 50, 53-55, 58, 60, 61, 64].

In many settings, there is a lack of experts on specific quality improvement methodologies, as Deblois & Lepanto [48] have highlighted in the context of Lean and Six Sigma methodologies. Alderwick et al. [61] and the CQC [58] also emphasised that not only healthcare staff need to develop the right skills and capabilities, but also board leaders and members of executive teams. The CQC [58] pointed out that leaders undergoing training to develop quality improvement skills is key to embedding a quality improvement culture in an organisation.

Understanding what skills are needed is a prerequisite for effective training-related decisions. However, the necessary skills are not always immediately obvious. Investment in technical skills and skills to navigate the social dimensions and social dynamics of quality improvement both matter. For example, and in the context of clinical communities for quality improvement, Aveling et al. [26] highlighted that the type of behaviour change that quality improvement efforts might require can lead to demand for unfamiliar skills. The authors flag the importance of identifying and providing enabling resources and the required training in technical, social and political skills. Bibby [64] has suggested that a skills audit prior to implementing an improvement intervention may help to identify what skills the people that are likely to be involved in a quality improvement effort might have and where gaps lie. Such an audit could help support evidence-based training-related investments. (Although not explicitly discussed in the reviewed literature, and thus more of a study team reflection, training in improvement is not a one-off activity: training strategies need to consider 'refresher' approaches and scale-up over time, so that a critical mass of staff can learn improvement skills. This may also help retain skills in light of staff turnover.)

An educational component can be integrated into quality improvement interventions through various means. These include lectures, online teaching materials, workshops, guideline and protocol dissemination, group work, simulations, scenarios and role play, and through experiential learning and feedback [16, 22, 41]. The appropriate means will be driven by the skills gaps that need to be targeted and by other contextual factors (e.g. resources). Gordon & Findley [22] have discussed the importance of observations, feedback and evaluation of the educational process. Studies reviewed by Brown et al. [16] and Caspar et al. [41] found that coupling an intervention with an educational component can have a positive impact on the intervention's success. Caspar et al. [41] noted that the way an educational component is delivered can be as important, or even more important, than the intervention itself.

Whereas some educational components are technical and specific to the quality improvement challenge or specialty at hand, others are somewhat more general in nature and can, if tailored and adapted appropriately, apply across different improvement contexts. For example, more general education and capability building may apply to skills in information management, teamworking, leadership, interpersonal communication skills and professional behaviour, negotiation skills, and some quality improvement methods [e.g. 20, 26]. In a report on organisational-level improvement efforts, Jones et al. [60] argued for the need to combine a basic understanding of improvement approaches such as Lean and tools such as Organizational Readiness to Change Assessment (ORCA) with capabilities to analyse data in order to monitor quality and performance. Flynn et al. [20], in reference to Lean quality improvement methods, have highlighted the importance of internally or externally delivered quality improvement coaching and mentoring, and a Health Foundation report on tips for spreading improvement cultures [55] considered the role of train-the-trainer models to build capability at group levels (but reports mixed evidence on their impacts). A review by Austin & Pronovost [39] referenced a study in which training residents and fellows in Lean Sigma methodology and having them subsequently lead a mentored quality improvement project was found to improve the training recipients' belief in quality improvement and to increase their self-reported quality improvement behaviours [69], cf. [39]. A CQC report [58] offered the example of a trust taking a strategic and systematic approach to developing improvement skills, which included identifying staff-specific training needs and addressing these with a variety of different learning opportunities (see Box 16).

Box 16: Training staff in quality improvement: East London NHS Foundation Trust's strategic and systematic approach to developing improvement skills

The East London NHS Foundation Trust took a strategic and systematic approach to developing quality improvement skills across different levels in the trust. It achieved this through various activities [58], including:

- An introduction to quality improvement as part of the induction process for new starters.
- A six-month improvement leaders programme, targeted specifically at individuals in leadership or management roles.
- Leadership responsibilities to identify training needs amongst their staff.

Leaders in the trust are also expected to identify training needs among their staff. The trust offers a range of different learning opportunities that leaders can recommend to their staff, such as intensive six-month courses, quality improvement refresher courses, workshops and webinars.

4.4. Using data for improvement purposes

In an evidence-based healthcare system, data serve many purposes. It is important for identifying improvement needs and for informing the design and strategy for rolling out improvement interventions, as well as for measuring progress and for evaluating the results of quality improvement efforts [8, 21, 23, 26, 27, 37, 51, 60, 61]. Aveling et al. [26] suggested that collecting and using both process and outcome data can also help in building improvement cultures – for example by helping establish shared norms and through assisting in setting common goals (they discuss this in the context of clinical communities for quality improvement).

Data underpins most quality improvement interventions in some way, but there are some quality improvement approaches which fundamentally focus, as the core element of the approach, on the use of data to assess improvement needs and/or performance, and to drive changes. For example, clinical audits use data to show areas in need of improvement or where improvements have been made over time, and to enable comparison with other organisations [8]. Similarly, Salford Royal NHS Foundation Trust became one of the first Global Digital Exemplars (GDEs) and is – as per the GDE definition – the first fully digitally enabled trust in England. They have developed their digital infrastructure and staff capabilities so that staff can record and analyse data efficiently and effectively [60]. Quality indicators were also discussed in the literature as an important approach for identifying process changes that can support higher-quality care [51]. Other surveillance systems (not necessarily audit related) can also help diagnose issues and inform improvement needs (see Box 17).

Box 17: The use of data generated by surveillance systems to improve care quality: identifying people at risk of end-stage kidney disease

Alderwick et al. [61] provided the example of a surveillance system for trained clinical laboratory staff to identify people at risk of end-stage kidney disease. This system, which uses existing laboratory data, was developed by and introduced at the Heart of England NHS Foundation Trust in the early 2000s. In 2004, a kidney consultant at the trust used blood test results from patients with diabetes to create estimated glomerular filtration rate (eGFR) graphs, which helped the wider clinical team assess the patients' risk of end-stage kidney disease. As the analyses were found to be effective, the use of the system was extended to cover all patients across the trust from 2012, enabled by a grant awarded by the Health Foundation. According to Alderwick et al. [61], the use of the system led to stabilisation of the number of people who had a renal replacement therapy within the trust (while at the same time the overall number in the UK increased).

There are diverse influences which affect how (and to what extent) data is used in improvement processes. For example, the general organisational culture and attitudes towards data and evidence matter greatly [8], including whether staff in organisations believe that data can inform improvement efforts and help them succeed. Promoting a culture that is receptive to the use of data is a key leadership responsibility and requires both senior leadership and management support [51].

Literature highlights that lack of awareness of what data exists and how to access it can sometimes be a barrier to using it for improvement purposes [36, 51, 60]. Thus raising awareness about its existence seems to be an important leadership and/or management role. For example, Lipworth et al. [36], in referring to an interview study of GPs' attitudes to the use of guidelines, identified that uptake would likely improve if primary care physicians knew about which guidelines they should implement for improvement and where these can be found.

How data (and associated feedback) is provided, when and to whom, influences how likely it is to be effective in guiding improvement activity [8, 51]. For example, in discussing the implementation of national clinical audits, Allwood [8] flagged the importance of direct contact with heads of departments when providing audit results on ongoing improvement efforts. Similarly, Benn et al. [51] highlighted that individuals involved in strategic and management decision making need to be involved in feedback processes. Benn et al. [51] have also emphasised that integrating feedback (in this case on quality indicator performance) into wider quality improvement strategies and programmes of organisations is likely to support achieving desired outcomes. Ivers et al. [24] suggested that combining feedback with other interventions (e.g. problem-based learning, improver groups) is more conducive to impact. Numerous reviews on the topic of data-driven quality improvement have flagged that timely feedback is essential for positive impact [8, 24, 38, 51, 60].

Trust in the quality of the data (e.g. in its accuracy and comprehensiveness), in the analysis methodology used, and its relevance for an individual or organisation, is key for staff buy-in to its use for improvement purposes [8, 38, 51, 52]. This trust is in part influenced also by the source of the feedback (i.e. its credibility) [21, 24, 51]. For example, Gleeson et al. [21] reviewed the use of patient experience data for quality improvement purposes and found that clinical staff criticised national surveys for their lack of specificity, with findings not being applicable to some settings and circumstances. When data is used to compare organisations, ensuring that comparisons are meaningful and accepted as valid by the communities working in the organisations being compared matters for its uptake. In referring to a study on using audit data to improve neonatal intensive care in Northern Ireland, Allwood [8] illustrated that comparing the audit results of an organisation to those of similar-sized ones was seen as enabling improvement activity, because staff perceived an increased resonance of the findings to their context [70], cf. [8].

Peer review as part of audits can support learning and exchange. As Allwood [8] has pointed out, feedback from peers in audits is seen as valuable because those receiving feedback think that their peers know what they are talking about. Sensitivity is also needed in how data is shared and reported, so as to militate against unintended consequences. For example, Allwood [8] identified a study in which public reporting was identified as a risk to implementation and impact from audits, due to clinician fears of a blaming culture. In this study, a staged process towards public reporting (i.e. not reporting everything from the start) was recommended as a way to overcome this barrier [8]. Allwood [8] also provided other examples of how trust in data quality and robustness can have an impact on engagement with quality improvement, including some mitigation strategies, such as better presentation of audit results (see Box 18). Others have reported that public reporting can be an extrinsic motivator to implement improvement programmes [37, 39].

Box 18: Examples of how trust in data quality and robustness can have an impact on engagement with quality improvement

Allwood [8] provided examples of various data-related issues and the role they have played in the implementation of clinical audits in the NHS. For example:

- A questionnaire-based national programme to monitor changes in health status after elective surgery has been implemented by the international healthcare group BUPA in 70 hospitals in the UK since 1998 [71], cf. [8]. Healthcare professionals had concerns about the content and presentation of the questionnaire data, including concerns related to the robustness of the data, lack of clarity regarding the analysis methodology and difficulty in interpreting results, and this impeded staff buy-in and engagement with the questionnaires. Allwood also reported on some mitigation mechanisms that were introduced by BUPA to help address these barriers. One example was the dissemination of Shewhart charts (a form of Statistical Process Control [see e.g. 72]) to provide feedback to participating hospitals and help with interpretation of audit results; reminder letters were also sent to those who should participate to mobilise engagement and awareness of the audit [71].
- Another study looked at national audits where histograms, examples of audit approaches used, as well as commentaries and references to articles relevant to the national audit were used to present the audit data, which helped decrease concerns regarding data quality and robustness and improve trust in the methods used [8].
- A study focused on audits in NHS hospital trusts in Scotland [73] which built on interviews with managers and clinicians. Allwood [8] reported that general lack of confidence in the audit indicators used, mistrust in the methodology and robustness of the data, lack of timely data sharing, lack of full dissemination of data and weak incentives to contribute to the audit were all barriers to engagement and to improvement [73], cf. [8].

Data and the improvement systems that the data support need to be presented, interpreted and communicated in a user-friendly and engaging way [8, 24, 36]. In this context, expert staff may need to support data interpretation activity. For example, Allwood [8] has highlighted that having members of the clinical audit team help clinicians interpret audit data enabled engagement with the data for improvement purposes. Depending on the nature of an intervention and its purpose and audience, a mix of qualitative and quantitative data may be important for sense-making. For example, Gleeson et al. [21] highlighted, in the context of patient experience data, that clinical and ward staff tend to see qualitative comments as more relevant than quantitative data (although this insight is based on a review by the Health Foundation of the literature on healthcare professionals' views on quality improvement initiatives). Ivers et al. [24] highlighted some formats for providing feedback that can be helpful in a clinical audit context, including case-effect charts and Pareto charts (i.e. a type of bar chart where bars are sorted in descending order and where a line graph represents the cumulative total of the bars' values [74]). Related to effective data communication, keeping engagement with data fresh and alive throughout ongoing improvement efforts is seen to support implementation, and can be enabled through activities such as meetings and training for staff, and by ensuring that data is used to document and reflect on progress on an ongoing basis [8, 52]. Quantitative data from, for example, rating or Likert-scale closed-question surveys might be more helpful in measuring issues than informing solutions [63].

Tools and guidance can help with data gathering processes, data analysis and interpretation [8, 19, 63]. For example, Allwood [8] highlighted that tools and guidance (e.g. from professional bodies, Royal Colleges, HQIP) improved the process of doing audits. Dixon & Pearce [63] identified a series of tools to support clinical audit processes and subsequent improvement actions (see Box 19 for examples from their guide), and Flodgren et al. [19] identified various tools that could help with the uptake of evidence and recommendations laid out in clinical guidelines (see Box 20).

Box 19: Examples of tools to support engagement with data in clinical audits (adapted from Dixon & Pearce [63])

An HQIP guide, which was developed for people leading, managing, hosting or doing clinical audits in healthcare organisations, identified and discussed a series of tools that could contribute to supporting the implementation of and engagement with clinical audit processes [63]. These include:

- **Tools to reach agreement.** There is a variety of tools that should help those planning an audit to reach a consensus regarding the focus and objectives of the audit. The identified tools are *brainstorming* (e.g. to identify potential subjects for the audit, any problems and issues that should be addressed, potential actions to address the problems and issues, etc.), *nominal group processes* (to help reach agreement by ranking identified items regarding the focus of an audit, its objectives, methods, etc.), *Delphi processes* (similar to nominal group processes, Delphi processes should help reach consensus, but identified items are not ranked but rated), *multivotings* (to reach agreement by voting for the identified items, e.g. focus of the audit, objectives, methods, etc.) and *affinity diagrams* (to group items identified at the brainstorming stage and help clarify them).
- **Tools to test the commitment of team members and others to clinical audit decisions.** When doing a clinical audit, there should be clarity about the commitment of team members to clinical audit decisions. Specific tools identified by Dixon & Pearce [63] to assess issues related to commitment are *force-field analyses* (to identify positive and negative influences affecting the audit, how strong these influences are and any actions for improvement), *readiness-for-change ratings* (to identify influences that help or hinder a planned change for improvement by rating the importance of the identified influences), *brainstorming* (to identify drivers and barriers to the clinical audit or any other actions for improvement) and *Delphi processes* (to rate individuals' commitment to the improvement activity).
- **Tools to search for evidence of best practice.** According to Dixon & Pearce [63], audit team members should search for existing best practices related to the main focus of the clinical audit. This can include looking at similar organisations' improvement efforts. Two tools that can help find such examples are *critical appraisal* (i.e. to systematically analyse existing evidence regarding reliability and validity as well as to identify whether these practices could be applied in the local context) and *benchmarking* (i.e. to identify other organisations one could make comparisons with).
- **Tools to analyse processes and relationships.** In a clinical audit, it is important to understand the care processes that are subject to the audit. Dixon & Pearce [63] highlighted the following tools to analyse care processes and relationships: *top-down process maps* (to identify and enable agreement on the main activities and to get more clarity about the steps involved in each activity), *detailed process maps* (to identify both value- and non-value-added steps in the process, work flows, potential impacts of a change, etc.), *cross-functional process maps* (which can build on the results of a top-down process map, but should be more detailed; they should clearly indicate who is doing which step in the clinical audit process), *work-flow, process layout or spaghetti maps* (to find inefficient steps as well as to map 'movements' of individuals (e.g. patients) and things (e.g. patient records) in a process) and *tree diagrams* (to break down objectives or desired outcomes into more specific parts as well as to map how these items are related to each other).

- **Quantitative tools**. These tools can be applied to quantitatively measure changes, but also to identify any problems and their causes as well as more generally to understand how care is delivered. Specific tools mentioned included *costing quality tools* (to identify any financial implications of changes to a process), *demand-capacity analyses* (e.g. to identify the current and potential future demand for a process or service as well as to assess the current capacity and the capacity needed to satisfy this demand), *statistics* (e.g. to analyse and better present quantitative data) and *surveys* (e.g. to better describe the sample or population of the focus of the audit).
- **Tools to understand variation in current practice.** For example, *run charts* (a line graph plotting data in chronological order that shows developments over time) and *control charts* (a run chart which includes lines that determine the statistical upper and lower control limits) can help identify patterns in audit data and help uncover the reasons for variations.
- **Tools to identify the reasons for shortcomings in current practice.** Examples mentioned by Dixon & Pearce [63] were *affinity diagrams* (e.g. to group identified issues), *'asking why five times'* (to identify the root cause of an issue and to go beyond the obvious), *benchmarking* (to make comparisons to other organisations) and *Fishbone/Ishikawa diagrams* (a cause-and-effect diagram to identify and structure the causes of an issue).
- **Tools to make changes in practice.** Dixon & Pearce [63] identified several tools: *action plan tables* (which list all activities that should be done and include information such as who is responsible for each activity and timelines), *benchmarking* (to find out about other organisations' processes and how these led to change), *brainstorming* (to collect any ideas about how change could be achieved), *contingency diagrams* (to visualise steps needed to make a change as well as any potential problems related to these steps), *critical path charts* (to map all tasks that could affect achieving the change within the given timeframe), *Delphi processes* (to rank priorities regarding the desired change), *force-field analyses* (to identify positive and negative influences affecting the desired change as well as to test commitment to change), *Gantt charts* (to visually map the individual steps of a plan and their timelines), *multivotings* (to reach agreement by voting for priorities for change), *nominal group processes* (to reach agreement by ranking priorities for change), *Programme Evaluation and Review Technique (PERT) charts* (diagrams showing how different steps in the process are interrelated), *process maps* (to describe all required steps in detail, including who is responsible for each step, any decision points, etc.), *readiness-for-change ratings* (to identify influences that help or hinder a planned change for improvement by rating the importance of the identified influences) and *tree diagrams* (to break down the steps of a process into more specific ones).

Box 20: Examples of tools to support uptake of evidence and recommendations in clinical guidelines

There is widespread evidence of variable uptake of clinical guidelines [e.g. 75, 76]. Flodgren et al. [19], through a Cochrane review, described various tools developed and shared by guideline producers to support the implementation of clinical guidelines and to increase adherence. They identified both tools that can be embedded in the guideline itself and tools that can accompany it.

These included e-learning tools that provide additional evidence behind National Institute for Health and Care Excellence (NICE) guidelines, accompanying quality standards for guidelines, problem-based small group learning sessions around specific guidelines, communities of practice, guideline apps and computer-based decision-support systems. The authors also referred to the American College of Cardiology's Guideline Clinical App: clinicians can access recommendations and updates relating to a guideline using their mobile devices (mobile phones, tablets). Users can customise the app to their own needs (e.g. adding bookmarks, taking notes) [77, 78], cf. [19].

It is worth noting, however, that Flodgren et al. [19] identified various limitations in the evidence base informing their review. For example, they only found four RCTs that were eligible for detailed review. The evidence base on the effectiveness of using the tools described in the four studies appeared inconclusive, partly based on the differing nature of the reviewed studies (e.g. different methods), which made comparisons and general conclusions regarding the effectiveness of tools difficult, as well as lack of references to baseline data from RCTs.

To be meaningful and engaging, the types of data collected and the process of collection, analysis and interpretation need to be adaptable to a local context (although the degree to which adaptation is possible is likely to vary across different types of data) [8, 38]. For example, Allwood [8] has highlighted the need to balance between a standardised and straightforward way of doing national audits, but also some freedom to adjust them to the local context.

Any engagement with data for improvement purposes requires a conducive data and IT infrastructure [8, 56, 60], ***technical support*** [8] ***and appropriate funding of activities associated with data generation, analysis and use*** [8, 51].

Lastly, evaluation is central to improvement activity and rests on the ability to collect, analyse and interpret good-quality data [10]. Effective evaluation of improvement efforts is often difficult to carry out both due to data quality and due to challenges in understanding the fidelity of intervention implementation and in distinguishing between association and causation when making inferences about the links between quality improvement activity and observed outcomes. This is especially the case in complex contexts where multiple improvement and service delivery activities are often taking place, and where change and turbulence are intrinsic to the social fabric of the service delivery environment [23, 34, 38, 45].

For example:

- Greenhalgh et al. [23] have pointed out that evaluations of PROMs feedback is challenging due the heterogeneity of feedback, variations in how PROMs are used (e.g. the format), and differences in the context and settings in which they are used.
- Ocloo et al. [45] noted that it is challenging to analyse and interpret data from evaluations of patient and

public involvement processes in quality improvement, due to the difficulty of isolating PPI from other contextual factors that may have an impact on change (as well as a general lack of underpinning theory and unstructured documentation).

In addition, measuring past performance (based on historical data that may be more readily available) is not always indicative of current status.

A Health Foundation report [55] flagged that evaluation should focus on the impact of improvements, but also on the extent of uptake and dissemination within teams, organisations and more widely.

4.5. Patient and public involvement, engagement and participation in improvement activity

The role of patients in quality improvement efforts is gaining prominence in quality improvement practice.

Patients and the public can contribute to improvement activity in various ways – both in patient and public involvement and engagement roles across the improvement efforts, and as quality improvement study participants or participants in intervention delivery. The NIHR and INVOLVE have tried to clarify the types of patient and public contributions to research. Although research is different from quality improvement, there is applicable learning to be gained from how patients and the public contribute to research. As discussed in Ball et al. [79], according to NIHR and INVOLVE, 'involvement' refers to contributions 'where members of the public are actively involved in research projects and research organisations', 'engagement' refers to roles where 'where information and knowledge about research is provided and disseminated' and 'participation' refers to roles 'where people take part in a research study' [80: p. 7] cf. [79: p. 13], or – in the context of our report – in a broad range quality improvement activity. However, in much of the evidence base on patient and public contributions to research, the terms involvement and engagement were used interchangeably, and it was not always entirely clear whether an article was talking about just involvement or engagement, or both. Similarly, the literature on quality improvement that we looked at seemed also to blur boundaries between involvement and engagement and used the terms loosely and interchangeably.

Patients and the public can contribute to identifying improvement needs and priorities, helping avoid waste of effort or duplication, and in suggesting solutions [7, 15, 23, 25, 27, 28, 31, 35, 50, 61]. Their input can be gathered through different mechanisms, for example through surveys, interviews, focus groups, advisory boards and committee roles and meetings, to name but a few. Bombard et al. [15], in a systematic review on engaging patients in improving the quality of care (that looks at engagement and involvement), identified various strategies to strengthen patient voice and support engagement through (amongst other influences) representation in quality improvement efforts, allowing time for the development of strong relationships, ensuring timely engagement to inform decision-making cycles, training to ensure appropriate skills, and facilitating interactions.

Above all, patient and public involvement, engagement and participation need to be meaningful – and this includes making a difference to the process of doing improvement and to the outcomes from improvement efforts. Bombard et al. [15] identified studies that reported on patient and public experiences of involvement and engagement, and reported both positive effects on patient experience (such as feeling empowered and valuing recognition) and negative experiences (such as patient requests and input being ignored as well as lack of managerial support). In addition, a recent report by members of our research team [79] looked at PPI in research (which has transferable lessons for improvement activity as well) and identified a series of enablers but also barriers to meaningful involvement, the latter at times driven by tokenistic practice or mandated practice, but also by a lack of robust evaluation evidence on what works and how in terms of PPI in healthcare research. PPI can have both positive and negative impacts and there is a need for more evaluation of PPI efforts to understand how and when they can be most effective, especially as PPI processes which are not carefully considered or meaningful can lead to disenfranchisement, strained relationships and project delays [79].

A series of reviews highlight that effective PPI involvement and engagement requires careful consideration of what specific roles service users play and how these roles are operationalised [27, 35, 45, 50]. For example, Liang et al. [35] have highlighted the importance of joint training of patients and providers for effective involvement and engagement, as well as clarity and formalisation of patient roles, support for informal and frequent interactions to build relationships of trust, involving patients early on and debriefs. Nair et al. [50] identified a series of practical issues which need to be addressed to support meaningful involvement and engagement, for example those relating to health literacy, language barriers (e.g. in involving migrant groups) and costs of travel to engagement events. Ocloo et al. [45] also highlighted the importance of appropriate resourcing of patient and public involvement and engagement activity.

In order for it to be meaningful, the approaches used to enable patients to contribute to quality improvement activity need to be carefully thought through. This is important so that the impact from patient and public contributions is not compromised due to weaknesses in the design of contribution mechanisms [15, 27] ***or due to a lack of understanding about whether they are feasible to adopt in a given implementation context*** [31]. For example, Baldie et al. [27] examined patient feedback as a specific approach to supporting improvement efforts in general practice (sometimes in combination with other quality improvement interventions). They found a relatively small impact from patient feedback on patient experience of services, due to a range of influences. These related to the nature of the feedback itself and its accessibility and timeliness, as well as to factors in the healthcare setting in which the patient feedback is being received (leadership commitment, resources), and perceptions of its wider purpose (e.g. is it geared at improvement or assessment) (see also Box 21). Gleeson et al. [21] and Greenhalgh et al. [23] have also identified timeliness of feedback data and staff culture and attitudes as determinants of uptake for quality improvement purposes. Similarly, Elwyn et al. [31] identified barriers to adoption of patient decision-support tools, due to cultures, attitudes and beliefs as well as resource constraints in the adoption environment. Clinician involvement in designing patient engagement interventions may support their subsequent uptake (see also Box 22). For example, Greenhalgh et al. [23] highlighted that PROMs are more likely to be adopted in efforts to improve patient care if clinicians are involved in designing PROMs initiatives and if the PROMs are aligned with issues that matter to clinicians.

Box 21: The importance of carefully designing interventions to support patient engagement with quality improvement in healthcare, in light of the social and organisational context

Baldie et al. [27] conducted a review of the use of patient feedback in quality improvement in healthcare. Their review drew on studies from the UK, the Netherlands, the US and Hong Kong and explored different types of written feedback from patients, provided at the practice or physician level in primary care. The feedback reported in the study was collected using a survey format (e.g. questionnaires assessing the practice, questionnaires asking for areas for improvement, visit surveys, ratings and comparative scores). This review mainly reflected the views of healthcare professionals in general practice who receive patient feedback.

An association was found between the way patient feedback data is provided and the likelihood that healthcare professionals will try to change practice as a result. According to Baldie et al., patient feedback is more likely to influence a change in practice if the data is seen as accessible; if it includes appropriate reference points and/or comments from patients; if it provides importance ratings in addition to experience scores; if the feedback is specific (e.g. specific to the care process or practitioner); if data is shared in an acceptable manner to the GP; and if the data includes areas of improvement that are already known by the professionals or that staff agree with (be it in relation to positive or negative feedback).

The review found that if staff disagree with feedback received, they are more likely to question the feedback in terms of its quality and methodology (e.g. data collection method, sample size). Feedback is also less likely to be well received or acted on when there is a perception by staff that it is being used to judge or assess performance rather than to formatively and constructively drive improvement. For example, the authors reported that some GPs in England saw a national patient survey as a ‘political tool with questions biased to elicit negative evaluations’ [27: p. 17] and that this influenced their engagement with the survey data.

Baldie et al. [27] found that in addition to some general resistance and scepticism, especially when feedback relates to relational aspects of experiences, other barriers include concerns about data validity or reliability; delays in receiving the data making action impossible/outdated; concerns that a patient’s single experience (i.e. one practice consultation) would be mixed with views of doctors’ personalities and assessing the practice; and general organisational, cultural and leadership barriers such as those related to a lack of leadership commitment, missing structures which should support listening to patient views, lack of acknowledgement of feedback as a quality indicator and the absence of resources (both internal and external) to address any issues raised by patients.

The authors also found that patient feedback (as part of improvement efforts) leads to relatively small changes overall on future patient experiences. Two studies did not find any statistically significant changes, one found small and non-statistically significant changes, and five studies reported mixed impacts (e.g. smaller increases or decreases in patient experience scores).

Box 22: Why efforts to give patients a role in improving their own healthcare can fail to gain traction if the healthcare system is not ready or receptive

Elwyn et al. [31] discussed the use of patient decision support interventions (DESIs) in routine clinical settings. DESIs are intended to help patients make informed clinical decisions and improve the quality of care, by engaging them in the decision-making process. Based on a literature review of the implementation of these tools, the authors suggested that the impacts of DESIs on patients gaining knowledge, greater understanding of probabilities and increased confidence in decisions are well established, yet also that widespread adoption is not occurring due to implementation challenges. These challenges include indifference on the part of some healthcare professionals due to a lack of trust and confidence in the content of DESIs and concerns that the tools will disrupt established workflows and increase time pressures on staff in healthcare organisations. Studies reviewed by Elwyn et al. [31] also highlighted that practitioners expressed the need for more training in how to use the tools, that DESIs might compete with other information that is provided to patients, and that clinicians did not view DESIs as part of the task they need to carry out. The capital and logistical infrastructure needed to initiate and maintain DESIs is also identified as a significant challenge to their effective use. Elwyn et al. [31] emphasised that the underlying issues that limit the adoption of this approach for engaging patients in clinical decision making are under-studied and under-specified. A more careful consideration of the context that could support their meaningful deployment is needed if they are to gain traction as an approach to support efforts to improve either the quality of care, patient experience or both.

4.6. Influences related to working as an interconnected system of individuals and organisations, influenced by internal and external context

Improvement activity in healthcare requires acknowledging and engaging with the systems nature of both organisations (microsystems) and of the wider healthcare landscape. Using systems perspectives when doing quality improvement helps recognise the complexities of healthcare organisations [58] and the interdependencies between organisations in different components of the healthcare system. It also sensitises improvers to the interdependence of influences affecting improvement activity [39]. To illustrate: a conducive data environment (e.g. one where relevant, accessible and accurate data is collected, analysed and used to inform improvement efforts) will not work to secure improvement without effective leadership; a culture of improvement and effective relationships will not work without requisite investment in training and skills development; and effective collaboration in improvement can only occur in the context of appropriate resourcing and infrastructure.

We are interested here in a specific aspect of applying systems thinking to quality improvement – namely the need to take into account the different levels of the internal and external context that influence how quality improvement initiatives unfold (e.g. individual, professional, departmental, organisational, local/regional/national). We discuss broader aspects of considering quality improvement interventions in the context of complex adaptive systems [81, 82] in Section 5, where we reflect on the learning gained from the reviewed papers.

Quality improvement efforts often require working at the level of the wider healthcare system (i.e. beyond the confines of a specific organisation that is seeking to improve), due to the service interdependencies between primary, acute, community and social care and in light of patient flows through the system [16, 61].

Taking account of local histories and context when planning for future activities matters greatly [28, 64]. The same interventions can have different outputs in different contexts, and are unlikely to work everywhere, every time [9, 10, 15, 17, 20, 23, 25-29, 31, 33, 34, 36, 37, 39, 41, 43, 49, 51, 53, 54, 56, 57, 59, 61, 64]. Baldie et al. [27], for example, discussed the impact of patient feedback and refer to several contextual factors that influence the outputs of the same intervention (they include factors related to staff resistance, resources and perceptions of data quality and value). Similarly, Flynn et al. [20] referred to contextual factors that can have an impact on the success of an intervention or quality improvement approach, such as organisational readiness and culture, organisational structure and silos within an organisation, existing quality improvement structures within an organisation, staff turnover, competing needs and demands, the complexity of the care processes and other local factors [20].

Intrinsic motivators related to an individual's internal behavioural drivers, and extrinsic motivators related to external influences such as rewards and punishments, can both – to varying degrees – influence how motivated clinicians are to improve performance on core processes of care, and how sustained improvement activities can be [39]. Austin & Pronovost [39] discussed intrinsic motivators (i.e. elements that are internal to an individual that motivate them to commit time and energy to a task) and how these can be enhanced through a number of organisational efforts. These are: clarity and communication of improvement goals from leaders of the intervention to all involved staff; the availability and creation of enabling infrastructures such as training and support to empower individuals and teams; stakeholder engagement and the creation of peer and learning communities that connect stakeholders both vertically and horizontally within organisations; and the establishment of reporting systems to ensure transparency and accountability in the provision of timely feedback. Austin & Pronovost also discussed interventions employing extrinsic motivators such as public reporting of performance and pay-for-performance models [39]. Brown et al. [16], in the context of clinical networks, highlighted that supportive policy environments and links with government agencies can help enable quality improvement activities. Conry et al. [18] also highlighted the importance of policymaker involvement, support and contribution, and Øvretveit [53] emphasised the importance of a clearly communicated vision and support for dedicated quality improvement programmes from political leadership.

Ensuring sustained support for implementation processes within adopting systems, through integrating various reinforcing factors into an intervention delivery throughout its duration, can influence improvement and the sustainability of improvement [41]. Caspar et al. [41] adopted Green & Kreuter's [83] typology of factors influencing an intervention's success, which groups factors relevant to the success of intervention implementation into three types. These are *predisposing factors* that support the creation of a shared vision for change and lay the foundation for change activity (e.g. communication, dissemination and education/training activity to modify staff beliefs, skills, knowledge or values); *enabling factors* (i.e. various conditions in the intervention environment such as changes to policy or guidelines, modifications to work schedules, and access to resources); and *reinforcing factors* to reinforce and sustain implementation of new skills or practices (e.g. peer-based support, on-the-job coaching, hands-on practice, supportive mentoring, increased supervision, team meetings, feedback, follow-up, rewards and recognition for success).

Caspar et al. [41] identified that interventions for practice change in long-term care facilities were least likely to be effective if they only included predisposing factors, and that education alone is rarely sufficient to produce change. They found that interventions are most likely to produce sustainable outcomes if they include reinforcing factors in the process of intervention implementation, and that the duration and depth of this reinforcing support appears to be associated with intervention effectiveness. Similarly, Flynn et al. [20] identified support from external or internal quality improvement coaches as important for the sustainability of quality improvement interventions (in this case Lean).

The details of an intervention design need to be carefully thought through in light of how the improvement intervention might land in a local context. Intervention design needs to be based on a deep understanding of what motivates individuals in a specific context and on how likely it is that the intervention will drive meaningful improvement activity or potentially have unintended consequences [10, 29]. This highlights the need to carefully think through the requirements and criteria for effective intervention implementation. Otherwise, interventions that are seemingly sensible by design can fail or have unintended consequences [29]. For example, Christianson et al. [29] discussed lessons learnt from evaluations of pay-for-performance programmes (mainly in the US, but also in the UK, Canada, Australia and Spain) and found that if financial incentives are not paid to or passed through the system to those responsible for behaviour change to improve quality of care (e.g. if a reward is paid to a group and not distributed to individual physicians), the amount and quality of behaviour change may be affected. They also found that financial incentives are more likely to be considered worth the investment required to achieve desired improvements if they represent a major potential change to practice revenues. However, they caution that pay-for-performance initiatives focusing on a limited number of measures may cause resources to be diverted away from other areas not emphasised by the incentive and can be prone to risks of gaming the system, with a potential unintended consequence of a decline in the overall quality of care [29].

To the extent possible, it is important to build in scope for adapting an intervention to local social and operational realities [38, 48, 54, 60]. Attempts to reproduce successful initiatives in one place often fail in other places [10]. For example, a study of the Matching Michigan initiative in England, which tried to reproduce a successful safety improvement project from the US that aimed to reduce bloodstream infections resulting from central venous catheters in intensive care units) found that contextual factors such as the legacy of previous quality improvement programmes had an impact on the project's success in the UK [10]. The study emphasised the importance of understanding why an initiative is successful and what contributes to success in order to be able to adapt it to meet local and contextual needs.

Related to this, the evidence base on the extent to which a prior history of doing improvement and the size of organisations and teams in a specific adoption context influence the process of improving and success from it is inconclusive. For example, a Healthcare Improvement Scotland report [56] identified that the size of an organisation and years of experience in doing quality improvement matter and suggested that repeated interactions (e.g. small groups of people working together on a regular basis) can support the sustainability of improvement cultures. However, a review by Hulscher et al. [34] of quality improvement collaboratives identified that larger teams (i.e. not small groups, but also not *too* large) positively influence changes, and that prior experience with quality improvement is not associated with a greater likelihood of success. A Health Foundation report [9] identified that critical mass matters in encouraging members of an improvement network to participate and helps spread good practice and accelerate behaviour change. Moreover, this report finds that critical mass also supports influencing people outside the network.

Lastly, the effectiveness of any intervention that is meant to act as an incentive will depend on other interventions taking place in the same context, at the same time. Christianson et al. [29] have argued that different combinations of interventions can reinforce each other, or be in conflict. Ng et al. [37] found that incentives such as accreditation are more likely to work in driving improvement if they are linked to financial incentives.

4.7. What can we say about the links between the process of improvement and reported outcomes?

The focus of this rapid evidence assessment is on learning about and from the processes of implementing quality improvement activity (and specifically to understand influences on the process), *not* on learning about the outcomes or effectiveness of quality improvement interventions. However, many of the publications we reviewed pursued multiple goals, sometimes with learning about intervention effectiveness and outcomes being a key aim and learning about the process of implementing quality improvement activity as secondary. Thus, although we did not explicitly set out to learn about the effectiveness of quality improvement interventions or about their outcomes within the scope of this study, we are able to offer some reflections and observations on this theme.

The reviewed publications considered a wide range of intended intervention outcomes, comprising improvements to healthcare quality, staff performance, patient safety, patient experience and clinical outcomes. Some of these identified positive impacts. To illustrate with a few examples:

- A systematic review of the impact of patient engagement in improvement activity identified multiple positive impacts on enhanced governance and institutional culture (e.g. levelling of power differences between patients, providers and staff), although these were not clinical outcomes but impacts on the processes, behaviours and structures involved in quality improvement activity [15].
- Another systematic review, this time exploring the impact of large-scale hospital- and system-wide improvement interventions on patient outcomes, concluded that such interventions improve hand-washing frequency, reduce rates of bacterial infection, improve monitoring of patient vital signs, reduce rates of antimicrobial resistance, reduce incidence of adverse events, and have mixed effects on patient satisfaction [17].

- A systematic review of the effectiveness of clinical networks in improving quality of care found overall positive effects on the quality of service delivery and patient outcomes [16].

However, evidence on the effectiveness of particular improvement interventions was highly inconclusive in many of the reviews we considered, with the same review sometimes identifying positive impacts from the implementation of an intervention in one context, but no impact or even negative impacts in another. For example, a review of the sustainability of Lean in healthcare identified three primary studies reporting positive outcomes in relation to sustainability and three reporting mixed (both positive and negative) outcomes regarding sustainability [20]. The same review presented evidence that Lean has in some cases been found to reduce waste and have a positive impact on efficiency, but that other attempts to introduce Lean in healthcare have been associated with 'superficial adoption, system dysfunction, and disengaged staff' [20]. The review authors concluded that the success and sustainability of Lean strongly depend on the context and culture in which it is implemented, citing influences such as staff engagement and values, staff turnover, leadership involvement, patient involvement and the role of external pressures on both individuals and the wider healthcare facility's culture. Similarly, a review of the use of extrinsic and intrinsic motivators to stimulate performance improvement found conflicting impacts from the implementation of pay-for-performance initiatives on quality of care [39]. The review offers two examples of pay-for-performance from the UK, one of which – the Advancing Quality programme – was credited with generating roughly 5,200 quality-adjusted life years and £4.4m of savings, while another – the quality outcomes framework for GPs – was found to have a limited and only temporary impact. The review authors suggested that differences in the extent to which pay-for-performance schemes lead to performance improvement may result from differences in the way programmes are implemented (e.g. as the only improvement effort versus as part of a larger quality improvement programme), the rate of performance-related pay, the validity of programme measures based on which payment levels are assessed, and/or local contextual factors such as the size of a healthcare organisation or concurrent incentive programmes.

Similarly, a Cochrane systematic review of the effects of audit and feedback found mixed evidence on the interventions' effects on patient outcomes, ranging from low to substantial effects; however, the review authors assessed the underlying evidence that informed their review as being of moderate quality [24]. A review exploring the impact of patient feedback about their care experiences in general practices also found differing effects: while two studies did not find any statistically significant changes, one found small and non-statistically significant changes, and five studies reported both positive and negative impacts on patient experiences [27].

In the case of reviews which identified conflicting findings regarding intervention effectiveness, it was difficult to discern whether this inconclusiveness results from differences in the way in which an intervention has been implemented (e.g. intervention fidelity or combination with other interventions), contextual factors, or differences in the design or quality of the studies evaluating the intervention and reporting on its implementation and outcomes.

The issue of intervention fidelity was recognised as an important determinant of quality intervention outcomes, but, as Dixon-Woods & Martin [84] have noted, fidelity is highly variable. Two King's Fund reports concluded that successful improvement is achieved through explicit adherence to a chosen model and rigorous application of a consistent approach [61], which can be supported through training in the quality improvement methodology and leadership support for robust implementation [7]. A King's Fund briefing for NHS boards and leaders argued that implementation fidelity may matter more than the selection of one method over another [61]. However, while fidelity is no doubt important, it is not the only influence. It is likely that the outcomes that evolve from intervention implementation are a result of the interactions between the design of the intervention, the fidelity of its implementation and the social and organisational context in which it is being deployed [28]. In addition, complete fidelity may not always be desirable (i.e. some adaptability of interventions to local contexts can be desirable, as discussed earlier in this report).

Just as intervention fidelity is an important determinant of success, several of our included reviews reported an association between particular experiences during the process of implementing improvement interventions and impacts from the intervention. These highlight important influences and features of implementation processes, and that no one variable alone can guarantee success: it is the combination of different influencing variables over time that determines implementation and its effects. For example, a review of extrinsic and intrinsic motivators of quality improvement concluded that quality improvement is more likely to succeed if it is approached in a systematic way, and if it includes elements of clear communication, infrastructure building, training, transparency and accountability [39]. Similarly, a systematic review of the effectiveness of clinical networks for improvement found that positive impacts depended on resources, credible leadership, efficient management, effective communication strategies and collaborative, trusting relationships being in place [16]. In contrast, distrust, tension and any competition between members (in particular over resources) are experiences that the review authors identified as barriers to successful clinical networks [16].

Any single intervention also needs to be nurtured. For example, a review of practice change interventions to improve quality of care in long-term care facilities found that the duration and depth of support appeared to be associated with intervention effectiveness, and interventions were most likely to produce sustainable outcomes if they included 'reinforcing factors', such as on-the-job coaching, hands-on practice, supportive mentoring, increased supervision and team meetings, in addition to 'predisposing factors' such as information communication and dissemination, and that education alone is rarely sufficient to produce change [41].

5 Reflections and implications for future research

5.1. An overview of the key influences on improvement processes in healthcare

This rapid evidence assessment has systematised existing learning on a diversity of influences on the process of implementing quality improvement efforts. It has attempted to go beyond only identifying the general influences that matter (e.g. leadership, data, relationships and culture, skills and competencies, service user involvement, and working as a system). The review attempted to explain and specify the specific dimensions of the influences that are particularly important for quality improvement. These influences are summarised in Boxes 23–28. There are also likely to be other influences (and associated dimensions) that matter, but the boxes below focus on those that appear to receive the most attention in the reviewed literature.

The insights gained should be helpful for practitioners of improvement, in terms of highlighting issues that they need to consider in the design and implementation of improvement initiatives. The information on the diversity of influences that matter (and on their nature and key components) could also be useful for the education and training of students and healthcare staff on quality improvement. We hope that the insights gained and the reflections we offer on areas in need of further research below are also helpful for the wider research community, especially in the context of targeting research efforts towards achieving practical value for improvement practitioners.

Box 23: What matters: key messages and insights related to leadership support of improvement efforts

- Involving different types of leaders and improvement champions: (i) clinical and managerial; (ii) from different specialties in areas of healthcare that depend on multi-professional teams; (iii) from different levels in an organisational hierarchy; (iv) experienced in managing complex patient conditions; (v) from different components of a healthcare system; and (vi) from outside provider organisations, such as in policy, funding and regulator communities.
- Clearly articulated roles and responsibilities for leaders (as well as for those who are being led).
- A long-term view on improvement (with milestones built in), supported by consistent and coherent strategies.
- Integrating improvement activity into wider organisational strategies, and to the extent possible, into everyday individual roles and responsibilities.
- Realistic goal-setting that balances ambition with what is feasible.
- Sustained and continuous engagement from leaders and managers over time (and not just at set up or completion phases).
- Staff trust in the values, vision and expertise of leadership.
- A compelling narrative from leadership on the value of improvement activity and on how and why leadership will support it.
- Ensuring that practical enabling mechanisms for staff to engage with improvement activity are built into the design of improvement initiatives (e.g. freeing-up clinical, managerial and administrative staff time, financial resources, IT infrastructure, facilities and equipment).
- Adaptation in leadership styles (ranging from those rooted firmly in social relationships to more hierarchical leadership approaches) to ensure appropriateness to specific social contexts, improvement interventions and points in time.

Box 24: What matters: key messages and insights related to relationships and interactions that support an improvement culture

- Relationship-building that can establish and communicate the alignment of the improvement intervention with the values and perceived roles and responsibilities of implementers.
- Creating both personal and collective benefits from collaborative improvement efforts, in support of sustainable improvement cultures.
- aEnvironments that support open discussion and transparency about improvement needs, opportunities and challenges (for collective sense-making and to build improvement cultures).
- Environments where frequent communications and regular interactions can take place between those involved in improvement activity, in order to sustain engagement and buy-in, support collective learning and reflection and inform ongoing actions (e.g. through meetings, regular newsletters).
- Relationships that embrace feedback as a way of supporting continual learning.
- Cultures that value diversity, voluntary participation and inclusiveness (e.g. collaboratives, clinical communities and networks, and experience-based co-design initiatives).
- Exchanging learning about the experience of doing improvement between different organisations and creating a shared understanding of the benefits that can accrue, the challenges that can be experienced along the way and how they might be addressed.
- A clear communication and dissemination strategy related to improvement efforts that considers what to communicate, to whom, how and when.

Box 25: What matters: key messages and insights related to skills and competencies for improvement

- Appropriately resourced staff training in requisite skills and knowledge – including training for both those at the coalface of improvement, and leadership and senior executives (albeit to varying degrees and in potentially different ways).
- Understanding the types of skills that need to be built to ensure that appropriate training is pursued (i.e. skills gaps are not always easy to identify and the skills needed for effective quality improvement span technical and social skills).
- Potential integration of educational components into improvement intervention design and implementation (e.g. through workshops, lectures, guidelines and protocols, simulations, scenarios, role play, experiential learning, feedback and online materials).
- Reinforcing and/or refreshing training through time (e.g. through on-the-job coaching).

Box 26: What matters: key messages and insights related to the use of data for improvement purposes

- Data serves multiple purposes in an improving healthcare system: data can help identify improvement needs, inform the design of improvement interventions and implementation strategies, and support monitoring and evaluation activity.
- Some improvement approaches (e.g. clinical audits) depend on data availability as a core enabler of improvement activity.
- Good evaluation is central to improvement, but is not possible without access to accurate and relevant data on the quality of care.
- Staff are not always aware of what data exists and how it can be accessed. Leadership has an important role to play in (formally and informally) raising awareness about access to data and about the implications of data use for improvement opportunities and activities.
- The organisational culture and staff attitudes towards data and evidence influence the extent to which they are used in improvement. This includes whether staff believe that data can help them improve and succeed; see data as relevant, meaningful, and valid in their context; trust data quality and accuracy; and see the source of the data as credible.
- The effectiveness of data in guiding improvement activity is also influenced by when it is provided, to whom and how. Feedback must be timely in order for it to have traction. Data needs to be presented, interpreted and communicated in user-friendly and engaging ways tailored to the purpose and audience: there is no one-size-fits-all way of communicating findings.
- Engagement with data needs to be ‘kept alive’ throughout an ongoing improvement initiative to support implementation, and to document and reflect on progress (e.g. as part of meetings, training, newsletters or emails).
- Tools and guidance can help with data gathering, analysis and interpretation for improvement purposes.
- Quality improvement that is driven by access to and use of data needs to secure a supportive IT infrastructure and technical support in resource planning.

Box 27: What matters: key messages and insights related to patient and public involvement, engagement and participation in improving healthcare quality

- Patients, carers and members of the public can contribute to improvement in diverse ways – in patient and public *involvement* roles (e.g. actively contributing to and advising on initiative design, implementation or evaluation and coproducing the effort); in patient *engagement* roles (where information and knowledge about improvement efforts is provided and disseminated to patients) or as participants in the delivery of an improvement study or improvement initiative.

- Enabling meaningful contributions from patients and the public requires clear communication about when and how service users can add value to improvement efforts; clear roles and responsibilities, feedback and ways of recognising contributions are also important.

- Involving patients and/or carers early in the process of establishing an improvement intervention and supporting informal and frequent interactions can help build and nurture relationships of trust, and can support effective involvement and engagement.

- A series of practical issues need to be considered in the design of patient and public involvement, engagement and participation strategies (e.g. health literacy, language barriers, costs of travel to engagement events, general resourcing).

- The approaches used to enable patients and the public to contribute need to be carefully thought through to ensure that they are feasible and engaging.

- Patient and public involvement can have both positive and unintended negative consequences (the latter potentially related to instances of tokenistic practice and when patient and public involvement is not carefully considered or relevant). Better evaluation evidence is needed on both PPI processes and outcomes relating to improvement in order to learn about what works best, when and how.

Box 28: What matters: key messages and insights related to the importance of working as an interconnected system, influenced by internal and external context

- Taking account of local histories and local contexts when planning for future improvement activities can enable more effective intervention design and implementation and can support efforts to build adaptive capacities into an intervention.
- Interaction between different components of the healthcare system (primary, acute, community and social care) is sometimes needed for the effective implementation of quality improvement efforts, for example when the clinical conditions and quality improvement issues that are being tackled are relevant and depend on actions of different organisations and take place in different components of the healthcare system.
- Factors internal to an organisation's management and governance approach (e.g. clear goals for improvement, enabling resources and infrastructure, inspiring leadership) and in the external context (e.g. policy mandates, payment regimes, reporting structures in the health system) can influence how committed clinicians are to quality improvement.
- Building in sustained support for implementing quality improvement interventions over time matters for success: factors that reinforce specific skills or practices over time can help (e.g. peer-based support, on the job coaching, feedback, reward and recognition).
- Interventions that seem sensible in principle can fail if implementation criteria and requirements are not carefully thought through prior to roll out.
- The evidence base on the impact of having previous experience of doing improvement on the ability to build and nurture improvement cultures is inconclusive.
- Critical mass is important for a thriving and sustainable improvement culture, but what constitutes critical mass and how it can be achieved merits further research.

We identified a range of critical factors influencing improvement process implementation that are likely to apply across diverse contexts. However, it is unlikely that any single factor on its own determines how improvement unfolds. The interactions between different drivers and influences (both context-related and related to the design of an intervention and to implementation fidelity) will ultimately determine the nature of an improvement process and its outcomes. Different factors can support or undermine each other.

In addition, and as we have shown throughout the report, improvement processes involve multiple stakeholders, but not all stakeholders are awarded equal attention in the literature. Much of the learning that we have drawn from the literature and within the scope of this report, in terms of what influences quality improvement processes, is geared primarily at senior managers and executives. Future research may wish to focus on a more granular approach to distilling learning for different professions or stakeholders in a healthcare system.

In the sections that follow, we overview and discuss some areas in need of future research. These relate to:

- Section 5.2: Understanding how challenges to implementing improvement can be addressed in practice.
- Section 5.3: Understanding how the design of an intervention and various influences in the internal and external context interact to determine the nature of improvement processes and their outcomes.
- Section 5.4: Exploring the practical applications of the insights gained about influences on improvement processes, in the context of developing tools to support improvement efforts and for informing national improvement capability building efforts.
- Section 5.5: Further research on the unintended consequences of improvement efforts.

5.2. Further research is needed to understand how the challenges to implementing improvement can be addressed in practice, and how knowledge about the influences on improvement processes can be incorporated into the design and implementation of improvement interventions

5.2.1. Why implementing improvement is challenging: 'There is nothing more deceptive than an obvious fact' (Arthur Conan Doyle)

In conducting this review, we found – somewhat unsurprisingly – that there is limited descriptive detail on the operational processes associated with implementing improvement. Thus, some of the insights shared in this review are in many ways not surprising or necessarily new, and scholars and practitioners of improvement may find some of them to be 'obvious' (though 'obvious' has its merits too – for example in boosting confidence in an existing evidence base and strengthening it).

Yet, even some relatively well-researched or 'obvious' needs can be difficult to meet in the practice of improvement. One reason for this may be the lack of capacity for implementation on the ground, due to a lack of financial resources or staff availability to implement improvement efforts; in addition, staff may not have the requisite capabilities. But the difficulty in translating 'the obvious' into actions may also in part be due to an absence of tailored, nuanced and context-specific recommendations which can ensure that general insights about what it takes to do improvement well can be made practical and actionable in a given context. Thus 'the obvious' can sometimes be deceptively difficult to embrace and internalise into the social, cultural and organisational context and activity flows in a specific environment. As Arthur Conan Doyle notes in Sherlock Holmes' adventure 'The Boscombe Valley Mystery': 'There is nothing more deceptive than an obvious fact' [85: p. 161]. Boxes 23–28 above synthesise key messages and insights on what matters in relation to the diversity of influences on improvement processes that have been discussed in this report. However, the evidence base on how to make these influences work in support of improvement activity in practice, and how to address challenges to ensuring enabling environments, remains limited and in some cases contradictory. We illustrate this below with examples from two areas of influence: 1) relationships and interactions to support an improvement culture; and 2) patient and public involvement and engagement:

Enabling relationships and interactions to support improvement cultures

We have highlighted different elements that need to be in place for relationships and interactions that support an improvement culture, but there is still a lack of consolidated evidence on whether and how organisational culture can be influenced. In fact, this remains an area of debate: different perspectives on culture (e.g. corporate culturalist, interpretative perspective) vary in the extent to which they see culture as something that can be controlled and shaped through managerial action [86-88]. Furthermore, there is also no 'best' culture – what constitutes a good culture is context-dependent [88]. Thus the levers that are likely to work in addressing challenges to building supportive cultures in one healthcare context may apply less in others. From a practical perspective, this implies the need for stakeholders to work together to identify actions, structures and systems that can support an effective culture within their local context.

Related to organisational culture, we have also pointed out earlier in this report that being able to proactively identify problems, conflict or marginalisation of traditionally less powerful groups such as patients and nurses, and to seek consensus on solutions, is important for cultures that support effective quality improvement. We flagged that open discussion and transparency is important to this end, but developing open and transparent cultures is by no means straightforward. We have discussed some approaches (such as improvement huddles) in the context of supporting effective communication about quality improvement initiatives [47]. However, the effectiveness of interventions that by design bring people together to share views and discuss progress (as per improvement huddles) will in part depend on the extent to which they can enable the 'voices' of different healthcare staff to be heard. This is riddled with challenges associated with organisational hierarchies and power dynamics [89], as well as the diversity of professional, social and cultural backgrounds healthcare staff come from [90]. For example, there are questions as to how practitioners of quality improvement can overcome issues related to trust between inter-professional groups and how a mutual understanding and awareness of the difficulties different professions encounter when doing quality improvement can be built [90]. Further research is needed to find practical ways to address these challenges.

We have also identified the need for involving diverse clinical and managerial professions and wider healthcare staff in improvement efforts. But working across professional boundaries in healthcare is challenging [91]. Interventions such as communities of practice have been proposed, where training and socialisation processes can help expand an individual's social identity beyond the boundary of their own professional group [90]. The importance of time away from clinical duties and of group processes that encourage regular interactions is also highlighted in the literature [92]. However, allowing healthcare staff time to engage in multi-professional team building is challenging when staff are firefighting to meet the day-to day-demands of patient care.

We also commented on the importance of sharing learning about quality improvement experiences between different organisational settings, and sharing learning also sometimes involves sharing data. This can both be politically challenging (for example when different settings are in competition with one another for patients or resources) and practically challenging (for example if the data that is shared as part of the exchanges is not captured in the same format and does not speak to the same measures and indicators or interventions).

Ensuring meaningful patient and public involvement and engagement

The evidence base that we have reviewed in this report flags the importance of involving patients and the public in improvement efforts. It also highlights the diversity of ways in which patients can contribute to improvement efforts and how their contributions can be supported (see Box 27 above). We have also acknowledged that patient and public involvement can have both positive and unintended consequences (related to, for example, tokenistic practice), and that better evaluation evidence is needed on patient and public involvement and engagement processes and outcomes in terms of quality improvement, in order to learn about what works best, when and how.

We know from the study of patient and public involvement in research that the drivers of involvement (in terms of what motivates healthcare researchers to involve or engage patients and the public) are varied. These drivers can span *ethical conditions,* for example a belief that it is morally the 'right thing to do' or that involvement will improve research quality or relevance, but also *pragmatic consideration*s, such as when involvement is identified as a condition of research funding, in response to policy drives to share power between researchers and the wider public, or to help with the recruitment and retention of study participants. Patients and the public engage due to varied reasons, including interest in a healthcare topic, often driven by personal experience, altruistic motivations to improve healthcare through research, general interest in contributing to the knowledge base, and due a desire to influence and reflect patient perspectives in research [79]. The drivers of involvement with improvement efforts are likely to share many features with the drivers of involvement in healthcare research.

Unless done well, there are risks that some of the drivers may lead to tokenistic practice, the inefficient use of resources in the healthcare system, and poor patient and public experiences of involvement and engagement [45, 79]. Further research is needed to understand how improvement efforts can best integrate involvement and engagement into their design and implementation. Such research should draw on a greater diversity of perspectives and experiences with patient and public involvement in improvement, and reflect the voices of diverse healthcare professionals, patients and members of the public.

In relation to the above, further research is also needed to better understand what level and type of interaction with patients and the public is most suitable for specific improvement initiative needs and in specific healthcare settings and clinical and disease areas. In the context of patient and public contributions to research, INVOLVE (the national advisory group on patient and public involvement and engagement with research in the United Kingdom) uses the term involvement to describe contributions 'where members of the public are actively involved in research projects and research organisations' [93]. Engagement is used to describe the process by which 'information and knowledge about research is provided and disseminated' to patients and the public, and participation to describe the process by which 'people take part in a research study' [93]. We need better evidence on when involvement as opposed to engagement is most appropriate and effective for a particular quality improvement intervention.

5.3. Better evidence is needed on the fidelity of intervention implementation, in order to understand how the design of an intervention and various influences in the internal and external context interact to determine the nature of improvement processes and their outcomes

Learning about the factors that influence improvement processes and their outcomes also requires attention to understanding the fidelity of intervention implementation. Not only a different outcome but also a very different experience could evolve when an intervention is implemented as intended, and when it is not. As Dixon-Woods & Martin [84] note, 'Fidelity in the application of QI methods is often variable. QI work is often pursued through time-limited, small-scale projects, led by professionals who may lack the expertise, power or resources to instigate the changes required. There is insufficient attention to rigorous evaluation of improvement and to sharing the lessons of successes and failures.' [84: p. 191]. There is a need for more robust and detailed evaluation evidence and systematised learning from process and outcome evaluations, on both the contextual factors that influence improvement processes (social, cultural, organisational, resource-related) and on the design features that influence the fidelity of intervention implementation. Such learning would require rich narrative accounts of improvement implementation processes in different contexts.

Context-specific, practical and actionable detail may be richer and more abundant in literature reporting on primary studies, which was outside the scope of this research. Future research seeking to learn from primary studies could add value to and enrich the learning we have shared in this report. However, it is unlikely that any one future research study could cover all relevant primary studies on the topic. As such, incremental learning would be most likely to accrue from an accumulation of studies considering a variety of clinical and disease areas, geographies, types of improvement interventions and parts of the healthcare pathway. It may also be that some study designs (e.g. ethnographic primary studies) would yield particularly rich and practically relevant descriptive narratives, although such narratives alone do not guarantee stronger evidence about the nature and implementation of influencing factors.

Furthermore, the same influences that affect improvement (e.g. leadership, relationships that support improvement, etc.) can play out differently in different healthcare contexts. For example, it is relatively obvious (though important to know) that the organisational culture and staff attitudes towards data and evidence (which in turn influence the extent to which data is used in improvement) depend on staff trust in the credibility of its source and in data quality and accuracy. But exactly what constitutes a credible source to specific professional communities and individuals will vary within and across contexts, as will the nature of quality, accuracy or data relevance concerns that need to be borne in mind. In some contexts, trusted individuals will be those in positions of leadership and authority. In others, it may be peers at the same level in a horizontal network.

Similarly, it is not surprising that a compelling narrative on the alignment of a quality improvement intervention with the values and perceived roles and responsibilities of those who will be implementing it is important for effective relationships that can support an improvement culture. But exactly how this alignment can best be communicated, to whom and by whom, will vary from context to context. Variables to consider include which types of individuals have the necessary expertise, social capital and/or authority to establish a collective vision, who implements the intervention, and what the relational dynamics and power hierarchies are in specific clinical areas.

Healthcare systems are complex adaptive systems [81]. Complex adaptive systems have several characteristics that make them hard to 'control' or prescribe solutions for. As discussed in a Health Foundation report [82], they have many elements which interact dynamically and in a non-linear fashion; they affect and are affected by other systems (and in fact can be embedded in other systems); it can be difficult to define their boundaries; their past history influences present behaviours; and they function in the presence of imperfect information (i.e. some parts of the system are not aware of the behaviour of the entire system and do not have access to all possibly relevant information and knowledge).

As Braithwaite [81] notes, we cannot understand the behaviour of healthcare systems simply by studying their components. When studying quality improvement processes and their outcomes, we need to consider how different influences that affect quality improvement in the healthcare system interact with each other and within the wider socioeconomic, political and cultural landscape (locally, regionally and nationally).

Interactions in a healthcare system can be unpredictable, and seemingly similar 'ingredients' can lead to different outcomes emerging in different settings. It is not just the ingredients that matter, but also the coordination 'recipe' and the nature of the 'chefs' who will be enacting it. The important aspects of a recipe are not always easy to codify, and the chefs can interpret a recipe in somewhat different ways and add tacit knowledge to the process. In line with this analogy, complex adaptive systems are not about simple cause and effect relationships; they are about dynamic processes [82].

Braithwaite [81] notes that the sheer number of influences affecting healthcare systems and the non-linearity of interactions between them (as complex adaptive systems) can make it hard to impose order, yet also observes that the forces of inertia are strong in healthcare systems and can be difficult to overcome. Thus mandating specific quality improvement programmes or initiatives (and prescribed 'designs') by local, regional or national policymakers does not necessarily lead to sustainable change. And whereas the take-up of change is challenging in one context, it is even more challenging to diffuse changes and to sustain them across contexts. According to Braithwaite, staff at the frontline have 'degrees of discretion to repel, ignore, modify or selectively adopt top down mandates…. Healthcare is governed more by local organisational cultures and politics than what the secretary of state for health or a remote policymaker or manager wants' [81: p. 2], and efforts to support quality improvement need to pay more attention to those at the frontline of care delivery.

All of this also points to the need for further research on the influence of context on improvement efforts. This is argued in a 2014 Health Foundation compilation of essays, *Perspectives on context* [94], where the authors flag how interactions between the components of a quality improvement intervention, how it is implemented and the environment (context) in which the implementation unfolds play a critical role in an intervention's success. In one of the essays, Bate highlights that the nature of a specific context can be prone to interpretation, which means that to really understand a context and its influence on quality improvement initiatives requires research approaches that enable deep immersion into the perspectives of those who live and breathe an implementation context [95]. In another essay, Dixon-Woods flags the need to go beyond clinical science methodologies and to include social science approaches in research on the influence of context [96].

Bate's essay [95] also flags the need to consider how the inner context (i.e. microcontext, intraorganisational contexts) and the outer, external context (i.e. macro, socioeconomic and political contexts) interact, and reflects on how modifiable different aspects of a context might be. Drawing on insights from Pettigrew ([97], cf in [95]), Bate flags that the external context is usually 'too big and distant to be managed, and has to be related to in the same way that a surfer would pick up and ride a wave, that is to say opportunistically, as one looks for an energy source to latch on to that will take one roughly in the direction in which one wants to go' [95: p. 10]. Bate reflects on six organisational contextual challenges for quality improvement: challenges relating to structuring, planning and coordinating quality improvement efforts; challenges to designing the physical and technological infrastructure to support quality improvement; political challenges to negotiating and securing buy-in and effective relationships for change; emotional challenges relating to inspiring and mobilising people by relating improvement to their deeper commitments and sentiments; educational challenges to ensuring a learning process to support continual improvement; and cultural challenges to ensuring that quality has a shared collective meaning and value within the organisation [95].

Similarly to Bate's essay, Robert & Fulop, in their essay in the same compilation, argue for the need for more explicit attention to micro, meso and macro levels of context and for better understanding of which aspects of context are more or less important and more or less modifiable [98]. What is more or less important or modifiable is also likely to vary across different organisational contexts. Øvretveit's essay [99] cautions that modifications to a context require resources – thus care is needed in investing resources into modifications, given that their effectiveness may not be established. He also flags the need for understanding whether some interventions are more 'context-robust' than others (i.e. more likely to succeed across different settings) [99: p.64].

5.4. Future research could also have practical applications in developing tools to support improvement efforts and in informing the design of national investments into improvement capability building

5.4.1. Future research could help inform the development of a profiling tool of the organisational readiness for improvement

The insights gained could help inform the design of a diagnostic/profiling intervention that could potentially be used to help assess the readiness of an organisational environment to embark on improvement. Indeed, Jones et al. [60] highlight that an assessment of organisational readiness is the first step for an improvement initiative, and consider organisational readiness along the dimensions of the learning climate, infrastructure, governance and leadership.

Further work would need to be done to refine the factors that would inform any such profiling tool and to ensure that the 'questions' the tool would ask (and how these are formulated) would support empirically rich and nuanced learning. It is likely that further work to establish an organisational readiness tool would require primary research that includes stakeholder consultation. Such a tool might be used both to help inform improvement activity ‘on the ground’ and to enrich the overall evidence base on improvement (given that current insights in the literature seem to be relatively high level, as discussed earlier). However, we caution that any such tool would need to undergo robust evaluation to ensure that it is effective and acceptable to stakeholders, and that its use is grounded in a sound evidence base.

Furthermore, any effort to develop an organisational readiness assessment tool would need to integrate learning from prior experiences. These types of tools have a long history. For example, Timmings et al. [100] discuss the process of developing an online readiness for change decision support tool for healthcare organisations. They flag the importance of end-user driven approaches to developing such tools, of identifying appropriate readiness assessment measures, and of piloting and evaluating the tools. Weiner et al. [101], based on a review of studies looking at the conceptualisation and measurement of organizational readiness for change (in healthcare and other fields) and an inspection of 43 instruments for measuring organisational readiness, identify that there is limited evidence of validity and reliability for most of the measures used in the tools (existing at the time, although these challenges persist today). Further research by Weiner et al. published in 2020 discusses some of the persistent challenges in this space, but also identifies some tools that have been shown to have good validity and reliability [102]. These include the Organisational Readiness for Implementing Change (ORIC) instrument and the Perceived Organisational Readiness for Change (PORC) instrument [102]. Weiner et al. [101], [102] also identify conceptual challenges to defining readiness, in relation to whether the concept needs to reflect only capability or also motivation (i.e a will to embark on change). The conceptualisation that is adopted will affect the design of a readiness assessment tool. Weiner et al. [101]] in addition flag various methodological challenges to do with the right timing of an assessment (which they argue should be after a decision to implement but before implementation) and with identifying who to include in the assessment. These types of challenges would need to be carefully considered in the development of readiness assessment tools, especially if such tools are likely to be used across contexts.

Once readiness is assessed, there is a need to ensure a viable and sustainable implementation plan for any organisational-level quality improvement effort that is to follow. Jones et al. [60] discuss the flow of activities and steps that need to be taken for a successful improvement imitative once organisational readiness has been assessed (step 1); highlighting the need to secure board support (step 2); followed by wider organisational buy-in (step 3); to invest in developing improvement skills and infrastructure (step 4); to align improvement activity with an organisation’s overall strategy (step 5); and to invest in sustaining an organisation-wide improvement approach over time, including in the face of external pressures (step 6). These steps, in combination with the influences on improvement that we have identified throughout this report (see Sections 4.1–4.7 and Boxes 23–28 above), could help inform the design and roll out of improvement interventions in the health system.

If an appropriately evidence-based and validated profiling tool were to be developed, it could be used to diagnose particular bottlenecks in ‘readiness for improvement’ in specific parts of health and care pathways or in particular disease and clinical areas or for particular patient profiles. To illustrate, it may be that data are more of a bottleneck in some clinical areas than in others, or that the skills and competencies needed for effective quality improvement are less established in some professions than in others. Similarly, it could be that in some clinical areas or for some patient profiles, the challenges to whole systems working are more acute than in others. Such profiling activity could potentially help expose and characterise the differences in improvement conditions, capabilities and capacities across the healthcare system and lead to a better coordinated and more systematic evidence base.

In addition, if a carefully designed and robustly evaluated improvement readiness tool was systematically applied across the healthcare system, we could, for example, better understand – with more granularity and 'real-world' applicability – what specific aspects of the social and organisational context need to be targeted in different clinical areas (e.g. oncology versus orthopaedics) and different components of a healthcare system in a specific clinical area (e.g. primary care, acute care and community care in mental health) to effectively implement improvement activities and support improvement cultures. We could perhaps also gain comparative learning on improvement capability-building needs across different parts of the improvement pathways (e.g. supply chain quality improvement issues, decommissioning-related quality improvement issues).

5.4.2. Future research could also help inform the design of national investments into improvement capability building

Learning from profiling activity could also potentially be used to help inform the design of national programmes and investments into improvement capability building in the NHS, potentially in collaboration with national policy and arm's-length bodies. Profiling activity across contexts could expose what improvement capability and motivation-related strengths and gaps are more or less shared across different settings. This learning could be applied to efforts to design a 'modular intervention' targeting the social and organisational context for improvement (and its influencing factors) across different healthcare settings. Such a modular intervention would have core components applicable across contexts and 'modules' tailored to the unique needs of specific improvement settings (e.g. different clinical fields).

Any activity to develop a national improvement intervention should not, of course, take place in a vacuum of learning from prior efforts and programmes and would require coordination with existing improvement efforts in the system (e.g. national clinical audits). National-level efforts aim to capture the benefits of scale, consistency and coordination in achieving quality improvement aims for patients and for the healthcare service, and focus on building capacity and capability across the healthcare system. However, experience from past and ongoing quality improvement programmes highlights some of the challenges to their effective coordination and implementation. For example, Peden et al. [103] conducted a stepped-wedge cluster-randomised trial of the effectiveness of a national quality improvement programme to improve survival after emergency abdominal surgery (EPOCH). They identified various challenges to nationwide implementation, including those related to ensuring staff have sufficient time for the quality improvement effort, appropriate resourcing, effective relationships, differing baseline positions of implementing organisations, and intervention complexity. As our review has shown, many of these challenges apply at local levels as well, but may be accentuated in national-level efforts, in light of their scale and hence in light of the resources that need to be invested to tackle them.

To give an alternative example, Robertson et al. [104] reflect on lessons learnt (to date) from the implementation of another national improvement programme, Each Baby Counts. This programme aims to reduce the number of stillbirths, early neonatal deaths and severe brain injuries in babies born at term by 50 per cent by 2020. They identify human factors such as fixation on one clinical issue leading to oversight in spotting another, staff stress and fatigue, and loss of situational awareness as common challenges to achieving the programmes improvement goals. They therefore flag the importance of developing platforms for shared learning between different implementing sites. The recognised importance of shared learning is reflected in the development of national quality improvement efforts that span diverse clinical contexts and professions, and that focus specifically on building learning communities. One example is the Q initiative, which aims connect people working in quality improvement across the healthcare system throughout the UK, to make it easier for them to share ideas, enhance their skills, and in doing so help bring about a change that benefits patients. An interim evaluation of this initiative highlighted the importance of achieving effective and coherent governance and leadership arrangements for a large and dispersed community without compromising its bottom-up and member-led ethos, and of sustaining the infrastructure that can support a large and continuously evolving improvement community [105]. Efforts to learn from past experiences are already translating into the design of new improvement programmes.

For example, in the UK, the national Maternity and Neonatal Safety Improvement Programme (MatNeoSIP) has a stated strong focus on influences on quality improvement related to social context (such as those related to safety culture, systems and processes, stakeholder engagement, and learning from success and errors) and on sharing learning between implementing organisations and across regions. Future research and evaluation of initiatives of this nature could help strengthen the knowledge base on how such social context influences can be mobilised in support of quality improvement, at a national scale.

Future research is also needed to better understand how national improvement investments can align with local improvement, change and transformation efforts, to mitigate against ‘initiativitis’ in the healthcare system and to support a better-coordinated quality improvement landscape.

5.5. Further research on the unintended consequences of improvement efforts is needed to ensure that any new improvement efforts can manage such risks

The myriad of quality improvement initiatives in the healthcare system, coupled with wider healthcare system transformation efforts, call for significant time investment and energy from the stakeholders who are involved. Thus launching new efforts, be they within a single organisation (or a few organisations), or at regional or national levels, runs the risks of introducing further ‘initiativitis’ into the healthcare system. This may have unintended effects on healthcare staff morale and/or detract from day-to-day patient care activities. There is also the risk of aspiring leaders and managers being incentivised to engage in quality improvement to support career progression, which can further contribute to ‘initiativitis’. Existing literature has explored some of the unintended consequences of quality improvement in terms of, for example, leading to fixation behaviour (e.g. measurement fixation), or when gains in quality as a result of improvement efforts in one area happen at the expense of care quality in another area [106, 107]. There is also potential for negative financial consequences [108]. Furthermore, patient experience may be affected by quality improvement efforts if they do not align with their expectations and views of what constitutes high-quality care [106]. Managers and executives in healthcare settings may be well placed to consider the potential unintended consequences of quality improvement efforts prior to investing resources into their design and implementation [108]. Further research is needed, however, to identify mitigation and risk management strategies for particular types of potential unintended consequences.

5.6. Conceptualising the types of future research that are needed and considering sampling implications

The research we have conducted has helped to identify (and begin to characterise) the factors and dimensions of a social, cultural and organisational context that need to be in place to support the 'effective landing' and implementation of improvement interventions.

Further nuance- and context-specific learning needs to be gained, including to enable any potential efforts to design an improvement readiness profiling tool and potentially to inform the design of an improvement intervention that could be widely applied across the system to build social, cultural and organisational capability for improvement across the NHS. This requires further primary research, and the design of such research needs to avoid uncovering 'more of the same'.

We hypothesise that the types of rich and granular insights that are needed could in part be enriched by learning from existing literature reporting on primary studies in specific fields, but that more practically relevant and detailed information might be captured through direct engagement with stakeholders in improvement activity, for example through primary research using methods such as interviews, surveys, ethnography and citizen science approaches. Ethnographic approaches can be particularly helpful for integrating rich descriptions with theory, in order to show general behavioural patterns in specific settings. It is likely that both longitudinal and cross-sectional study designs would be needed to arrive at a more comprehensive evidence base. To enable generalisable learning from an accumulation of studies taking place in diverse clinical and geographical contexts, it would be important to combine insights from primary studies with synthesising reviews and with theoretical perspectives.

The focus of engagement with stakeholders (including through citizen science) would need to be on uncovering rich, detailed empirical evidence on how improvement conditions and practices manifest themselves in reality, in a given context. Most directly, this would require attention to 'converting' the diverse influences we have identified (Boxes 23–28) into questions that could lead to the requisite detail being exposed and captured.

Such primary research might seek to answer the following questions:

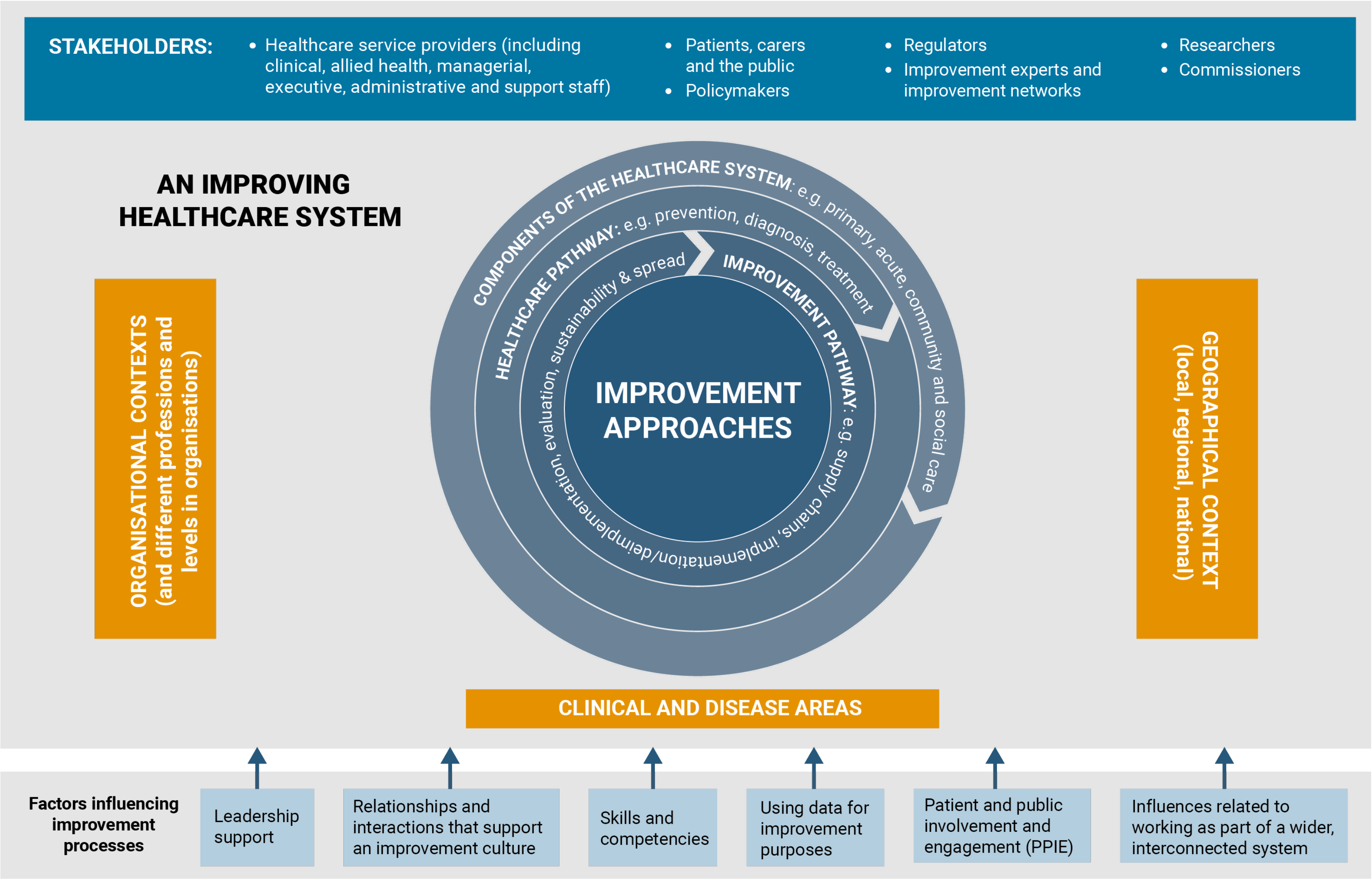
1. How do key influences on improvement play out in practice, in an improving healthcare system? How does this vary across:
    - Different improvement interventions/approaches/models?
    - Different parts of improvement pathways (e.g. supply chains, implementation, commissioning and decommissioning, evaluation, sustainability and spread)?

  - Different parts of the healthcare pathway (diagnosis, prevention, treatment)?
  - Different components of the health and care system (primary care, acute care, community and social care)?
  - Different stakeholder groups (including different clinical, allied health, managerial, executive and administrative professions; patients and the public; policymakers, regulators, improvement experts and consultants, improvement networks, the research community, commissioners)?
  - Different clinical and disease areas?
  - Different organisational contexts (and across different levels in organisational hierarchies)?
  - Different organisations across the country/different local contexts in a specific clinical area?
2. What can we learn about the process and from the experience of doing improvement through longitudinal research and historical analyses? Learning from the past and from in-depth longitudinal studies of improvement processes could inform meaningful learning about how improvement capability can be built, sustained and lost in a system.
3. How are different stakeholders addressing challenges in the social, organisational and cultural context locally (and nationally) as they relate to the diversity of factors influencing improvement? This could help draw out formative learning that can inform an improvement intervention (that could be trialled in the future).

Various stakeholder groups may be relevant to consult in future research. Our analysis suggests that these include:

1. Healthcare service providers: In the literature we reviewed, the focus seems to be mainly on acute care/hospitals. Expanding the range of sectors studied – for example to include community and mental health services – is likely to be of benefit.
2. Improvement networks/Peer communities: This group would include networks bringing together individuals involved in quality improvement in healthcare at national, regional or local levels, and they may include networks or communities that focus on one stakeholder group or that span many. Experts on quality improvement approaches are likely to form a part of some networks and communities, together with other stakeholders (e.g. healthcare professionals, managers, executives in provider organisations, service users, etc.).
3. Professional organisations: In a UK context, this group would include for example the royal colleges and various other professional societies and charities (and specifically the quality improvement initiatives within them).
4. Health charities/foundations: For example, this group would include charities funding and supporting activities aiming to improve the quality of patient care and patient safety through research or other types of activity (e.g. through supporting improvement initiatives and networks).
5. Commissioners: Commissioners of services can also impact on the resourcing of improvement initiatives and on their sustainability.
6. Policymaking, arm's-length bodies and regulators: This group would include government departments, arm's-length bodies as well as regulators overseeing or

Figure 2: An improving healthcare system



engaged with quality improvement efforts nationally or regionally.

7. Patients and members of the public: This group would include patients and members of the public involved in quality improvement initiatives (as well as patients who can comment on the quality of services based on their experience even if not directly involved in quality improvement initiatives).
8. Academia and other research organisations: This group would include individuals involved in quality improvement research at universities or other research organisations.

In addition to insights on the types of stakeholder groups to engage, there are some other important sampling considerations for future research. Not all of these could be addressed by any single study. However, our research suggests that it would be important to, across a portfolio of research, ensure the engagement of clinical, executive and operational leadership in organisations, and individuals at different levels in organisational hierarchies. This is because they all have a role to play in the success, spread and sustainability of quality improvement activities. Speaking to frontline staff (clinical, operational and administrative) can help expose nuanced insights and detail associated with their practical experiences and operational realities. Frontline staff can also sometimes provide insights on the less obvious challenges to implementing quality improvement as well as be a source of fresh and out of the box thinking about new opportunities and ways of managing challenges. Given that much of the current literature focuses on learning targeted at senior managers and leadership, integrating the frontline more prominently into research studies and developing recommendations geared at frontline staff seems to be an area in need of particular attention. Similarly, there is a need for research that can distil recommendations for policymakers and in doing so support national level improvement efforts.

Future research should also seek to draw learning from multiple and diverse settings in which the same or similar interventions were implemented, to be able to shed some light on transferable learning. This should include settings (and individuals within them) who are already committed to improvement as well as organisations who have less of a history improvement activity.

Lastly, it is important to note that some of the obstacles and drivers of the quality improvement process may relate to the actions of stakeholders other than those that are immediate/directly engaged in quality improvement activity. For example, wider actors involved in service delivery – such as in the supply chains, or in the commissioning and decommissioning of care/services – may have an impact on the experience and process of doing quality improvement. They may also be a source of important learning in future research.

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