REGULATION FOR IMPROVEMENT?
A STUDY OF HOW IMPROVEMENT CAPABILITY IS CONCEPTUALISED BY HEALTHCARE REGULATORY AGENCIES IN THE UNITED KINGDOM

A thesis submitted to The University of Manchester for the degree of Doctor of Philosophy in the Faculty of Humanities

2017

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<th>Description</th>
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<td>Allied health professional</td>
</tr>
<tr>
<td>AMBS</td>
<td>Alliance Manchester Business School</td>
</tr>
<tr>
<td>BPM</td>
<td>Business process management</td>
</tr>
<tr>
<td>CEO</td>
<td>Chief Executive Officer</td>
</tr>
<tr>
<td>CHKS</td>
<td>Caspe Healthcare Knowledge Systems</td>
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<tr>
<td>CI</td>
<td>Continuous improvement</td>
</tr>
<tr>
<td>CINAHL</td>
<td>Cumulative Index to Nursing and Allied Health Literature</td>
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<tr>
<td>CQC</td>
<td>Care Quality Commission</td>
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<tr>
<td>CQI</td>
<td>Continuous quality improvement</td>
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<tr>
<td>CSF</td>
<td>Critical success factor</td>
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<tr>
<td>DCV</td>
<td>Dynamic capabilities view</td>
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<tr>
<td>DUQuE</td>
<td>Deepening our Understanding of Quality improvement in Europe</td>
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<tr>
<td>EFQM</td>
<td>European Foundation for Quality Management</td>
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<tr>
<td>FT</td>
<td>Foundation Trust</td>
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<tr>
<td>HIS</td>
<td>Healthcare Improvement Scotland</td>
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<td>HIW</td>
<td>Healthcare Inspectorate Wales</td>
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<td>HMIC</td>
<td>Health Management Information Consortium</td>
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<td>HRM</td>
<td>Human resource management</td>
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<tr>
<td>IHI</td>
<td>Institute for Healthcare Improvement</td>
</tr>
<tr>
<td>IHI-QI</td>
<td>Institute for Healthcare Improvement’s approach to quality improvement.</td>
</tr>
<tr>
<td>ISQuA</td>
<td>International Society for Quality in Healthcare</td>
</tr>
<tr>
<td>JCAHO</td>
<td>Joint Commission on Accreditation of Healthcare Organisations</td>
</tr>
<tr>
<td>MBQA / MBNQA</td>
<td>Malcolm Baldrige [National] Quality Award</td>
</tr>
<tr>
<td>MeSH</td>
<td>Medical subject headings</td>
</tr>
<tr>
<td>MUSIQ</td>
<td>Model for Success in Quality</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
</tr>
<tr>
<td>NHS FT</td>
<td>NHS Foundation Trust</td>
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<tr>
<td>NHS non-FT</td>
<td>NHS non-Foundation Trust</td>
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<tr>
<td>OA</td>
<td>Organisational ambidexterity</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<td>PDSA</td>
<td>Plan – Do – Study – Act (an improvement heuristic, based on the Deming wheel. Also, referred to as PDCA. (Plan – Do – Check – Act).)</td>
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<td>QI</td>
<td>Quality improvement</td>
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<td>QIRN</td>
<td>Quality Improvement Research Network</td>
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<td>QM</td>
<td>Quality management</td>
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<td>QMS</td>
<td>Quality management systems</td>
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<tr>
<td>RBV</td>
<td>Resource based view</td>
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<td>RQIA</td>
<td>Regulatory and Quality Improvement Authority</td>
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<tr>
<td>TDA</td>
<td>Trust Development Authority</td>
</tr>
<tr>
<td>TPS</td>
<td>Toyota Production System</td>
</tr>
<tr>
<td>TQI</td>
<td>Total quality improvement</td>
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<tr>
<td>TQM</td>
<td>Total quality management</td>
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<tr>
<td>VRIN/VRIO</td>
<td>Valuable, rare, inimitable and non-substitutable (or valued, rare, inimitable and organisation)</td>
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<tr>
<td>WTE</td>
<td>Whole time equivalent</td>
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# Glossary

Accreditation: The process in which certification of competency, authority, or credibility is presented. Typically involves the use of voluntary and independent external assurance processes, such as a multi-disciplinary peer review of a team or an organisation to understand if pre-defined quality standards are being met and the outcomes of this review are shared publicly. It can be viewed as a variant of regulation.

Assessment: Careful examination or scrutiny by a regulatory agency, usually by teams of experts who visit sites to collect data of existing practice against standards. May also be performed via a table top exercise through a review of submitted documents and verbal discussion.

Assessment report: Published reports documenting the performance of an organisation and comparing them with the standards to identify strengths and weaknesses.

Coding stripe: Coding stripes provide a visual image in NVivo software to indicate which sections of text have been coded overall and for a specific code.

Dimensions of improvement capability: The aspects or features of improvement capability.

Dynamic: Refers to the external environment in which an organisation operates which changes over time, such as the level of competition, changing technologies or political mandates, creating uncertainty.

Dynamic capability: The term dynamic capabilities refers to a firm's ability to integrate, build, and reconfigure internal and external competences to address a rapidly changing environment (Teece et al., 1997).

Capability / capabilities: Refers to the key role of adapting, integrating and reconfiguring key organisational resources and skills to anticipate or adapt to a changing environment.

Improvement: A change or addition to a person or object that represents an advance on another in excellence or achievement.

Improvement capability: Resources and processes supporting both the generation and the diffusion of appropriate innovations across an organisation (Adler et al., 2003).
<table>
<thead>
<tr>
<th><strong>Improvement approaches</strong></th>
<th>Improvement approaches encompass concepts, ideas and empirical tools and techniques. These include lean, six sigma and total quality management (TQM).</th>
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<tr>
<td><strong>Inspection</strong></td>
<td>Careful examination or scrutiny by a regulatory agency, usually by teams of experts who visit sites to collect data of existing practice against standards.</td>
</tr>
<tr>
<td><strong>Inspection report</strong></td>
<td>Published reports documenting inspection visit performance of an organisation and comparing them with the standards to identify strengths and weaknesses (see assessment report).</td>
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<td><strong>Integrative review</strong></td>
<td>A method used to review literature which allows disparate qualitative and quantitative instruments and frameworks to be systematically reviewed (Hawker et al., 2002).</td>
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<td><strong>Microfoundations</strong></td>
<td>Microfoundations are used to unpack collective concepts into individual factors in order to understand their impact. The microfoundations of dynamic capabilities can be unpacked into three parts: sensing, seizing and reconfiguring (Teece, 2007).</td>
</tr>
<tr>
<td><strong>Node</strong></td>
<td>Information in NVivo10 is stored in nodes. The term node is used to indicate a connection point and where conceptual points branch out into sub components. Nodes are used to develop coding frames.</td>
</tr>
<tr>
<td><strong>NVivo10</strong></td>
<td>Software enabling qualitative data analysis</td>
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<td><strong>Regulation</strong></td>
<td>Sustained and focused control exercised by a public agency over activities which are valued by a community (Selznick, 1985).</td>
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<tr>
<td><strong>Service user</strong></td>
<td>The term 'service user' is widely accepted in the fields of health and social care and refers to anyone who is a patient or other user of health and/or social services. It can also be used for a consumer or user of products and services.</td>
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References


Abstract

The University of Manchester
Joy Furnival
Doctor of Philosophy
Regulation for improvement? A study of how improvement capability is conceptualised by healthcare regulatory agencies in the UK
17/2/2017

Unexplained variations in organisational performance in healthcare are a continued focus of research, political, and public interest. Regulatory agencies are always seeking new ways to reduce variation and improve performance, and the use of approaches to develop improvement capability is increasingly encouraged. However, the regulatory perspective on improvement capability is under researched.

This research study seeks to understand how regulatory agencies in the United Kingdom (UK) assess improvement capability within healthcare organisations. It explores how improvement capability is conceptualised, compares the regulatory arrangements across the UK, and examines assessment and enforcement policies and practices, before developing a conceptual framework for improvement capability.

The research study uses data from 48 interviews, 90 regulatory policy documents and 30 assessment reports. Regulatory conceptualisations of improvement capability are explored through cross-case comparison and qualitative analysis. A review of 70 instruments and frameworks for the assessment of improvement capability from the literature identifies that there are plural conceptualisations of improvement capability. The findings from the review are synthesised into eight dimensions of improvement capability which are used to analyse the empirical data and to develop a conceptual framework.

The analysis finds an emergent trend towards responsive regulatory models which aim to develop improvement capability. However, the analysis identifies ambiguity in regulatory agencies’ conceptualisation of improvement capability with two dimensions of improvement capability used more frequently than others in regulatory assessments. Regulatory agencies need to clarify their conceptualisation of improvement capability and supplement their assessment processes to further understand local circumstances. This can be used to inform more flexible regulatory responses, including the tailored provision of improvement support to develop improvement capability. This requires greater regulatory effort and resources, and the analysis finds there are three areas of tension, linked to regulatory roles, resources and relationships.

The research study proposes a conceptual framework of improvement capability that can be used to clarify regulatory conceptualisation and assessment of improvement capability. Greater conceptual clarity will strengthen regulatory agencies’ assessment, diagnosis and prediction of organisational performance trajectories, and support the advancement of more appropriate, effective and responsive regulatory interventions, including the development of improvement capability.
Declaration

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I also owe significant thanks to all the regulatory organisations who participated in this research study and to the employees who facilitated access within the organisations, and to the participants themselves. I thank them for sharing their views and thoughts honestly, for sharing with me documents about their organisation, and for recognising the value of this research to the regulatory and improvement community in healthcare. I also thank them for their feedback which they provided on the draft research papers I shared with them.

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sacrifices whilst I completed my PhD. I thank him for his unrelenting support and motivation along the way.
Section 1
Chapter 1 - Introduction

This chapter introduces the background to the research study and explains the rationale for undertaking this study. It presents the research question and concludes with an overview of the structure of the study.

1.1 Background to the research study

Unexplained variations in organisational performance in healthcare continue to be a significant focus of research, political and public interest (Jha et al., 2010). Patient safety, financial and quality performance variations are regularly described as excessive and receive substantial attention (Dobrzykowski et al., 2016; McFadden et al., 2009; Li and Benton, 2006). In the US, the report ‘To Err is Human’ by the Institute of Medicine (Kohn et al., 2000), suggested that variation in safety performance due to medical errors was responsible for approximately 98,000 deaths annually, while more recent studies have estimated this to be much higher at between 200,000 and 400,000 deaths (Makary and Daniel, 2016; James, 2013). These studies suggest that medical errors resulting from healthcare variations are the third largest cause of death in the US, with only heart disease and cancer costing more lives, although this is contested (Shojania and Dixon-Woods, 2016). Therefore, healthcare regulatory agencies and healthcare organisations are increasingly seeking new ways to ensure high quality care and improved performance.

Regulation in healthcare is used as a policy to assure and protect patients from harm, inequity, and excessive performance variation. In addition, it ensures improvements for patients, and where necessary holds healthcare organisations to account for their poor performance (Walshe, 2003). Nevertheless, despite these aims regulation is criticised for obstructing and hindering improvement efforts through an adversarial, inflexible and bureaucratic approach (Baldwin et al., 2012; Brennan, 1998; Bardach and Kagan, 1982). Recognising these challenges, variations, such as ‘responsive regulation’ (Braithwaite, 2011), are increasingly proposed in order to improve performance (Berwick et al., 2015; Ham, 2014). These encourage the use of improvement approaches which support the development of improvement capability within healthcare organisations suited to local circumstances.
In England, new regulatory regimes are developing in response to the Francis Inquiry (2013) into poor care in one healthcare organisation and a review of patient mortality in hospitals (Keogh, 2013). Mortality reviews commissioned in other parts of the UK (for example the Lanarkshire review in Scotland, Healthcare Improvement Scotland, 2013) are similarly influencing regulatory regimes.

1.2 Review of the literature

Healthcare regulation and improvement is the focus of this research and this is positioned at the boundary of three overlapping bodies of knowledge: regulatory theory, improvement and the dynamic capabilities view (DCV).

The literature reviewed in Chapter 2 highlights that regulation and accreditation in healthcare and other sectors has been the topic of much debate over the past 20 years (Parker, 2013; Ayres and Braithwaite, 1992). Regulatory theory outlines the three aims of regulation, namely accountability, assurance and improvement, yet acknowledges that each of these aims can have varying priorities and can be delivered through several regulatory models. One regulatory model, responsive regulation (Ayres and Braithwaite, 1992), suggests that regulatory agencies and regulated organisations need to collaborate to ensure regulatory effectiveness. A responsive regulatory model is increasingly accompanied by a developmental perspective and capability interventions, whereby regulatory agencies proactively provide tailored improvement support and encouragement for organisations to develop improvement capability.

One way of providing support, aid and development to organisations is through capability interventions (Talbot, 2010). These include the use of improvement approaches, such as business process management (BPM) (Hammer and Champy, 1993) and total quality management (TQM) (Oakland, 2003) to develop improvement capability. The literature on healthcare improvement is long standing, and builds on a substantial body of performance research from industrial and healthcare sectors (D’Andreamatteo et al., 2015; Nicolay et al., 2012; Shortell et al., 1995; Berwick, 1989). However, the literature contains little about the regulatory conceptualisation of improvement capability, and it is argued that organisations do not always have the capability to ensure that improvements are delivered to the
public, with further research required to understand regulatory enforcement actions, which can include capability interventions (Black and Baldwin, 2012).

Davidoff et al. (2015) argue that improvement research within the literature is insufficiently theoretical, while Talbot (2010) suggests several theories to support capability led approaches, which are argued to have considerable theoretical overlap (Vogel and Güttel, 2013). Three of these theories are reviewed in detail in Chapter 2, which also describes how further research is needed across the theories that focuses on specific capabilities, the factors that support their development, and the establishment of empirical evidence, particularly within the public sector. This research study draws on the DCV (Teece and Pisano, 1994) to provide stronger theoretical framing. This is utilised because it takes a process view of performance and it emphasises that improved performance is contingent on the organisational capability to purposefully create, extend and modify its resources through routines over time.

To respond to the calls in the literature, this research study focuses on healthcare organisation regulatory agencies in the UK and explores how improvement capability is conceptualised and assessed from their perspective. The literature review describes how there is little research that explores the interaction of both regulation and improvement approaches, and the development of improvement capability. It is argued that further research is needed that explores the impact of the combination of approaches and how regulatory agencies should encourage improvement (McDermott et al., 2015; Parker, 2013). Moreover, there is little research undertaken within healthcare which examines the challenges of a responsive regulatory approach encouraging the development of improvement capability, whilst concurrently continuing to assure and protect patients and holding healthcare organisations to account if required (e.g. Nielsen and Parker, 2009). It is possible that the lack of focus on how improvement capability is conceptualised and assessed by regulatory agencies hinders its development and hampers agencies and healthcare organisations in understanding their improvement strengths and weaknesses, thereby preventing the tailoring and ‘responsiveness’ of improvement capability development plans and associated outcomes.
1.3 Research design and process

An observational approach with a comparative case study design is used in this research and the reasons for these choices are discussed in Chapter 3. Phase 2 consists of two parts which reflect the two stages of data analysis. The data collection and related data analysis processes are shown in Figure 1.1. The phases are aligned with the research objectives and are reflected in the four papers detailing each phase of the research study presented in the alternative format.

Figure 1.1: Research process

An integrative literature review (Whittemore and Knafl, 2005) was conducted during phase 1, which identified 70 assessment instruments and frameworks (quantitative and qualitative). These were evaluated against criteria appropriate for the type of instrument or framework (i.e. a quantitative instrument was evaluated against validity and reliability criteria), and identified constructs used for improvement capability. The measurement constructs and associated measurement items extracted from the 70 instruments and frameworks were inductively analysed and themed into eight dimensions of improvement capability.

During phase 2 (parts a and b) three sets of empirical data, including documents and interviews from each of the six agencies and assessment reports of healthcare organisations, were analysed using the improvement capability measurement constructs and dimensions identified in phase 1, as the a priori coding framework. In phase 2 (parts a and b) an exploratory study was conducted with regulatory agencies to identify current approaches to the assessment and development of improvement capability, and how also it is conceptualised. Six regulatory agencies
across the devolved health systems in the UK participated and this sample represents all the agencies who have a remit to review healthcare organisational performance on behalf of the public in the UK. This sample was chosen as the context for the research study due to the natural experiment of devolved health systems in the UK, which allows a simple comparison.

Finally, in phase 3 the findings from the integrative literature review conducted during phase 1 were set in the wider context of resource based theories in order to develop a conceptual framework for improvement capability.

1.4 Scope of the research study

This research focuses on healthcare organisation regulatory agencies in the UK and explores how improvement capability is conceptualised and assessed from their perspective. The use of the natural experiment of the devolution of health systems in the UK, through a comparison of regulatory arrangements in the UK, minimises other impacts, such as significant differences in healthcare funding, provision, health system maturity, and workforce development, from confounding the results that may have been evident if a comparison was made within other countries.

However, the research study does not explore how improvement capability is conceptualised by healthcare organisations, nor does it explore their experiences and perceptions of regulatory assessment. Furthermore, this research does not examine the relationship between regulatory development of improvement capability and organisational performance outcomes. In addition, this research study focuses on organisational regulatory agencies rather than health professions regulatory agencies (for example the General Medical Council), as these may only provide partial perspectives of improvement capability within organisations.

1.5 Thesis structure

This thesis consists of three main sections and in Section 1 (Chapters 1, 2 and 3), the background to the research study is outlined and the research is situated within the literature, while the methodological approach taken is also established. In Chapter 2 the theoretical background of regulation, improvement and dynamic capabilities are discussed in order to guide the research study. The chapter examines the role of regulation and improvement in healthcare, and includes a critical review of the
theory. A cross-disciplinary and cross-sectoral approach was taken, drawing on improvement and regulatory theory from law, policy, industrial, operations management, and safety fields, as well as clinical research.

Amalgamating these insights, Chapter 2 explores why research to understand the conceptualisation and assessment of improvement capability is needed, and specifically sets out why a regulatory perspective is taken. Gaps within the literature are identified and the research question is developed. Chapter 3 sets out the epistemological and ontological approach taken, and includes the research design and the methodological approach utilised. The methods used within the research are detailed in this chapter, including identification of the study sample, justification for the use of interviews and documentation review, and the analysis processes employed. Chapter 3 also provides a critique of the methods used.

This thesis is written in the alternative format and four papers (Chapter 4, 5, 6 and 7) are presented in Section 2 detailing the findings from each phase of the research. These papers are written in a format suitable for potential journal submission and publication and present the findings, analysis and conclusions from each successive phase of the research study. These four papers inevitably contain some information that is also included elsewhere within this thesis.

Section 3 (Chapter 8) presents the discussion and conclusions for the whole research study. The discussions of the findings from the four papers are expanded and the findings are integrated and related to the wider theoretical context which was articulated in Chapter 2. The implications from these findings are drawn together to provide an understanding that can inform regulatory design and development. The chapter also reflects on the research study and suggests further research avenues.

1.5.1 Alternative format

There are three main reasons for the adoption of the alternative format for this thesis. The conventional thesis format is criticised for requiring the duplication of scholarly work to rewrite chapters of theses into a format suitable for publication and dissemination (Thomas et al., 1986). Therefore, the alternative format is used for this thesis because this approach supports research dissemination in a format that is more suitable for submission to conferences, as well as peer-reviewed journals.
The author was partially motivated to complete a PhD in order to learn how to write for journal publication, and the skills required to develop academic papers are different to those needed to produce a conventional thesis (Jensen et al., 2003).

The alternative format is used because the research study design was structured into three phases which fell naturally into individual papers which examine the research topic from different angles. Consequently, the references associated with each chapter or paper are also included at the end of each chapter rather than at the end of the thesis. Each paper is preceded by a short introductory section which places the paper within the context of the whole thesis and demonstrates the links between each paper.

1.5.2 Nature of the author’s contribution

This thesis and all contributions to it have been written in full by the author. The introduction, literature review, data collection, data analysis and manuscript drafting has all been solely undertaken by the author. It is written in alternative format and therefore the four papers presented in Section 2 are also co-authored by the thesis supervisors Professors Kieran Walshe and Ruth Boaden. The co-authors have contributed by reviewing the many chapter and paper versions, and providing critical feedback for incorporation into chapter revisions. The contribution made by the co-authors to the papers in Section 2 is within the normal expectations from doctoral supervisors. At the time of submission, paper 2 (Furnival et al., under review) has been submitted for publication in a peer reviewed journal and is under revision following review, and a revised version of this paper has been developed for incorporation into a book chapter. Versions of papers 1 and 3 (Furnival et al., in development-a; Furnival et al., in development-c) will be submitted to peer reviewed journals in the first half of 2017, and paper 4 (Furnival et al., in development-b) in the latter half of 2017.

1.6 Chapter summary

This chapter introduces the research within the wider context of healthcare performance improvement. It has indicated that the research focuses on healthcare organisation regulatory agencies in the UK and explores how improvement capability is conceptualised and assessed from their perspective. It has provided a brief overview of the background to the research study, and the research gaps and
related questions. It has also outlined the scope and intended contribution of the research study. Finally, the chapter has outlined the structure of the thesis and has justified the reasons for the selection of the alternative format for this thesis.
References


Chapter 2 - Literature review

This chapter details the background to the research and reviews the literature on healthcare regulation and improvement, and considers which theoretical perspective may be useful whilst conducting the research study. After the introduction, the methods used to develop the background to the chapter are briefly outlined. The background to this research is then presented in three areas: regulatory theory, capability interventions and resource-based theories of performance. This chapter critically examines the extant academic literature to synthesise the research context across regulatory and improvement domains using a dynamic capabilities perspective. Finally, the research problem identified through this literature review is outlined, together with the associated research question and objectives. The chapter positions and justifies the need for the research and details the purpose of the research study, including its contribution to knowledge and impact.

2.1 Introduction

The global challenge faced in improving healthcare performance, as outlined in Chapter 1, has led many governments to establish or strengthen systems for formal oversight, accountability, regulation and improvement in healthcare (Kachalia et al., 2016; Bevan, 2008; Mello et al., 2005; McLoughlin et al., 2001).

Talbot (2010) suggests that there are four main categories of public intervention to improve performance: managerial/contractual interventions, market or systemic change, user voice and choice and capability interventions (Table 2.1). Each is underpinned by differing theoretical perspectives and involve different actions by regulatory and organisational actors. Performance improvement interventions are typically used concurrently, but in a disconnected way, and it is argued that there is insufficient understanding about how these interventions interface or interact (Walshe et al., 2010). Furthermore, performance interventions are rarely used solely to improve performance, as interventions are also used to provide assurance to service users, and regulators may use performance interventions to identify ‘failing’ organisations and to support regulatory enforcement (Talbot, 2010).
Table 2.1: Categories of performance interventions
(adapted from Talbot, 2010)

<table>
<thead>
<tr>
<th>Intervention type</th>
<th>Description</th>
<th>Theoretical perspective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Managerial-contractual interventions</td>
<td>Direct and top down management control Use of contractual levers. Delegation of enforcement of minimum standards by regulatory agencies. Use of performance reporting and targets.</td>
<td>Institutional theory</td>
</tr>
<tr>
<td>Market or quasi-market systemic change</td>
<td>Systemic reforms to stimulate competition between organisations. Use of transparency approaches, such as league tables and performance charts, to stimulate competition. Requires independently produced performance data.</td>
<td>Public choice theory</td>
</tr>
<tr>
<td>User voice and choice</td>
<td>Empowers users of services and products through formal ‘rights’ and specific entitlements, and through choice of service provider.</td>
<td>Public choice theory</td>
</tr>
<tr>
<td>Capability interventions</td>
<td>Focuses on support to organisations through direct action, resource management approaches and improvement, e.g. lean, business process reengineering, leadership development programmes.</td>
<td>Resource based theories</td>
</tr>
</tbody>
</table>

Lillis and Lane (2007) outline how ‘outside-in’ approaches, such as contractual, market and regulatory interventions have dominated the research literature. ‘Outside-in’ approaches use managerial, consumer standards, and market-based methods to sustain a competitive advantage and improved performance. Lillis and Lane (2007) propose an increased focus on ‘inside-out’ perspectives, such as capability and capacity interventions. These alternative interventions are underpinned by resource based theories that focus on the exploitation and development of unique organisational resources and capabilities (Barney and Clark, 2007; Helfat et al., 2007; Barney, 2001). Shortell et al. (1998) argue that capability interventions are more likely to be successful when there is a conducive regulatory environment and agreed focused priorities.

Some research has begun to understand the conditions and factors required for organisations to develop self-improving programmes and strengthen improvement capability and support prospective performance improvement (Kaplan et al., 2013; Bevan et al., 2008; Baker et al., 2008). However, whilst ‘outside-in’ interventions,
including regulation, have been the subject of much research, little attention has been paid to understanding the interactions between interventions (Talbot, 2010), such as the regulatory role in understanding and developing capability interventions.

2.1.1 Approach taken for the general literature review

To identify a research gap and to inform the development of a research study design, a general literature review was initially undertaken. The approach to the initial review began with several seminal texts concerned with regulatory theory, including Bardach and Kagan (1982), Ayres and Braithwaite (1992) and Baldwin et al. (2012b). These texts introduced the researcher to the main arguments for and against regulation, and why regulation arises. Next, backwards and forwards citation searching was used to inform a wider reading of the regulatory literature. A similar approach was taken to review the body of literature connected to resource based theories and improvement capability. In addition, literature was identified using several search keyword strategies, including thesaurus terms, free-text terms, and broad-based terms, in order to optimise searching for qualitative evidence (Shaw et al., 2004).

This approach identified that the literature is broad, ambiguous and fragmented, with high levels of terminological heterogeneity across many disciplines. Therefore, this initial searching approach required supplementation, because whilst conventional searching within the social sciences identifies most references, further high quality references needed to be identified through other searching techniques (Papaioannou et al., 2010).

To strengthen this approach, and build and synthesise a general review of the literature on regulation, improvement capability and resource-based theories of performance, further multiple cycles of iterative literature searching and browsing took place to support serendipitous discovery (Greenhalgh and Peacock, 2005). This involved snowballing strategies and the use of personal knowledge and connections to seek out more obscure literature until saturation was reached. Randolph (2009) indicates that the most effective searching method ‘may be to search the references of the articles that were retrieved, determine which of those seem relevant, find those, read their references, and repeat the process until a point of saturation is reached, a point where no new relevant articles come to light’ (p7). These
approaches ensured a wide range of perspectives and sources were identified, and led to the development of a database containing over 1740 articles, books and texts concerning regulation, improvement and resource-based theories of performance. These sources were used to develop and synthesise a general review of the literature, which is detailed in this chapter.

2.2 Healthcare regulation

Healthcare regulation has developed to address consumer and health stakeholders’ demands for improved safety, quality and performance. The central purpose of regulation is the abatement of control of societal risks and to ‘fix important problems’ (Sparrow, 2000). Regulation arises to ensure that organisations and individuals modify their behaviour to guarantee compliance with regulations and achieve desired goals and outcomes. Regulation has various definitions (Healy, 2016 (2011)) and is often misunderstood as only the enforcement of legal rules, being seen as a burden or ‘red-tape’. However, it is frequently defined as the ‘sustained and focused control exercised by a public agency over activities which are valued by a community’ (Selznick, 1985, p363), and as ‘the sustained and focused attempt to alter the behaviour of others according to defined standards and purposes with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard setting, information gathering and behaviour modification’ (Black, 2002, pp1-35). Similarly, Brennan (1998) describes regulation as a set of ‘rules’ that impose or steer behavioural practices with key characteristics that exercise control over an activity that has value to a community, such as healthcare. Therefore, regulatory agencies are not limited to simply being public or state actors or to having a legal basis.

For regulation to function there must be an acknowledged authority, centralised oversight, third-party accountability, and action in the public interest (Boyd and Walshe, 2007; Walshe, 2003). Regulation can use both direct and indirect enforcement mechanisms for these ‘rules’ in order to affect quality, such as the suspension or threatened suspension, or through the provision of improvement support and incentives. Enforcement mechanisms such as these are argued to motivate care providers to improve care through behavioural change and to avoid punitive enforcement actions (Berwick et al., 2003).
2.2.1 Why regulate?

The literature describes three main aims of regulation: improvement, assurance and accountability (Ogus, 2004; Walshe, 2003; Klein and Scrivens, 1993). Regulation is argued to occur for two main reasons, which are to protect and adjust for market failure, and to protect the public interest (Ogus, 2004; Walshe, 2003). Regulation for market failure is argued to arise in situations such as where providers may fail to provide a service and be unable to meet public needs and demands, through insufficient quantity, due to the politically unacceptable distribution of services, or where only one provider serves a large geographical region and is a monopoly supplier and price controls may be required (Baldwin et al., 2012b; Boyne et al., 2003; Walshe, 2003).

Other public interest reasons are argued to include the delivery of collective benefit, where there are moral hazards and risks (Feintuck, 2012), to reduce discrimination and further social solidarity (Prosser, 2006), to mitigate shortages of critical goods or where there is unequal bargaining power. Moral hazards also arise where consumers may not pay directly for services, such as in healthcare where insurers or commissioners meet the costs of medical provision, and regulation arises for the collective benefit. Similarly, it is contended that regulation arises when patients cannot judge the quality of a healthcare service for themselves due to information asymmetry, or to resolve shortages through rationing or the imposition of standards to increase co-ordination or supply (Baldwin et al., 2012a).

2.2.2 Growth of regulation

Early forms of regulation within medicine, which can still be identified today, involved medical professionals setting their own standards of good conduct and practice that were self-regulating (Berwick, 2016; Brennan and Berwick, 1996). This approach maintained a level of professional autonomy and arguably maintained a closed system, thereby reducing external transparency and accountability. Power (1997) describes the growth of the ‘audit society’ over the last few decades, whereby organisational auditing and checking of organisations, as well as professionals, has flourished (Hood et al., 2000; Day and Klein, 1990), and is known as the ‘regulatory ratchet’ (Ayres and Braithwaite, 1992). The cost and burden on society caused by regulation, such as intrusion, loss of autonomy and restricted practices, has been perceived as less than the potential cost of the harms, dangers and risks that may
occur without it (Sparrow, 2012). This trend has increasingly led to society placing reliance and confidence in measurement, audit and control systems and regulation, which have been designed by the ‘audit profession’, rather than the profession being reviewed and controlled, such as doctors for healthcare (Sparrow, 2012).

2.2.3 Regulatory models

Regulation can be viewed as rooted conceptually in a positivist and rational organisational model. This indicates that organisations and their associated structures and processes to meet their organisational goals can be analysed and reviewed objectively. This underlying perspective has been substantially critiqued within healthcare, where it is argued that performance goals cannot be objective and are inherently value-laden (Bevan, 2008). It is also argued that the simplicity and rational perspective behind regulation does not fit well in healthcare and clashes with the complexity of healthcare practice, where decisions are more negotiated, politically messy and situated within professional cultures (Beaussier et al., 2015).

There are multiple and divergent approaches for healthcare regulation (Walshe, 2003; Boyd and Walshe, 2007) and there is little attempt to resolve this paradigmic issue. These can be themed as three main models: compliance (Parker, 2000), deterrence (Reiss, 1984) and responsive (Ayres and Braithwaite, 1992), and are summarised in Table 2.2.
Table 2.2: Comparison of regulatory models

<table>
<thead>
<tr>
<th>Regulatory model</th>
<th>Deterrence (Reiss, 1984)</th>
<th>Compliance (Parker, 2000)</th>
<th>Responsive (Braithwaite, 2011; Ayres and Braithwaite, 1992)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regulatory assumption</strong></td>
<td>Organisations are amoral calculators. Assumes that they will deliberately break laws and rules if they can do so undetected (Bardach and Kagan, 1982).</td>
<td>Organisations will try to do the ‘right’ thing, although things will go wrong.</td>
<td>Assumes regulatory agencies can be both ‘vengeful and forgiving’ (Scholz, 1984). Accepts that a small number of organisations will not be trustworthy and a ‘benign big gun’ may be needed to deter them from non-compliance.</td>
</tr>
<tr>
<td><strong>Assumptions about regulatory approach</strong></td>
<td>Most organisations will comply only if forced to do so.</td>
<td>Co-operation with organisations will be more effective than coercion (May, 2005).</td>
<td>Trust-based regulation will ensure improvement more effectively than other models.</td>
</tr>
<tr>
<td><strong>Assumptions about regulatory motivation</strong></td>
<td>Organisations comply because they fear the consequences of non-compliance and need to be ‘deterred’ from non-compliance (May, 2005).</td>
<td>Organisations comply because of their civic obligations and because it is ‘the right thing to do’ (Walshe, 2003).</td>
<td>Organisations mostly comply because they believe in social responsibility, but some need knowledge of potential or actual deterrence and enforcement (Ayres and Braithwaite, 1992).</td>
</tr>
</tbody>
</table>

2.2.3.1 Deterrence regulation

Deterrence models assume that organisations are ‘amoral calculators’ (Bardach and Kagan, 1982), and assume that organisations will deliberately break rules and laws if it is in their own interest and they feel they can do so undetected. They also assume that organisations comply only if forced to do so; therefore, rules and laws require enforcement. This model assumes that organisations comply with regulations and desired standards of behaviour because they fear the consequences of non-compliance (May, 2005). This relatively simple and positivistic model is argued to be used most often where there are high numbers of regulated organisations and where there is an arms-length relationship between the regulated organisation and the regulatory agency (Walshe, 2003).
Deterrence models seek strict compliance to protect the public with clear expectations and rules established for organisations that are often formalised and authorised in law. Definitive consequences are outlined should these rules not be met, often in the form of improvement notices, sanctions or fines, which have the advantages of being perceived as fair to all and even handed, and acts as a symbol of fidelity to the law and dedication to uphold it (Bardach and Kagan, 1982). This simplicity means that less highly trained regulatory staff may be needed relative to other regulatory models, and it is arguably a politically safer model. However, despite the relatively simple approach due to standardisation, deterrence models are criticised for using inflexible and unreasonable approaches (Bardach and Kagan, 1982). These include the excessive use of regulations, determining the technologies or procedures to use regardless of local circumstances even when these requirements may be superfluous, and expecting small organisations to be able to deliver to the same standards as large organisations even though they have fewer resources. Furthermore, there is excessive ‘nit-picking’ over insignificant standards relative to standards that if unmet may cause much higher levels of social harm (Bardach and Kagan, 1982). Deterrence regulatory models can also be expensive and slow to administer if many organisations fail to meet the standards, due to the legalistic enforcement of the standards (Baldwin et al., 2012b). Moreover, if many organisations are prosecuted for failing to meet the standards then this may undermine regulatory agencies’ ability to fulfil other duties, and concerns may be raised concerning their ability to ensure compliance, thereby weakening their legitimacy (Baldwin et al., 2012b).

2.2.3.2 Compliance regulation

Regulatory agencies using compliance models assume that organisations try to do the ‘right’ thing and accept that things can sometimes go wrong (Walshe, 2003; Parker, 2000). Compliance models emphasise collaboration, negotiation and persuasion, as the preferred processes to be used, rather than coercion (Baldwin et al., 2012a). Compliance models use standards to compare the performance of regulated organisations against, and it is argued that non-compliant organisations need support to resolve any issues in order to meet the minimum standards. Compliance models are based on the assumption that organisations may fail to meet performance expectations or behavioural standards either because they were unaware
of the problem, they are unaware of potential solutions to the problem, or may not have sufficient capability to resolve the causes of poor performance (May, 2005).

Compliance models are argued to have several strengths. It is contended that regulatory agencies using compliance models work to build trust between organisations and regulatory agencies, which ensures information sharing amongst parties and access to services and facilities for inspection (Bardach and Kagan, 1982). Compliance models help to induce organisational cooperation and reduce disruption, and take a less positivistic stance than deterrence models (Bardach and Kagan, 1982). In addition, compliance models are more flexible and may permit organisations to do ‘less’ than the standards require in specific circumstances where the rules do not seem sensible, and use this to ‘trade’ for compliance in more serious areas, with agencies able to use their position to influence policy about non-effective rules (Baldwin et al., 2012a; Parker, 2000). Finally, compliance models reduce ‘legalistic’ or ‘ritualistic’ regulation (Braithwaite et al., 2007; Brennan and Berwick, 1996) and are less adversarial, instead stressing reciprocity and a congenial working relationship (Bardach and Kagan, 1982).

However, compliance models are also criticised for a number of reasons. It has been suggested that compliance models make agencies vulnerable to organisational influence and regulatory capture (Makkai and Braithwaite, 1992), laxity or corruption. Organisations may also become more complacent, due to the perception of little consequence should standards be missed. Finally, agencies using compliance models are argued to lead to excessive documentation that is used for regulatory purposes by either the regulator or regulated organisation (Walshe, 2003).

2.2.3.3 Responsive regulation

Responsive regulation uses a combination of deterrence and compliance regulatory approaches adapted to suit specific circumstances (Braithwaite, 2011; Ayres and Braithwaite, 1992). As with compliance regulation, responsive regulation also assumes that regulated parties are trustworthy and motivated by social responsibility. Responsive regulatory models assume that differing regulatory action will be needed for different organisational circumstances, and that these need to be taken into account in addition to motivational assumptions and assessed performance; therefore, regulatory strategies need to be flexible and relational (Ayres and Braithwaite, 1992). Responsive regulation assumes that trust-based regulation will
improve quality of care more effectively than other models (Ayres and Braithwaite, 1992).

Underpinning responsive regulation is the notion that regulatory agencies can be both simultaneously ‘vengeful and forgiving’ (Scholz, 1984). This conceives that the interactions between regulatory agencies and organisations are a form of the ‘prisoner’s dilemma’ and that the regulatory agency has a choice of whether to ‘punish or persuade (co-operate)’, and the regulated organisation has a choice of whether to co-operate with or challenge such regulatory interventions. Scholz (1984) indicates that a social optimum is reached when both a regulatory agency and a regulated organisation choose co-operation (Ayres and Braithwaite, 1992). This particular combination is more flexible, and reduces the required regulatory monitoring and associated costs. Consequently, a regulated organisation redistributes resources previously spent on compliance activities on improvement activities, and focuses on delivering the underlying regulatory goals (Ayres and Braithwaite, 1992). However, Scholz (1984) indicates that it is tempting for agencies and organisations to move away from cooperative strategies due to the opportunistic promise of short term rewards or because of a myopic focus on standards compliance and legalistic battles. To resolve this ‘prisoner’s dilemma’, Scholz (1984) proposes a flexible and responsive regulatory approach, whereby agencies use a forgiving stance with cooperative organisations, but become more punitive should an organisation reduce cooperation.

There are four main advantages of responsive regulation, as it is more flexible, and makes greater use of relationships and persuasion to meet challenging standards. It is a pragmatic model that allows regulatory agencies to take either a compliance or deterrence approach with high or low performing organisations contingent on the level of risk or perceived harm (Parker, 2013). Regulatory intervention escalates through a hierarchy if performance worsens, and the threat of the ‘benign big gun’ remains as an option and a deterrence to organisations who may consider failing to meet standards (Ayres and Braithwaite, 1992). Responsive regulation is more suited to organisations and sectors seeking long-term improvement, rather than short-term compliance. Finally, highly skilled and knowledgeable regulatory employees are required who can adapt enforcement approaches quickly contingent on the circumstances, offering rewarding career paths.
However, a number of problems exist, including this regulatory model being more demanding for regulatory agency staff (Bardach and Kagan, 1982). In addition, the model is harder to operationalise and adapt for large numbers of regulated organisations (Walshe, 2003). It may also be difficult to recruit and train large numbers of regulatory staff, and many inconsistencies may arise from regulatory employees’ interpretations of standards, expected performance and subsequent actions. This may undermine the organisational understanding of expected behavioural standards and rules, and reduce shared comprehension surrounding compliance (May and Wood, 2003). Flexible regulatory responses can be perceived as unfair and inequitable, through the creation of conditions whereby some competitors get a better deal, or where vulnerable groups get a worse deal due to the lowering of standards. Flexible approaches may result in inconsistent or weak regulatory decisions increasing the rate of harm (Beaussier et al., 2015). Finally, responsive regulation was developed from game theory (the prisoner’s dilemma), which conceptualises co-operation and control as substitutes and polar opposites, rather than concepts that mutually reinforce organisational compliance (Six, 2013). Variants of responsive regulation models include smart regulation (Gunningham and Grabosky, 1998), risk-based regulation (Black, 2010), and self-regulation (Sparrow, 2012). McDermott et al. (2015) provide one of the few empirical studies within healthcare, and describe hybrid regulatory agencies that simultaneously use both compliance and deterrence approaches to support performance improvement.

Improvement through self-regulation is increasingly proposed as a ‘middle way’ between those arguing for reduced regulatory burdens and centralised state run regulation, and to improve organisational responses to regulatory demands (Sparrow, 2012). Regulatory agencies have sought to move beyond directly assessing organisational performance or quality of care through mechanisms such as inspection. Agencies seek to understand the underlying organisational characteristics or attributes which are important for an organisation to develop and sustain its own programmes of self-regulation and improvement. Self-regulation is an attractive approach, both politically and pragmatically, for governments due to shrinking financial resources to fund regulatory models and growing criticism of the costs, together with a reduced appetite for governmental intervention (Gunningham and Rees, 1997). Self-regulation can be used where harms and risks are observable
and controllable within an organisation and where organisations will disclose identified issues (Sparrow, 2012).

It is argued that there are two main ways in which organisations can regulate themselves: voluntary self-regulation and enforced self-regulation (Baldwin et al., 2012b). Voluntary regulation means regulatory activity is typically performed by an organisation itself, or by a professional or industrial association, such as a medical royal college, with some governmental oversight. This typically may involve the development of voluntary ‘codes of conduct’ or internal standards or guidelines that are the result of negotiation rather than formal legislation (Ayres and Braithwaite, 1992).

Enforced self-regulation is where organisations themselves perform regulatory functions, including self-monitoring, self-directing, self-enforcing and improving, through the setting of their own bespoke rules and standards. Enforced self-regulation allows organisations to be reviewed against standards that are organisationally set (Ayres and Braithwaite, 1992). This has many advantages for governments as the costs of regulating activities are passed on to regulated organisations, although this does not necessarily mean that the overall regulatory costs are less. In addition, organisations can achieve greater levels of monitoring and inspectorial depth due to their specialised and insider knowledge of potential risks and issues. In order to enforce compliance, organisations can use any improvement approach best suited to their circumstances, and do not need to be as concerned with building a strong and legally enforceable case if required to evidence the potential risk or violation to escalate through the enforcement pyramid. Organisations can also set more appropriate and tailored standards for their circumstances, patient groups and local priorities, although these may still require regulatory approval. Local standards may be more stringent and thus facilitate more improvement than minimum regulatory standards. Nevertheless, localised self-regulation standards help to reduce regulatory capture, non-compliance and innovation hampering (Ogus, 2004; Stewart, 1981), and mitigate the risk of excessively detailed, uniform regulatory standards or enforcement solutions which may be inappropriate for the local circumstances.

However, Ayres and Braithwaite (1992) also caution about the risks of such an approach, indicating that the costs of increased regulation must be borne by
regulated organisations. This can reduce economies of scale, reliability and consistency, as organisations build their own regulatory monitoring units. Self-regulation is also argued to increase delays and bureaucracy to approve localised rules and monitoring processes, develop inadequate enforcement processes, and increase the risk of gaming, requiring additional self-regulatory rules and protections (Short and Toffel, 2008). Finally, some standards by their nature need to be set nationally to reduce harms, for example maximum pollution levels regardless of local variation and discretion with respect to the regulations. These types of risks require higher level analysis, monitoring and enforcement, which are beyond the sphere of influence for one self-regulating organisation as they may not be visible from a decentralised perspective (Sparrow, 2012).

Accreditation or a third-party review can be described as an ‘approach that is ‘quasi-regulatory’. It is used as a term to signify that an organisation has met a specific set of standards established by a recognised external group (Worthington and Silver, 1970). Accreditation initially involved the use of voluntary and independent external assurance processes, such as a multi-disciplinary peer review of a team or an organisation to understand if pre-defined quality standards are being met, with the outcomes of such reviews shared publicly (Shaw et al., 2010; Shaw, 2004). Thus, accreditation can be used as a form of public accountability (Mumford, 2013), and is a system-wide intervention used to improve healthcare quality performance through the application of evidence based practices and standards (Schmaltz et al., 2011; Greenfield and Braithwaite, 2008; Braithwaite et al., 2006).

Accreditation is argued to differ from regulation due to its voluntary nature, whereby organisations and individuals decide to become ‘accredited’ by developing a programme of improvement work to meet the required accreditation standards and receive the subsequent certification if these standards are met. The certification acts as both a symbol of quality for external customers, a source of pride for the organisation, and a driver for improvement. However, increasingly, purchasers of services or regulatory agencies may require organisations and individuals to meet accreditation schemes as part of their contracting or assessment processes. For purchasers or commissioners of services, the accreditation certification may be a prerequisite requirement to supply a service, thereby effectively making accreditation mandatory for some organisations. For regulatory agencies this is in effect adopting
the accreditation standards as their own, thereby removing the voluntary nature of accreditation and arguably removing the difference between accreditation and regulation (Pomey et al., 2005; Saufl and Fieldus, 2003).

There are many different accreditation organisations, including the International Society for Quality in Health Care (ISQuA), the Joint Commission on Accreditation of Healthcare Organisations (JCAHO) for US organisations, and those that accredit different healthcare services, for example Caspe Healthcare Knowledge Systems (CHKS) in the UK, or Excellence Awards, such as the European Foundation of Quality Management (EFQM) or the Baldrige Award in the USA (European Foundation for Quality Management, 2014; National Institute of Standards and Technology, 2013-14).

Proponents of ‘smart’ regulation (Gunningham and Grabosky, 1998) argue that responsive regulatory strategies can be enhanced through ‘self-regulation’, whereby organisations review their own performance to ensure standards, and the use of third parties, such as accreditation bodies, to supplement detection approaches. They argue that multiple bodies will produce better regulation and support more tailoring of enforcement activity, as well as sharing the burden of regulatory activity, subsequently freeing up regulatory resources to examine sector wide strategic issues and potentially reducing the costs of regulatory agencies. Taking the ideas of ‘smart’ regulation further, ‘meta-regulation’ minimises the role of the state and minimises inspections, and instead focuses on the encouragement of self-regulation and systems of internal control and improvement, which can then be scrutinised instead (Parker, 2007). Proponents of this type of regulation suggest that it encourages self-reflection about performance and thus ongoing improvement, although there is little agreement that such systems for internal control and improvement are sufficient for this.

2.2.4 Regulatory processes

Regulatory agencies use three main processes to implement their regulatory models and deliver their aims, namely direction, detection, and enforcement, which can have different levels of emphasis (Walshe, 2003; Hood, 1999). However, there is little guidance as to which combination of processes is most suited to healthcare or how each process influences and relates to each other.
2.2.4.1 Direction

Direction includes the definition of standards, the removal of systemic barriers and external policy impetus. Standards can be defined as instruments which encourage the ‘pursuit or achievement of value, a goal or an outcome, without specifying the action(s) required’ for them to be delivered rather than being prescriptive (Braithwaite and Braithwaite, 1995, p307). Standards can be used to express the main outcomes of the regulatory regime or define elements of required behaviour from organisations and individuals, and can be portrayed in guidance or best practice documents, or formally developed and consulted upon by a regulatory agency. Maximum waiting times in healthcare for surgery are an example of a performance standard that requires organisations to modify their behaviour through organisational processes to ensure that patients receive their surgical treatment within the required time.

However, standards can be rigidly implemented and can have unforeseen consequences on other aspects of the process or service, which may reduce performance in some areas and distort priorities. Using the same example, reducing waiting times for surgery has been argued to have reduced care quality, as more clinically urgent cases have had to wait whilst long waiting but non-clinically urgent cases have been treated to ensure that their waiting time did not become excessive. Furthermore, standards can be difficult to define and agree within complex and ambiguous areas of healthcare, making assessment and enforcement difficult (Rutz et al., 2013).

Regulatory agencies can also work to influence stakeholders within organisations and networks to support behavioural change. For example, through the development of funding incentives and the development and distribution of guidance documents, or changing other rules, such as immigration requirements to allow organisations to recruit skilled staff in shortage areas to ensure specification standards for staffing are met. Finally, regulatory agencies can influence policy and also how policy is affected in practice through discretion.

2.2.4.2 Detection

Detection is the process of understanding whether and how far regulatory requirements, such as standards, are met. This is typically delivered through inspection and assessment against defined standards employed by regulatory
agencies, supplemented with other intelligence gathering methods, such as performance indicator monitoring, incident reporting, and complaint information. This requires a good information flow between regulated organisations and regulatory agencies due to information asymmetry. Detection through performance assessment is integral to good regulatory management for accountability and transparency (Baldwin et al., 2012b). Detection relies upon adequate measurement methods to reliably assess performance against defined objectives appropriately, and requires publication to enhance openness rather than engendering defensiveness (Bardsley, 2016; Boyd et al., 2016). Accurate, valid and reliable assessments are also required to ensure that regulatory agencies understand organisational motivations, and to assess current organisational capabilities to inform enforcement strategies. Regulatory agencies using responsive regulation rely on detection to clarify the motivation of an organisation, the level of risk or perceived harm, and the capability to improve (Ayres and Braithwaite, 1992).

2.2.4.3 Enforcement
Enforcement is important as it ensures that regulatory requirements are met. Several methods are used to enforce behaviour change and meet requirements, encompassing cooperative, persuasive and supportive, as well as insistent, coercive and punishing (Hutter, 1989; Braithwaite, 1985). These include criminal penalties (Bouwman et al., 2015) and public disclosure (Nunes, 2011), credentialing, education, direct action or improvement support, and self-regulation (Brennan, 1998). Regulatory bodies have the discretion to select a combination of enforcement strategies, from deterrence models that emphasise a punitive approach of sanctions and compliance models which emphasise collaboration and negotiation rather than coercion, particularly if it is viewed that there is a low likelihood of conviction. Furthermore, local ‘street-level bureaucrats’ (Lipsky, 2010) have interpretative leeway to vary these methods regardless of regulatory policy if they feel that they can ensure better results via this flexibility (Bardach and Kagan, 1982).

Responsive regulatory models use a combination of enforcement methods contingent on regulatory detection outcomes. Despite this there is little guidance as to how best to optimise the mix of compliance and deterrence. It is suggested that regulatory agencies make judgements regarding rule types and styles of regulated organisations to best produce compliance. This is completed by asking about undesirable
behaviour and who is responsible for it, considering which enforcement strategy will best lead to compliance, and which rules complement this strategy (Baldwin et al., 2012b). This assumes that types of regulated organisations can be easily classified and that regulatory agencies are sufficiently skilled in the nuances of the regulations and organisational business to make responsive judgements, thereby reducing regulatory unreasonableness. However, it has been noted that the increase in responsibilities by individual inspectors to make local and flexible judgements increases stress for agency employees (Bardach and Kagan, 1982) and also increases the propensity for regulated organisations to argue that there has been discriminant, inconsistent and unfair regulatory enforcement approaches.

This more flexible approach allows regulatory agencies to take punitive sanctions against the worst organisations, whilst supporting compliance with organisations that are voluntarily improving and meeting regulatory requirements. A ‘responsive regulation’ pyramid (Ayres and Braithwaite, 1992) is utilised, detailing the regulatory enforcement tactic to be used at different levels of harm or risk, with compliant requirements justifying persuasive and non-invasive tactics at the bottom, escalating to punitive and severe sanctions for those few organisations that persistently fail to meet requirements. An illustration of a typical responsive enforcement pyramid is shown in Figure 2.1.

![Figure 2.1: Example enforcement pyramid](adapted from Ayres and Braithwaite, 1992)
The benefits of flexible enforcement allow regulatory agencies to adapt their strategies contingent on the performance of organisations and their response to regulatory intervention. The pyramid ensures clarity for organisations regarding the costs of non-compliance and the freedoms given for compliance. However, a responsive regulatory model can only be successful with sufficient and reliable information flows between regulatory agencies and organisations, in order to allow appropriate identification of levels of risk and performance. This model also requires sufficient skilled resources to implement the differing enforcement tactics. Furthermore, there is some evidence that the combination of enforcement styles causes confusion, and may not enforce compliance any differently compared to pure deterrence or compliance approaches (May and Wood, 2003).

2.2.5 Benefits of regulation

There are argued to be significant benefits from healthcare regulation (Ng, 2013; Suñol et al., 2009), and a number of evaluative studies report the significant progress to improve care and performance (Devkaran and O'Farrell, 2015; Falstie-Jensen et al., 2015; Kim and Cha, 2015; Hosford, 2008). Regulation supports the identification of improvement areas through the provision of valuable feedback (Furness, 2009) and enhances patient safety, secures additional funds, promotes organisational change (Suñol et al., 2009), and ensures the maintenance of high standards of performance (Gunningham, 2012), while Braithwaite (2010) highlights the non-clinical benefits, particularly for organisational culture, reputation, and positive leadership. Enforcement strategies, including direct improvement support, can provide much needed impetus for change, additional capacity and capability for improvement, and ‘fresh eyes’, helping problems and issues to be seen in new ways, stimulating problem solving (Sparrow, 2000) and action which can accelerate and increase performance improvement.

2.2.6 Challenges facing regulation

Despite the huge growth in regulation and increased emphasis on its use globally and within healthcare, regulation is increasingly critiqued. Systematic and narrative reviews of the literature report inconsistent findings (Brubakk et al., 2015; Kilsdonk et al., 2015; Hinchcliff et al., 2012; Greenfield and Braithwaite, 2008). The main arguments for and against deterrence and compliance regulation are shown in Table 2.3.

52
Table 2.3: Advantages and disadvantages of compliance and deterrence approaches  
(adapted from Baldwin et al., 2012)

<table>
<thead>
<tr>
<th>Deterrence approaches</th>
<th>Against</th>
<th>Compliance approaches</th>
<th>Against</th>
</tr>
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<tbody>
<tr>
<td>Highly effective at changing corporate culture</td>
<td>Penalties and sanctions are insufficiently severe to incentivise compliance</td>
<td>Can provide responses to risks</td>
<td>Increased vulnerability to regulatory capture</td>
</tr>
<tr>
<td>Reduce risk of infringement</td>
<td>Costs of compliance may be disproportionate to the costs of infringement</td>
<td>More effective at preventing an occurrence of harm than the deterrence approaches</td>
<td>There may be inconsistent rule interpretation by inspectors leading to less compliance incentive for ‘good apples’</td>
</tr>
<tr>
<td>Create social sentiments of disapproval creating social pressure to comply</td>
<td>There may be inconsistent interpretation of rules by inspectors</td>
<td>Is flexible and adaptable for local circumstances</td>
<td>Less ‘tough’ approaches reduce incentives to comply</td>
</tr>
<tr>
<td>Induce political shifts so that firmer approaches can be taken</td>
<td>Encourages creative compliance and gaming</td>
<td>Fosters good information flows between regulated organisations and regulators</td>
<td>Fails to deter those who have no interest in complying voluntarily</td>
</tr>
<tr>
<td></td>
<td>May fail to identify the best way to improve performance</td>
<td>Encourages higher performance than the standards require</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Can cause resentment and a lack of cooperation by regulated organisations</td>
<td>Cost-conscious use of resources</td>
<td></td>
</tr>
<tr>
<td></td>
<td>High costs of prosecutions</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Short term focus on infringements</td>
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<td></td>
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</table>
One of the problems associated with regulation is regulatory capture (Boyd and Walshe, 2007; Makkai and Braithwaite, 1992), i.e. when the relationship between the regulator and the regulated organisation becomes so strong that any assessment of the provider may be biased through dependency and there is no longer support for an external assessment programme. This criticism is particularly relevant to regulatory agencies using compliance approaches. Other criticisms include a lack of evidence for its effectiveness (Lanteigne and Bouchard, 2015; Flodgren et al., 2011; Paccioni et al., 2008), and the challenges of clarifying and ensuring consensus on regulatory objectives (Grepperud, 2015). Other noted issues include high costs (Ng, 2013; Mumford, 2013), inflexibility (Brennan, 1998), tunnel vision (Mannion et al., 2005), ritualistic and bureaucratic compliance (Braithwaite et al., 2007; Smith, 1995; Meyer and Rowan, 1977), a short term focus (Walshe, 2003), the stifling of innovation and improvement (Ogus, 2004; Stewart, 1981), loss of autonomy (Donabedian, 1988), and creating a climate of fear (Ostaszkiewicz et al., 2015; Berwick, 2013; Repenning and Sterman, 2001). In addition, there are significant measurement and self-reporting concerns linked to inconsistency, a lack of validity and unreliability (Bardsley, 2016; Tuijn et al., 2011), the increased propensity of gaming (Hamblin, 2008), and dependence on value-judgements of inspectors and surveyors (Jaafaripooyan, 2014). Furthermore, regulatory agencies are also criticised for only focusing on past and present performance, rather than prospective performance (Braithwaite et al., 2010; Walshe and Shortell, 2004).

Both deterrence and compliance enforcement models face particular challenges and criticisms (Table 2.3), although there is less literature regarding the effectiveness of compliance approaches (Gunningham, 2012). Organisations that fail to comply with regulation but intended to, may contest deterrence interventions by suggesting that it is too harsh, and in so doing, increase resistance to the regulatory regime. Organisations that do comply, often described as ‘good apples’, incur compliance costs and may consider non-punitive strategies with non-compliant organisations as unfair. Research suggests that this can undermine regulatory compliance through a perceived lack of punishment (Shapiro and Rabinowitz, 2000; Shapiro and Rabinowitz, 1997). Nevertheless, there is little guidance as to which approach or blend of approaches to use with whom and in what circumstances.
Finally, further external assistance may limit organisational autonomy for improvement, increase defensiveness (described as an ‘foreign irritant’ (Donabedian, 1988)), and potentially undermine confidence, described as the ‘capability trap’ (Repenning and Sterman, 2001). This may change leadership power in detrimental ways with unforeseen consequences, and undermine internal commitment and legitimacy for improvement actions. Research has also outlined that despite the voluntary nature of accreditation, many of the challenges related to regulation are also relevant to accreditation (Greenfield et al., 2014; Mumford, 2013; Shaw et al., 2010).

Despite all the criticisms and problems associated with regulation, and policies to reduce ‘red tape’ and the regulatory burden, it is argued that there are more reasons to regulate, than deregulate (Walshe, 2003).

### 2.2.7 Healthcare regulation: challenges for research

This section has outlined key aspects of regulatory theory and its application within healthcare, together with the main reasons for why regulation arises, namely to protect against market failure and in the public interest. It has examined the extremes of regulatory enforcement and questioned whether it is more appropriate for regulatory agencies to ‘punish or persuade’ (Braithwaite, 1985). The three regulatory approaches of deterrence, compliance and responsive regulation, have been outlined as different ways of influencing and changing organisational behaviour, together with the underlying perspectives for each strategy.

Table 2.4 shows how there is contradictory evidence for regulatory interventions, with some studies describing significant benefits for organisational outcomes and performance, whereas others criticise regulation due to the high costs, inadequate effectiveness, and hindrance of innovation and improvement. Five reviews of the extant literature find inconsistent evidence to indicate that healthcare regulation contributes to the improvement of care (Kilsdonk et al., 2015; Brubakk et al., 2015; Hinchcliff et al., 2012; Flodgren et al., 2011; Greenfield and Braithwaite, 2008). A systematic study of 122 articles shows that regulation is not linked to measurably better care quality as perceived by patients (Hinchcliff et al., 2012), while other systematic reviews indicate the factors that may be responsible for improvement are unclear (Kilsdonk et al., 2015; Greenfield and Braithwaite, 2008). Moreover, they
state that there is insufficient high quality and rigorous research to support the
evaluation of regulation (Kilsdonk et al., 2015; Brubakk et al., 2015; Flodgren et al.,
2011). For example, one study reports finding no association between performance
and regulation when comparing accredited and non-accredited organisations (Bogh
et al., 2015), whereas other studies find a positive association (Falstie-Jensen et al.,
2015; Touati and Pomey, 2009).

In a retrospective review of 36 inspections in the Netherlands, Hovlid et al. (2015)
question whether measures used in regulatory programmes are suited to the
improvement of care and suggest that they risk having a limited impact on care
improvement. Regulation is also criticised for being a periodic process that leads to
reactive rather than proactive practice and persistent deficits (Devkaran and
O'Farrell, 2015; Devkaran and O'Farrell, 2014). There is also criticism that the
impact is lost over time (Pomey et al., 2010). In addition, regulatory agencies are
criticised for infrequent interactions with organisations, which can hinder accurate
assessments of their performance, motivations and capabilities (Braithwaite and
Hong, 2015; Gunningham, 2015), particularly when using a form of responsive
regulation (Ayres and Braithwaite, 1992).
Table 2.4: Existing literature reviews of healthcare regulation

<table>
<thead>
<tr>
<th>Author</th>
<th>Title</th>
<th>Sample</th>
<th>Findings</th>
<th>Further research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flodgren et al. (2011)</td>
<td>Effectiveness of external inspection of compliance with standards in improving healthcare organisation behaviour, healthcare professional behaviour or patient outcomes.</td>
<td>2 studies &lt;May 2011</td>
<td>A paucity of high-quality controlled evaluations of the effectiveness of external inspection systems. No firm conclusions could therefore be drawn.</td>
<td>There is a need for further studies across a range of settings and contexts. If an experimental design cannot be used then other non-randomised designs (such as interrupted time-series designs) could be used. Economic evaluations are also required.</td>
</tr>
<tr>
<td>Hinchcliff et al. (2012)</td>
<td>Narrative synthesis of health service accreditation literature.</td>
<td>122 empirical studies from &lt;2012</td>
<td>Inconsistent links between accreditation and performance.</td>
<td>Further high quality experimental design studies are required.</td>
</tr>
<tr>
<td>Brubakk et al. (2015)</td>
<td>A systematic review of hospital accreditation: the challenges of measuring complex intervention effects.</td>
<td>20 studies &lt; 2014</td>
<td>No conclusions could be reached due to scant evidence. Low level of methodological rigour.</td>
<td>Studies addressing how and why the interventions might work, rather than just the effects of accreditation are required.</td>
</tr>
</tbody>
</table>
Extant research highlights the potential for regulation to facilitate and promote change within organisations (Hinchcliff et al., 2012; Pomey et al., 2010; Greenfield and Braithwaite, 2008; Pomey et al., 2004). Nevertheless, there is a need for healthcare regulation to make positive contributions to the improvement of care, possibly through the integration of accreditation and improvement programmes (Anderson, 2015; Suñol et al., 2009; Valentine, 2007). There is also a call for studies to focus on new ways of regulating, its evaluation (Parker, 2013) and studies to investigate regulatory assessment and enforcement patterns and their impact on [inspected] organisational ability to improve care (Hovlid et al., 2015), as well as predictive ability (Braithwaite et al., 2010). Calls to focus on regulatory processes that encourage proactive and positive improvement to care delivery are also made (McDermott et al., 2015; Ham, 2014; Berwick, 2013; Braithwaite, 2013). Future studies need to recognise that a main challenge to regulation is the lack of organisational capacity to comply with enforcement interventions (Black and Baldwin, 2012), and further evaluation of the cost-benefits of regulatory strategies vis-à-vis other improvement approaches is also needed (Mumford et al., 2015; Hinchcliff et al., 2012; Flodgren et al., 2011).

Furthermore, little is known about what organisational attributes or attribute combinations enable capability development and studies into this aspect are required (Andrews et al., 2015). Empirical studies of public management in different contexts are needed (O'Toole Jr and Meier, 2015), together with studies that compare different regulatory agencies, performance frameworks and their regulatory designs (Nutley et al., 2012; Downe and Martin, 2007), particularly for those using a form of responsive regulation (Nielsen and Parker, 2009).

Finally, a stream of literature emphasises the need for research to focus on the potential role of consumers and service users within the regulatory process (Hinchcliff et al., 2012). This is important because the specific engagement of consumers and service users, such as governance boards of regulatory agencies, ensures that there is a focus on service user experiences, not simply the achievement of health outcomes (Walshe, 2002). Moreover, the service user (the patient) has the clearest overview of the whole care pathway and can provide valuable information, which can include signals about the technical quality of care (Adams et al., 2015; Downe and Martin, 2007). Greater involvement of service users in regulatory
activity will strengthen the credibility of programmes and further research on the effectiveness and efficacy of different participatory strategies is therefore necessary (Hinchcliff et al., 2016; Adams et al., 2015).

2.3 Capability interventions

At the beginning of this chapter four categories of interventions used by regulatory agencies to improve performance were outlined (Table 2.1). Performance improvement interventions are increasingly being used to supplement externally driven regulating strategies (including market or quasi market system change and contractual interventions), and these can be described as capability interventions (Table 2.1). The aim of this section is to review and critique the literature on capability interventions.

Capability interventions are increasingly used to supplement regulatory enforcement methods, and focus on providing aid and support to existing interventions, such as restructuring, specific reforms or development support (Talbot, 2010). It is argued that these can take the form of leadership support or replacement, and the development of improved processes for people management, strategy, planning, innovation and resource management (Talbot, 2010). Capability interventions include the use of improvement approaches, such as BPM (Hammer and Champy, 1993), TQM (Oakland, 2003), and lean (Womack and Jones, 1996), which have been widely implemented within the public sector (Talbot, 2010). There are a number of different types of capability and the next section focuses on improvement capability.

2.3.1 Improvement capability

Several definitions of improvement capability in the literature are derived from a range of views, sectors and theoretical perspectives, and are shown in Table 2.5. One perspective proposes that improvement capability comprises the improvement skills and abilities of individuals within organisations (Kaminski, 2014; Bevan, 2010). This perspective implies that improvement capability is a set of technical skills which can be taught; however, this view seems to omit the wider organisational context for improvement.

An alternative perspective advocates that improvement capability consists of organisational-wide processes and practices of innovation (Bessant and Francis, 1999; Bessant and Caffyn, 1997). This perspective indicates that improvement
capability is something that incorporates the organisational context for improvement, in addition to the technical skills for improvement approaches.

Given the range of definitions and perspectives, it appears that improvement capability as a concept faces the risk of being ‘all things to all men’, which whatever the problem at hand is what is required to ensure improvement. To prevent the reification of improvement capability as a concept, clarity about how it is conceptualised and defined is required (Giudici and Reinmoeller, 2012).

Table 2.5: Improvement capability definitions

<table>
<thead>
<tr>
<th>Definition</th>
<th>Author</th>
<th>Sector</th>
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<tbody>
<tr>
<td>The ability to incrementally increase [manufacturing] performance using existing resources</td>
<td>Swink and Hegarty (1998)</td>
<td>Manufacturing</td>
</tr>
<tr>
<td>Organisational wide processes of focused and sustained incremental innovation</td>
<td>Bessant and Francis (1999)</td>
<td>Manufacturing</td>
</tr>
<tr>
<td>Resources and processes supporting both the generation and diffusion of appropriate innovations across an organisation</td>
<td>Adler et al. (2003)</td>
<td>Healthcare</td>
</tr>
<tr>
<td>The strength or proficiency of a bundle of interrelated organisational routines for incrementally improving existing products/processes</td>
<td>Peng et al. (2008)</td>
<td>Manufacturing</td>
</tr>
<tr>
<td>The ability to consistently improve current processes and to learn new ones</td>
<td>Anand et al. (2009)</td>
<td>Cross-Sector</td>
</tr>
<tr>
<td>The people that have the confidence, knowledge and skills to lead change</td>
<td>Bevan (2010)</td>
<td>Healthcare</td>
</tr>
<tr>
<td>Knowledgeable and skilled human resources able to lead the design of improvement initiatives, to achieve measurable results, execute (i.e. develop, test, measure, and implement changes) the improvement efforts, and sustain the results</td>
<td>Kaminski et al. (2014)</td>
<td>Healthcare</td>
</tr>
<tr>
<td>An organisational strategy to implement and spread quality improvement programmes across an organisation</td>
<td>Babich et al. (2016)</td>
<td>Healthcare</td>
</tr>
</tbody>
</table>

2.3.2 Improvement approaches in healthcare

Many healthcare organisations, management consultants and ‘best practice’ organisations describe the benefits that have resulted from developing improvement capability by using improvement approaches to ameliorate performance in healthcare organisations. For example, there are a number of high profile cases, such as Virginia Mason (Plsek, 2013; Blackmore et al., 2011), Johns Hopkins (Pronovost et
al., 2013) and Thedacare (Toussaint, 2013), all in the US and also many other qualitative case studies (see for example Burgess and Radnor, 2013).

Improvement approaches, encompassing concepts, ideas and empirical tools and techniques (Walshe, 2009), build on work developed in the twentieth century by Juran (1951), Deming (1984) and Shewhart (1931), amongst others. There is a wide array of different improvement approaches, including BPM (Hammer and Champy, 1993), lean (Netland and Powell, 2017; Womack and Jones, 1996), six sigma (George, 2004; Pyzdek and Keller, 2003) and the Institute for Healthcare Improvement’s approach to quality improvement (IHI-QI) (Scoville and Little, 2014; Langley et al., 2009).

Within healthcare, improvement approaches have been adapted for new contexts, and confusingly have often used alternative terminology, with healthcare approaches such as ‘continuous quality improvement’ (CQI) (McLaughlin and Simpson, 1999), ‘total quality improvement’ (TQI) (Iles and Sutherland, 2001), ‘improvement science’ (Health Foundation, 2011), and ‘quality management’ (Berwick et al., 1990/2002). These various terms are used interchangeably in practice (Savage et al., 2016; Walshe, 2009), and this has led to a bewildering range of approaches with different terminology that seem to include different tools and techniques, despite the underlying similarity.

Boaden and Furnival (2016) indicate that there are several fundamental issues that underpin improvement, whatever terminology or approach utilised, although the emphasis on the issues varies. These include taking a process view (Slack et al., 2004), flow (Brideau, 2004), variation (Snee, 1990), the role of the ‘customer’ or ‘service user’, and the role of people. Improvement approaches are used exclusively or in combination, although there is a lack of guidance and evidence within the literature as to which approach is appropriate in what circumstances (Øvretveit, 2003). There are several helpful review publications that synthesise the various approaches, how and where they may be used, and the supporting evidence for their use (Boaden and Furnival, 2016; Fereday, 2015; Powell et al., 2009; Boaden et al., 2008). However, improvement approaches are widely critiqued for several reasons, and many literature reviews indicate inadequate evidence of their effectiveness to support the use of improvement approaches in healthcare.
2.3.2.1 Critiques of improvement approaches

It is claimed that improvement approaches take a ‘one size fits all’ perspective, and the approach can be used to solve innumerable problems with very little adaptation for local context (Sitkin et al., 1994). However, improvement approaches stress the importance of local adaptation to context and the need for a deep understanding of the complexity of the local environment and culture, requiring the development of a management system together with congruent leadership behaviours (Blackmore and Kaplan, 2016; Kaplan et al., 2014; Emiliani, 1998). It is also argued that these critiques have failed to take account of learning and the role of exploration in improvement approaches, which prevent a ‘one size fits all’ approach (Sitkin et al., 1994).

The approaches focus on generating ‘control’ and are all an extension or variant of Taylorism, where individual workers are seen as less important than the organisational whole (Carter et al., 2014; Carter et al., 2011; Boje and Winsor, 1993). This perspective suggests that organisations maximise profits through a top down management approach, with little thought to staff experience or the workplace environment, thereby leading to exploitation (Mehri, 2006) and work intensification, rather than empowerment (Lindsay et al., 2014; Stanton et al., 2014; Jones et al., 2013; Babson, 1993). However, improvement approaches propose the focus of the work to be the ‘customer’ or the ‘patient’, rather than an organisation or employees (Boaden and Furnival, 2016). Furthermore, while developing a ‘management control system’ may be a purpose of using the industrial methodologies, ‘control itself’ does not cause an obstacle to success or safety risks, rather it is the management style and way it is implemented that may cause impediment if this is insufficiently interactive and includes insufficient collaborative working between employees and managers (Demartini and Mella, 2014; Koukoulaki, 2014).

It is also argued that employees are inappropriately required to rigidly follow operating instructions for tasks that are highly specialised and fragmented, rather than ‘craft’ production. This critique has been especially taken up within healthcare, where it is argued that each patient is different and the skill and ‘craftsmanship’ of medics and clinicians is critical to ensuring best possible care, and that the standardisation of methods and procedures in this context is inappropriate (Hartzband and Groopman, 2016; Sheps and Cardiff, 2014; Winch and Henderson,
2009). However, there is a growing evidence base supporting the use of standardisation approaches and checklists within healthcare to support improvement (Arriaga et al., 2013; Gawande, 2010; Haynes et al., 2009; Panella et al., 2003).

Moreover, proponents of improvement approaches vehemently argue that the purpose of improvement approaches is for the ‘respect for society’ (Emiliani, 1998) and that they need to simultaneously benefit owners, workers and communities. Improvement approaches seek to harness the imagination and participation of the workforce to deliver improvement and redesign processes, which requires a high level of trust and teamwork and the relinquishing of power (Berwick, 2003; Grant et al., 1994). Further proponents suggest that Taylorism has been misunderstood, with the ideas and principles behind it having been misused by ‘charlatans’, and that the principles do not equate to the exploitation of employees, particularly given the focus on respect for people and benefit to society as a whole (Emiliani, 2007). They further suggest that critics of improvement approaches assume that Taylorism and improvement approaches are all implemented appropriately, in the same way and with the same level of competency, and that the methods have not evolved, learning from implementation challenges and changing contexts (Balle, 2016; Emiliani, 2016). In addition, there is growing evidence that routines, such as those used in improvement approaches, are performed with significant variation and differ from the ostensive aspect of the routines (Feldman and Pentland, 2003).

Finally, improvement approaches are criticised as insufficiently theoretical and evidence based (Young and McClean, 2008; Shojania and Grimshaw, 2005; Dean and Bowen, 1994; Spencer, 1994). Research to understand improvement approaches and explain why, how and where the approaches ‘work’ and where they seem not to and why, has largely fallen behind the wide uptake of their use (Dixon-Woods and Martin, 2016; Shojania and Grimshaw, 2004; Walshe and Freeman, 2002).

However theoretical work is developing, for example the theory of swift even flow (Schmenner and Swink, 1998) contributes theoretically to lean and similar improvement approaches (Samuel et al., 2015). Related theories, such as systems theory (Willis et al., 2014; Seddon, 2008), the theory of constraints (Goldratt and Cox, 1984), and queuing theory (Boer et al., 2015), have also contributed to the theoretical development of improvement approaches. Nevertheless, further theoretical work and robust external evaluation are strongly needed to continue to
advance and understand improvement approaches, to explain why and how they ‘work’ in different circumstances to build understanding, and to inform and strengthen improvement capability.

2.3.2.2 Effectiveness of improvement approaches

Few examples of healthcare improvement approaches have been independently and rigorously evaluated (Hunter et al. (2014) is an example) and there is weak evidence to support the use of improvement approaches in healthcare. A non-exhaustive list of 16 literature reviews of improvement approaches conducted over the last decade is detailed in Appendix A. Together, these reviews indicate inconsistent evidence of the benefits and the use of improvement approaches in healthcare. Moreover, there are few studies that analyse the economic or financial implications of quality improvement approaches (Øvretveit, 2012; Øvretveit, 2009), clinical outcomes (DelliFraine et al., 2010), system wide impact (Costa and Godinho Filho, 2016), or development of a measurement framework for the improvement approach (Daultani et al., 2015; D’Andreamatteo et al., 2015). This stymies attempts to determine the impact of improvement approaches and hinders a comparison of policies that recommend improvement approaches with alternative policies, such as regulation. The reviews also indicate the wide variation and fragmentation of the field, with work being conducted across disparate disciplines, such as operational research, management research, medical research, and health services research. In addition, several of the reviews took place over the same period with similar keywords and yet several different studies were found or omitted across the reviews.

Four broad reasons for the lack of evidence are described by Dixon-Woods and Martin (2016): ‘projectness’, the valorisation of improvement approaches as ‘magic bullets’, the lack of scaling, and fidelity. ‘Projectness’ (Dixon-Woods et al., 2012) is where an intervention occurs on the margins of mainstream activities and it is difficult for an intervention to become institutionalised as part of the wider organisational norms. This can mean that improvement approaches risk being tolerated or ignored during what is perceived as a time-limited use of an approach (Dixon-Woods et al., 2012).

‘Magic bullets’ (Walshe and Freeman, 2002) can be described as providing effective solutions to previously unsolvable problems. Healthcare organisations have repeatedly been observed to try out and then discard one improvement approach after
another, rather than sticking to one and learning to use it over time (Walshe and Freeman, 2002). Organisations are observed to repeatedly seek a sizable improved performance from an improvement approach and to then discard it when their results are less predictable and more modest (Shojania and Grimshaw, 2004). Furthermore, improvement approaches have also been dismissed as management ‘fads’ (McCann et al., 2015; Seddon, 2012), yet variants of improvement approaches, from their beginnings during the Industrial Revolution, have continued to evolve. Different incarnations of improvement approaches have been developed to resolve previous application challenges and to support adaptation for local circumstances and specific industry requirements. Further ‘fads’ are described as an important element of the innovation cycle for organisations because they play vital functions in drawing the attention of many organisations to problems and solutions that have long remained overlooked (Abrahamson, 1991).

Dixon-Woods and Martin (2016) argue that many improvement activities are small-scale and often conducted as part of academic requirements by professionals in training, rather than by a higher skilled workforce with the resources, power and infrastructure to deliver the changes required. Moreover, other authors highlight the lack of resources and improvement capability and capacity to scale up improvement approaches from ‘within’ organisations (Berwick et al., 2015; Ham, 2014; Spear, 2005). The tactic of ‘letting a thousand flowers bloom’ (Fillingham, 2008) whilst ensuring a wide number of improvement projects take place, does not necessarily ensure any alignment with organisational or stakeholder needs, and may lead to ongoing duplication of effort and a lack of organisational learning.

A systematic review of 74 studies using plan-do-study-act (PDSA) cycles found that less than 20% of the studies documented the use of a sequence of improvement cycles, and many reported an application that failed to align with the features of the method (Taylor et al., 2014). Other studies described a lack of fidelity in the documentation of the application of improvement approaches (Jones et al., 2016) and in the application of improvement approaches (Kringos et al., 2015). Dixon-Woods and Martin (2016) argue that whilst the visible ‘outer appearance’ of improvement approaches are reproduced, the internal mechanisms (or set of mechanisms) are not, leading to the potential dilution of capability interventions. Emiliani (2007) notes the significant differences between what he describes as ‘real lean’ and ‘fake lean’;
the latter being conducted by both charlatans and practitioners with insufficient improvement capability and unlikely to deliver the desired results and organisational behaviours.

Therefore, it can be argued that the results that are described to have been achieved by high performing organisations because of their improvement approaches (for example Virginia Mason Medical Centre, or Johns Hopkins (Plsek, 2013; Pronovost et al., 2013)) are not able to be replicated in other organisations, particularly in healthcare if there is little fidelity in the use of the improvement approaches. It is argued that healthcare organisations struggle to execute improvement approaches and that their effectiveness heavily depends upon two elements: the local contextual factors (Kaplan, 2010) and the way approaches are implemented (Reed and Card, 2015; Walshe and Freeman, 2002). They include the lack of adaption and tailoring of approaches largely developed within specific industrial sectors. Several factors are frequently noted as important: the improvement team, support and organisation, improvement capability and capacity, and the external environment (Kringos et al., 2015).

There is a failure to use improvement approaches as they were designed to be used, possibly due to a lack of skills, expertise, improvement capability and capacity (Taylor et al., 2014; Gagliardi et al., 2010; Walley et al., 2006). Reed et al. (2016) suggests that to increase the impact from the use of improvement approaches, greater mastery and fidelity in the application of improvement approaches is required. Moreover, it is suggested that the investment and commitment to develop a supportive infrastructure is critical to developing a mastery of improvement approaches and thereby establishing organisations with improvement capability at scale (Reed, 2016; Reed et al., 2016; Ham et al., 2016).

2.3.3 Improvement: challenges for research

The evidence and critiques of improvement approaches and improvement capability outlined within this section can be summarised into two themes: effectiveness and conceptual.

Despite many systematic reviews there is little consistent evidence to suggest that the use of improvement approaches is effective, which may be due to the paucity of appropriate research designs (Dixon-Woods and Martin, 2016; Øvretveit, 2011).
The literature indicates that further evaluative studies of organisational use of improvement approaches are needed, and in particular, system-wide studies are required (Costa and Godinho Filho, 2016). Studies that explain why some improvement activities are successful and others are not, are needed, together with an increased focus on failed interventions.

As improvement approaches are criticised for being insufficiently theoretical, theoretically founded research is required in order to understand improvement approaches and their interaction with their local context to fully detail the mechanisms that may or may not lead to improved performance (Dixon-Woods and Martin, 2016; Davidoff et al., 2015). Other studies have also identified the need for more knowledge concerning the managerial abilities and skills to balance trade-offs and ensure improvement (Burnett et al., 2015). Studies are also required to develop assessment frameworks for improvement approaches (D’Andreamatteo et al., 2015), to support the evaluation of improvement approaches, and to facilitate comparison. Øvretveit (2011) argues that defining concepts more precisely, such as improvement capability, is necessary for data gathering and for understanding the influence of these factors.

2.3.4 Policy salience

This research study examines an increasingly salient area of health policy. Over the duration of this research study improvement capability has been of growing importance in policy terms across healthcare as regulatory agencies and organisations respond to policy objectives that aim to improve health and healthcare quality, whilst at the same time ensuring value for money. The Berwick report (Berwick, 2013) underlined this salience by indicating that:

‘Improvement requires a system of support: the NHS needs a considered, resourced and driven agenda of capability-building in order to deliver continuous improvement.’ (Berwick, 2013, p4)

Partly in response to this report and other national inquiries (Kirkup, 2015; Francis, 2013), policy makers and regulatory agency concerns have shifted towards strengthening capability building to support organisations to improve using collaborative approaches. For example, two English regulatory agencies have become one agency, known as NHS Improvement. Following their operational merger in 2016, a new single oversight framework (NHS Improvement, 2016) was
published, which specifically includes improvement capability within one of five themes to be used to oversee NHS provider organisations. It states that the identification of current leadership and improvement capability, together with the other themes (quality of care, finance and use of resources, operational performance, and strategic change) will inform the level of support each organisation needs. However, improvement capability is not explicitly defined within the framework, and it emphasises the use of several existing metrics and survey data to inform regulatory oversight. This, according to NHS Improvement, will ensure that appropriate support is signposted, offered or mandated to organisations. However, the framework does not specify the details of the support that may be offered, other than indicating that there will be some ‘universal’ support and some ‘tailored’ support. Towards the end of 2016, NHS Improvement set out further details in a national framework for action on improvement in NHS-funded services in England, alongside several other national bodies. This national framework re-iterates the growing salience of improvement capability within healthcare policy by outlining proposed actions to:

‘Build improvement capability among providers, commissioners, patients and communities.’ (National Improvement and Leadership Development Board, 2016, p29)

2.4 Resource based theories of performance

The healthcare improvement literature is argued to have significant gaps and weaknesses due to the lack of conceptual frameworks and insufficient use of theory (Davidoff et al., 2015; Alexander and Hearld, 2011; Foy et al., 2011; Walshe, 2007). Downe et al. (2010) highlights the importance of identifying the underlying theories of improvement for approaches to organisational assessment and improvement. There are many different theories of performance across a whole range of social science disciplines and branches (Talbot, 2010). Earlier in this chapter, it is indicated that capability led interventions are underpinned by resource-based theories of performance (Table 2.1).

To ensure a stronger theoretical framing for this research study, the aim of this section is to review and discuss three resource based theories of performance, and to identify one for use in the research study. These are the resource based view (RBV), the DCV and organisational ambidexterity (OA) (Table 2.6). These have been
selected as three widely known resource based theories of performance, which have had a significant impact on debates and are interdisciplinary in nature. Vogel and Güttel (2013) indicate that there are similar resource based theoretical foundations for DCV, RBV and OA in management research, but it has been identified that there is unclear differentiation between the related theories (Hitt et al., 2016b).

2.4.1 Resource based theories: relevance to the public sector?

Resource based theories of the firm have been most heavily researched in rapidly changing environments where innovation has been seen as essential to ensure a competitive advantage, such as semi-conductor processing and electronics (Easterby-Smith et al., 2009). Increasingly, research using these theories is developing outside of these sectors, such as in low-tech and traditional industries (Makkonen et al., 2014; Protogerou et al., 2012), and also in the public sector, including healthcare (Dobrzykowski et al., 2016; Piening, 2012; Singh et al., 2011; Pablo et al., 2007), although further research is still needed (Burton and Rycroft-Malone, 2014; Smith and Umans, 2015).

However, ‘competitive advantage’ is perceived differently within the for-profit and public sectors, as public sector organisations exist to meet the needs of existing client groups, rather than to achieve profits or a market share (Collins, 2005) and may not exist within a competitive environment. Hansen and Ferlie (2016) question the appropriateness of resource based theories for public sector organisations, given their focus on the achievement of competitive advantage and profit, and it is argued that models and theories imported from the private sector are ill-suited for the distinctive complexities and culture of public sector organisations (Currie et al., 2008). Nevertheless, stringent performance requirements from regulatory agencies may act as powerful proxy measures of competitiveness (Harvey et al., 2010), as do other factors such as patient choice (Propper, 2012) or reputation (Doran and Roland, 2010; Bate et al., 2008) in quasi-market contexts (Burton et al., 2014).
Table 2.6: Theory comparison

<table>
<thead>
<tr>
<th>Theory</th>
<th>Resource based view (RBV)</th>
<th>Dynamic capabilities view (DCV)</th>
<th>Organisational ambidexterity (OA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principles</td>
<td>Sustained superior performance depends on organisational strategic resources and strategic decision making. Resources must be valuable, imperfectly inimitable, rare and exploitable (VRIN) (Barney, 1995).</td>
<td>Emphasises that superior and sustained performance depends on the organisational capacity to purposefully create, extend and modify its resource base through a bundle of organisational routines which must be sustained overtime (Su et al., 2014; Helfat et al., 2007).</td>
<td>Defined as the ability of an organisation to simultaneously pursue both explorative (discontinuous) and exploitative (incremental) innovation (O'Reilly and Tushman, 2004).</td>
</tr>
<tr>
<td>Primary focus</td>
<td>Resources</td>
<td>Routines</td>
<td>Knowledge</td>
</tr>
<tr>
<td>Components</td>
<td>Organisations need to structure, bundle and leverage organisational resources synchronously to achieve a superior performance (Sirmon et al., 2007).</td>
<td>Organisations need to sense, seize and reconfigure organisational routines (Teece, 2007).</td>
<td>Organisations need to explore and exploit knowledge (Benner and Tushman, 2015; Benner and Tushman, 2003).</td>
</tr>
<tr>
<td>Evidence</td>
<td>Newbert (2007) found modest empirical support for the RBV theory from a systematic review of 55 studies. Crook et al. (2008) indicate strong results from a meta-analysis of 125 studies. However, Nason and Wiklund (2015) found no empirical support for the theory from a meta-analysis of 113 studies.</td>
<td>Pezeshkan et al. (2016) found a positive relationship between dynamic capabilities and performance from a systematic review of 89 studies.</td>
<td>Research suggests that the ability to be ‘ambidextrous’ is positively associated with outcomes at all levels of analysis (Danneels, 2011; Lavie et al., 2010). Positive relationships identified during a meta-analysis of 69 studies found them to be contingent on contextual factors (Junni et al., 2013).</td>
</tr>
<tr>
<td>Theory</td>
<td>Resource based view (RBV)</td>
<td>Dynamic capabilities view (DCV)</td>
<td>Organisational ambidexterity (OA)</td>
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<tr>
<td>Critiques</td>
<td>Conceptual limitations – tautological and vague (Kraaijenbrink et al., 2010; Eisenhardt and Martin, 2000)</td>
<td>Conceptual limitations – tautological (Vogel and Güttel, 2013; Di Stefano et al., 2010)</td>
<td>Fragmented body of research with large diversity in conceptualisation and operationalisation (Birkinshaw and Gupta, 2013; O’Reilly and Tushman, 2013)</td>
</tr>
<tr>
<td></td>
<td>Objective nature does not allow for the subjective nature of knowledge (Warnier et al., 2013; Foss et al., 2008)</td>
<td>Contradictions and inconsistency in definitions (Ambrosini and Bowman, 2009; Arend and Bromiley, 2009)</td>
<td>Lack of distinctive contribution when compared to other theoretical phenomena (Birkinshaw and Gupta, 2013; Turner et al., 2013)</td>
</tr>
<tr>
<td></td>
<td>Internal focus, overlooks contextual factors (Rashidirad et al., 2015)</td>
<td>Lack of measurement approach (Pavlou and El Sawy, 2011; Weerawardena and Mavondo, 2011)</td>
<td>Improved measurement needed (Birkinshaw and Gupta, 2013; Junni et al., 2013)</td>
</tr>
<tr>
<td></td>
<td>Static nature (Teece, 2012; Helfat et al., 2007)</td>
<td>The impact of managerial cognition and associated decision making is overlooked (Mollick, 2012; Eggers and Kaplan, 2013)</td>
<td>Little research to understand the explanatory ‘micro-mechanisms’ underlying ambidexterity (Turner et al., 2013)</td>
</tr>
<tr>
<td></td>
<td>Lack of predictive ability (Hinterhuber, 2013)</td>
<td>Extensive focus on macro perspectives, rather than microfoundations and their assembly (Felin et al., 2015; Eggers and Kaplan, 2013; Subramony and Pugh, 2015)</td>
<td>Lack of research to understand the role of managers in understand how to balance the dual aims of exploration and exploitation (Turner et al., 2013)</td>
</tr>
<tr>
<td></td>
<td>Customers are treated as a homogenous mass or are even missing (Hinterhuber, 2013; Möller et al., 2008)</td>
<td>Divorces cognition and emotion, and pays little attention to subconscious processes (Hodgkinson and Healey, 2011)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Emphasis on macro-perspectives (Molina-Azorín, 2014)</td>
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</tr>
<tr>
<td>Origins</td>
<td>For-profit sector (Wernerfelt, 1984; Barney, 1991)</td>
<td>For-profit sector; studies have tended to focus on the manufacturing and technology sectors (Hogan et al., 2011).</td>
<td>For-profit sector, typically manufacturing or high technology (Seshadri et al., 2010).</td>
</tr>
</tbody>
</table>
Furthermore, public sector organisations typically deliver services rather than manufacture products. Service sectors differ in three main ways (Subramony and Pugh, 2015): services cannot be stored, rather they are intangible and delivery is relational; ‘production’ and ‘consumption’ is simultaneous and inseparable; and the role of the end user (patient in healthcare) co-produces the service, that is, they are an active participant in the service.

Resource based theories are described as being suitable for both for-profit and non-profit (and thus public sector) organisations (Peteraf and Barney, 2003), and of relevance due to their focus on how to use and develop resources to create value. Moreover, public sector organisations are increasingly using managerial strategies to improve organisational performance and manage with less resources in order to secure ongoing financial resources and because of increased devolved responsibility in the public sector for both acquiring resources and achieving results (Llewellyn and Tappin, 2003). Finally, in healthcare resource based theories with important ideas about improving performance and research are under-developed (Crilly et al., 2013). These strategic perspectives have the potential to increase the value and outcomes for patients, staff and organisations within the public sector (Burton et al., 2014).

2.4.2 Resource based theories

This section discusses and critiques three relevant resource based theories of performance (RBV, DCV and OA). The section outlines the research gaps identified through a review of these theories and concludes by explaining why DCV will be drawn upon in this research study, with the reasons for this selection outlined.

2.4.2.1 Resource based view

The basic principles of the RBV suggest that persistent superior performance is related to the strategic resources that an organisation possesses, using a firm’s resources as a unit of analysis (Barney, 1991; Amit and Schoemaker, 1993). The RBV theorises that internal forces drive firms’ decision-making, and superior competitive advantage is mostly driven internally by organisational resources and deployment decisions (Rumelt, 1982; Wernerfelt, 1984; Barney, 2001). The RBV assumes that organisations gain a sustained competitive advantage through a strategy to acquire, accumulate, combine and exploit their heterogeneous resources (Hansen and Ferlie, 2016).
The RBV indicates that for an organisation to have a sustained competitive advantage (Barney and Clark, 2007), it must have resources that meet four criteria: valuable, imperfectly inimitable, rare and exploitable by the organisation, known as the VRIN or VRIO framework (Barney, 1995). Thus a strategic resource must be able to reduce costs or increase customer value, while to be valued it must be sufficiently rare, inimitable, and difficult to substitute so that competitors cannot gain parity (Barney, 1991), examples of such resources include reputation, patents and unique knowledge.

A considerable body of literature has been established to support the RBV with somewhat inconsistent findings. One review of 55 empirical studies suggests only modest empirical support (Newbert, 2007) and a meta-analysis of 125 studies (Crook et al., 2008) indicates a robust relationship in line with the theoretical expectations. In contrast, Nason and Wiklund (2015) found no support from a meta-analysis of 113 studies, despite following the same methodology as Newbert (2007).

### 2.4.2.2 Limitations of the resource based view

There are five main critiques of the RBV: its ‘internal focus’, the limits of its conceptualisation, the characteristics of resources, the limited role of managers within the theory, and its static nature. Critics of the RBV suggest that a purely internal focus could lead to overlooking contextual factors (Rashidirad et al., 2015), such as buyer (healthcare commissioner or regulator) needs, industry technological change, and competitor behaviour change. They also argue that a pure external focus may lead to an increased emphasis on industry structure, which may not benefit an organisation. Furthermore, its focus on rare and inimitable resources may not be desirable in services where it is in the public interest to share new ways of working or knowledge to benefit customers, patients or other stakeholders, such as in healthcare. Other proponents indicate that both external and internal driven theories are both useful when improving organisational performance (Spanos and Lioukas, 2001).

The focus on resources is criticised for being an all-encompassing concept that is conceptually vague and tautological (Kraaijenbrink et al., 2010; Lockett et al., 2009; Priem and Butler, 2001; Eisenhardt and Martin, 2000). It introduces confusion between the use of resources and the resources themselves, and insufficiently focuses on the links and configuration of the resources (Rashidirad et al., 2015). It does this
by suggesting that specific valued, inimitable, rare and exploitable resources lead directly to a superior performance, rather than the use of these strategic resources to create value (Warnier et al., 2013).

Resources themselves are viewed objectively, and this characterisation does not allow for the subjective nature of knowledge and its interpretation (Foss et al., 2008; Warnier et al., 2013). The RBV fails to adequately represent and take account of the manager’s role in delivering a superior performance within the VRIN framework, despite acknowledging that firms need to make managerial decisions to acquire, accumulate, combine and exploit resources (Sirmon et al., 2007).

Finally, the RBV is viewed as static and the extension of this view into the DCV acknowledges this problem (Teece, 2012; Helfat et al., 2007, pp.100-114). The DCV develops the concept of continually changing organisational routines in response or anticipation of stakeholder changes to ensure survival.

2.4.2.3 Dynamic capabilities view

The DCV suggests that organisational performance is driven through bundles of routines, described as distinctive capabilities, that are used to purposefully create and modify resources and routines that are contingent on the local circumstances (Helfat et al., 2007; Teece and Pisano, 1994). It developed in part in response to the criticisms of the RBV, and emphasises the routines that organisations use to develop changes in response and anticipation of fluctuations in the external environment, such as regulations or customer requirements, beyond the static state. Dynamic capabilities are ‘the capacity of an organisation to purposefully create, extend and modify its resource base’ (Helfat et al., 2007, p3). This perspective indicates that organisations have routines that allow them keep anticipating and adapting as the environment changes, and to sustain these routines overtime (Su et al., 2014). Dynamic capabilities are rooted in high performance routines within organisations’ processes and are conditioned by an organisation’s history (Teece and Pisano, 1994). Dynamic capabilities often comprise simple and experimental processes to solve complex issues in new ways via organisational adaptation as the environment changes (Eisenhardt and Martin, 2000). There are many different dynamic capabilities which can strengthen organisational performance (Peng et al., 2008), including innovation capability (Cole, 2001), managerial capability (Kraaijenbrink et al., 2010) acquisition capability (Helfat et al., 2007) and improvement capability
(Bessant and Francis, 1999), which can be developed and used independently or in tandem.

‘Dynamic’ refers to the external environment in which an organisation operates that changes over time, such as the level of competition, changing technologies or political mandates, thereby creating uncertainty. The term ‘capabilities’ refers to the function of adapting, integrating and reconfiguring organisational resources and skills to anticipate or adapt to the changing environment (Teece and Pisano, 1994). Capabilities to implement different practices, e.g. improvement capability to implement TQM (Anand et al., 2009), may differ across and between organisations.

Organisations may have different levels of resources or may have created resource bundles differently (intentionally or otherwise) (Hitt et al., 2016a). This perspective assumes that organisations with larger dynamic capabilities have the potential to outperform organisations with less dynamic capabilities, and that the capability to ‘orchestrate’ resources influences organisational performance (Sirmon et al., 2011). However, there is no assurance that such a potential will lead to the expected results, and further research is required to examine the internal and external factors that may enable or disable dynamic capabilities to deliver their potential (Barreto, 2010).

Teece (2007) describes the ‘microfoundations’ of dynamic capabilities as ‘the distinct skills, processes, procedures, organisational structures, decision rules and disciplines’ which undergird enterprise level capabilities. Dynamic capabilities have been described as consisting of three clusters of activities or ‘microfoundations’: (1) identification and assessment of an opportunity (sensing); (2) mobilisation of resources to address an opportunity and to capture value from doing so (seizing); and (3) reconfiguration/continued renewal (transforming) (Teece, 2012). ‘Sensing’ microfoundations are described as the capacity, including skills and processes, to detect opportunities emerging within ecosystems, markets and technologies, before they fully materialise (Denrell et al., 2003). ‘Seizing’ microfoundations are required once opportunities have been detected and strategic choices and associated investment is then required to pursue an opportunity. This requires an environment that can review objective data, and where honest opinions can be offered to reduce bias and prevent ‘anti-cannibalisation’ which is when incumbents use self-serving behaviour to protect their constituencies within organisations (Teece, 2009).

‘Reconfiguration’ microfoundations are the third element of dynamic capabilities
and are needed to move new opportunities into established routines, either within an organisation or outsourced to another organisation.

As decentralised organisations are required to ensure flexibility and responsiveness, organisational conflicts between the need to control and innovation can emerge, and these need ‘orchestrating’ to ensure balance, using for example collaborative networks together with tight performance management systems. Implicit within this dynamic capabilities framework is recognition that the execution of best practice operations management and improvement approaches is no longer sufficient to ensure long term high performance (Helfat et al., 2007).

2.4.2.4 Limitations of the dynamic capabilities view
The DCV is criticised because of a lack of consistency in definitions, including contradictions (Zahra et al., 2006; Arend and Bromiley, 2009). Like the RBV, the DCV is criticised for being tautological, where it is argued that dynamic capabilities lead to improved performance, and organisations with improved performance have dynamic capabilities, for example in Collins (2001). Critics also point out that some organisations with dynamic capabilities do not always perform well over time. However, whilst dynamic capabilities and associated routines can be developed through the accumulation of experience and repeated execution (Argote, 2012), without use the capability will not be sustained (Helfat and Peteraf, 2003).

It is also argued that there are other ways to support improved performance in organisations in changing environments, including the use of ad-hoc problem solving, which may be cheaper than the investment required to develop long term dynamic capabilities (Winter, 2003). Finally, critics have argued that there is a lack of an assessment approach for dynamic capabilities, with proxies and vague item scales being used (Pavlou and El Sawy, 2011), and further research is needed to contribute to this substantive issue (Weerawardena and Mavondo, 2011).

2.4.2.5 Organisational ambidexterity
Abernathy (1978) describes the ‘productivity dilemma’ as a focus on productivity improvement that potentially inhibits the flexibility to innovate, as standards and efficiency crowd out difference and diversity (variation), and may even contribute to reduced performance. Organisations that become too ‘good’ at exploitation fall into a competency trap, whereas those that are better at exploration risk falling into a

OA is defined as the ability of an organisation to simultaneously pursue both explorative (discontinuous) and exploitative (incremental) innovation (O'Reilly and Tushman, 2004). This is the notion of balancing the need to deliver incremental and radical change simultaneously within an organisation in order to secure survival and long term performance. Improvement approaches, such as TQM, are suggested to be a form of process management (Benner and Tushman, 2003; Benner and Tushman, 2015), focusing on quality control, compliance and standardisation, by exploiting existing knowledge and developing a bureaucracy that inhibits innovation. It is argued that exploration focuses on unknowns, requiring experiments to develop learning. Gibson and Birkinshaw (2004) indicate that there are always trade-offs to be made between exploitation and exploration, and whilst these trade-offs can never entirely be eliminated, the most successful organisations reconcile them to a larger degree, and in so doing enhance their long-term performance. Exploration is described as a focus on discovery, autonomy, learning new things and innovation, whereas exploitation is described as a focus on efficiency, control, certainty and variation reduction (March, 1991), in other words, putting existing knowledge into practice.

Whilst OA was initially developed as a separate concept from RBV and DCV, there is much commonality between the theories with the focus on developing knowledge, resources and routines within an organisation, and there are also shared foundations across the three theories (Vogel and Güttel, 2013). Some researchers have described OA as a form of dynamic capability (O’Reilly and Tushman, 2008; Helfat and Winter, 2011).

Researchers have developed three main solutions for organisations to help them to balance exploration and exploitation, and to develop their ambidexterity: structural (Benner and Tushman, 2003), switching (Boumgarden et al., 2012) and contextual (Adler et al., 1999; Gibson and Birkinshaw, 2004). Structural ambidexterity involves the distinct separation of different business functions, but with shared organisational goals and values, and a clear role for executives to resolve conflicts and manage paradoxes. It is suggested that during times of organisational crisis, structural separation of exploratory efforts is crucial to buffer experimental and
learning efforts from inertial exploitation activity (Benner and Tushman, 2015). This includes formal structural separation through ‘spinouts’, where an organisation chooses formally to separate either exploration or exploitation into a different company or through outsourcing. Switching or ‘organisation vacillation’ is where organisations choose to either explore or exploit contingent on the organisational and environmental context, and which may not always be in balance (Boumgarden et al., 2012). Finally, contextual ambidexterity is decentralised and requires individuals to decide for themselves when and how to perform both these conflicting demands (Raisch and Birkinshaw, 2008). This is exemplified by a study of the Toyota Production System (TPS) at New United Motor Manufacturing Inc., whereby employees were asked to both follow routines to make cars and at the same time complete non-routine tasks by identifying improvement opportunities, that could be written down and evaluated at the end of a shift or within a quality circle (Adler et al., 1999). They describe TPS as an approach to ensure contextual ambidexterity, balancing both exploration and exploitation, rather than a form of process management (Benner and Tushman, 2003) and thus exploitation.

2.4.2.6 Limitations of organisational ambidexterity
Research suggests that the ability to be ‘ambidextrous’ is positively associated with outcomes at all levels of analysis (Danneels, 2011; Lavie et al., 2010), although much of the research on ambidexterity has been conducted within the for-profit sector, typically within manufacturing or high-technology industries, with very little in healthcare or the public sector (Seshadri et al., 2010).

Researchers also indicate that there is an insufficient distinctive contribution of OA research, with a large diversity of conceptualisation and operationalisation (Birkinshaw and Gupta, 2013; O'Reilly and Tushman, 2013). This heterogeneity of conceptualisation also hinders measurement of OA (Birkinshaw and Gupta, 2013; Junni et al., 2013), and there is little research to understand the variables and mechanisms underpinning ambidexterity (Turner et al., 2013). Finally, there is insufficient research to understand how the dual aims of exploration and exploitation are balanced and what role managers take (Turner et al., 2013).
2.4.3 Resource based theories: challenges for research

Whilst each theory has grown from different research streams, there is considerable theoretical overlap. Vogel and Güttel (2013) confirm the findings of Di Stefano et al. (2010) that there are similar theoretical foundations for the DCV, RBV and OA in management research, although there is unclear differentiation between the related theories (Hitt et al., 2016b).

These three theories are critiqued similarly (Table 2.7) in five main areas: conceptualisation and measurement; sectors; focus of analysis; role of managers and empirical evidence. All three theories developed within the private sector, and there is little evidence for these theories within the public sector, including healthcare. Finally, there are calls for more research to understand what makes up ‘resources’, ‘capabilities’ or ‘ambidexterity’, using case-study research, longitudinal research and strengthened conceptualisation, and the understanding of the micro-foundations. Table 2.7 outlines where calls for further research exist for each theory.

This section has outlined the different theoretical perspectives and the resource based theoretical position taken given its emphasis on developing organisational resources and capabilities to support organisational survival, competitive advantage, performance improvement, and its focus on value. Three specific resource based theories, RBV, DCV and OA have been reviewed and critiqued, and theoretical challenges for research in the literature outlined, which have remarkably similar issues, regardless of the choice of resource based theory.
Table 2.7: Theoretical challenges for research

<table>
<thead>
<tr>
<th>Conceptualisation</th>
<th>Resource based view</th>
<th>Dynamic capabilities view</th>
<th>Organisational ambidexterity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus needed on specific resources and capabilities, and non-financial performance (Rashidirad et al., 2015; Hinterhuber, 2013).</td>
<td>Further research is needed to identify and focus on the mechanisms, conceptual insights and links between capabilities (Felin et al., 2015; Vogel and Güttel, 2013; Salvato and Rerup, 2010; Ambrosini and Bowman, 2009). Easterby-Smith et al. (2009) suggest further DCV research could helpfully contribute by focusing on specific functional capabilities. Research to establish linkages between firm-specific processes and dynamic capabilities across firms (Wang and Ahmed, 2007). Definitional clarity and theoretical development is required (Giudici and Reinmoeller, 2012).</td>
<td>Research to understand the explanatory micro-mechanisms (Turner et al., 2013). More studies to focus on multiple levels of OA simultaneously to specify how linkages between OA at different levels contribute to performance (Birkinshaw and Gupta, 2013; Junni et al., 2013).</td>
<td></td>
</tr>
<tr>
<td>Focus of Analysis</td>
<td>Further empirical research to identify the characteristics of best practice in their market and their existing environmental and technological contexts (Rashidirad et al., 2015).</td>
<td>Research needed to examine internal and external factors that may enable (or inhibit) organisations to develop their performance (Barreto, 2010). Research to understand the organisational factors associated with capability development and microfoundation aggregation needed (Barney and Felin, 2013; Wilden et al., 2016).</td>
<td>Detailed understanding of individual and group ambidexterity is needed (Turner et al., 2013). Cross-boundary ambidexterity research within eco-systems to extend the existing intra-organisational research (O'Reilly and Tushman, 2013).</td>
</tr>
<tr>
<td>Resource based view</td>
<td>Dynamic capabilities view</td>
<td>Organisational ambidexterity</td>
<td></td>
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<tr>
<td>---------------------</td>
<td>---------------------------</td>
<td>-----------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Sectors</strong></td>
<td>Little research to understand RBV (and related DCV) within public sector organisations (Burton and Rycroft-Malone, 2014; Szymaniec-Mlicka, 2014; Crilly et al., 2013).</td>
<td>Little research completed within the public sector (Piening, 2012; Hogan et al., 2011; Easterby-Smith et al., 2009).</td>
<td>Little research within the public sector (Smith and Umans, 2015).</td>
</tr>
<tr>
<td><strong>Role of Managers</strong></td>
<td>Research to understand how managers effectively bundle resources (Sirmon et al., 2007).</td>
<td>Further research on resource orchestration needs to extend into managerial cognition and decision making (Eggers and Kaplan, 2013).</td>
<td>Research to understand the role of managers and top management teams in decision making (Birkinshaw and Gupta, 2013). Detailed qualitative studies are required to understand how conflicts between exploitation and exploration are managed (O'Reilly and Tushman, 2013; Turner et al., 2013).</td>
</tr>
<tr>
<td><strong>Empirical Data</strong></td>
<td>Longitudinal, empirical and case research needed to understand how resources change over time (Lockett and Wild, 2013; Newbert, 2007; Sirmon et al., 2007). Longitudinal studies required to establish causal links between resources and capabilities, and performance (Hinterhuber, 2013).</td>
<td>More empirical research (particularly longitudinal) to evaluate dynamic capabilities is needed (Pezeshkan et al., 2016; Giudici and Reinmoeller, 2012; Easterby-Smith et al., 2009).</td>
<td>More evidence from the public sector and from healthcare settings required (Seshadri et al., 2010; Smith and Umans, 2015).</td>
</tr>
</tbody>
</table>
2.5 Chapter conclusions and overall research study aims

There are many approaches that can be used to encourage performance improvement, which are based on different management theories. One approach is a capability intervention, which is increasingly used to supplement regulatory interventions. Capability interventions focus on providing aid and support to existing interventions, such as restructuring, specific reforms or development support (Talbot, 2010). It is argued that these can take the form of leadership support or replacement, and the development of improved processes for people management, strategy, planning, innovation and resource management, using improvement approaches (Talbot, 2010).

Another approach uses regulatory strategies, with both deterrence and compliance enforcement approaches to ensure performance improvement. Regulatory agencies face challenges and are criticised for a lack of a prospective focus, for restricting improvement and innovation, and for a lack of consistent evidence of the benefits of regulation strategies given their costs. Improvement capability development interventions are also criticised for a lack of evidence of effectiveness, and critics have argued that a mix of both approaches is needed. In addition, increased fidelity is needed when using these approaches to understand the organisational context and adjust accordingly.

This chapter has highlighted the paucity of research to understand how regulatory agencies encourage improvement and make prospective assessment judgements about existing organisational motivations and improvement capability allowing regulatory enforcement strategies to be adapted. Furthermore, whilst responsive regulation offers a more flexible model for regulatory agencies, allowing both deterrence and compliance models, there is still more to understand about how regulatory organisations develop models that use this combination to improve healthcare, and this area remains under-researched.

To respond to these gaps in the literature, the research study examines in detail how regulatory agencies in UK healthcare conceptualise and make assessments about improvement capability within organisations to inform enforcement strategies. It is argued that assessment is a conceptual issue requiring construct definition and the
development of appropriate valid and reliable measurement instruments (Van de Ven, 2007).

Therefore, this research study focusses on the following question and research objectives within healthcare regulatory agencies based in the UK:

- How do regulatory agencies assess improvement capability within healthcare organisations?

Objectives:

a) To understand and define improvement capability
b) To understand similarities and differences in how improvement capability is currently conceptualised and assessed in practice
c) To develop a conceptual framework for assessing improvement capability

This question implicitly assumes two things: first, regulatory agencies want to assess improvement capability; and second, improvement capability is a construct that can be assessed.

The research study draws on the DCV (Teece and Pisano, 1994) to understand how improvement capability is conceptualised and measured in practice from a regulatory perspective through a comparative analysis. DCV is selected for use within this research study because it takes a process view of performance and has a focus on how routines bundle, orchestrate and interact over time. In addition, improvement capability is viewed as a dynamic capability within the literature (Bessant and Francis, 1999).

The next chapter details the research design and methods used to answer the above research question and associated objectives.
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transformational change in NHS North East. Health Service Delivery Research, 2(47).


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Chapter 3 - Research methodology

3.1 Introduction

This chapter details the research approach and methodology used to conduct this research study. It describes the research sample selected, together with the data collection and analysis methods. As this thesis is written in the alternative format, Section 2 includes four papers which also include small sections on the research methodology used, leading to limited duplication within this thesis.

The chapter proceeds as follows: first the epistemological position of the research, its objectives, research design and plan are outlined, followed by details of the data collection process (Section 3.2) and the qualitative analysis methods employed (Section 3.3). It also describes the dissemination methods used during the research study to both share learning widely in order to receive ongoing feedback to develop and improve the research as it developed. Section 3.4 details the research limitations and outlines the criteria used to assess and describe the quality of the research study, including the ethical processes followed.

3.1.1 Epistemological and ontological position of the research

Epistemology is concerned with the limits, nature and sources of knowledge (Martin, 2010) and together with the ontological position, informs the research approach. Robson (2011) outlines a number philosophical approaches, including positivism, relativism (including social constructivism), pragmatism and realism. A positivist approach believes that knowledge creation progresses though direct observation of concrete phenomena (Symon and Cassell, 2006), whereas a relativist approach considers that ‘facts’ only gain ‘truthfulness’ after significant discussion, and knowledge cannot be objective or separate to the phenomenon under investigation (Potter and Wetherell, 1987). A social constructivist approach suggests that phenomena are influenced through social biases and are interpreted through the different cultural backgrounds and perspectives of the researchers and individuals (Gill and Johnson, 2010). Whereas, pragmatism recognises the need for different epistemological and thus methodological approaches, depending on what might be most useful for both the process of the research itself and for the beneficiary of the research outcomes (Van de Ven, 2007). Realism asserts that the world is
continuously changing, and theories generated through science are fallible (Robson, 2011). A realist approach considers that in order to contribute to knowledge, researchers need to be open to alternative viewpoints and critiques to improve their research, allowing theory anomalies to continue to evolve.

The epistemology appropriate for the research study was considered in light of the research objectives and the researcher’s own preferences. The researcher trained as an engineer and has spent her career to date working in the field of improvement within industry and healthcare. This professional background has influenced the researcher whose preference, on reflection, is to take a pragmatic philosophical approach (Emison, 2001). However, pragmatism would not have been appropriate for this research question and objectives, because these require the consideration of different conceptualisations of improvement capability. This indicates that alternative epistemological approaches would benefit and develop the research, whereas the pragmatic approach would only consider the view that may be the ‘most useful’.

The research design was chosen by considering the most appropriate and suitable epistemological and ontological approach and associated methods for the chosen research question concerning improvement capability. Healthcare quality and performance are highly subjective and value laden concepts and initially a realist approach was selected because it is suited to the examination of problems from different viewpoints and critically reviews these for bias. In addition, it explores deep understandings surrounding why events occur, even when they are more abstract in nature and unobservable. It is recognised that a realist approach may not always acknowledge inherent power relations; however, a positivist approach would ignore the context, history and organisational circumstances within which improvement capability needs to develop, and is less suitable for use with qualitative methods and consequently was discounted as an approach. Similarly, a pragmatic approach only considers the ‘most useful’ approach.

However, whilst a realist approach was initially selected, as the research developed it became clear that this was not fully relevant and an interpretive perspective was used instead. A social constructivist approach became more appropriate to provide the base for a research study of different subjective conceptualisations perspectives of
improvement capability, and was the most appropriate for the research question and associated objectives.

This research study plans to develop a conceptual framework and evaluate existing regulatory strategies and approaches towards the assessment of improvement capability by integrating various theoretical elements into a coherent understanding. Qualitative research methods are ideal for this type of research study, as it provides rich and deep information about topics, and is useful for the development of theoretical constructs and models. Furthermore, a social constructivist epistemological approach is suitable for qualitative methods which are required to understand how regulatory agencies conceptualise and assess improvement capability and to support an understanding of varying perspectives. This social constructivist approach rejects the possibility of a theory-neutral observational language and suggests that all perceptions of reality are inherently subjective (Gill and Johnson, 2010). Therefore, research cannot be conducted by neutral and objective researchers, and ongoing critical appraisal and reflexivity is required throughout the research process to identify potential biases, consider their impact and to ensure rigour. Therefore, a qualitative research approach to understand the conceptualisation and assessment of improvement capability was chosen and used after considering the ontological and epistemological position of the research.

3.1.2 Research design

This research study examines regulatory interventions to assess and develop improvement capability in healthcare organisations and to understand how improvement capability is conceptualised. Øvretveit (2011) outlines several research designs when studying the field of healthcare improvement, which are grouped into the three approaches, detailed in Table 3.1. This shows that experimental approaches use different methods to understand if an intervention causes changes to measurable outcomes, while observational approaches describe broader factors about how interventions are implemented. Observational ‘natural’ experiments can improve the validity of empirical findings, and are useful to political scientists across a wide range of topics (Dunning, 2008). Finally, an action evaluation approach provides feedback to adjust the intervention and its implementation.
Table 3.1: Research designs  
(adapted from Øvretveit (2014))

<table>
<thead>
<tr>
<th>Approach</th>
<th>Research design</th>
<th>Description</th>
<th>Data</th>
<th>Type of research questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental and quasi-experimental.</td>
<td>Randomised control trials Stepped wedge designs Time series design</td>
<td>Interventions are treated as experiments and are pre-planned Often use controls.</td>
<td>Data is collected before the change and after it Typically, quantitative data, though qualitative can be used</td>
<td>Effectiveness Outcome</td>
</tr>
<tr>
<td>Observational and naturalistic</td>
<td>Audit or cohort evaluations Cross-sectional studies Case comparison</td>
<td>An intervention is observed in its natural setting Few controls Typically, case based</td>
<td>Data is collected to describe the interventions and its effects Qualitative and quantitative data</td>
<td>Effectiveness outcomes and implementation</td>
</tr>
<tr>
<td>Action evaluation</td>
<td>Action evaluation</td>
<td>Experimental and observational approaches can be used, although typically, observational designs are employed</td>
<td>Data is used to feedback to implementers to improve the implementation of the intervention</td>
<td>How to improve the intervention while it is being implemented</td>
</tr>
</tbody>
</table>

The choice of research design depends on the research question and a number of other factors, including organisational access, ethical concerns, and the audience (Buchanan and Bryman, 2007). Yin (2013) indicates that for a research question posed with a ‘how or why’, then a case study design is appropriate if no control over behavioural events is required and there is a focus on contemporary events. The research question for this research study fits these criteria, as it aims at providing theoretical and empirical explanations of how improvement capability is conceptualised and assessed from a healthcare regulatory perspective. Moreover, there is little empirical work on regulatory agency perspectives of improvement capability and its assessment, therefore an exploratory qualitative approach, using interviews and a document review is appropriate. In keeping with the research
objectives and the epistemological and ontological position, a comparative case study design with an observational approach was chosen for this research study.

### 3.1.3 Research plan

The research study was conducted in three phases, with phase 2, the empirical data collection and analysis consisting of two parts. These are aligned with the research objectives, and are reflected in the four papers detailing each phase of the research study in the alternative format. Details are provided in Table 3.2.

#### Table 3.2: Research plan

<table>
<thead>
<tr>
<th>Research Objective</th>
<th>Research Phase</th>
<th>Paper</th>
</tr>
</thead>
<tbody>
<tr>
<td>To understand and define improvement capability</td>
<td>Phase 1 – Integrative literature review of instruments and frameworks for assessing improvement capability</td>
<td>1</td>
</tr>
<tr>
<td>To understand similarities and differences in how improvement capability is currently defined and assessed in practice</td>
<td>Phase 2a – Empirical data collection and analysis of documents and interviews from healthcare regulatory agencies</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Phase 2b – Empirical data collection and analysis of assessment reports from healthcare regulatory agencies</td>
<td>3</td>
</tr>
<tr>
<td>To develop a conceptual framework for assessing improvement capability</td>
<td>Phase 3 – Development of an improvement capability conceptual model</td>
<td>4</td>
</tr>
</tbody>
</table>

Phase 1 developed a detailed integrative literature review that examined all forms of assessment processes for improvement capability, both qualitative and quantitative. These were evaluated against criteria appropriate for the type of instrument or framework and reliability criteria, and identified constructs used for improvement capability. Phase 2 encompassed the empirical data collection (part a) and analysis (part b), using a qualitative approach to understand existing regulatory approaches for the assessment of improvement capability. It utilised document review and interviews to collect data regarding improvement capability and thematic analysis. Phase 2b also reviewed specific assessment reports using content, thematic and matrix analysis. Finally, phase 3 developed a conceptual framework for improvement capability based on the outcomes from phases 1 and 2.
3.1.4 Ethics

The Alliance Manchester Business School (AMBS) ethics process was followed and permission to proceed was received. Health Research Authority decision tools were also completed, which indicated that NHS research ethics approval was not required. All interview participants were given an information sheet about the research study in advance, and were informed as to how their interview data would be recorded and used in the study. Interview participants were assured of their personal anonymity and confidentiality. All interview participants were asked to authorise research consent forms, with participants taking part remotely via a telephone interview asked to verbally confirm their consent to take part in the research on the recording and this is captured within the interview transcripts. Transcripts of the interviews were shared with the participants to allow time for any points of clarity to be made. This allowed interview participants to withdraw from the research study, if on reflection they no longer wished to contribute to it. Finally, as a condition of access, two regulatory agencies requested that details of specific NHS organisations involved in their regulatory process would also remain confidential.

3.2 Data collection

The research study data collection process was aligned to the research objectives and conducted in three phases, as detailed in Table 3.2. This involved using qualitative data collection through a detailed integrative review and the use of interviews and document analysis. The research process was shown in Figure 1.1.

The first phase of the research study consisted of identifying the existing instruments and frameworks that seek to measure this construct, either in whole or in part. An initial working definition for improvement capability based on that of Bessant and Francis (1999) was used, and related keywords were developed to inform the design of an integrative literature review. The integrative review identified 70 instruments and frameworks and their associated constructs, and the review, analysis and findings are detailed in the paper 1 (Furnival et al., in development-a) which is presented in Chapter 4. The following sub-sections describe the methodologies used for the integrative review in more detail than the paper is able due to journal word limit constraints.
3.2.1 Integrative literature review (phase 1)

A detailed literature search of instruments and frameworks that assess improvement capability within organisations was undertaken. There are many different methodological approaches to literature reviews, including systematic (Tranfield et al., 2003), scoping (Arksey and O'Malley, 2005), narrative synthesis (Mays et al., 2005), and integrative (Cooper, 1982; Whittemore and Knafl, 2005).

An integrative literature review process was utilised (Cooper, 1982; Broome, 1993; Whittemore and Knafl, 2005) as it is a method that allows disparate qualitative and quantitative instruments and frameworks to be reviewed systematically (Hawker et al., 2002). This requires that the values and assumptions underpinning a review to be explicit, in order to offset the risk of bias involved in a narrative or qualitative review (Tranfield et al., 2003). This provides a more valid approach that leads to the synthesis of the literature. Systematic reviews and meta-analysis, whilst more robust and repeatable, are narrower by design. Furthermore, they exclude the use of multiple methodologies and differing contexts within a study and are usually used to review clinical evidence and the strength of results to inform future practice through combining statistical results where possible. Therefore, to use this approach for this research study, instrument or framework designs would need to be similar in order to be comparable. This research study wanted to include all possible designs of instruments and frameworks at this stage; therefore, these approaches were excluded. Similarly, a scoping review (Arksey and O'Malley, 2005) does not synthesise the findings and conclusions. However, the research study needed to be systematic and be comprehensive in order to find the relevant instruments and frameworks, and an integrative review was selected as the most appropriate method.

Cooper (1982) describes five main steps in an integrative review: (1) problem formulation; (2) data collection; (3) evaluation of data points; (4) data analysis and interpretation; and (5) the presentation of results. This general approach was followed, with a detailed and systematic approach for data collection and synthesis (Denyer and Tranfield, 2006). The integrative review is primarily used to summarise the accumulated state of knowledge with respect to the assessment of improvement capability and to generate new perspectives and areas for further research (Torraco, 2005).
Tables to summarise the data found within the review were used, together with theming of instrument and framework type, and content analysis of the instruments and frameworks. Subsequently, the results go beyond that of simply summarising the content of the reviews, and also synthesise comparisons and conclusions (Cowell, 2012).

3.2.2 Integrative review approach

Problem formulation (step 1) to inform the integrative review took place whilst the background to this research study was developed, and identified that there was little consensus and agreement about improvement capability. The subsequent research question and objectives sought to understand how improvement capability is conceptualised and assessed, and a new detailed search was planned to inform a detailed review of the literature in this area.

The initial searching informed an operational definition of improvement capability and also alternative terminology or phrases that may be used instead of improvement capability within different disciplines or sectors. Using an integrative review approach was advantageous for this, protecting its validity, as the process allows several a priori operational definitions to be used whilst searching. It also allows the researcher to identify new definitions and concepts that may not have been considered during the research study, potentially leading to more robust conclusions (Cooper, 1982).

To collect the data (step 2), key healthcare and business databases, including Scopus, HMIC, Web of Science, Medline and CINAHL were searched following a systematic search protocol. A detailed, iterative approach was taken, including the use of snowballing and ancestry strategies to find more obscure sources (Greenhalgh and Peacock, 2005) within very diverse and fragmented sources of evidence. A diverse range of literature and peer-reviewed journals on improvement capability assessment were drawn from until saturation; nevertheless, the search strategy used may not have been exhaustive.

Searching took place between September 2014 and January 2015 to examine the existing literature base with respect to the assessment of improvement capability. To evaluate the collected data (step 3), detailed inclusion and exclusion criteria, both the process and keywords were reviewed within the research team. Paper 1 (Furnival et
al., in development-a) details the keywords used, the inclusion and exclusion criteria, and number of articles found and excluded at each stage of the searching process. Paper 1 details the data analysis and interpretation (step 4), and presents the findings from the integrative review (step 5).

3.2.3 Empirical data collection (phase 2, parts a and b)

To study the assessment of improvement capability and its conceptualisation within healthcare regulatory agencies, documentation review and purposive interviews were chosen for data collection. This phase of the research study built on the learning from the integrated literature review to understand how improvement capability is conceptualised and assessed in practice. This phase of the research study aimed to address specifically the research objective to understand similarities and differences in how improvement capability is currently conceptualised and assessed in practice.

The research study was conducted with interview participants from six healthcare organisational regulatory agencies across the UK, which represent all the healthcare regulatory agencies in the UK. Initial regulatory agency contacts were identified through introductions through the author’s professional network, Manchester University and the Health Foundation who funded this research study. Care was taken to ensure that this approach did not lead to systematic error due to access bias (Goldstein, 2002). Access to the interview participants was gained in very little time (Thomas, 1993; Hertz and Imber, 1995), unlike the evidence detailing that this could be a major undertaking (Aberbach and Rockman, 2002). Directors of regulation, inspection, policy or strategy in the agencies were initially approached for an exploratory conversation, and a briefing note about the research was included (see Appendix B). All six regulatory agencies agreed to participate in the research study and to facilitate the recruitment of interview participants. Documentary data, including publicly available strategic plans and reports, together with organisational assessment reports from the regulatory agencies were also collected. The full data sample is shown in Table 3.3.
### Table 3.3: Data source sample

<table>
<thead>
<tr>
<th>Agency</th>
<th>Documents</th>
<th>Interviews</th>
<th>Assessment reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>2010-15</td>
<td>2014-15</td>
<td>2013-15</td>
</tr>
<tr>
<td><strong>Selection criteria</strong></td>
<td>Publicly available strategic plans; Annual reports; Operational reports.</td>
<td>Clinical &amp; non-clinical; Cross-section; Board member; Back office; Assessors.</td>
<td>Publicly available acute and/or community reports; Range of performance judgements; Identified during interviews.</td>
</tr>
<tr>
<td>HIS</td>
<td>18</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>HIW</td>
<td>13</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>RQIA</td>
<td>17</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>CQC</td>
<td>13</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>Monitor</td>
<td>16</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>TDA</td>
<td>13</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>90</strong></td>
<td><strong>48</strong></td>
<td><strong>30</strong></td>
</tr>
</tbody>
</table>

### 3.2.4 Documentation review

Documentation review was one of the main forms of data collection. In social research documents are traditionally the primary sources of evidence and receptacles of inert content; however, they can also be viewed as key components of dynamic networks (Prior, 2008). Documents are argued to influence social interactions and organisations, through referring to the aspirations and intentions of a place or people at a point in time (Prior, 2008). Documents are described as the ways that people or organisations represent or account for themselves, and they can provide a mechanism for understanding and making sense of organisational and social practices (Coffey, 2014). In addition, it is argued that documents can ‘tell people what to do’, ‘stir up’ conflict, and trigger new actions (Prior, 2016).

The primary focus of the documentation review was on improvement capability assessment approaches, the development of improvement capability through policies and processes, and the conditions needed to sustain and benefit from improvement capability across sectors. The documentation review examined existing assessment approaches detailed by regulatory agencies and associated strategies. Formal documents and reports, such as annual reviews, objectives, annual accounts and other organisational documents, were extracted from regulatory websites and other sources, and subjected to analytical reading (Hakim, 2000). Secondary sources of
information (Thomas, 1993) were also carefully reviewed, including press articles about the agencies and related commentary pieces, in order to inform the research study from multiple sources with different perspectives (Goldstein, 2002). This helped to form a more detailed view of the regulatory agencies and their contexts. Thematic and content analysis are key strategies for data exploration of documents (Krippendorff, 2004). A broad spectrum of material can be used, including formal documents and records, and ‘everyday’ documents, such as notes, diaries, letters, photographs, maps or newspapers (Coffey, 2014). Consideration to information not contained with the documents and the trustworthiness and credibility of the documents was taken.

The initial review of documents and website material informed the development of the interview framework and background preparatory work (Ostrander, 1993; Berry, 2002). The documentation review of both literature and regulator documents, allowed in depth preparation and analysis prior to the interviews, and inconsistencies between intent and action could be identified which was supplemented by content analysis (see Section 3.3.4). Briefing notes on the regulatory agencies were developed in preparation for the interviews in order to swiftly establish credibility and rapport with the interview participants, as well as to conduct the inquiry.

### 3.2.5 Interviews

Interviews were conducted with a cross-section of employees from each regulatory agency and used to understand regulatory perceptions of improvement capability for comparison between countries and between agencies. Interviewing is argued to have many advantages, as it allows subjective meanings from the interview participants to be collected regarding a topic, and complex, and potentially contradictory data can be collected which may not be through quantitative approaches (Green and Thorogood, 2009). However, interviewing is time and labour intensive. It also presents challenges, as individuals in key roles may be difficult to access and to establish trust and rapport with due to perceptions of research, individual status, research purposes and time considerations due to heavy diaries (Green and Thorogood, 2009; Cassell and Symon, 1994). Nevertheless, all six regulatory agencies agreed to take part and six to ten interview participants were targeted within each, based on their role and the agency structure. An information sheet about the
research study was shared with the agency and each participant in advance of the interview (see Appendix C). Interviews (including telephone interviews) with representative regulatory agency employees were held to compare their responses with the findings from the documentation review and to ask further questions regarding the assessment of improvement capability.

A semi-structured interviewing approach with three main questions (Thomas, 1993; Aberbach and Rockman, 2002; Berry, 2002) was used as a checklist of issues (Ostrander, 1993) and a strategy to attempt to mitigate validity and reliability issues (Berry, 2002), together with providing reflexivity (Green and Thorogood, 2009; Banister et al., 2011). It was also used to reduce any propensity to ask leading questions and to simplify coding and data analysis (Aberbach and Rockman, 2002). Interviews were recorded and transcribed with consent, and later shared for accuracy with interview participants. A copy of the consent form is shown in Appendix D.

The initial, revised (after the first interview) and final interview questions (after the first five interviews) are shown in Appendix E; during the process of interviewing the questions were reflected upon and adapted. Since the interview design was semi-structured, these questions only provide an indication about the themes discussed in the interviews. Modification and adaptation of the questions was required during interviews to tailor the questions to the interview participant’s role and the responses given to the initial questions to probe deeper and clarify further.

During the interviews participants often wanted to know where the researcher had worked previously and with whom, described as ‘checking out’ (Ostrander, 1993) in order to understand the researcher’s role and credibility. The researcher was able to use this experience or ‘street smart’ (Hirsch, 1995) as an advantage in establishing the interview and developing a rapport with the interview participants. Participants were asked for their views on different regulatory designs and detection approaches, conceptualisations of improvement capability, and different enforcement approaches. Interview participants were also asked to describe potential risks to their plans and what challenges may be faced both to develop improved capability, but also how this might improve performance or otherwise.

Interviews were face-to-face where possible or by telephone when required, providing formative information regarding regulatory design, understanding, challenges and purpose with respect to improvement capability and how strategies to
develop improvement capability are planned, implemented and evaluated within healthcare organisations. This information was not readily available from the available documentation, thus interviewing was an appropriate form of data collection (Thomas, 1993) and supplemented the documentary analysis. The researcher was careful to maintain control of the interviews (Berry, 2002) and to ensure that questions were answered rather than avoided or answered obliquely, which would making coding and data analysis more challenging (Aberbach and Rockman, 2002). However, elite interviewing by its very nature is limited to certain perspectives and worldviews about hospital boards and patient safety that may have excluded marginal or underrepresented perspectives. The interviews were digitally recorded and professionally transcribed with consent from the interview participants. The transcriptions were subsequently shared with the interview participants in order to check for any inaccuracies and to gain any further clarification required (Thomas, 1993). An example interview transcript is shown in Appendix F.

There were 48 interview participants; only one individual declined to be interviewed and an alternative interview participant was contacted. A cross-section of staff from different functions and with different levels of seniority was sought, including those from both clinical and non-clinical backgrounds, to ensure a diversity of participants. Roles ranged from board level executives through to inspectors and project managers. The interviews were completed between October 2014 and April 2015, and lasted between 28 minutes and 1 hour 24 minutes each. Details of the interview sample were shown in Table 3.3 and further details are provided in Table 3.4. Confidentiality and anonymity were assured for the interview participants.
Table 3.4: Interview sample

<table>
<thead>
<tr>
<th>Agency</th>
<th>Interviews</th>
<th>Generic roles of those who participated</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIS</td>
<td>8</td>
<td>Director/Deputy Director (x2); Head of Department (x3); Senior Assessor/Inspector/Project Manager (x1); Team Leader (x1).</td>
</tr>
<tr>
<td>HIW</td>
<td>9</td>
<td>Director/Deputy Director (x5); Head of Department (x1); Senior Assessor/Inspector (x1); Senior Manager (x2).</td>
</tr>
<tr>
<td>RQIA</td>
<td>9</td>
<td>Director/Deputy Director (x2); Head of Department (x2); Senior Assessor/Inspector (x1); Assessor/Inspector/Project Manager (x4).</td>
</tr>
<tr>
<td>CQC</td>
<td>8</td>
<td>Head of Inspection (x2); Head of Department (x1); Senior Manager (x2); Senior Assessor/Inspector (x2); Assessor/Inspector/Project Manager (x1).</td>
</tr>
<tr>
<td>Monitor</td>
<td>7</td>
<td>Director/Deputy Director (x4); Head of Department (x1); Assessor/Inspector/Project Manager (x2).</td>
</tr>
<tr>
<td>TDA</td>
<td>7</td>
<td>Director/Deputy Director (x6); Senior Manager (x1); Assessor/Inspector/Project Manager (x1).</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>48</strong></td>
<td></td>
</tr>
</tbody>
</table>

3.2.6 Assessment reports

To understand current practice in the assessment of organisations by regulatory agencies, a review of assessment reports was conducted. Assessment reports from the regulatory agencies were purposely selected between the period 2013 and 2015 to understand how constructs of improvement capability were being assessed in practice. The sample represented both high and low performing organisations and the reports were publicly available (the selection criteria are available in Appendix G). During the interview process in Phase 2, interview participants often referred to a specific assessment report and organisational examples that they felt showed high or low performing organisations with respect to improvement capability, and these reports were sought out where possible. The final sample consisted of five assessments per agency, totalling 30 assessment reports.

3.3 Data analysis and dissemination

Several data analysis methods were used for each part of Phase 2 of the research study, both in parallel and consecutively. The analysis methods included thematic analysis, qualitative software analysis, content analysis, and matrix coding.
Thematic analysis was used for the two main areas of empirical data to code and analyse documents, interviews and assessment reports. Qualitative software was used to facilitate the thematic and content analysis, and to generate simple visual displays of data to allow new insights to be triggered. Content analysis was used within the integrative literature review and the empirical data collection from the assessment reports to understand improvement capability constructs and their use or otherwise within regulatory activity. Matrix coding was used during the analysis to generate tables to enable data to be compared to inform the analysis. Sections 3.3.1-3.3.6 detail each analysis method in turn and the reasoning for its use within this research. Reflections on the data analysis methods used are detailed within Section 3.4.

3.3.1 Thematic analysis

Thematic analysis was used for the two main areas of empirical data to code and analyse documents, interviews and assessment reports during Phase 2. It was also used to inductively analyse the extracted measurement constructs and items from the integrative literature review.

Thematic analysis is a research method used to identify, analyse and report patterns (themes) within data with the assistance of a template of codes (Braun and Clarke, 2006; King, 2004; Berry, 2002; Crabtree and Miller, 1999). A coding template supports the organisation of the data and helps to describe it in rich detail, supporting the interpretation of the research topic through the identification of themes (Boyatzis, 1998). This was an appropriate method to use given the epistemological stance of the research and the qualitative methods utilised. Creativity and judgment was required to make sense of and transform massive amounts of data and text into theory, to reduce the volume of raw information, to sift trivialities from substance, and to identify significant patterns and themes. Thematic analysis, whilst flexible, can also be criticised for its lack of a theoretical approach (Braun and Clarke, 2006); however, using an a priori coding framework for the template somewhat mitigated this risk, as the template was based upon empirical data, itself linked to the dynamic capabilities theoretical perspective (Helfat et al., 2007). An example of an interview and the codes used is shown in Appendix F.
3.3.2 Coding framework

The constructs identified from the integrative literature review (paper 1) were used as the a priori coding frame. The documents, interviews and assessment reports were reviewed and coded using the same initial a priori template during Phase 2, and the initial and final coding frameworks are shown in Appendix H. The revised template developed during the document and interview coding, and implications of the changed codes are discussed in the findings for Phase 2a of the research study in paper 2 (Furnival et al., under review). The coding frame was sufficient for coding the assessment reports with few new codes being developed during coding.

An iterative process of coding took place, with transcripts and documents undergoing three cycles of coding in order to capture each element of text with the most appropriate code, reflective of its meaning. Several cycles of coding were required in order recode, filter and focus on salient points (Saldaña, 2013). Whilst described as a linear, systematic process, the analysis was iterative and flexible. Coding can be viewed as the ‘critical link’ between data collection and the explanation of meaning (Charmaz, 2001). Coding took place during and after the interview data collection process as an analytic tactic (Miles and Huberman, 1994). Analytic reflective memos were written during the process of coding to capture emergent patterns and concepts present within the data (Saldaña, 2013; Miles and Huberman, 1994) and as an initial analysis process to tease out the data in the messages (Robson, 2011). Boyatzis (1998, p1.) describes a ‘good code’ as one that captures the qualitative richness of a phenomenon.

3.3.3 Qualitative software analysis

Qualitative research produces a large amount of textual data, and to manage this, the interview transcriptions and documents, including assessment reports, were imported into the interpretive software NVivo10 to analyse the data more effectively (Sinkovics and Alfoldi, 2012). This was used to support the coding, analysis and interrogation of the data. The a priori coding framework was entered as nodes, and the text was coded by identifying segments of data representative of the code. This allowed rapid storage retrieval and manipulation of the text, allowing fast data sorting into the codes. Using this software allowed the quick comparison of codes and facilitated a review of coded text together with the refinement and development of coding themes. Careful attention was given during coding to minimise the risk of
overemphasis and the development of a superficial view of qualitative research (Coffey and Atkinson, 1996). Furthermore, the ease of coding electronically runs the risk of developing a high number of codes from very short sentences, thereby fragmenting the data. This can potentially lead to over-reductionism and the risk of losing the sense of the interview participants. The expansion functions in NVivo10 were used to mitigate this risk, ensuring that fragments of text were coded appropriately given their context. These codes were then inductively analysed.

Following coding a three step process proposed by Bazeley (2013) was applied to the themes: describe, compare and relate. This process involved describing and reviewing each theme (called a node in NVivo10) within each regulatory agency. Each theme was then compared across agencies, seeking similarities or differences, to consider why this may be (relate). The classification and querying functionality within NVivo10 was utilised to facilitate this, and during the process the previous coding was scrutinised to ensure that the themes were representative of the initial data analysis and assigned codes. Coding consistency was also compared and this was achieved using the coding density and coding stripe functionality within NVivo10, an example of this coding for an assessment report is shown in Figure 3.1.
Figure 3.1: Screenshot of coding density and stripes
The screenshot in Figure 3.1 shows an excerpt of coding from a Care Quality Commission (CQC) report within the sample (CQC, Report B). This is used to both demonstrate the coding process and to explain why despite ‘leadership’ being an assessment domain within the CQC processes, it recurs less frequently within the content analysis. The extracted screen shot shows a summary paragraph for the ‘well-led’ domain on the left-hand side, and the coding stripes for this extract of text on the right-hand side, using the NVivo10 analysis functionality. The coding stripes allow the NVivo10 user to see at a glance the coding density, as all the text is coded, as highlighted in grey, on the left-hand side of the screenshot, while the darker vertical stripes on the right-hand side of the screenshot show the level of coding intensity. All stripes cannot be seen on the extracted screen shot, and the smaller shaded stripes to the right align with the extract of text coded to that ‘node’. Text references to the organisation reviewed in this report have been obscured to preserve anonymity.

This extract of coding demonstrates that despite the whole paragraph being titled ‘well-led’, the actual text within that paragraph related to many different codes, including communication, customer/patient involvement, culture, strategy and policy, and employee commitment and engagement. These coding nodes were consolidated into the improvement capability dimensions detailed later in paper 1 (Furnival et al., in development-a) and are shown in Table 3.5.
### Table 3.5: Example of coding

<table>
<thead>
<tr>
<th>Coded text segment</th>
</tr>
</thead>
<tbody>
<tr>
<td>“…staff engagement at the trust was impressive”</td>
</tr>
<tr>
<td>“…the CEO led from the top…”</td>
</tr>
<tr>
<td>“…staff were encouraged to, and rewarded for improving patient experience”</td>
</tr>
<tr>
<td>“…there was a strong sense of support and alignment between clinicians and managers”</td>
</tr>
<tr>
<td>“…there was a clear vision…”</td>
</tr>
<tr>
<td>“…as a result, [these values] were embedded…”</td>
</tr>
<tr>
<td>“…the Potential Acquisition…”</td>
</tr>
<tr>
<td>“…the trust demonstrated a strong patient-centred culture…”</td>
</tr>
<tr>
<td>“…the strength and depth of leadership…”</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Original coding node</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employee commitment and engagement</td>
</tr>
<tr>
<td>Leadership</td>
</tr>
<tr>
<td>Empowerment</td>
</tr>
<tr>
<td>Teamwork</td>
</tr>
<tr>
<td>Strategy and policy</td>
</tr>
<tr>
<td>Values, ethics and behaviours</td>
</tr>
<tr>
<td>Communication</td>
</tr>
<tr>
<td>Culture Patient and public involvement</td>
</tr>
<tr>
<td>Leadership</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Improvement capability dimension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employee commitment</td>
</tr>
<tr>
<td>Leadership commitment</td>
</tr>
<tr>
<td>Employee commitment</td>
</tr>
<tr>
<td>Employee commitment</td>
</tr>
<tr>
<td>Strategy and governance</td>
</tr>
<tr>
<td>Organisational culture</td>
</tr>
<tr>
<td>Employee commitment</td>
</tr>
<tr>
<td>Organisational culture; Service-user focus</td>
</tr>
<tr>
<td>Leadership commitment</td>
</tr>
</tbody>
</table>

#### 3.3.4 Content analysis

This research used summative content analysis during Phase 2b, alongside thematic analysis. Summative content analysis was also used to analyse the constructs extracted within the integrative literature review. Content analysis is a data analysis method that is used to make inferences through identifying specified characteristics systematically and objectively (Holsti, 1968). It is used to interpret meaning from the content of the textual data and is a widely-used analysis method with three distinct approaches, namely conventional, directed, or summative (Hsieh and Shannon, 2005), which use different coding approaches and frames. Conventional analysis develops the codes from the data, whereas in a directed approach the coding frame is developed from a theoretical approach or from appropriate research findings. A summative approach compares text data through the counting of segments of coded text via coded notes or keywords to inform the analysis.
A summative approach allows a comparison and interpretation of the findings regarding the assessment of improvement capability in assessment reports through both methods. This phase of the research study used the constructs identified during the integrative literature review in Phase 1 as the coding frame. This is highlighted in further detail in paper 1 (Furnival et al., in development-a). The frequency of occurrence of each construct, either as a manifest or latent object, was reviewed after the coding process was completed. Next, quantitative analysis and a comparison of the qualitative data in the reports was conducted and compared with analysis from Phases 1 and 2a, and this is discussed in the concluding chapter. The findings from Phase 2b of the research study is detailed in paper 3 (Furnival et al., in development-c) which is presented in Chapter 6.

The main advantages of using content analysis during Phase 2b of the research study was that it has clear and transparent processes, minimises personal bias and is easily replicable, whilst being unobtrusive. In contrast, whilst content analysis is able to support the ‘what’ questions about how improvement capability is being assessed and inspected, in practice is it unable to support understanding about why it is being assessed and inspected in that way. Furthermore, content analysis depends significantly on the quality of the data held within the assessment reports and the quality of the coding processes, as discussed in Section 3.4.

3.3.5 Matrix coding

Matrix analysis was used to develop comparisons and explanations following coding (Miles and Huberman, 1994) during Phase 2 of the research and within the integrative literature review in Phase 1, as described in paper 1 (Furnival et al., in development-a). Matrix analysis was used to present data in tables to allow concepts to be organised in different ways and is a way of displaying qualitative data in simple accessible forms suitable for interpretation (Nadim and Cassell, 2004). This allowed comparisons and contrasts to be made of the data between different regulatory agencies, interview participants and between different improvement capability constructs. The analysis using tables was completed using both manual approaches and matrix coding queries in NVivo 10 (Bazeley and Jackson, 2013).
3.3.6 Conceptual framework development (phase 3)

The integrative literature review conducted during Phase 1 (Furnival et al., in development-a) informed the design and development of a conceptual framework for improvement capability drawing on the DCV. This was developed by building on existing practice and frameworks, which could be either self-administered or utilised by external agencies to understand the improvement capability of an organisation to improve in the future and this phase of the research study (Phase 3) is detailed in paper 4 (Furnival et al., in development-b) which is presented in Chapter 7.

A conceptual framework explains the main items to be studied, through the identification of key factors, constructs and variables. Frameworks can be basic, comprehensive, theory-driven, causal or descriptive (Miles and Huberman, 1994) and are typically graphical. The process of developing a conceptual framework for improvement capability involved building theory through the identification of the most pertinent constructs and selecting these as the variables of importance out of the larger number of potential constructs. This process forces the selection of the most meaningful constructs and indicates the areas that would be most appropriate to assess and measure.

To develop the conceptual framework, visual processes of model development in NVivo10 were used to initially track the potential constructs as ‘nodes’, which Miles and Huberman (1994) describes as ‘bins’. The functionality within NVivo10 was used to move and consider different relationships between the constructs within the model. This was performed as an iterative cyclical process, which was ongoing during Phases 1 and 2, to inductively develop refinements to the framework over time and as data was collected. The conceptual model for improvement capability thus evolved and developed out of the fieldwork and literature analysis.

3.3.7 Data analysis summary

The a priori template helped to commence data analysis quickly as it was immediately ready to use. During the process new codes emerged inductively and needed developing to add into the coding frame. These newer codes related to the experience of regulatory agencies to assess organisations, and the structure and processes used to organise the assessments, rather than simply the dimensions that are reviewed in organisations. New initial codes were developed, for example
related to assessment processes and perceived conflicts between the enforcement strategies of regulatory agencies. New codes were tracked carefully as they emerged and transcripts were re-coded during the cycles to ensure that all text was appropriately coded according to the emerging codes; while this was a simple process to follow it was both time consuming and laborious. Occasionally, it was unclear if existing codes could be used to code each piece of text, or if two codes or a new code would be more appropriate, and both were used and tracked. In addition, some codes collected large quantities of text and needed further subdivision. NVivo10 functionality was used at this point to record the reasons for the resultant coding choice, allowing this to be traced during the analysis phase if required. The functionality in NVivo10 allowed compound queries to be performed on the data to check for words that had not been coded (Bazeley and Jackson, 2013), and other functionality, such as coding stripes to visualise coding patterns, was also used to check for consistency and coding density. Together with matrix coding, these analysis approaches were used to compare and analyse the collected data.

3.3.8 Dissemination methods

The emergent research design and findings were disseminated during the research process as opportunities became available. The research study was developed into publishable papers that form the main body of this thesis, and are presented in Section 2. Papers from the research study were presented at the Quality Improvement Research Network (QIRN) meeting in Pisa, Italy during 2015, the International Organisational Behaviour in Healthcare Conference in Cardiff, Wales in 2016, and at other research events during the development of this thesis. The publication strategy was supported through a range of tactics, including social media promotion to raise awareness of the research. Contacts with the regulatory community were maintained following interviews and research outputs were shared with contacts (as requested) and in presentations as these became available to inform regulatory development work, thereby strengthening the external validity of the research study. The initial integrative literature review has informed further research within maternity services in the UK, where an initial instrument for assessing improvement capability at a departmental level is in development.
3.4 Limitations of the research

This section explores the limitations of the research design and potential quality issues. The steps taken to mitigate the risks to the quality of the research study are described.

There are several potential limitations in this research design, which are beyond the control of the researcher. One limitation is that the field of health policy research, particularly with respect to regulation, is fast changing. For example, during this research study in England two regulatory agencies merged their operations, new regulatory models were in development, and restructuring across healthcare organisations was underway resulting from the Health and Social Care Act, 2012. Therefore, the fluidity of policy and policy changes makes it challenging for research studies to explore and understand correlations and the impact from different models and approaches taken by regulatory agencies.

Another limitation is that data was only collected from regulatory agencies, and data could have been collected from regulated healthcare organisations and patient groups to support and enhance the research design. However, whilst it would have been interesting and worthwhile to explore these different perspectives, additional data collected from these groups would have made this research into a different study. This research focuses specifically on the perspectives and actions of regulatory agencies, rather than their partners and stakeholders.

Finally, whilst qualitative research provides rich information, is easily conducted over time and examines causal relationships, a further limitation from this research design is that it only focuses on a UK based sample of regulatory agencies, and thus it might be questioned for its representativeness and generalisability for regulatory agencies operating outside of the UK healthcare context. However, generalisation in the majority of qualitative studies cannot be seen in probabilistic terms that would make general claims about a population from a sample (Eisenhart, 2009). Instead three other forms of generalisation are relevant for qualitative research: sample to population, case to case transfer, and theoretical (Firestone, 1993; Kennedy, 1979). For this research study generalisability is theoretical, based on the assumption that the theory is useful for other similar situations (Yin, 2013) and can be used to make sense of the situation studied.
There are a number of practical standards and criteria that can be used to assess the quality of the research conclusions (Bryman et al., 2008; Altheide and Johnson, 1994; Lincoln and Guba, 1985), which differ across research paradigms and differing terms have been developed. The following two subsections describe potential risks to the research quality from researcher bias and how these are mitigated through reflexivity.

3.4.1 Researcher bias

There are four related areas of potential bias from the researcher’s role, which link to the researcher’s background and previous role as an improvement leader in English NHS organisations.

One of the researcher’s previous employing organisations was subject to significant regulatory enforcement action, which resulted in the termination of a large programme of improvement activity. This experience of working as an improvement leader within an organisation subject to enforcement action was challenging, and it is difficult to reconcile regulatory aims of improvement with a regulatory intervention that terminated a significant improvement programme, for which the organisation had international acclaim and successful results. Given this history, following commencement of the research study the researcher held negative views about the value of regulatory agencies and their ability to deliver improvements for patients and the public. The researcher was aware of this potential bias and actively tried to mitigate against the risk of this through reflexivity.

The researcher has worked in organisations to lead improvement work using improvement approaches for almost 20 years with varying levels of success. At the beginning of the research process the researcher viewed that these improvement approaches, such as lean and six-sigma, were the primary ways in which improvement can and should be delivered, and that regulation and other forms of external improvement approaches were unnecessary. These views were underpinned through practice and experience, where improvement actions taken delivered changed metrics and benefits for patients and customers, whereas regulatory activity seemed only to add to the bureaucratic burden, delaying and in some cases, preventing improvement activity from taking place. Therefore, the researcher had considerable scepticism regarding the value and benefit of regulation for improving
patient care. There was the potential risk of confirmatory bias in the research, which would confirm the inability of regulation to deliver improvements in patient care and that alternative methods would be preferable, ignoring any contradictory evidence. Again, this risk was mitigated through reflexivity and through the increased knowledge of the evidence base for healthcare regulation and other forms of improvement.

Another area of potential bias was paradoxically both helpful and potentially problematic. Due to the researcher’s previous roles and background, the researcher had a wide-ranging number of contacts and networks, and could use these and associated reputation to facilitate access to the regulatory agencies. However, the researcher had met some of the interview participants previously, and some interview participants were aware of the researcher’s previous role and the organisational context with respect to regulatory intervention. This contextual knowledge may have affected the interview participant insights’ positively, through opening-up and using that as a shared area for discussion about the benefits and risks of regulation, and through sharing of agency documents and other access due to the established relationship, for example being asked to return to join other meetings or to ask for the researcher’s expertise. However, it may also have limited comments from interview participants with whom the researcher already had a relationship through their own concern for impact or willingness to share, given this history.

This research was funded by the Health Foundation, a national charity based in the UK whose remit is to support healthcare improvement. The charity has previously funded the researcher to complete a leadership development programme, including an academic qualification in healthcare improvement, and has funded several improvement programmes within the researcher’s former employing organisation. This ongoing relationship with the funder had the potential to cause bias, should the researcher have felt that the findings of the research needed to align with and support the Health Foundation’s position and view on improvement in healthcare. However, whilst the researcher did, and still does, feel obliged to provide a ‘return-on-investment’ to the Health Foundation for their support, the research findings were not influenced by existing Health Foundation work other than when their publications were appropriately referenced. The Health Foundation did provide facilities and support for several doctoral forums and peer review opportunities.
To mitigate against the risk of bias and excessive subjectivity, the researcher reviewed the collected data for congruent and divergent viewpoints, and was as reflexive as possible in order to generate dependable insights, to synthesise the findings, and to allow transferability of the learning into other areas.

### 3.4.2 Reflexivity

Reflexivity is described as a vital approach to reduce researcher bias and impact of value judgements through actively trying to understand the assumptions and beliefs that underpin research activity and to pay attention to researcher subjectivity. Reflexivity involves explicitly reflecting on and noticing the way in which research is carried out and understanding how the process of undertaking research shapes its outcomes (Hardy et al., 2001; Finlay, 2002). It assists in the analysis of how subjective elements may influence a researcher and supports the development of a greater understanding of the researcher’s role and impact on the research, thereby increasing its ‘trustworthiness’ and ‘integrity’ (Finlay, 2002; Cassell, 2005).

The researcher was introduced to the practice of reflexivity whilst completing a Masters in Leadership prior to commencing her doctoral thesis. During this process the researcher commenced the writing of journal notes and other memos using a notebook (Nadin and Cassell, 2006) to capture thoughts and patterns to help to ‘notice what is being noticed’ and ‘how the researcher felt about what was noticed’. This allowed the researcher to reflect on her leadership practice, and associated underlying assumptions and beliefs. The researcher continued this practice following the completion of the Master’s degree and into the commencement of her PhD. This allowed the researcher to practice reflexivity even before commencing fieldwork through being introspective and reflecting on her motivations and biases (Tracy, 2010). During the fieldwork, the researcher used a journal to take notes before and after each interview, as soon as pragmatically possible. This included information about who had been met, first impressions and reflections of the interview, and how the researcher had felt during the interview. On one or two occasions the researcher had met the interview participant previously, although the participant name was not recognised in advance, and the researcher took time to consider how this recognition affected both her and the participant. The researcher also considered what the main themes were from the interview responses and the reaction to the questions from interview participants and also captured these in the
journal. This allowed the researcher to adapt the interviewing style and questions as appropriate, and to consider the implications of the answers given during the interview. The notes were transcribed into the NVivo10 database that was developed for the research, and were coded and used to develop analytic memos.

3.5 Conclusions

This chapter has presented an account of a complicated and phased research process, which has been simplified through presentation as a process flowchart (Figure 1.1). This has clarified the main research design and methodological decisions made and the reasons for these choices whilst conducting the research study. The chapter has described the epistemological position of the research together with the research question and objectives to clarify the research design choice. The methodological details for data collection, analysis and dissemination have been described. Finally, this chapter has identified the research study limitations, areas of potential research bias, and the steps taken to mitigate these problems.
References


Section 2

Section 2 is written in the alternative format and contains four research papers. Each paper includes background information and a methods section, and this mean that there are sections of text which are duplicated within other parts of the thesis, particularly within the background and methodology chapters (Chapters 2 and 3).
Chapter 4 - Paper 1: Conceptualising and assessing improvement capability: a review

Joy Furnival, Kieran Walshe and Ruth Boaden

Introduction to paper 1

This paper is the first of four presented within Section 2, and (Furnival et al., in development-a) incorporates an integrative review of the literature of assessment instruments and frameworks for improvement capability from across sectors. The review establishes keywords from a range of fragmented and diverse research across several disciplinary fields, to seek assessment frameworks and models that had been empirically tested. It identifies 70 different instruments and frameworks, many of which do not have strong reliability or validity.

Paper 1 examines the assessment constructs and domains of the instruments and frameworks and explores the level of overlap within these constructs. Using inductive thematic analysis, a synthetic framework of eight dimensions of improvement capability is developed. This is used later in the research study as a coding framework for the analysis of regulatory assessment documents, interviews and reports (Furnival et al., in development-c; Furnival et al., under review) and to inform the development of a conceptual framework for improvement capability (Furnival et al., in development-b) which draws on the DCV (Teece et al., 1997).

References

Abstract

Purpose: The literature is reviewed to examine how ‘improvement capability’ is conceptualised and assessed to identify future areas for research.

Design/methodology/approach: An integrative and systematic search of the literature was carried out covering multiple sectors and disciplines including healthcare. Inclusion criteria were a requirement for the instrument or framework to be empirically tested, peer reviewed and written in English. Information was extracted about the sources of the instruments, the sectors in which they were developed or used, the measurement constructs or domains they employed and where and how they were tested.

Findings: The review identified 70 instruments and frameworks that have been used to assess improvement capability, which are diverse and contain different assessment approaches with little content consistency. This demonstrates the ambiguity of improvement capability as a concept and the difficulties involved in its operationalisation. Four groups were identified, each taking a different conceptualisation: improvement models, maturity models, change models and governance models. Two-thirds of the instruments and frameworks have been subject to tests of reliability and half for validity. Many of the instruments have little apparent theoretical basis and are not used widely.

Research limitations/implications: The assessment and development of improvement capability needs clearer and more consistent conceptual and terminological definitions used across disciplines and sectors. There is scope to learn from existing instruments and frameworks and this research study proposes a synthetic framework of eight dimensions of improvement capability. Future instruments need robust testing for reliability and validity.

Originality/value: This research study contributes to practice and research by presenting the first review of the literature on the conceptualisation and assessment of improvement capability across disciplines and sectors.
Introduction

Variation in organisational performance persists across organisations and sectors, and identification of the factors which influence organisational performance is vital and has been of interest since the 1950s (Penrose, 1959; Porter, 1980). The dynamic capabilities view (DCV) (Teece and Pisano, 1994), suggests that organisational capabilities, knowledge and routines are essential elements of improving performance. In the business and management literature, researchers have increasingly sought to understand how organisations integrate, build and reconfigure internal and external competencies, deploy organisational routines, and improve performance through their use of these “dynamic capabilities” (Teece et al., 1997; Helfat et al., 2007; Ambrosini and Bowman, 2009). Research indicates that capabilities account for much variation in performance and suggests that organisations will only have successful improvement strategies when there are appropriate capabilities that suit the local and external conditions (Shortell et al., 1998; Alexander et al., 2006). Some have contended that quality improvement (QI) programmes and methods such as Total Quality Management (TQM), Business Process Management (BPM) and Lean should be seen as ways to develop such dynamic capabilities (Anand et al., 2009; Bessant and Francis, 1999).

While the literature outlines a number of healthcare organisations that have been successful at improving performance through improvement approaches, particularly in the US (Bohmer, 2016; McGrath and Blike, 2015; Kaminski et al., 2014; Plsek, 2013; Pronovost et al., 2013), many organisations are less successful. Studies have focused on why organisations are unable to deliver anticipated results from the use of improvement approaches and describe capability gaps (Repenning and Sterman, 2002; Repenning and Sterman, 2001). Some researchers have argued that a systematic approach to developing improvement capability is required (Babich et al., 2016; Langley et al., 2009; Oliver, 2009; Berwick et al., 2003).

However, improvement capability is ambiguously defined and challenging to assess. It seems that improvement capability requires further conceptualisation (Gonzalez and Martins, 2016; Nisula and Kianto, 2013; Peng et al., 2008; Jørgensen et al., 2003; Lillis and Lane, 2007) and research is needed to understand how improvement capability is developed (Jørgensen et al., 2003; Godfrey, 2013), and to explore...
whether variation in improvement capability may explain inter-organisational variation in performance. Thus, the purpose of this paper is:

- to clarify how improvement capability is conceptualised and assessed
- to identify areas for future research and development

It contributes to research and practice as an integrative review of the literature on improvement capability across sectors including healthcare. An integrative review (Whittemore and Knafl, 2005) is used to summarise the empirical literature in order to provide an in depth understanding of the current approaches for the assessment of improvement capability, with direct application for policy and practice (Broome, 1993). The integrative review includes literature from 1989 to 2015 and from 43 journals in three main disciplinary areas: operations management, general and strategic management, and healthcare.

After the definition of the methods and the scope of the integrative review, including a summary of 14 existing literature reviews from specific sectors and disciplines, an analysis of 70 diverse instruments and frameworks reported in the literature drawn from several disciplinary fields and sectors is presented. Detailed analysis highlights conceptual, terminological and methodological differences through a comparative analysis of the constructs and methods. The research study reviews and categorises the instruments and frameworks by theme, explores instrument reliability and validity, and inductively develops a synthetic framework of eight improvement capability dimensions. Finally, it concludes by outlining the implications for research and practice, and proposes a future research agenda.

**Methods**

**Search strategy**

An integrative review (Whittemore and Knafl, 2005) of instruments and frameworks with empirical evidence was conducted, as this approach allowed for instruments and frameworks using diverse methodologies, for example qualitative interviews and quantitative surveys. The integrative review used a systematic and explicit search process to ensure rigour and reproducibility (Briner and Denyer, 2012), following the steps outlined by Grimshaw et al. (2003), and was conducted between September 2014 and January 2015. Keywords were selected through a general review to take
account of terminological differences for the assessment of improvement capability. For example, keywords included ‘quality improvement’ and ‘continuous improvement’, together with differing measurement methodological choices, such as ‘instrument’ and ‘tool’. Library staff were consulted in order to develop the search algorithms and Figure 4.1 details the search keywords.

Keyword Strategy (Group 1 combined individually with group 2)

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>assess*</td>
<td>continuous improv*</td>
</tr>
<tr>
<td>measur*</td>
<td>improv*</td>
</tr>
<tr>
<td>index</td>
<td>improv* capabilit*</td>
</tr>
<tr>
<td>inspect*</td>
<td>quality manag*</td>
</tr>
<tr>
<td>model</td>
<td>quality improv*</td>
</tr>
<tr>
<td>instrument</td>
<td>TQM</td>
</tr>
<tr>
<td>framework</td>
<td>TQM capabilit*</td>
</tr>
<tr>
<td>tool</td>
<td>absorptive capacity</td>
</tr>
<tr>
<td></td>
<td>improv* capacity</td>
</tr>
<tr>
<td></td>
<td>maturity</td>
</tr>
<tr>
<td></td>
<td>business excellence</td>
</tr>
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<td></td>
<td>intangible assets</td>
</tr>
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<td></td>
<td>change capacit*</td>
</tr>
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<td></td>
<td>change capabil*</td>
</tr>
<tr>
<td></td>
<td>transform capacit*</td>
</tr>
<tr>
<td></td>
<td>transform capabil*</td>
</tr>
</tbody>
</table>

Figure 4.1: Search keywords

The search used an iterative approach, searching forwards and backwards within citations and related literature reviews to find more obscure sources (Greenhalgh and Peacock, 2005) until saturation was reached. The searching strategy mitigated the challenges of relying solely on database searching (Greenhalgh and Peacock, 2005; Boell and Cecez-Kecmanovic, 2014) through the use of snowballing strategies.

Selection criteria

The search sought to identify qualitative and quantitative instruments and frameworks that assessed improvement capability and related practices or factors within organisations; all sectors were included. Articles were discarded if a study
did not contain empirical data to test the instrument or framework. Where multiple articles detailing studies of the same framework or instrument were found, then the earliest article describing the framework or instrument was included and the remainder were discarded, for example the use by Grandzol and Gershon (1998) of the framework by Anderson et al. (1995).

There are a number of similar country-specific quality awards which assess improvement capability, consequently only the three most popular quality award frameworks were included: the Deming Prize (2014), the European Foundation for Quality Management (EFQM) (2014) and the Baldrige Award (National Institute of Standards and Technology, 2013-14). The search excluded journal articles that were not peer reviewed or written in English. Peer reviewed journals are considered to have the highest impact on the field and have validated knowledge (Podsakoff et al., 2005). A flowchart was developed to reduce the risk of inconsistency in decision making (Figure 4.2). Finally, Scopus, Web of Science, Medline, HMIC, Embase and the Cochrane Database of Systematic Reviews were searched

Confirm measurement or assessment instrument↓
Confirm topic area is linked to improvement↓
Confirm topic area is linked to people, practices, capabilities (enabling)↓
Confirm empirical data testing instrument is included or within a separate paper↓
If a literature review, check review included findings and extract data↓
Check if same instrument (or minor variation of) as other studies, keep initial or original instrument paper only↓
Include in integrative review

Figure 4.2: Inclusion criteria flowchart

Summary of searching strategy

The initial search identified 23,127 papers and after the removal of duplicates, the application of filters, and title review, this was reduced to 750 papers. Application of the search criteria and snowballing strategies led to a final sample of 70
frameworks or instruments (Figure 4.3), and identified 14 literature reviews. Appendix I lists and details the full sample.

![Flowchart of search strategy](image)

**Figure 4.3: Search strategy flowchart**

The search results by journal are shown in Table 4.1, indicating that a wide range of disciplines is covered, and that improvement capability is therefore important in a range of areas of study.

**Table 4.1: Articles by journal**

<table>
<thead>
<tr>
<th>Journal</th>
<th>Number of articles</th>
</tr>
</thead>
<tbody>
<tr>
<td>International Journal for Quality in Healthcare</td>
<td>6</td>
</tr>
<tr>
<td>Journal of Operations Management</td>
<td>6</td>
</tr>
<tr>
<td>Total Quality Management and Business Excellence</td>
<td>5</td>
</tr>
<tr>
<td>BMJ Quality and Safety</td>
<td>4</td>
</tr>
<tr>
<td>Decision Sciences</td>
<td>4</td>
</tr>
<tr>
<td>International Journal of Quality and Reliability Management</td>
<td>4</td>
</tr>
<tr>
<td>International Journal of Operations and Production Management</td>
<td>3</td>
</tr>
<tr>
<td>Quality Management in Healthcare</td>
<td>3</td>
</tr>
<tr>
<td>Total Quality Management</td>
<td>3</td>
</tr>
<tr>
<td>TQM Magazine</td>
<td>3</td>
</tr>
<tr>
<td>American Journal of Medical Quality</td>
<td>2</td>
</tr>
<tr>
<td>Health Services Research</td>
<td>2</td>
</tr>
<tr>
<td>Production Planning and Control</td>
<td>2</td>
</tr>
<tr>
<td>TQM Journal</td>
<td>2</td>
</tr>
<tr>
<td>Total number of other journals containing one publication</td>
<td>29*</td>
</tr>
</tbody>
</table>

* Total journals includes literature reviews. Please note some reviews also include the development of an instrument and have not been counted twice.
Figure 4.4 uses the same analysis approach and shows how the development of assessment instruments and frameworks for improvement capability has grown over time since the first instruments were developed during the 1990s.

Figure 4.4: Number of publications over time

**Literature reviews**

The search identified 14 literature reviews with varying inclusion criteria and timeframes: nine reviews of TQM and excellence models; two reviews of maturity models within industrial settings; one review of healthcare organisational assessments; and two reviews of healthcare improvement systems. However, this research study did not identify any reviews that specifically covered literature across sectors, including industrial, service and healthcare settings. Therefore, this research study comprehensively reviews literature from across all sectors and models. A summary detailing the findings of the literature reviews is presented in Table 4.2.
Table 4.2: Summary of the literature reviews

<table>
<thead>
<tr>
<th>Author &amp; year</th>
<th>Title</th>
<th>Sector</th>
<th>Date period</th>
<th>No.</th>
<th>Search terms</th>
<th>Key findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brennan et al. (2012)</td>
<td>Measuring organisational and individual factors thought to influence the success of quality improvement in primary care: a systematic review of instruments.</td>
<td>Healthcare (Primary Care)</td>
<td>Not stated</td>
<td>41</td>
<td>Questionnaire; instrument, instrumentation, instruments; tool; measuring, measures, measure, measurement; QI; organisational change; TQM, CI, change and practice, quality of life</td>
<td>Literature synthesis leading to a common core of factors to support primary care improvement. The critical factors identified are: customer based approach, management commitment &amp; leadership, quality planning, management based on facts, CI, human resources, learning, process management and co-operation with suppliers.</td>
</tr>
<tr>
<td>Doeleman et al. (2013)</td>
<td>Empirical evidence on applying the European Foundation for Quality Management Excellence model: A literature review.</td>
<td>Not stated</td>
<td>2002-2012</td>
<td>24</td>
<td>EFQM</td>
<td>Found that evidence is limited to descriptive research. Concluded that the use of EFQM does improve organisational results, and is an effective tool for benchmarking. Indicated that participative approach, intrinsic motivation and leadership are important driving forces.</td>
</tr>
<tr>
<td>Groene et al. (2013)</td>
<td>A systematic review of instruments that assess the implementation of hospital quality management systems.</td>
<td>Healthcare (Acute)</td>
<td>1990-2011</td>
<td>18</td>
<td>Generic: Quality management systems AND hospital AND instrument (and variations thereof)</td>
<td>Indicates that there is a set of instruments that can assess quality management systems implementation in healthcare. These examine core areas including process management, human resources, leadership, analysis, and monitoring. They differ in areas of conceptualisation and rigour requiring further research.</td>
</tr>
<tr>
<td>Author &amp; year</td>
<td>Title</td>
<td>Sector</td>
<td>Date period</td>
<td>No.</td>
<td>Search terms</td>
<td>Key findings</td>
</tr>
<tr>
<td>--------------</td>
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<td>-----------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Heitschold et al. (2014)</td>
<td>Measuring critical success factors of TQM implementation successfully: A systematic literature review.</td>
<td>Industry</td>
<td>Not Stated</td>
<td>62</td>
<td>TQM, implementation, CSFs AND instrument</td>
<td>Through identification and analysis of critical success factors for TQM, measured quantitatively within industrial settings, a three-level framework with 11 dimensions for TQM is developed.</td>
</tr>
<tr>
<td>Kaplan (2010)</td>
<td>The influence of context on QI success in healthcare: A systematic review of the literature.</td>
<td>Healthcare (Acute)</td>
<td>1980 – 2008</td>
<td>47</td>
<td>TQM, CQI, QI implementation, quality management, PDSA, PDCA, lean management, six sigma Organisational behaviour, culture, teamwork, theory, change, structure</td>
<td>Identified that leadership, culture, data infrastructure and data systems, and length of improvement implementation were important for successful improvement. Indicated that research was limited due to the lack of a practical conceptual model and defined measures and definitions.</td>
</tr>
<tr>
<td>Author &amp; year</td>
<td>Title</td>
<td>Sector</td>
<td>Date period</td>
<td>No.</td>
<td>Search terms</td>
<td>Key findings</td>
</tr>
<tr>
<td>--------------</td>
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</tr>
<tr>
<td>Mehra et al. (2001)</td>
<td>TQM as a management strategy for the next millennia.</td>
<td>Industry</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Thorough review of TQM literature; identifies 45 elements that affect implementation, grouped into five areas - human resources focus, management structure, quality tools, supplier support and customer orientation. Finds that TQM efforts must emphasise self-assessment of capabilities.</td>
</tr>
<tr>
<td>Minkman et al. (2007)</td>
<td>Performance improvement based on integrated quality management models: what evidence do we have? A systematic literature review.</td>
<td>Healthcare (Chronic Care)</td>
<td>1995 – 2006</td>
<td>37</td>
<td>Baldrige, EFQM, MBQA, excellence model, quality award AND chronic care, chronic care model</td>
<td>Found that there is limited evidence that the use of excellence models improves processes or outcomes. Chronic care models show more evidence and further research should focus on integrated care settings.</td>
</tr>
<tr>
<td>Motwani (2001)</td>
<td>Critical factors and performance measures of TQM.</td>
<td>Industry</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Not stated</td>
<td>Following a literature review 45 performance measures of TQM are identified together with seven critical factors.</td>
</tr>
<tr>
<td>Rhydderch et al. (2005)</td>
<td>Organisational assessment in general practice: A systematic review and implications for QI.</td>
<td>Healthcare (Primary Care)</td>
<td>1996 - 2003</td>
<td>13 papers ; 5 assessments</td>
<td>Organisational assessment; assessment method</td>
<td>Review indicated a developing field for measuring aspects of primary care. Found there was a paucity of peer reviewed assessments and assessment focus varied with different perspectives of QI.</td>
</tr>
<tr>
<td>Author &amp; year</td>
<td>Title</td>
<td>Sector</td>
<td>Date period</td>
<td>No.</td>
<td>Search terms</td>
<td>Key findings</td>
</tr>
<tr>
<td>--------------</td>
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<td>-----</td>
<td>--------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Röglinger et al. (2012)</td>
<td>Maturity models in BPM.</td>
<td>Industry</td>
<td>Not stated</td>
<td>10</td>
<td>BPM maturity models</td>
<td>Identified 10 BPM maturity models. Finds that the basic principles and descriptions are well defined, however guidelines on their use and purpose need developing.</td>
</tr>
<tr>
<td>Sila and Ebrahimpour (2002)</td>
<td>An investigation of the TQM survey based research published between 1989 and 2000: A literature review.</td>
<td>Industry</td>
<td>1989 – 2000</td>
<td>76</td>
<td>TQM, strategic QM, QM, best practice, TQ, TQI, business excellence, performance excellence, quality excellence, CI, CQI, QI, QA, world class manufacturing</td>
<td>25 factors identified. Found that more surveys needed to identify the extent factors that contribute to TQM in companies and to understand some of the conflicting results, ideally through longitudinal studies, of which none were identified.</td>
</tr>
<tr>
<td>Van Looy et al. (2012)</td>
<td>A conceptual framework and classification of capability areas for business process maturity.</td>
<td>Industry</td>
<td>Not stated</td>
<td>69</td>
<td>Process maturity</td>
<td>Developed three maturity types: business process maturity, intermediate business process orientation maturity and business process orientation maturity, which represent different levels of capability. Found that there is a lack of consensus on capability areas.</td>
</tr>
<tr>
<td>Wardhani et al. (2009)</td>
<td>Determinants of quality management systems (QMS) implementation in hospitals.</td>
<td>Healthcare (Acute Care)</td>
<td>1992-2006</td>
<td>14</td>
<td>TQM; Quality Assurance healthcare, hospital, implement.</td>
<td>Identified six supporting and limiting factors for QMS implementation: organisational design, culture, quality structure, technical support, and leadership and physician involvement. Found that the degree of QMS implementation is proportional to the degree of employee empowerment, risk free environments and innovation emphasis.</td>
</tr>
</tbody>
</table>
Summary of the literature reviews

The 14 literature reviews were grounded in several different paradigms of quality assurance, improvement and organisational theory and this was reflected in their content. Assessment approaches had developed separately in those paradigms; therefore, despite a growing body of literature, each paradigm had its own distinctive terminology and perspectives on how to conceptualise and assess improvement capability. In some reviews, there was a lack of clarity about the instrument and framework constructs, even in related paradigms, and it is unclear how constructs were interpreted and operationalised due to heterogeneity. For example, literature review articles outlining BPM maturity models (Van Looy et al., 2012; Röglinger et al., 2012) detail elements connected with improvement capability; however, they had different content and coverage of constructs, despite being conducted during a similar period. This highlights the terminological ambiguity of the field, and the challenges of searching within it and synthesising this diverse literature.

Findings

The literature search identified 70 instruments and frameworks that met the search criteria. Data extracted from the papers included the abstract, measurement variables, domains or constructs, assessment method, instrument quality, validity and reliability (for quantitative instruments), and the country and sector it had been used or tested in. A summary of the instruments and frameworks and the extracted data is presented in Appendix I.

Definitions of improvement capability

This review finds that there are many terminological and definitional differences across sectors. Some conceive of improvement capability as a dynamic capability, that is “an organisation-wide process of focused and sustained incremental innovation” (Bessant and Francis, 1999, p1106) while others see it primarily in terms of human capital, as “knowledgeable and skilled human resources” (Kaminski et al., 2014, p29) or in terms of organisational assets as “resources and processes, supporting both the generation and the diffusion of appropriate innovations” (Alder et al., 2003, p14). The definition for improvement capability proposed by Bessant and Francis (1999) was initially used in this review, and related keywords were developed to inform the literature search.
**Measuring improvement capability**

Some authors assert that the lack of operational definition, reliable measures, and evaluation hinders the assessment of improvement capability (Gagliardi et al., 2010), and argue that new robust ways of measuring key constructs are needed (Emmons et al., 2012; Counte and Meurer, 2001). The 70 instruments and frameworks are inductively categorised thematically into four groups or quality improvement paradigms. Table 4.3 illustrates how each group conceptualises improvement capability and the most common measurement constructs.

The instruments and frameworks are further analysed by study location and sector. This shows that approximately half of the instruments and frameworks were developed within the US and 40% were developed in the healthcare sector.
### Table 4.3: Thematic group

<table>
<thead>
<tr>
<th>Group</th>
<th>No. in group</th>
<th>Conceptualisation of improvement capability</th>
<th>Common constructs (used in &gt;25% of group)</th>
<th>Source/Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement models</td>
<td>43</td>
<td>Assumes that defects can be prevented and eliminated through proactive approaches, and this is inherently part of improvement capability.</td>
<td>Leadership; Customer focus; Strategy and policy; Measurement, benchmarking and information; Suppliers, stakeholders and partnerships; Skills and training; CI practices and tools; Communication; People and human resource management</td>
<td>Adam (1994); Adam et al. (1997); Adebanjo and Kehoe (1999); Ahire et al. (1996); Anand et al. (2009); Anderson et al. (1995); Baidoun (2003); Batalden and Stoltz (1993); Benson et al. (1991); Black and Porter (1996); Bou-Llusar et al. (2009); Claver et al. (2003); Criado and Calvo-Mora (2009); Dahlgaard et al. (2011); Douglas and Judge (2001); European Foundation for Quality Management (2014); Flynn et al. (1994); Deming Prize Committee (2014); Kaplan et al. (2013); Lakhal et al. (2006); Lammers et al. (1996); Lee et al. (2002); Mohanty and Lakhe (1998); Morris et al. (1999); National Institute of Standards and Technology (2013-14); Parker et al. (1999); Peng et al. (2011); Politis and Siskos (2010); Powell (1995); Prybutok and Ramasesh (2005); Pun (2002); Rao et al. (1999); Saraph et al. (1989); Shortell et al. (1995); Valmohammadi (2011); Wali et al. (2003); Warwood and Antony (2003); Wu et al. (2010); Zeitz et al. (1997); Zhang et al. (2007)</td>
</tr>
<tr>
<td>Maturity models</td>
<td>9</td>
<td>Assumes that quality practices to eliminate defects are learned over time, embedded across organisations, are path dependant, and that this significantly affects improvement capability.</td>
<td>Strategy and policy; CI practices and tools; Leadership; Culture; Customer focus; Suppliers, stakeholders and partnerships; Skills and training; Organisational learning and knowledge; process design and conformance; Measurement, benchmarking and information</td>
<td>Bessant and Francis (1999); Software Engineering Institute (2006); Cronemyr and Danielsson (2013); Hammer (2007); Jochem et al. (2011); Joly et al. (2012); Lombarts et al. (2009); Nightingale and Mize (2002); Yen-Tsang et al. (2012)</td>
</tr>
<tr>
<td>Group</td>
<td>No. in group</td>
<td>Conceptualisation of improvement capability</td>
<td>Common constructs (used in &gt;25% of group)</td>
<td>Source/Author</td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------------</td>
<td>-------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Change models</td>
<td>12</td>
<td>Assumes the way changes are managed influences the success or otherwise of improvement activity. Assumes that improvement capability is influenced significantly by cultural and contextual dimensions</td>
<td>Leadership, skills and training; Quality management and governance; Culture; Strategy and policy; CI practices and tools; Results and outcomes; Mind-set; Communication; Environmental and historical context</td>
<td>Benn et al. (2012); Berlowitz et al. (2003); Bobiak et al. (2009); Gagliardi et al. (2010); Judge and Douglas (2009); Kianto (2008); Klemenc-Ketiš et al. (2013); Olsson et al. (2003); Robert et al. (2011); Schwartz et al. (2010); Solberg et al. (2008); Ulrich and Lake (1991)</td>
</tr>
<tr>
<td>Governance models</td>
<td>9</td>
<td>This group takes an increased quality control, assurance, and compliance focus on quality. Takes a risk based view, and assumes that these risks may prevent quality and must be managed, and thus this is inherently part of improvement capability.</td>
<td>Leadership; Customer focus; Suppliers, stakeholders and partnerships; Skills and training; Culture; Strategy and policy; People and human resource management; Measurement, Benchmarking and Information; CI practices and tools; Customer/patient involvement</td>
<td>Ismail et al. (2009); Ivanovic and Majstorovic (2006); Lobo et al. (2012); Schilling et al. (2010); Secanell et al. (2014); Silimperi et al. (2002); Terziovski and Dean (1998); Wagner et al. (1999); Yeung et al. (2003)</td>
</tr>
</tbody>
</table>
**Improvement models**

The improvement models group includes assessment approaches that focus on organisation-wide efforts to develop climates in which the organisation continuously improves its ability to deliver high-quality products and services to customers. Many instruments and frameworks in this group are based on the theoretical work by Anderson et al. (1995).

From the 70 instruments and frameworks identified, 40 (57%) conceptualise improvement capability as being grounded in improvement models, where self-reflection, assessment and external review provide critical feedback and an opportunity to improve. These instruments and frameworks focus on constructs such as leadership, strategy, customer focus, stakeholder engagement and CI, identified by Deming and other quality leaders to develop the frameworks and scales as attempts to measure and provide empirical data for TQM and its critical factors and constructs. Three frameworks and instruments relate to quality awards, requiring self-assessment before submitting an application for detailed external assessment through site visits. The remaining instruments and frameworks, bar two (Dahlgaard et al., 2011; Batalden and Stoltz, 1993), are externally administered cross-sectional surveys or structured interviews (Criado and Calvo-Mora, 2009; Claver et al., 2003). Some instruments and frameworks (Black and Porter, 1996; Powell, 1995; Flynn et al., 1994; Saraph et al., 1989) are designed for manufacturing plants rather than for organisations, and often include very specific binary indicators, such as whether a statistical process control is used. A minority of the improvement models group of instruments and frameworks originate in healthcare (Batalden and Stoltz, 1993; Douglas and Judge, 2001; Kaplan et al., 2013).

**Maturity models**

The maturity models group includes assessment approaches that examine the degree of formality and optimisation of processes, from ad hoc practices to pro-active optimisation and processes over time, with many building on Crosby’s maturity grid (1979).

Nine instruments and frameworks take a maturity perspective on improvement capability. The maturity model approach assesses constructs typically against five or six levels of maturity, usually ranging from ‘novice’ or ‘not implemented’, through to ‘expert’ or ‘fully implemented’. These are used to identify priority areas for
organisations to develop capabilities. For example, the Bessant and Francis (1999) maturity model is similar in concept to the maturity grid developed by Crosby (1996). Many capability maturity models in particular, are variants of the Standard Appraisal Method for Process Improvement (SCAMPI) (Software Engineering Institute, 2006) and a detailed review of maturity models has been completed by Van Looy et al. (2012). The instruments and frameworks in this group are mostly designed to be used for self-assessment or external assessment by accrediting organisations. This group also focuses on leadership, strategy and customer focus, but most lack constructs related to people/customers and to stakeholders.

**Change models**
The change models group assessment approaches that focus on the human side of change and improvement, examining individual and organisational behaviours and the conditions and context that nurture change and improvement capabilities. Constructs include culture and leadership, developed initially from the work by Ulrich and Lake (1991).

There are eight instruments and frameworks in the change model group and these have an organisational development perspective on improvement capability and emphasise that leadership of CI practices are key factors in improvement capability (for example Ulrich and Lake (1991)). The majority of these instruments and frameworks originate in healthcare and all but one, utilise interviews or survey multiple staff within the sampled organisations. Most constructs relate to aspects internal to an organisation. Only one instrument in this group (Bobiak et al., 2009) includes a customer focus construct, and only two include a stakeholder construct, indicating a limited focus on alignment with external requirements by the instruments and frameworks.

**Governance models**
The governance models group includes assessment approaches that examine systematic policies and management systems to manage risk through assessment and comparison with standards within organisations. These instruments and frameworks are quite diverse, but a number develop from the initial work of Wagner et al. (1999).
The nine instruments and frameworks in the governance models group take an assurance and rules-based perspective on improvement capability. All are designed to be administered by a third party except for Schilling et al. (2010), where a central corporate function administers the framework to many hospitals within its organisation. The Deepening our Understanding of Quality Improvement in Europe (DUQuE) project (Groene et al., 2010; Secanell et al., 2014; Wagner et al., 2014) has several scales and indices to measure different aspects of quality management for comparison between organisations. The main constructs in this group are almost identical to that within the improvement models group, but with an additional emphasis on culture.

**Development of the concept**

The development of measures of improvement capability commenced in the mid-1990s in industrial operations management and healthcare, and focused on determinants of performance improvement and TQM or continuous quality improvement (CQI). These initial instruments and frameworks examine whether elements of TQM or other improvement models are in place, on the presumption that there are causal links between these elements and performance results. These instruments often gain views from only one or two people in the organisation regarding the implementation of improvement, carrying the risk of bias from respondents (Heitschold et al., 2014), and do not provide further information about the spread or depth of implementation.

New streams of research from the late 1990s onwards have addressed this issue, attempting to assess implementation maturity and the embeddedness and consistency of implementation. Whilst the notion of organisational capabilities for change was developed in the early 1990s (Ulrich and Lake, 1991), frameworks and instruments using these definitions developed later during the 2000s, seemingly independently from other instruments and frameworks. Throughout this timeframe there has been ongoing development of instruments and frameworks that take a compliance orientation, focusing on identifying risks and defects, and developing improvement actions based on the results.
Assessment approach

The instruments and frameworks use differing methods to gather data. Two-thirds (66%) of the instruments and frameworks identified are employee surveys designed for use at one point in time, and few have been used longitudinally. The remainder are one-off assessments using case studies and interviews, generally designed for benchmarking across organisations or subsections, such as manufacturing plants, business units or clinical departments. They identify strengths and weaknesses within an organisation against a defined standard, or between other organisations and units.

Sampling approaches and response rates

The sampling size, approach and response rates vary considerably within the survey instruments identified and a third party or corporate body usually undertakes data collection. Two-thirds of the surveys involved contacting only one or two respondents within an organisation (see Solberg et al. (2008)), and whilst these individuals may have considerable knowledge to complete the survey, their responses may not adequately represent their organisation. The remainder use cross-sectional samples with many respondents from an organisation (see Kianto (2008)) or collect data via interviews and observations. Samples in studies of instruments and frameworks range from 2,142 respondents across seven organisations (Schwartz et al., 2010) to single responses from 1,082 organisations (Wagner et al., 1999) and 25,940 respondents from 188 organisations Secanell et al. (2014). Response rates are variable, ranging from 6% in a sub-sample (Wu et al., 2010) to 100% (Baidoun, 2003; Solberg et al., 2008). Little attention is given to the potential biases arising from different sampling methods, sample sizes and response rates.

Instrument and framework use

There are few papers which describe how the results of the assessments are used. Publicity material from the quality award frameworks (National Institute of Standards and Technology, 2013-14; Deming Prize Committee, 2014; European Foundation for Quality Management, 2014) state that they are highly used, valued and imitated. However, no single instrument or framework for measuring improvement capability seems to be widely utilised.
Comparison of instrument and framework constructs

Analysis of the instrument and framework constructs reveals that there is wide heterogeneity (Table 4.3), reflecting the paradigmatic divergence in the models and the diverse terminology employed. No construct is included in all the frameworks and instruments identified. Pareto analysis (Figure 4.5) of the constructs reveals that 22 constructs account for 80% of those measured, and the most frequent relate to leadership, suppliers and partners, customer focus, measurement, skills, training, and improvement practices. Within the groups for each model there is more consistency, with a maximum of 10 constructs accounting for 80% of the total within each group, except for the maturity models group which has 16. Construct differences may relate to the sector and area being improved. For example, to improve organisational culture it may be more important to use factors linked to the main constructs within the change models and dependent upon sector, and this may assist with instrument selection to ensure that terminology used fits with the area under investigation.

It was notable that no instruments or frameworks included constructs that measured or assessed the level of embeddedness of improvement capability. This might mean that the instruments and frameworks focused on the current improvement capability but were not designed to assess the future trajectory of development of improvement capability (Su et al., 2014).
Figure 4.5: Frequency of constructs
Improvement capability dimensions

Four groups of improvement capability assessment instruments and frameworks are outlined in this paper. Within the 70 instruments and frameworks identified, 40 (57%) are categorised as improvement models, and a further nine (13%) are categorised as governance models (which has quite similar constructs). A further inductive analysis across all instruments was undertaken, and this led to the development of a synthetic framework of eight dimensions of improvement capability. These were: organisational culture; data and performance; employee commitment; leadership commitment; service-user focus; stakeholder and supplier focus; process improvement and learning and strategy and governance. Descriptions were developed for each dimension using the individual definitions of items and constructs identified in the literature and are shown in Table 4.4.

Table 4.4: Improvement capability dimensions

<table>
<thead>
<tr>
<th>Improvement capability dimension</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organisational culture</td>
<td>Core values, attitudes and norms and underlying ideologies and assumptions within an organisation</td>
</tr>
<tr>
<td>Data and performance</td>
<td>Use of data and analysis methods to support improvement activity.</td>
</tr>
<tr>
<td>Employee commitment</td>
<td>Encompasses the level of commitment and motivation of employees for improvement.</td>
</tr>
<tr>
<td>Leadership commitment</td>
<td>Described as the support by formal organisational leaders for improvement and performance.</td>
</tr>
<tr>
<td>Process improvement and learning</td>
<td>Systematic methods and processes used within an organisation to make ongoing improvement through experimentation.</td>
</tr>
<tr>
<td>Service-user focus</td>
<td>Relates to the identification and meeting of current and emergent needs and expectations from service users.</td>
</tr>
<tr>
<td>Stakeholder and supplier focus</td>
<td>Extent of the relationships, integration and goal alignment between an organisation such as public interest groups, suppliers and regulatory agencies.</td>
</tr>
<tr>
<td>Strategy and governance</td>
<td>Represents the process in which organisational aims are implemented and managed through policies, plans and objectives.</td>
</tr>
</tbody>
</table>

The eight dimensions identified from the literature on the assessment of improvement capability could be seen as eight high level routines that when assembled together in particular ways, bundle to form ‘improvement capability’. The eight dimensions include two which could be seen specifically as those routines
that help to understand and pro-act or react to the changing environment, entitled service-user focus and supplier and stakeholder focus. Service-user focus is critical as customer satisfaction and the ability to respond quickly to changing demands affects the success or failure of an organisation (Mehra et al., 2001; Heitschold et al., 2014). Stakeholder and supplier focus represents customers and suppliers that are not service users, for example service commissioners, regulatory agencies, patient representative groups, pharmaceutical and medical device suppliers, and healthcare charities.

The remaining dimensions represent organisational routines and include the decision-making processes within leadership routines. These make explicit the choice of ‘do we change in reaction or anticipation to the insights we have identified’ and the intent to so do so, together with the routines that put these decisions into practice.

Assessment of instrument and framework quality
The empirical testing of instruments and frameworks has two main properties: reliability and validity (Carmines and Zeller, 1979). The reliability of instruments and frameworks is concerned with the level of random measurement error and consistency (Flynn et al., 1990). Internal consistency measures how well different items in scales vary together within a sample and is typically measured through Cronbach’s alpha (1951; Nunnally, 1994), and scales should possess a reliability of >0.8 (Carmines and Zeller, 1979). Out of the 70 instruments and frameworks identified, 44 (63% of total) included reliability information, most using Cronbach’s alpha; however, only 14 instruments and frameworks (20%) reported values above 0.8 (see Berlowitz et al. (2003); Ismail et al. (2009)).

The validity of instruments and frameworks is concerned with if they actually measure what is intended (Litwin, 1995) and how closely the measure relates to the underlying concept. Poor validity arises through non-random measurement error that has a systematic biasing impact (Carmines and Zeller, 1979). There are three main forms of validity: content, criterion and construct. Construct validity is proposed by Carmines and Zeller (1979) as being central to validity measurement in social science. It assesses the relationships between measures within instruments and frameworks, and their consistency with theory. It includes two elements of validity,
convergent and divergent (or discriminant), which assess if different methods for
obtaining information produce similar results and whether the measurement area is
distinct (Litwin, 1995). Construct validity is measured through factor analysis for
each construct, requiring one-dimensionality (Claver et al., 2003). Poor construct
validity indicates theoretical flaws or the inability of the construct to measure what is
intended.

Half of the papers on instruments and frameworks reported construct validity, but
their use of different construct validity measures hinders comparison. For example,
Ahire et al. (1996) and Bou-Llussar et al. (2009) use the Bentler-Bonett measure
(1980) for convergent validity, with all results being above or close to 0.9 thereby
indicating strong validity, whereas Flynn et al. (1994) assess construct validity via
factor analysis. Most self-assessment and qualitative frameworks have little
information regarding framework validity and reliability, although some describe
how team consensus and researcher reflexivity is used to build in reliability and
trustworthiness, including Bessant and Francis (1999) and Robert et al. (2011). An
overview of instrument reliability and validity is provided in Appendix I, which
shows that overall, there is limited focus on reliability and validity, particularly
construct validity within the existing instruments and frameworks.

Discussion and implications

This research study has found that there is wide heterogeneity across the 70
instruments and frameworks for assessing improvement capability which have been
reviewed. It is interesting that none have become mainstream across sectors and
geographies, while only a few have been tested properly for validity and reliability.
Further, many of the constructs within the instruments and frameworks are
somewhat ambiguous and inter-related, and there are widespread differences in
conceptualisation, definitions and terminology used. This heterogeneity may be a
reflection of different paradigmatic perspectives or conceptualisations of
improvement capability. For example, a narrow definition of improvement
capability focused on improvement methods and data might lead to measurements of
aspects such as improvement skills and training and could likely lead to actions such
as setting up an improvement training programme, where the numbers completing
the programme are tracked. In contrast, a more people-centred perspective could
lead to a focus on understanding patient and staff experiences and contributions to
improvement capability, and a much more qualitative and relational approach to assessing and developing improvement capability.

The synthetic framework of eight dimensions of improvement capability presented in this paper represents a pluralistic perspective of improvement capability and seeks to balance the different paradigmic approaches identified. This recognises that measures of different dimensions may be appropriate for different purposes and usages. For example, regulatory agencies still need to make judgement assessments in order to fulfil their roles of accountability and assurance, as well as improvement. Patients and the public may expect regulatory agencies to assess organisational improvement capability. This means that regulatory agencies need to be more explicit and transparent about the paradigm they are taking to conduct their business to support selection and development of an appropriate operational definition and associated assessment instrument or framework. This will clarify the strengths and risks of selecting such an instrument or framework, allowing stakeholders, including patients, to recognise potential blind spots in the assessments. It will also clarify accountability and assurance requirements for organisations being assessed.

The choice of perspective of improvement capability and associated instrument or framework may be contingent on organisational requirements and context. For example, a regulatory agency wishing to assess and compare multiple organisations on their improvement capability may focus on dimensions such as strategy and governance, leadership commitment and data and performance; while an organisational development consultancy advising organisations might find it more useful to focus on dimensions such as organisational culture, employee and leadership commitment and service-user focus.

There are many areas of commonality across the instruments and frameworks, and approaches such as dynamic capabilities theory (Vogel and Güttel, 2013) could be useful both in synthesis and in providing the theoretical foundation for the development of future measures of improvement capability. Vogel and Güttel (2013) note that the DCV literature, like that on measures of improvement capability, has rather less focus on some perspectives from organisational theory, such as leadership and change management. Therefore, it could provide a basis for the conceptual synthesis of the dimensions found in this research, prior to empirical testing.
This integrative review has identified gaps related to conceptualisation, instrument quality, particularly validity, and uptake. It is striking that few of the papers presenting instruments and frameworks focused on how, where and for what purposes, they might be used. Research in this area could concentrate on understanding this further in order to test if there is a linkage between the conceptualisation of improvement capability, the purpose for which it is being used, and its take up and use.

**Conclusions**

This review provides a comprehensive overview of the current research literature on conceptualising and measuring improvement capability in organisations, and we can identify several fruitful avenues for further research. First, the detailed conceptualisation of improvement capability requires more attention, drawing on relevant theoretical frameworks such as the literature on dynamic capabilities to provide a more coherent and consistent theoretical foundation for work in this area. Second, the absence of any widely accepted, empirically tested and validated instruments and frameworks for assessing improvement capability suggests that the development of such an instrument is needed, and this review and the synthetic framework we have presented may be the first step in that process. Third, the utility of measures of improvement capability, their deployment and uptake in organisations, and the effects this may have on improvement and performance are a much-neglected area needing further research.
References


Chapter 5 - Paper 2: Emerging hybridity: comparing UK healthcare regulatory arrangements

Joy Furnival, Kieran Walshe and Ruth Boaden

Introduction to paper 2

Paper 1 (Furnival et al., in development-a) detailed an integrative review of the literature on assessment instruments and frameworks for improvement capability across sectors. These had a variety of users, including regulators, accreditation organisations and national oversight bodies. Paper 2 (Furnival et al., under review) examines regulatory agencies’ perspectives of improvement capability, rather than such a wide range of users. It focuses on the NHS in the UK through a review of six organisational regulatory agencies that oversee acute care within devolved health systems.

This paper compares the regulatory arrangements, priorities, plans and methods in use by regulatory agencies. It uses documentary analysis and interviews to compare the different enforcement policies and practices used by regulatory agencies. In line with the large variety of perspectives of improvement capability identified through the literature review, the regulating agencies also have diverse perspectives of improvement capability, and articulated a will to develop it. This was evidenced through the identification of an emergent trend; whereby regulatory agencies were employing both deterrence and compliance enforcement strategies concurrently.

Three tensions of such hybrid strategies are explored in the paper: roles, resources and relationships, and relate to the tensions between holding to account and developing co-operation to develop improvement capability. The paper suggests potential ways to reconcile these tensions and their impact by strengthening the regulatory assessment of improvement capability.

References

Abstract

Purpose
Healthcare regulation is one means to address quality challenges in healthcare systems and is carried out using compliance, deterrence and/or responsive approaches. The four countries of the UK provide an opportunity to explore and compare different regulatory models. The aim of this paper is to understand emerging regulatory models and associated tensions.

Methodology
This paper uses qualitative methods to compare the models using template analysis through coding of documentary and interview data. Data was collected from 48 interview participants representing a cross-section of roles from six organisational regulatory agencies. Documents, including board papers, inspection guidelines and policies, were analysed.

Findings
The analysis highlights that effective regulatory oversight of quality is contingent on the ability of regulators to balance their requirements to assure and improve care. The findings show that regulatory agencies in the four countries of the UK have different approaches and methods of delivering their missions. Nevertheless, they face common problems which relate to the level of alignment between their stated goals, methods, and stakeholder relationships, including with those that they regulate. This paper reports that new hybrid regulatory models are being developed which use improvement support interventions in parallel with deterrence and compliance approaches.

Originality/Value
This paper shows through its comparison of UK regulatory agencies that the development and implementation of hybrid models is complex. It contributes to the research by identifying three tensions related to hybrid regulatory models: roles, resources and relationships.

Keywords
Regulation; Quality; Quality Assurance; Hybridity; Compliance; Quality Improvement

Article Classification: Research Paper
Introduction

In the four countries of the UK different healthcare regulatory arrangements have developed, which provides an opportunity to study these different healthcare regulatory models.

The purpose of this paper is:

- To understand and analyse healthcare regulatory models within the UK
- To identify regulatory model developments
- To understand the tensions related to the development of new regulatory models

The paper is organised as follows: first, the background outlines the relevant regulatory theoretical concepts; next, the method and scope of the paper is detailed; and finally, the current regulatory architecture and the trend towards the use of hybrid models and associated tensions are described in the findings and discussion. The paper concludes by outlining the contribution of the work.

Healthcare regulation

Regulation can be defined as ‘sustained and focused control exercised by a public agency over activities which are valued by a community’ (Selznick, 1985, p363). Regulation arises for several reasons, including the need to adjust for market failures, unequal bargaining power, critical goods shortages, or moral hazards (Feintuck, 2012), where the consumer pays indirectly for services or to reduce discrimination and further social solidarity (Prosser, 2006). Healthcare regulation addresses stakeholders’ demands for improved performance.

Walshe (2003b) describes three main aims of regulation: improvement, assurance and accountability, together with three regulatory models: compliance, deterrence (Reiss, 1984) and responsive (Ayres and Braithwaite, 1992). Deterrence models assume that organisations are ‘amoral’ (Bardach and Kagan, 1982) and will deliberately break rules, thus compliance must be enforced. In contrast, compliance models assume organisations will seek to comply with regulatory requirements if they can, and focus on persuasion and encouragement rather than formal or punitive enforcement.
Responsive regulation emphasises the combination of both ‘deterrence’ and ‘compliance’ models (Ayres and Braithwaite, 1992; 2007). This flexible model allows regulators to choose their approach depending on performance or risk levels (Parker, 2013). Regulatory intervention escalates (or de-escalates) through a hierarchy as performance changes. This form of regulation assumes that trust-based models will improve care more effectively (Ayres and Braithwaite, 1992; 2007), and is more suited to organisations and sectors seeking long-term improvement, but it is challenging to sustain with large numbers of organisations.

In this paper a responsive regulatory model is described as a ‘hybrid’ model, and the term is used to refer to a regulatory agency that uses a combination of deterrence and compliance models. McDermott et al. (2015) describe hybrid regulators who simultaneously use compliance and deterrence models to support performance improvement, building on the perspective that hybridisation is a process in which plural underpinning assumptions and logics are in play within an organisation (Skelcher and Smith, 2015).

There are three main regulatory processes: direction, detection and enforcement. Direction defines standards and removes systemic barriers through the provision of external policy impetus, while detection refers to the measurement and monitoring of performance. Enforcement is central to regulation and covers the methods used to educate, persuade, influence and force behavioural change (Hutter, 1989; Walshe and Shortell, 2004).

Regulation provides valuable feedback supporting improvement and requires high standards of performance to be maintained, which otherwise may not be (Gunningham, 2012); despite this, it is often critiqued. Flodgren et al. (2011) finds a lack of effectiveness, while other problems include high costs (Ng, 2013), inflexibility (Brennan, 1998), tunnel vision (Mannion et al., 2005), inhibiting innovation (Stewart, 1981), provider capture (Boyd and Walshe, 2007), ritualistic and bureaucratic compliance (Braithwaite et al., 2007), a short term focus (Walshe, 2003b), loss of autonomy (Donabedian, 1988) and the generation of fear (Berwick, 2013).

Recognising the limits of deterrence and compliance regulatory models, alternative supportive and more contingent models using professionalism and improvement
support are increasingly proposed (Ham, 2014). These models are intended to ensure that healthcare systems can deliver high performance and can be viewed as a variation of responsive regulation. However, there are few studies (e.g. McDermott et al., 2015) which have analysed the impact and influence of these emerging models. This paper contributes to knowledge through a comparative analysis of healthcare regulatory agencies across the UK.

**Methodology**

This paper focuses on the six UK organisational regulatory and scrutiny agencies, namely the Care Quality Commission (CQC), Monitor, Trust Development Authority (TDA) in England\(^1\), Healthcare Inspectorate Wales (HIW), Healthcare Improvement Scotland (HIS), and the Regulatory and Quality Improvement Authority (RQIA) in Northern Ireland. Hospital-based care is the main area of focus for this paper, since it accounts for the majority of healthcare expenditure in the UK and all four countries oversee this healthcare area.

Following ethical approval to proceed, the research study identified and analysed healthcare policy documents from each devolved country that included information related to regulatory purpose, strategy, and results. In addition, a cross-section of 48 employees were interviewed. Initial contact via the Directors of policy, strategy or regulation within the agencies assisted in the identification of a cross-section of interview participants. The interview participants held a variety of roles, including board-level executives and inspectors, with a mixture of clinical and non-clinical backgrounds from each regulatory agency. Participation was voluntary and confidential. The interviews took place between October 2014 and April 2015. Details of the interview sample are shown in Table 5.1.

\(^1\) Since this research was completed Monitor and the TDA have become part of the same organisation with the operational name of NHS Improvement.
Table 5.1: Interview sample

<table>
<thead>
<tr>
<th>Agency</th>
<th>Number of interview participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIS</td>
<td>8</td>
</tr>
<tr>
<td>HIW</td>
<td>9</td>
</tr>
<tr>
<td>RQIA</td>
<td>9</td>
</tr>
<tr>
<td>CQC</td>
<td>8</td>
</tr>
<tr>
<td>Monitor</td>
<td>7</td>
</tr>
<tr>
<td>TDA</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
<td>48</td>
</tr>
</tbody>
</table>

This research study used a semi-structured interview process based on the documentary analysis (Thomas, 1993). Questions included ‘what is the aim and purpose of this agency?’, and ‘what types of interventions do you use and why?’, and testing of the questions took place through five pilot interviews. Interview participants were provided with copies of the transcripts to allow for any clarifications. The use of interviews allowed complex, subjective, and sometimes contradictory, data to be collected from participants that could not be gathered via other approaches. The data collected from interviews and documents was analysed iteratively using an a priori coding template developed from the literature. This was used to compare the current regulatory architectures, models and aims, and supported the organisation and interpretation of data through the identification of themes.

**Results**

The results are presented in three sections. with the first section introducing the landscape of regulatory architecture in the UK, while the second section compares regulatory designs across the UK. The final section explores the tensions facing regulatory agencies when using hybrid models.

**The UK regulatory architecture**

This section outlines the current regulatory architecture and scope within each UK country, summarised in Table 5.2 and 5.3.
Table 5.2: Agency comparison

<table>
<thead>
<tr>
<th>Country and population</th>
<th>Name</th>
<th>Staff (WTE)</th>
<th>Expenditure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scotland: 5.3M</td>
<td>Healthcare Improvement Scotland (HIS)</td>
<td>329</td>
<td>£20M (14/15)</td>
</tr>
<tr>
<td>Wales: 3M</td>
<td>Healthcare Inspectorate Wales (HIW)</td>
<td>59</td>
<td>£3M (14/15)</td>
</tr>
<tr>
<td>Northern Ireland: 1.8M</td>
<td>Regulatory &amp; Quality Improvement Authority (RQIA)</td>
<td>152</td>
<td>£7.6M (13/14)</td>
</tr>
<tr>
<td>England: 53M</td>
<td>Care Quality Commission (CQC)</td>
<td>2681</td>
<td>£240M (14/15)</td>
</tr>
<tr>
<td>England: ~149 FTs</td>
<td>Monitor</td>
<td>532</td>
<td>£72.3M (14/15)</td>
</tr>
<tr>
<td>England: ~90 non-FTs</td>
<td>Trust Development Authority (TDA)</td>
<td>315</td>
<td>£65M (14/15)</td>
</tr>
</tbody>
</table>

HIS was established in 2011 and combines a number of predecessor Scottish organisations. Its aim and purpose is to advance improvement in healthcare in Scotland, and to support providers to deliver safer, more effective and more person-centred care. HIS does not review social care services, and a separate inspectorate oversees this.

HIW was established in 2004 and is a unit of the Welsh Assembly Government. It has wide-ranging responsibilities, including inspections of health boards and trusts, the regulation of independent healthcare providers, general practices, pharmacies and dental practices. Like HIS, HIW does not oversee social care services.

RQIA was established in 2005 and is the main scrutiny body for Northern Ireland’s care system, where it provides independent assurance about the quality of health and social care services. It aims to regulate, scrutinise and drive improvements in health and social care services.

In England, the regulatory architecture is more fragmented, and there are three main healthcare provider regulatory agencies, the CQC, TDA and Monitor. All of them have overlapping roles, assuring quality in care services in hospital, community, mental health and ambulance services, yet despite this, each have different remits, scopes and focuses.

The CQC was formed as a single integrated regulator in 2009 from a merger of predecessor organisations. CQC’s purpose is to ensure health and social care
services provide people with high quality care and to encourage improvement (Care Quality Commission, 2013), which is achieves largely through inspections. The CQC covers a wide range of services across the care spectrum, including primary care, community care, social care, mental health, dentistry and acute care in 56,000 care delivery locations in England (Care Quality Commission, 2015).

The English National Health Service (NHS) has been pursuing a policy to develop Foundation Trusts (Walshe, 2003a). Monitor is the sector regulator of Foundation Trusts in England, a non-departmental public body of the Department of Health. Established in 2004, Monitor’s role was to authorise, monitor and regulate Foundation Trust finances, quality and performance. However, following the Health and Social Care Act in 2012, its role now extends to include price setting, preventing anti-competitive behaviour whilst promoting care integration, and protecting health services if providers become unsustainable.

The TDA is a special health authority of the Department of Health set up following the Health and Social Care Act in 2012. It provides the oversight, scrutiny, and performance management of non-Foundation Trusts on behalf of the Department of Health and develops them into Foundation Trusts. The TDA does not have formal regulatory powers.

**Comparison of regulatory agencies across the UK**

Table 5.3 details the scope of each of the regulatory and scrutiny agencies. All of them oversee NHS acute, community, mental health and ambulance care within their respective country.
There are substantial differences, for example the CQC and RQIA also oversee social care, whereas HIS, HIW, Monitor and the TDA do not, and others have unique specialist responsibilities, such as HIW for pharmacies. This means that each regulator has different volumes and types of healthcare organisations to oversee with responsibility for different cohorts of the UK population; consequently, a common denominator for comparison is difficult to identify. For example, the TDA only oversees approximately 90 NHS organisations, whereas the CQC inspects almost 56,000 care delivery locations (Care Quality Commission, 2015).

Despite this, some comparisons can be made. The £3 million budget for HIW seems remarkably small considering the range of work it completes, particularly when compared to RQIA, which has over double the budget for a smaller population, even after accepting that RQIA has additional social care responsibilities. HIW’s budget also seems small compared to HIS, with population differences, the requirement for HIS to develop health councils and standards, and developing improvement programmes perhaps accounting for the differences.

The CQC has over 56,000 locations to scrutinise and a budget of £240M, whereas Monitor and TDA have significantly fewer organisations to scrutinise and yet their

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**Table 5.3: Regulatory scope**

<table>
<thead>
<tr>
<th></th>
<th>HIS</th>
<th>HIW</th>
<th>RQIA</th>
<th>CQC</th>
<th>Monitor</th>
<th>TDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>Community</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>Mental health</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>Ambulance</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>Primary care</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Dentistry</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Pharmacies</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Social care</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Commissioning</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
<td></td>
<td>x</td>
<td></td>
</tr>
<tr>
<td>Independent sector</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NHS Trusts or Boards (non FTs)</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
</tr>
<tr>
<td>NHS FTs</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>×</td>
<td>×</td>
<td></td>
</tr>
</tbody>
</table>

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182
expenditure in 2014/15 together equals over half that of the CQC. Furthermore, the TDA’s expenditure is approximately £237k more per organisation than Monitor (£722k versus £485k, respectively). This may partly reflect additional monies allocated through the TDA to organisations as financial support.

All six agencies have been established since 2004, with the most recent being the TDA in 2012, and all except the TDA have seen growth in their scope since their establishment. This often follows emerging quality failures, for example in Lanarkshire, Scotland (Healthcare Improvement Scotland, 2013b). All four countries have held inquiries into cases of poor care, which have affected the scope, responsibilities and the regulatory model used (Table 5.4).
### Table 5.4: Impact of responses to quality issues on regulatory agencies

<table>
<thead>
<tr>
<th>Agency</th>
<th>Issue</th>
<th>Response</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIW</td>
<td>Care concerns at Abertawe Bro Morgannwg University (ABMU) Health Board and wider concerns about effectiveness of HIW.</td>
<td>Trusted to Care Independent Review (Andrews and Butler, 2014); HIW Review (Marks, 2014)</td>
<td>Independent review of concerns at ABMU and the Welsh Health and Social Care Committee review of HIW in 2013. Followed by a formal review of HIW (Marks, 2014).</td>
</tr>
<tr>
<td>RQIA</td>
<td>Incidents at Belfast Health and Social Care Trust and Northern Care Health and Social Care Trust.</td>
<td>Instigated reviews by RQIA of the Trusts concerned. The Minister in parallel initiated a review of the Northern Irish health and social care system (Donaldson et al., 2014)</td>
<td>The review of the health and social care system found that RQIA had little visibility and the healthcare system needed to strengthen its approach to improving quality.</td>
</tr>
<tr>
<td>CQC</td>
<td>High mortality rates and patient neglect at Mid-Staffordshire NHS Foundation Trust, similar failings at other sites.</td>
<td>The Mid Staffordshire Inquiry (Francis, 2013), Morecambe Bay Inquiry (Kirkup, 2015), Winterbourne View (Department of Health, 2012).</td>
<td>Development of a new inspection approach based on the NHS England reviews of high mortality trusts conducted in response to the Francis Inquiry.</td>
</tr>
<tr>
<td>Monitor</td>
<td>As CQC</td>
<td>As CQC</td>
<td>Change in role following 2012 Health and Social Care Act.</td>
</tr>
<tr>
<td>TDA</td>
<td>As CQC</td>
<td>TDA did not exist during the time of these issues; however, the impact of them influenced the design of the organisation.</td>
<td>Established following 2012 Health and Social Care Act.</td>
</tr>
</tbody>
</table>
It is not clear how the regulatory agencies choose the processes they use to discharge their regulatory responsibilities, but often this seems to be in reaction to the national and political context, rather than through a deliberative process. This suggests that the regulatory agencies are path-dependent in how they deliver their regulatory aims of improvement, assurance and accountability, reacting to the external environment, rather than making an explicit choice of regulatory model.

This paper analyses the specific goals and regulatory models of each agency. Table 5.5 provides a summary of this analysis, and is further supplemented by Table 5.6. Categorising the regulatory model for each agency was not simple, as the models can be viewed as a continuum and there is not an easy dividing line, as each agency may demonstrate aspects of several regulatory models. For this analysis, the dominant model in use is shown. The term ‘hybrid’ is used to illustrate an emergent responsive regulatory approach, whereby regulatory agencies are primarily using enforcement methods that comprise of improvement support through direct action, and that this is tailored contingent on organisational circumstances and performance. Three agencies met these criteria and are categorised as ‘hybrid’ regulators, while the remaining three agencies are categorised as primarily using a compliance model of regulation. This is because these three agencies described the use of detection methods that remained unchanged, regardless of organisational circumstances, and because the enforcement methods used did not include improvement support through direct action.
<table>
<thead>
<tr>
<th>Agency</th>
<th>Documentary data</th>
<th>Interview data</th>
<th>Agency model</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIS</td>
<td>‘We are the national healthcare improvement organisation for Scotland, established to advance improvement in healthcare.’ (Healthcare Improvement Scotland, 2014)</td>
<td>“...a blend of approaches: So, we have the scrutiny, assurance, we have the clinical expertise ... independent fair and objective assessment ... [and] ...support improvement efforts” (Interview participant G, HIS)</td>
<td>Hybrid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“[we]... help providers in Scotland to improve their improvement capability” (Interview participant A, HIS)</td>
<td></td>
</tr>
<tr>
<td>HIW</td>
<td>‘Our purpose is to provide independent and objective assurance on the quality, safety and effectiveness of healthcare services, making recommendations to healthcare organisations to promote improvements.’ (Healthcare Inspectorate Wales, 2014)</td>
<td>“we go out and inspect and we find ...an organisation is meeting the standards... then we wouldn’t seek improvement ...beyond that” (Interview participant B, HIW)</td>
<td>Compliance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“we are not an improvement agency, but we should be operating in a way which supports improvement” (Interview participant A, HIW)</td>
<td></td>
</tr>
<tr>
<td>RQIA</td>
<td>‘The most important priority for RQIA is to make sure that our inspection systems and processes convey clearly to the public how well a service is performing in respect of the... minimum standards.’ (Regulation and Quality Improvement Authority, 2015)</td>
<td>“We provide assurance... about the quality of services” (Interview participant D, RQIA)</td>
<td>Compliance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“our primary role is to question them, to challenge them early, and then they can then start making... improvements” (Interview participant A, RQIA)</td>
<td></td>
</tr>
<tr>
<td>CQC</td>
<td>‘We make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.’ (Care Quality Commission, 2013)</td>
<td>“We monitor, we inspect and we regulate and make sure that these services meet the fundamental standards” (Interview participant CQC D)</td>
<td>Compliance</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“it’s very clear in the CQC that we’re not improvement facilitators, we’re regulators ” (Interview participant C, CQC)</td>
<td></td>
</tr>
<tr>
<td>Agency</td>
<td>Documentary data</td>
<td>Interview data</td>
<td>Agency model</td>
</tr>
<tr>
<td>----------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Monitor</td>
<td>‘[We set] a required standard that all NHS providers must meet... [We] control the risk that foundation trusts, once authorised, fall back below the required standard. If they do, we take remedial action...We will focus in particular on the capabilities that drive long-term performance.’ (Monitor, 2014)</td>
<td>“where trusts fail to deliver certain minimum standards ... [we] work with those trusts to ensure that they improve their position and restore themselves to ... that minimum standard” (Interview participant A, Monitor)</td>
<td>Hybrid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“[Our] mandate is basically to improve the capability of FTs” (Interview participant G, Monitor)</td>
<td></td>
</tr>
<tr>
<td>TDA</td>
<td>‘The TDA oversees NHS trusts and holds them to account... while providing them with support to improve.’ (Trust Development Authority, 2014)</td>
<td>“[Trusts] know that they are being held to account for their performance but they also know that they will get support and help and development rather than just being criticised” (Interview participant G, TDA)</td>
<td>Hybrid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“[Our role is] supporting oversight of our Trusts, ...[and] that have asked for some support because they feel that they need to make some improvements” (Interview participant E, TDA)</td>
<td></td>
</tr>
</tbody>
</table>
However, a detailed comparison reveals some differences, including regulatory model and methods. Table 5.6 summarises the main methods utilised by the regulatory agencies to fulfil their duties.

**Table 5.6: Agency methods**

<table>
<thead>
<tr>
<th>Process</th>
<th>Method</th>
<th>HIS</th>
<th>HIW</th>
<th>RQIA</th>
<th>CQC</th>
<th>Monitor</th>
<th>TDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detect</td>
<td>Unannounced inspections</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Planned inspections/reviews</td>
<td>÷</td>
<td>÷</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Thematic, specialist and peer review</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Performance monitoring</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Self-assessment / declaration</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td></td>
</tr>
<tr>
<td>Direct</td>
<td>Develops standards</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Provides improvement support through direct action</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enforce</td>
<td>Highlights best practice</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Statutory powers (NHS &amp; independent care)</td>
<td>Independent care only</td>
<td>Independent care only</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td></td>
</tr>
</tbody>
</table>

All six regulatory agencies use some form of detection methods to understand the current care provision. These include self-assessment against standards (all), formal onsite inspections (CQC, HIS, HIW, RQIA) or thematic reviews of areas such as older peoples care or governance (CQC, HIS, HIW, RQIA). There are also some differences, for example some agencies develop standards (CQC, HIS, Monitor). The table also highlights that the hybrid agencies (HIS, Monitor and TDA) provide direct improvement support.
The analysis illuminates how compliance activities dominate regulatory work and that improvement activities tend to be limited to the promotion of best practices. Half the agencies define their role as assuring the public of care standards and use similar methods with each organisation regardless of performance or risk levels (CQC, HIW, RQIA), thereby meeting the description of that of a compliance regulator. However, HIS, Monitor and TDA describe more interventionist models to educate and improve, rather than simply influence, through formal improvement programmes, for example the Scottish Patient Safety Programme (Healthcare Improvement Scotland, 2014b), quality improvement programmes in areas such as mortality (Trust Development Authority, 2014b) and strategy development support (Monitor, 2014a).

**Tensions within hybrid models**

The analysis highlights a tension caused through the combination of assurance, accountability and improvement goals:

“*We’re part of the architecture that can make organisations simply focus on the problem of today, ... [whereas] organisations need to find that balance between addressing today [and] tomorrow.*” (Interview participant F, TDA)

“*...it’s quite clear that we’re there to scrutinise and to regulate, but we’re also there to try to help improvement... it isn’t always easy to fit the two together.*” (Interview participant H, CQC)

“*[NHS] Boards are saying actually don’t confuse us. You can’t come in with an inspection hat on and then an improvement one.*” (Interview participant C, HIS)

This paper identifies three themes from this tension between compliance and improvement support with emerging hybrid models: regulatory role, resources and relationships.

**Regulatory roles**

Interview participants and documents describe a tension between the roles of assuring the public of safe, quality care and improving care.

‘Quality care cannot be achieved by inspection and regulation alone. The main responsibility for delivering quality care lies with [those that provide], arrange and fund local services.’ (Care Quality Commission, 2013)
‘The Berwick report (2013) highlights the vital role that ‘intelligent inspection’ plays. However, this cannot stand alone and must be combined within a system of improvement.’ (Healthcare Improvement Scotland, 2014a)

“We’re very clear what our role is when we go in and our role is not to run the trust or run a piece of work.” (Interview participant A, TDA)

“They’re their own problems, because if we solve it for them, then they haven’t worked it through, and I couldn’t solve it.” (Interview participant A, RQIA)

Some agencies are concerned that delivering improvement activity compromises their ‘role’ to conduct objective detection. Interview participants also raised concerns regarding accountability should the improvement support not lead to the expected outcomes.

“There is a danger of conflict, that we mark our own homework… a hospital [could] say, but you’ve been working with us on this so the failure is also partly yours.” (Interview participant A, Monitor)

“When trusts aren’t performing, there is a lot of pressure in the system, to say…to almost indicate that it’s wilful. It’s almost as if they’re failing for reasons which they should be able to stop.” (Interview participant C, TDA)

“We don’t make standards because it would be an uncomfortable place to be, to be the regulator and review against your own standards.” (Interview participant E, RQIA)

**Resources**

The choice of regulatory approach has ramifications for planning and execution, as it affects the type of resources (e.g. information technology versus clinical skills) and experienced staff that are needed by a regulatory agency, and influences the financial resources available for other regulatory tasks. For example, compliance models need more inspectors, whereas hybrid models need more improvement facilitators. This makes the choice of regulatory model more path-dependent and slow to change. Analysis suggests that that few employees have key skills or experience of improvement within regulating agencies. Shortages need addressing through development, recruitment and investment.

“We had no resources to take it forward.” (Interview participant B, HIS)

“We’ve got quite a big, sort of, issue about needing to invest in our staff...you can’t just outsource...we just don’t have the time and need some supplemental space to be able to really engage with [improvement]. So, it is quite a big challenge for us.” (Interview participant A, CQC)
“There [is] a challenge to find people of those skills.” (Interview participant B, HIW)

It is clear from the interviews and documents that some interview participants resist such developments. This may be due to the lengthy period and costs of developing skills, or to disagreements regarding the regulatory aims and concerns regarding local accountability.

“[I wonder] how knowledgeable the inspectors are around improvement methodology because you can’t judge it unless you know what you’re looking for… I think the inspectors lack the improvement methodology understanding… we don’t have the special advisors either.” (Interview participant C, CQC)

“We haven’t got anything like the number of people working within Monitor that have the [improvement] experience they’d need… some people would say, this isn’t a job for a regulator.” (Interview participant F, Monitor)

‘RQIA has limited capacity […] to encourage service providers to continuously improve.’ (Regulation and Quality Improvement Authority, 2015a)

Regulatory agencies report pressures linked to resources and describe a trade-off required between detection and enforcement activities and the resources available.

“…we would have to think carefully about whether our time’s better spent doing [improvement work] or another inspection somewhere else.” (Interview participant B, HIW)

“…with regulation, you have to prioritise, if we were regulating everybody it wouldn’t have any impact and [we] wouldn’t have enough resources.” (Interview participant B, Monitor)

Relationships

Interview participants commented on their need to maintain effective working relationships with organisations, and to establish trust and openness to assure the public that their assessments of care quality are fair, trustworthy and accurate. However, interview participants acknowledge the risks of negative reporting, noting that detection and enforcement, together with tough media and political scrutiny, can develop a destabilising effect on organisations and associated relationships.

“…if you establish good ongoing relationships outside the inspection regime then it’s less about you coming in and more about the team that the hospital knows…” (Interview participant C, CQC)
“...You're still having that professional distance as a regulator but you get to know the chief exec... and they get to know you...”  (Interview participant F, HIW)

“The approach of some providers might be... they’re a regulator so I don’t want to go near them whereas some of our best relationships with trusts are...coming to us very early for advice.” (Interview participant B, Monitor)

However, analysis of documents indicates that agencies believe that enforcement action, both punitive and supportive, must be transparent to prevent regulatory capture to maintain public trust in ‘independent and objective’ regulatory agencies.

‘HIW will report clearly, openly and publicly on the work that we undertake in order that citizens are able to access independent and objective information on the quality, safety and effectiveness of healthcare in Wales.’ (Healthcare Inspectorate Wales, 2014a; Healthcare Inspectorate Wales, 2014b)

‘By publicly reporting our findings, we provide assurance to the public that standards are being met, or that action is being taken where improvements are needed.’ (Healthcare Improvement Scotland, 2013a)

These two contrasting perspectives of confidentiality and openness, are more difficult to reconcile.

“There is an inherent tension with that confidential, closed-doors inquiry support with the requirements for us as a body about public accountability and transparency.” (Interview participant G, HIS)

Finally, external stakeholders, such as the media, may use information differently, hindering relationship development, mutual trust and care improvement in some circumstances. Those providing care may be concerned that information disclosure may deter an honest discussion of problems due to these stakeholders (Berwick et al., 2003).

**Discussion and implications**

This paper describes how regulatory agencies in the four countries of the UK have different organisational remits, scopes, approaches and methods of delivering their mission (Table 5.3, Table 5.5 and Table 5.6). The analysis suggests that effective regulatory oversight relates to the ability of regulatory agencies to balance the requirements to assure and improve care. Hybrid regulatory models are emerging in response, such as the approach taken by HIS, Monitor and the TDA.
‘Hybridity’ is a concept widely used to describe organisational responses to changes in governance (Skelcher and Smith, 2015), and it is argued that it may support the reconfiguration of organisational models as circumstances change, accommodating multiple demands and developing new ideas (Miller et al., 2008). However, hybridity may also lead to the disruption of existing professional communities and identities (Smith, 2014), unstable organisations which may fracture under sustained pressure (Denis et al., 2015), and contradictions caused by plural institutional logics (Skelcher and Smith, 2015). Fischer and Ferlie (2013) argue that regulatory regimes consist of various values, norms and instruments that cannot be readily combined, and it is sometimes argued that structural separation may be needed to manage the tensions that arise (Kippist and Fitzgerald, 2009; McDermott et al., 2015). Nevertheless, hybrid models can produce stable states and can improve performance relative to traditional models (Miller et al., 2008). This paper suggests that hybrid regulatory models may be more effective in producing improvement, but also more complex to design and implement, and difficult to sustain.

Hybrid models require a regulatory agency to be able to differentiate between organisations and tailor regulatory interventions accordingly. For example, do all organisations require improvement support or only those who have poor performance or high risk levels? Is pro-active improvement support offered to all organisations regardless of performance to prevent future poor performance? How should this be prioritised? It can be argued that regulatory agencies seeking to use hybrid models need to do more to articulate their underlying improvement model (Davidoff et al., 2015). Hybrid models require a range of resources in order to deliver improvement support, as well as to provide assurance. However, regulatory agencies face challenges to recruit or develop staff with the appropriate background and skills in improvement.

There remains a risk that high levels of intervention and support for improvement could jeopardise the trustworthiness of the regulator as an independent assessor, strain relationships, and blur roles and accountabilities. Moreover, when the main motivation within organisations for improvement derives from external regulation, organisations may exert less effort in implementation (Piening, 2011). This could inhibit healthcare organisations from investing and developing long-term improvement capability of their own, leading to a dependence on external
improvement support from a regulatory agency and increasing their resource requirements.

Instead of providing high levels of ongoing intervention and support for improvement, healthcare regulatory agencies could strengthen their approaches to assure and improve care by focusing on the assessment and development of improvement capability, as well as seeking to ensure compliance with standards and performance within regulated organisations. This could help to ensure that regulatory agencies are supporting the development of more proactive approaches to the improvement of quality without directly doing improvement work for or to organisations, thereby allowing regulatory agencies to benefit from the advantages of hybridity whilst limiting some of the risks outlined above.

**Conclusions**

Effective healthcare regulation requires the recognition of the inherent tensions between the regulatory aims of improvement, accountability and assurance. Hybrid models are emerging within UK regulatory agencies to assure and improve care, using direct improvement support for organisations to supplement other regulatory interventions. This paper identified that the development of hybrid models is complex and emergent. There are three key areas of tension linked to roles, resources the knowledge by presenting findings which further the understanding and emergence of hybrid models in healthcare regulation.
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Chapter 6 - Paper 3: Regulatory approaches to conceptualising and assessing improvement capability in healthcare organisations: a qualitative study of healthcare regulatory agencies in the UK

Joy Furnival, Kieran Walshe and Ruth Boaden

Introduction to paper 3

In paper 2 (Furnival et al., under review) it was identified that regulatory agencies are increasingly enforcing healthcare organisations to meet required standards through both deterrence and compliance models, each developing hybrid variants of responsive regulation. Paper 3 (Furnival et al., in development-c) continues to present and analyse empirical data collected from regulatory agencies and focuses on the assessment practices of regulatory agencies, comparing these with the stated intent, policies and plans of the regulatory agencies to develop improvement capability. This paper presents data using the framework based on the findings within paper 1 (Furnival et al., in development-a).

Content and thematic analysis is used to compare regulatory agencies using the eight improvement capability dimensions identified in the literature review in paper 1. This paper moves beyond a description of current practice to the identification of gaps, differences in assessment practice and regulatory intent, and considers why this may be. Finally, whilst paper 2 considered the views and intent of regulatory agencies, paper 3 considers the actions of the regulatory agencies and the congruence of this action with both regulatory agency intent, and the improvement capability literature.

Paper 3 does not aim to provide a case study or inter-agency comparative data regarding organisational assessment. Instead it seeks to analyse current conceptualisations of improvement capability from a regulatory perspective, informed by the literature. It also assumes that improvement capability can be identified in organisations through the eight dimensions identified in the literature and thus can be analysed in this way. Paper 3 further enhances our understanding of
how regulatory agencies conceptualise and assess improvement capability within organisations.

References


Abstract

Background
Healthcare regulatory agencies are increasingly concerned not just with assessing the current performance of the organisations they regulate, but with assessing and influencing their underlying improvement capability and likely future performance trajectory. This research study examines how improvement capability is conceptualised and assessed in practice by healthcare regulatory agencies in the UK.

Methodology
Qualitative analysis of data from six healthcare regulatory agencies in the UK was conducted. Three data sources were analysed using an a priori framework of eight dimensions of improvement capability identified from the literature. Data sources included interviews with regulatory agency staff, policy documents, and assessment reports.

Results
This research study finds that healthcare regulatory and improvement agencies in the UK want and need to be able to assess improvement capability accurately, and to develop tailored interventions that improve performance and quality effectively within organisations. Of the eight dimensions of improvement capability identified in a comprehensive review of that literature, process improvement and learning, and strategy and governance, dominate assessment in practice, and together with data and performance also represent most emphasis in agency policy documents and interviews. The remaining dimensions have a varied emphasis in policy documents and interviews, but featured less frequently within assessment reports. The dimension service-user focus receives the least frequency of use in policy documents and interviews, and was infrequently used in assessment reports. It may be that dimensions which are relatively easy to review and ‘measure’, such as documents for strategy and governance, dominate assessment processes, or this may indicate gaps in regulatory agencies’ assessment instruments, knowledge and expertise of improvement capability, and the practical difficulties in operationalising regulatory agency intentions to reliably assess and develop improvement capability.
Conclusions

Regulatory agencies in the UK seek to assess improvement capability in healthcare organisations in order to predict performance trajectories and tailor interventions, but out of eight dimensions of improvement capability, two dominate assessment and its conceptualisation. Furthermore, the definition and meaning of assessment instruments and assessment practices requires development. This will strengthen the validity and reliability of agencies’ assessment, diagnosis and prediction of organisational performance trajectories, and support the development of more appropriate and effective regulatory interventions.

Introduction

Unexplained variations in healthcare performance continue to be a significant focus of public and political attention (Makary and Daniel, 2016; Jha et al., 2010). In response to such variations, widespread concerns about patient safety (Wachter, 2010; Leape et al., 2009), and high-profile instances of failures in healthcare (Kirkup, 2015; Francis, 2013), many governments have introduced or strengthened systems for formal oversight, accountability and regulation in healthcare (Kachalia et al., 2016; Bevan, 2008). However, regulatory agencies themselves have often faced criticisms that their regulatory methods or regimes are not able to assess performance or quality accurately, or to diagnose and intervene to improve performance and quality effectively (Bardsley, 2016; Tuijn et al., 2011). In addition, the costs and benefits of regulation have also been questioned (Mumford, 2013).

In response to such criticisms, some regulatory agencies have sought to move beyond directly assuring organisational performance or quality of care through mechanisms such as inspection and assessment, and are implementing programmes to strengthen the underlying organisational characteristics for organisations to develop and sustain their own improvement programmes through improvement approaches. In the wider academic literature, these characteristics are termed ‘improvement capability’, defined as the ‘resources and processes, supporting both the generation and the diffusion of appropriate innovations across the organisation’ (Adler et al., 2003, p14). This builds on a dynamic capabilities view, which suggests that organisational performance is driven through bundles of routines, described as distinctive capabilities, that are used to purposefully create and modify resources and
routines that are contingent on local circumstances (Helfat et al., 2007; Teece and Pisano, 1994). However, the tacit nature of capabilities creates significant barriers to imitation, substitution or assessment (Peng et al., 2008). A comprehensive literature review identified eight dimensions of improvement capability to support its assessment and development (Table 6.1).

**Table 6.1: Dimensions of improvement capability**  
(Furnival et al., in development-a)

<table>
<thead>
<tr>
<th>Coding dimension</th>
<th>Description</th>
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<tbody>
<tr>
<td>Organisational culture</td>
<td>Core values, attitudes and norms and underlying ideologies and assumptions within an organisation</td>
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<tr>
<td>Data and performance</td>
<td>Use of data and analysis methods to support improvement activity.</td>
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<td>Employee commitment</td>
<td>Encompasses the level of commitment and motivation of employees for improvement.</td>
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<td>Leadership commitment</td>
<td>Support by formal organisational leaders for improvement and performance.</td>
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<tr>
<td>Process improvement and learning</td>
<td>Systematic methods and processes used within an organisation to make ongoing improvement through experimentation.</td>
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<tr>
<td>Service-user focus</td>
<td>Identification and meeting of current and emergent needs and expectations for service users, for example patients.</td>
</tr>
<tr>
<td>Stakeholder and supplier focus</td>
<td>Extent of the relationships, integration and goal alignment between the organisation and stakeholders such as public interest groups, suppliers and regulators.</td>
</tr>
<tr>
<td>Strategy and governance</td>
<td>Process in which organisational aims are implemented and managed through policies, plans and objectives.</td>
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</table>

For regulatory agencies assessing improvement capability may be important for two reasons. First, it may provide greater assurance about current performance; regulatory agencies can only undertake limited direct assessments of the quality of care, but may take some assurance that organisations with relatively higher improvement capability can monitor and assure quality for themselves. Second, improvement capability may have some value in predicting future performance, especially if problems with the quality of care are found. Organisations with more improvement capability may be more adept to deal with such problems and bring about improvement for themselves, while those with limited improvement capability may need external support and intervention. More fundamentally, by focusing on assessing improvement capability, regulatory and improvement agencies are likely to
encourage healthcare organisations themselves to pay greater attention to how they build and sustain improvement capability.

There are six regulatory agencies\(^2\) overseeing the healthcare system across the four countries of the UK, with several incorporating some assessment of improvement capability into their inspection, assessment or oversight regimes. However, there is little published literature that has examined how regulatory and improvement agencies can assess improvement capability within organisations. This research study examines how improvement capability is conceptualised and assessed in practice by healthcare regulatory agencies in the UK.

**Methodology**

The focus of the research study was the regulation of hospital-based care, which accounts for the majority of UK healthcare expenditure. Thus, the six healthcare regulatory agencies based in the UK that have responsibility for the oversight of hospital care were selected for the research study and all agreed to participate. These are the Care Quality Commission (CQC), Monitor, the Trust Development Authority (TDA) in England, Healthcare Improvement Scotland (HIS), Healthcare Inspectorate Wales (HIW), and the Regulatory and Quality Improvement Authority (RQIA) in Northern Ireland.

Qualitative methods offer an effective, flexible and common approach for data gathering. Three data sources from the agencies were used: policy documents, interviews and assessment reports (Table 6.2).

\(^2\) Since this research was completed Monitor and the TDA have become part of the same organisation with the operational name of NHS Improvement
In order to understand how regulatory agencies define and conceptualise improvement capability and expressed intentions, published policy documents were identified, including agency strategies, operational plans, and annual reports (n=90). Following ethical approval to proceed, Directors of policy, strategy or regulation within the agencies were contacted to take part in the research study and they supported the identification of suitable interview participants. Seven to nine interviews were held per agency (n=48) representing a cross-section of clinical and non-clinical employees, including board-level roles, back office support, and inspectors. Interviews were conducted face-to-face or via the telephone between October 2014 and April 2015; participation was voluntary and confidential. A semi-structured interview framework was used to examine agency purpose, intent, roles, methods and their understanding and assessment of improvement capability. Testing of the questions took place through pilot interviews. Interviews were recorded, anonymised and transcribed, and verbatim transcriptions were shared with participants to clarify any inaccuracies in the recordings. A few amendments were requested and were largely limited to grammar improvements and clarifications to recording problems.

Finally, five assessment reports per agency were selected (n=30). The selection criteria required that they were publicly available, they represented a range of

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Table 6.2: Data sources and sample size

<table>
<thead>
<tr>
<th>Agency</th>
<th>Documents</th>
<th>Interviews</th>
<th>Assessment reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection criteria</td>
<td>Publicly available strategic plans; annual reports; operational reports</td>
<td>Clinical &amp; non-clinical; cross-section, board, back office and assessors</td>
<td>Publicly available acute and/or community; range of performance judgements; identified during interviews</td>
</tr>
<tr>
<td>HIS</td>
<td>18</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>HIW</td>
<td>13</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>RQIA</td>
<td>17</td>
<td>9</td>
<td>5</td>
</tr>
<tr>
<td>CQC</td>
<td>13</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>Monitor</td>
<td>16</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>TDA</td>
<td>13</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>90</td>
<td>48</td>
<td>30</td>
</tr>
</tbody>
</table>
organisational performance, or they were referred to by interview participants as specific examples related to improvement capability. Two agencies in the sample do not routinely publish the results of their assessment processes; instead assessment reports for these agencies were identified through a detailed review of board reports from the agencies and regulated organisations. This may have influenced the extent to which the sample collected was representative of the range of organisational performance assessed.

Policy documents, interview transcripts and assessment report texts were loaded into electronic qualitative analysis software (NVivo10), and the eight dimensions of improvement capability (Table 6.1) were used as an a priori coding template to support content and thematic analysis of the policy documents, interviews and assessment reports (Saldaña, 2013; Miles and Huberman, 1994). The combination of sources allowed a comparison of agencies’ expressed intent with practice. Coding consistency was reviewed using NVivo10 functionality to compare coding density and frequency across data sources (Bazeley and Jackson, 2013).

**Results**

This section begins by describing UK agencies’ aims for improvement capability. It then discusses the content analysis of the data sources using the identified improvement capability dimensions, comparing agencies where appropriate. Following this, analysis themes are discussed.

**Aims of regulatory and improvement agencies**

Analysis of agency policy documents identifies that agencies express intentions to strengthen improvement capability, with some agencies more explicit in their aims than others (Table 6.3). HIS and Monitor have specific strategic aims linked to developing improvement and associated capability in the National Health Service (NHS) in Scotland and England, respectively. Other agencies were less explicit, such as in Northern Ireland and Wales, where a governmental aim to build capability exists rather than a specific one as within RQIA and HIW.
### Table 6.3: UK regulatory and improvement agencies and associated improvement capability aims
(adapted from Furnival et al. under review)

<table>
<thead>
<tr>
<th>UK country &amp; population</th>
<th>Agency</th>
<th>Remit</th>
<th>Improvement capability aim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scotland: 5.3M</td>
<td>HIS</td>
<td>To advance improvement in healthcare in Scotland, and to support providers to deliver safer, more effective, person-centred care.</td>
<td>‘[Our / The QI Hub’s] purpose is to support NHS Scotland to develop the capacity, capability and infrastructures to excel in quality improvement with the aim of delivering the highest standards of care.’ (Healthcare Improvement Scotland, 2014)</td>
</tr>
<tr>
<td>Wales: 3M</td>
<td>HIW</td>
<td>To inspect health boards and trusts, and regulate independent healthcare providers, general Practitioner practices, pharmacies and dental practices.</td>
<td>‘Fundamentals of care – Standard 6 ‘Participating in quality improvement activities, organisations and services reduce waste, variation and harm by […].’ (Welsh Assembly Government, 2010)</td>
</tr>
<tr>
<td>Northern Ireland: 1.8M</td>
<td>RQIA</td>
<td>To provide independent assurance about the quality of health and social care services.</td>
<td>‘We will promote the use of accredited improvement techniques and ensure that there is sufficient capacity and capability within the health and social care [system].’ (Department of Health Services and Public Safety Northern Ireland, 2011) (No explicit RQIA statement)</td>
</tr>
<tr>
<td>England: 53M</td>
<td>CQC</td>
<td>To ensure health and social care services provide people with high quality care, and to encourage improvement.</td>
<td>‘[Our purpose is to] make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.’ (Care Quality Commission, 2013)</td>
</tr>
<tr>
<td>England: ~149 Foundation Trusts</td>
<td>Monitor</td>
<td>To authorise, monitor and regulate foundation trust finances, quality and performance including price setting, preventing anti-competitive behaviour, whilst promoting care integration and protecting health services if providers become unsustainable.</td>
<td>‘We will focus in particular on the capabilities that drive long-term performance: […] We will also place more weight on the assessment of these capabilities […].’ (Monitor, 2014)</td>
</tr>
<tr>
<td>UK country &amp; population</td>
<td>Agency</td>
<td>Remit</td>
<td>Improvement capability aim</td>
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<tr>
<td>England: ~ 90 Non-Foundation Trusts</td>
<td>TDA</td>
<td>To provide the oversight, scrutiny, and performance management of non-foundation trusts on behalf of the Department of Health and develop them into foundation trusts.</td>
<td>‘We want more than ever to focus on support and development …Our assessment of the credibility of plans, will focus on five broad areas […] including] leadership capability’, (Trust Development Authority, 2014).</td>
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</tbody>
</table>
Content analysis

Figure 6.1 presents the content analysis of the assessment reports and compares the coding frequency of the improvement capability dimensions within agency policy documents, interviews and assessment reports.

Overall, the analysis revealed that the dimensions of process improvement and learning, and strategy and governance, were most frequently found. Other dimensions were found less frequently, with service-user focus being the least...
frequent, and this skewed pattern was relatively consistent across agencies and data sources.

Table 6.4 shows representative examples of quotations from across the dimensions and were selected to illustrate how the agencies conceptualise the dimensions across the three data sources. The table highlights how each dimension is used by the different regulatory agencies, adding depth to the initial content analysis in Figure 6.1. This also enabled the examination of coding consistency across the data sample and to understand why dimensions were coded with different frequencies. For example, ‘leadership’ is a named assessment criterion for three of the regulatory agencies (Monitor, TDA and CQC); however, the content analysis indicated a low frequency of coding to the leadership commitment dimension across the data sources compared to other dimensions. The coding was reviewed for consistency, indicating that whilst assessment reports used leadership commitment as a high-level criterion, specific leadership activities, such as developing plans or communicating widely, fall within other dimensions in the assessment reports in this analysis and were coded as such. Perhaps this is to be expected as leadership commitment can cover many different aspects, can be used as a ‘catch all’, and does not exist within a vacuum.
### Table 6.4: Representative sample of quotations across the data sources and dimensions

<table>
<thead>
<tr>
<th>Process improvement and learning</th>
<th>Policy documents</th>
<th>Interviews</th>
<th>Assessment reports</th>
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<tbody>
<tr>
<td></td>
<td>‘Opportunities for continuous learning by staff will be resourced and planned in order to continuously improve quality.’ (Quality 2020, Department of Health Services and Public Safety Northern Ireland, 2011)</td>
<td>“We require them to report in their annual governance statement on what their quality improvement methodology actually is.” (Interview participant G, Monitor).</td>
<td>‘The trust encouraged innovation using recognised ‘Quality Improvement’ methodology. Approximately [X] consultants had undergone training in this and members of staff we spoke to were able to give examples of how they had been encouraged to drive change and improve their service.’ (Report E, CQC).</td>
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<td></td>
<td>‘One of the 10 ‘must do’ patient safety essentials is the use of the Scottish Patient Safety Programme care bundle for preventing infections when inserting and maintaining a peripheral vascular catheter.’ (Driving Improvement in the Quality of Healthcare. Annual Report 2013-2014, HIS, 2014)</td>
<td>“We’ve tended to think there’s quite a lot of tools and methods out there and we probably don’t want to just…go in and say, we’re going to use the IHI model, then people will stop doing whatever else they’re doing.” (Interview participant B, CQC)</td>
<td>‘There has been extensive training in quality improvement techniques including [X] staff trained in lean [and other methods].’ (Report C, HIS).</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Strategy and governance</th>
<th>Policy documents</th>
<th>Interviews</th>
<th>Assessment reports</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>‘Does the board have a credible strategy to provide quality, sustainable services to patients and is there a robust plan to deliver?’ (Well-led framework for governance reviews: guidance for NHS foundation trusts. Monitor, 2014b)</td>
<td>‘[We] ask a Chief Exec what are the values of the organisation and what’s the strategic direction of the organisation, and they should be able to articulate that, and so should every member of staff that you speak with.’ (Interview participant D, CQC)</td>
<td>‘We are concerned that there is serious disconnect between the strategic planning processes and clinical and operational services… there is a mismatch in priorities and understanding regarding the practical delivery of clinical services and the development of strategic plans.’ (Report A, HIS).</td>
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<td></td>
<td>‘Our scrutiny activities include an ongoing programme to quality assure clinical governance processes and the quality of healthcare services provided across NHS boards in an impartial and objective way.’ (Our Strategy, 2014-2020. HIS, 2014)</td>
<td>‘I’m not saying I’ve no interest in the policy, but the policy is not what I’m interested in; it’s how it’s carried out on the ground that I’m interested in.’ (Interview participant E, RQIA)</td>
<td>‘Staff with governance responsibilities can explain how this works, and front-line staff know how to raise concerns. While there are a number of examples of issues being escalated, and acted upon, we have not seen evidence of a robust and systematic escalation process from ward to Board.’ (Report A, Monitor).</td>
</tr>
<tr>
<td>Data and performance</td>
<td>Policy documents</td>
<td>Interviews</td>
<td>Assessment reports</td>
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<td>‘Measurement is vital for both assurance and improvement. It must become second nature to all staff at all levels… The wider organisation and national level will look for assurance that outcomes are improving overall.’ (Achieving Excellence. The Quality Delivery Plan for the NHS in Wales, Welsh Assembly Government, 2012)</td>
<td>‘[We look] at the data that we routinely have available to us, a range of different sources … which gives us a view of how trusts are performing … we would look at benchmarking them against each other, looking at both ends of the spectrum, both the good and the perhaps not so good.’” (Interview participant E, TDA)</td>
<td>‘The review team noted that the measures were self-reported by wards, but it also noted the lack of active challenge of the high reported compliance rates at Board level, even when related outcome measures were not improving.’ (HIS, Report C)</td>
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<td>‘The need for better access to benchmarking data was the most consistent development need identified [...] the NHS TDA has developed its information provision and performance framework which includes a number of high level dashboards.’ (Delivering for Patients: the 2014/15 Accountability Framework for NHS Trust Boards, TDA, 2014)</td>
<td>‘We look at from a board’s point of view, so what sort of targets are they setting the organisation, how are they tracking those and how can they demonstrate that they, as a board, have improved performance?’” (Interview participant E, Monitor)</td>
<td>‘Local outcomes were regularly audited and the trust was able to demonstrate how it had changed practice to improve results for patient’s year on year. The trust also benchmarked itself, and compared well against, national comparators.’ (CQC, Report B)</td>
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<tr>
<td>Stakeholder and supplier focus</td>
<td>Policy documents</td>
<td>Interviews</td>
<td>Assessment reports</td>
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<td></td>
<td>‘These inspections look at how effectively […] services are working together and if they are delivering the best possible outcomes for the people who use those services.’ (Driving Improvement in the Quality of Healthcare. Annual Report 2013-2014, HIS, 2014b)</td>
<td>“So, if you’re getting examples of … We’ve worked with the trust … we’ve achieved the following service developments, we’ve improved, you know, length of stay or whatever, that’s a real positive, you don’t get that a lot, but it’s something about the quality of their relationships and the track record.” (Interview participant B, TDA)</td>
<td>‘There was evidence of limited engagement and communication between secondary and primary care. For improved patient outcomes, this is an area that needs to be reviewed and developed.’ (Report C, RQIA)</td>
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<td></td>
<td>‘It will be increasingly important for HIW […] to collaborate and coordinate their activities to scrutinise the performance of […] organisations to assess the quality of integrated care.’ (An Independent Review of the work of Healthcare Inspectorate Wales. The way ahead: to become an inspection and improvement body. Marks, 2014)</td>
<td>“How do they work with external providers, particularly community services and health visitors, and mental health… we actively check in two ways to make sure that they are working with and collaborating.” (Interview participant F, CQC)</td>
<td>‘The Trust has involved stakeholders (e.g., governors, staff, CCG) in the development of quality objectives and associated plans.’ (Report A, Monitor)</td>
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<tr>
<td>Employee commitment</td>
<td>Policy documents</td>
<td>Interviews</td>
<td>Assessment reports</td>
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<td>‘RQIA will support and encourage individuals and organisations […] to be committed to the principles of best practice and continuous improvement.’ (Corporate Strategy. 2015-2018, RQIA, 2015)</td>
<td>‘If you haven’t got that ownership locally you… things are far more likely to succeed and it’s all […] just key principles in terms of ownership, engaging people, involving them in the change.’ (Interview participant F, HIS)</td>
<td>‘In the NHS 2013 Staff Survey, [X]% of staff reported that they felt satisfied with the quality of work and patient care they were able to deliver. This compared with a national average of [Y] %.’ (CQC, Report B)</td>
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<tr>
<td>‘Most staff are aware change is necessary. They want to see how change will bring value and benefits to the people they care for. They also need to see how they can contribute to the changes, how their voice will be heard and, importantly, how they will be enabled to work differently in a way they know will bring about better, more quality-focused services to their patients and clients.’ (Together for Health. A Five-Year Vision for the NHS in Wales, Welsh Assembly Government, 2011)</td>
<td>‘I would want to see that there’s a good connection between the board and the operational side of the organisation, that there’s strong clinical engagement, that they’re starting to just take ownership of some of the issues and get a grip of some of them.” (HIW, Interview participant H)</td>
<td>‘We found that staff were committed to delivering good quality care and they were kind and caring. In many cases, we found issues with staff numbers, vacancies, resilience and skill mix.’ (HIW, Report B)</td>
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<tr>
<td>Leadership commitment</td>
<td>Policy documents</td>
<td>Interviews</td>
<td>Assessment reports</td>
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<td></td>
<td>‘Strong and effective leadership within organisations from the “board to the ward” is essential to drive improvement.’ (Delivering for Patients: the 2014/15 Accountability Framework for NHS Trust Boards, TDA, 2014)</td>
<td>“I’ve seen examples of really good strong leadership from individual people, like a chief executive or a director, a key lead within a service, but that […] again how sustainable is that, because if it’s one person driving everything, it’s not going to keep working.” (Interview participant H, CQC).</td>
<td>‘There has been a lack of leadership within the organisation which has resulted in the failure to unite staff behind a common purpose.’ (Report A, HIS).</td>
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<td></td>
<td>‘Monitor has been tasked with making sure public providers of NHS care are well led, delivering quality care on a sustainable basis.’ (Monitor Annual Plan 2014-15, 2014)</td>
<td>“[One thing that gives] insight into the leadership is, we keep finding issues of inconsistency, so two wards right next to each other are very, very different. Two wards within the same specialty on different sites that are managed in completely different ways, and again, that begins to give you a sense of an insight into the quality of the leadership.” (Interview participant D, HIW).</td>
<td>‘Strong managerial and professional leadership is required at all levels… There should be a shared commitment to making the system work. With strong leadership, it is easier to manage the tensions that arise.’ (Report B, RQIA).</td>
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<tr>
<td>Organisational culture</td>
<td>Policy documents</td>
<td>Interviews</td>
<td>Assessment reports</td>
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<td></td>
<td>‘The boards of NHS organisations have a critical role in leading a culture which promotes delivery of a high quality, high value service.’ (Achieving Excellence. The Quality Delivery Plan for the NHS in Wales, Welsh Assembly Government, 2012)</td>
<td>“How do you support staff and build that behaviour and culture? ... How do we build that peer pressure, that social acceptability, the whole environment people work in? [...] That’s the challenge for the board.” (Interview participant E, HIW).</td>
<td>“The culture of the team working within the department was one of cohesiveness, with staff displaying a very high level of professionalism and enthusiasm for the work they did.’ (Report B, CQC)</td>
</tr>
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<td></td>
<td>‘The planning guidance also covered a range of other areas in relation to building a safety culture.’ (Board Papers, Trust Development Authority, March 2015)</td>
<td>“We perhaps talk in random terms about the culture of the organisation but we really don’t get to grips with the culture of the organisation ... I suppose there are some sources of information that we would look at but whether you really understand the culture of the organisation from that.” (Interview participant C, Monitor).</td>
<td>‘The vast majority of staff we spoke with said that they were unable to understand how decisions were made and were also unable to consistently describe to us the lines of accountability. There was a strong and consistent reference to a dysfunctional management structure and a ‘reactive culture’. ’ (Report A, HIS)</td>
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<tr>
<td>Service-user focus</td>
<td>Policy documents</td>
<td>Interviews</td>
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<td>‘Our primary duty – and therefore our mission – focuses on patients…. Making a difference for patients will govern all that we do.’ (Monitor’s strategy 2014-17. Helping to redesign healthcare provision in England, Monitor, 2014a).</td>
<td>‘We’ve got [...] public and patient involvement (PPI) – and that’s going to drive the engagement of the service users [but organisations could not] engage with the person because that person had to be identified through the PPI office; and that just never happened.’ (Interview participant J, RQIA).</td>
<td>‘The Trust has a patient reference group, a consultative group including a number of patient representatives which allows the trust to hear feedback on the quality of its services and to consult with service users on proposed service developments.’ (Report D, TDA)</td>
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</tr>
<tr>
<td>‘CQC is on the side of people using health and social care services, their families and carers, highlighting where services are good and outstanding, and taking action where there is need for improvement.’ (Business plan. April 2015 to March 2016. An update to our three-year strategy: raising standards, putting people first, 2013-16, CQC, 2015)</td>
<td>‘We talk about the fact that patients should be involved, and we encourage the trusts to involve the patients in their work, in their improvement work, in what goes on, in the scrutiny of what they’re doing, but we don’t actually have a large amount of public and patient involvement.’ (Interview participant G, TDA).</td>
<td>‘During some inspections, we observed the completion of a ‘This Is Me’ profile which captures important information about the person, their preferences and daily routines.’ (Report B, HIW)</td>
<td></td>
</tr>
</tbody>
</table>
Three themes emerge from the analysis of the assessment of improvement capability: conceptualisation, assessment data and assessment practices.

Conceptualisations
The first theme identified is that it was problematic to define, conceptualise and operationalise improvement capability. For example, policy documents and interviews stressed the importance of developing improvement capability but faced definitional difficulties when articulating precisely, and consistently, what was meant by improvement capability. Furthermore, it was evident that the term was used inconsistently, boundaries between dimensions were blurred, and that it is a nebulous, ambiguous and subjective concept. For example, whilst interview participants were keen to stress the importance of organisational culture, it was acknowledged that it was a difficult concept to grasp, assess, and for organisations to influence (see Table 6.4).

Assessment data
The second theme highlights the challenges resulting from regulatory access to data, and identifies that existing and available data are used as proxy data sources in the absence of more appropriate data sources. For example, in Table 6.4 three data sources from Wales are highlighted within the dimension of employee commitment. These demonstrate the differences between assessment intentions and the data used during assessments. These examples, together with the other quotations in this dimension, also highlight how annually collected and available data from NHS staff surveys or locally produced staff turnover and vacancy data are used as indicators, despite policy intentions stressing employee contribution, ownership and engagement, rather than staffing numbers and proxy measures for employee commitment, such as vacancy rates and resilience.

Assessment practices
Assessment practices for improvement capability are limited as there is variable understanding of improvement capability by regulatory agency staff. The variable understanding of improvement capability during assessments risks causing variation, bias and inconsistency through a self-confessed lack of knowledge. Interview data indicated that assessors were still learning how to assess for improvement capability and were unclear what evidence to seek. Most regulatory agencies were only beginning to focus on assessing and developing improvement capability in
organisations. Thus, whilst policy documents and interview participants stressed this intent, further development of assessment practices, assessment processes and assessor understanding of improvement capability was still needed.

“It is such a new area for our inspectors to, sort of, look at and look at it in this way.” (Interview participant B, CQC)

“We really need to understand the current state better and part of that is about understanding the capability of the workforce and the people that we’re actually going to be [...] supporting [...], but we’re not quite there yet systematically.” (Interview participant C, HIS)

**Discussion and implications**

This research set out to explore how improvement capability is conceptualised and assessed by UK healthcare regulatory agencies. The research study found that all agencies aim to assess and develop improvement capability, but that two dimensions of improvement capability from a framework of eight dominate assessment: process improvement and learning, and strategy and governance. Other dimensions identified from the literature, such as employee commitment or organisational culture, are used less frequently during assessment, with some variation between agencies. Finally, in contrast to agency strategic messages to place the patient at the centre of their work, this research identifies that the area of lowest content frequency within policy documents and interviews was service-user focus, with only a small increase in the frequency of use in assessment documents.

Three themes emerge from this analysis of the assessment of improvement capability: conceptualisation, assessment data and assessment practices. A limited conceptualisation of improvement capability is operationalised by agencies when compared with the literature (Furnival et al., in development-a). In line with other healthcare studies, for example Brennan et al. (2012), this research study finds that the assessment data used by agencies need further development to ensure that evidence collected does measure dimensions of improvement capability, which will strengthen the validity of the assessments. Furthermore, there are concerns that impact on measurement consistency, validity and reliability (Tuijn et al., 2011; Bardsley, 2016), and the dependence on value-judgements of inspectors and surveyors (Jaafaripooyan, 2014), Finally, assessors need further skills, knowledge and guidance to assess across the broad range of improvement capability dimensions,
in order to strengthen assessment in practice and reliability. These findings suggest that current assessments focus on dimensions which are easier to measure with more tangible evidence, such as the existence of a strategic plan, in contrast to the assessment of dimensions that are more ambiguous and difficult to assess. There are a number of existing validated models that could be used to strengthen assessments in these dimensions, for example for organisational culture there are a number of existing models (Gambi et al., 2015; Prenestini et al., 2015) which could strengthen assessment effectiveness and resultant regulatory judgements. These findings suggest a regulatory intent that is still emerging, has been more difficult to implement in practice than anticipated, or that agency policies are not being implemented.

The themes provide suggestions for the development of agencies’ assessments of improvement capability within organisations. Regulatory agencies may use their assessments to determine and design their enforcement approach with organisations. Without a broader conceptualisation of improvement capability, enforcement approaches may not be designed to adequately meet organisational needs and be less effective. For example, agencies may inadequately or inaccurately assess an organisation’s capability to improve, instead indicating that external support is required, leading to the poor use of resources by both agencies and organisations, and negatively impacting morale. Finally, inaccurate assessments may undermine confidence in an organisation by local populations and stakeholders.

Building on these suggestions will assist agencies in meeting their aims of developing improvement capability through more effective assessment. This would enable agencies to ensure that organisations focus across all dimensions holistically. Furthermore, a broader conceptualisation would support increased attention on patient care across care pathways and between organisations, supporting the development of service integration through the use of the stakeholder and supplier, and service-user focus dimensions; it would also strengthen the reliability and validity of regulatory assessments.

Further research is required to support assessment and the subsequent tailoring of improvement support to organisations. This needs to be based on an understanding of their existing improvement capability, and to strengthen understanding about how improvement capability emerges or dissipates within organisations. Nevertheless, it
is important to acknowledge the limitations of this research study, which largely relies on cross-sectional data from a regulatory agency perspective. Perspectives from assessed organisations would provide richer data and help to continue to build our understanding of improvement capability.

Conclusions

This research study set out to consider how regulatory and improvement agencies assess improvement capability. Its analysis of policy documents, interviews and assessment reports shows that whilst all these agencies aim to assess and develop improvement capability within healthcare organisations, two out of eight dimensions of improvement capability dominate assessment. This may be due to the difficulty in operationalising the dimensions that comprise improvement capability due to measurement, knowledge, and practice gaps.

Empirically, this research study has addressed a gap in the knowledge regarding the assessment of improvement capability, and the results provide a starting point for the development of which factors could be considered in the assessment of improvement capability. Better understanding and assessment of improvement capability will allow more tailored development approaches by regulatory and improvement agencies. This research study has highlighted the need for regulatory agencies to further conceptualise improvement capability in order to inform their assessment and subsequent development. This will strengthen agencies’ assessment, diagnosis and prediction of organisational performance trajectories, and support the development of more appropriate and effective regulatory interventions.
References


Chapter 7 - Paper 4: A dynamic capabilities view of improvement capability

Joy Furnival, Ruth Boaden and Kieran Walshe

Introduction to paper 4

Paper 4 (Furnival et al., in development-b) is concerned with the theoretical conceptualisation of improvement capability building on the integrative literature review in paper 1 (Furnival et al., in development-a). It employs several related ideas in the literature concerning what makes up a ‘dynamic capability’, such as improvement capability and draws from the ‘microfoundations’ framework (Teece, 2007). Paper 4 conceptualises improvement capability as a dynamic capability that comprises specific organisational routines that are bundled together in a unique way to adapt and react to specific local configurations and external circumstances.

The paper complements the empirical findings from papers 2 and 3 (Furnival et al., in development-c; Furnival et al., under review), and enhances the understanding of the configuration of improvement capability and how this relates to the external environment. Further research is required to understand how these are orchestrated and change over time. Finally, an initial conceptual framework is proposed, although further testing and validation of the framework is required before a more detailed, valid and reliable measurement instrument can be developed.

References

Abstract

Organisations increasingly operate in rapidly changing environments and present wide variation in performance. It can be argued that this variation is influenced by the capability of an organisation to improve: its improvement capability. However, there is wide variation in its conceptualisation within the literature, and there has been insufficient theoretically based research on capability-led interventions for improvement. This paper sets out the current diverse body of research on improvement capability and develops a theoretically based framework.

The conceptualisation of improvement capability in the literature is reviewed before describing and critiquing three capability-led theoretical perspectives. One of these, the dynamic capabilities view, takes a process view of performance and focuses on how organisational routines bundle and interact. Therefore, this is used to explore how improvement capability can be understood, and contributes to the literature by identifying and organising the dimensions of improvement capability. Dynamic capabilities are configured from three constituent microfoundations: sensing, seizing and reconfiguring, which can be unpacked into individual factors and which require orchestration. Eight improvement capability dimensions identified from the literature are inductively categorised into these microfoundations. This illustrates that the three microfoundations that make up a dynamic capability are present in the identified improvement capability dimensions.

This theoretically based framework provides a richer and more complete explanation of how improvement capability can be configured within an organisation. Breaking improvement capability into its component parts helps explain why some organisations are less successful in performance improvement than others. Orchestration of microfoundations is required to ensure that a focus on one microfoundation is not at the expense of another. This perspective can support managers to identify improvement capability dimensions in need of attention. Further research is now required to understand in detail how the dimensions of improvement capability are orchestrated, inter-relate, and aggregate at a micro-level. Empirical research is particularly required from non-market situations, such as the public sector and healthcare.
Introduction

Organisations increasingly operate in uncertain environments and present a wide variation in performance. Organisations continue to seek solutions to ensure improved performance and this has continually been a fruitful area of research (Zott, 2003). Talbot (2010) describes four approaches that can be taken to ensure improved performance in the public sector, each based on differing theoretical perspectives: managerial and contractual interventions; market mechanisms set through the policy context such as regulation; user choice and voice; and capability interventions. Capability-led interventions include those which focuses on support to organisations through direct action, such as a capability development programme, or restructuring, such as mergers or leadership replacement (Talbot, 2010).

There has been insufficient theoretically based research on capability-led interventions and performance improvement (Talbot, 2010; Downe et al., 2010), and this is the gap addressed in this paper. The current diverse body of research on improvement capability is structured into a theoretically based framework, and this contributes to the literature by identifying and organising the dimensions of improvement capability. These are categorised theoretically using the microfoundations of dynamic capabilities.

The paper is organised as follows: first improvement capability is introduced, followed by three theories of performance improvement, including the dynamic capabilities view (DCV). The microfoundations of the DCV are then used to examine improvement capability and the paper concludes by discussing the implications for further research.

Improvement capability

There are several definitions of improvement capability within the literature which derive from a range of views and theoretical perspectives, and different definitions identified from the literature are presented in Table 7.1. One perspective describes improvement capability as consisting of organisational wide processes of focussed and sustained incremental innovation to maximise creative problem solving (Bessant and Francis, 1999; Bessant and Caffyn, 1997), while Adler et al. (2003) describe improvement capability as supporting innovation across an organisation. Alternatively, Peng et al. (2008) distinguish improvement capability as focusing on
existing products and processes, rather than innovation capability. This focuses on developing new products and processes, and can also lead to improved organisational performance. Interestingly, later definitions from healthcare take a human capital and actor-driven perspective, where improvement is delivered through individuals and their leadership. This perspective describes improvement capability as encouraging staff to learn skills for conducting improvements (Kaminski et al., 2014; Bevan, 2010). However, Babich et al. (2016) return to the earlier definition provided by Adler et al. (2003), which takes a process view whereby organisational improvement is generated through following particular procedures and methods. Recognising this heterogeneity in the conceptualisation of improvement capability, it is important that the literature consolidates and builds on previous research in a structured way (Barreto, 2010); therefore this research study also takes a process view of improvement capability.

### Table 7.1: Improvement capability definitions

<table>
<thead>
<tr>
<th>Definition</th>
<th>Author</th>
<th>Sector</th>
<th>Perspective</th>
</tr>
</thead>
<tbody>
<tr>
<td>The ability to incrementally increase [manufacturing] performance using existing resources</td>
<td>Swink and Hegarty (1998)</td>
<td>Manufacturing</td>
<td>Process view</td>
</tr>
<tr>
<td>Improvement capability consists of organisational wide processes of focused and sustained incremental innovation</td>
<td>Bessant and Francis (1999)</td>
<td>Manufacturing</td>
<td>Process view</td>
</tr>
<tr>
<td>Resources and processes, supporting both the generation and the diffusion of appropriate innovations across the organisation</td>
<td>Adler et al. (2003)</td>
<td>Healthcare</td>
<td>Process view</td>
</tr>
<tr>
<td>It refers to the strength or proficiency of a bundle of interrelated organisational routines for incrementally improving existing products/processes</td>
<td>Peng et al. (2008)</td>
<td>Manufacturing</td>
<td>Process view</td>
</tr>
<tr>
<td>The ability to consistently improve current processes and learn new ones</td>
<td>Anand et al. (2009)</td>
<td>Cross-sector</td>
<td>Process view</td>
</tr>
<tr>
<td>The people that have the confidence, knowledge and skills to lead change</td>
<td>Bevan (2010)</td>
<td>Healthcare</td>
<td>Actor driven</td>
</tr>
</tbody>
</table>
Improvement capability is knowledgeable and skilled human resources able to lead the design of improvement initiatives, to achieve measurable results, execute (i.e., develop, test, measure, and implement changes) the improvement efforts, and sustain the results.

An organisational strategy to implement and spread quality improvement programmes across their organisation

<table>
<thead>
<tr>
<th>Definition</th>
<th>Author</th>
<th>Sector</th>
<th>Perspective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement capability is knowledgeable and skilled human resources able to lead the design of improvement initiatives, to achieve measurable results, execute (i.e., develop, test, measure, and implement changes) the improvement efforts, and sustain the results</td>
<td>Kaminski et al. (2014)</td>
<td>Healthcare</td>
<td>Actor driven</td>
</tr>
<tr>
<td>An organisational strategy to implement and spread quality improvement programmes across their organisation</td>
<td>Babich et al. (2016)</td>
<td>Healthcare</td>
<td>Process view</td>
</tr>
</tbody>
</table>

A comprehensive literature review of instruments and frameworks used to assess improvement capability details 70 instruments, and identified more than 22 heterogeneous constructs (Furnival et al., in development-a). The review synthesises these constructs into eight dimensions of improvement capability, and these are described in Table 7.2. Assembled together, the dimensions can be viewed as eight high level routines that bundle to form improvement capability. However, further theorisation of the improvement capability dimensions is required.

**Table 7.2: Dimensions of improvement capability**

(Furnival et al., in development-a)

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organisational culture</td>
<td>Core values, attitudes and norms and underlying ideologies and assumptions within an organisation</td>
</tr>
<tr>
<td>Data and performance</td>
<td>Use of data and analysis methods to support improvement activity.</td>
</tr>
<tr>
<td>Employee commitment</td>
<td>Encompasses the level of commitment and motivation of employees for improvement.</td>
</tr>
<tr>
<td>Leadership commitment</td>
<td>Support by formal organisational leaders for improvement and performance.</td>
</tr>
<tr>
<td>Process improvement and learning</td>
<td>Systematic methods and processes used within an organisation to make ongoing improvement through experimentation.</td>
</tr>
<tr>
<td>Service-user focus</td>
<td>Identification and meeting of current and emergent needs and expectations from service users.</td>
</tr>
<tr>
<td>Stakeholder and supplier focus</td>
<td>Extent of the relationships, integration and goal alignment between the organisation and stakeholders such as public interest groups, suppliers and regulatory agencies.</td>
</tr>
<tr>
<td>Strategy and governance</td>
<td>Process in which organisational aims are implemented and managed through policies, plans and objectives.</td>
</tr>
</tbody>
</table>
To summarise, improvement capability is a widely-used term with considerable ambiguity regarding its definition, meaning and operationalisation. It can be seen as useful and important within the improvement literature and community; however, it is inadequately theorised. The next section considers the theories concerned with organisational capability and how they can provide theoretical foundations.

**Theoretical perspectives**

There are many different theories that could be used to underpin theoretically based research concerning improvement capability, and Table 7.3 outlines three capability-led theories of performance (Talbot, 2010). These are the resource based view (RBV), organisational ambidexterity (OA) and the DCV. The table highlights the main principles, focus and components of each theory, and provides information on the support for and critiques of these theories.

The RBV proposes that persistent superior performance is related to organisational strategic resources. It theorises that organisations are comprised of a mix of tangible and intangible resources, such as physical, human and organisational capital (Barney, 1991). Differences in the distribution of these resources within organisations are understood to account for performance variation. The RBV suggests that internal forces drive firms’ decision-making on how best to deploy organisational resources (Rumelt, 1982; Wernerfelt, 1984). Strategic resources must be valuable, sufficiently rare, inimitable and exploitable (known as the VRIN framework) (Barney, 1991; Barney, 1995). The RBV focuses attention on the internal resources or strengths within an organisation to manage uncertainty, rather than capitalising on the opportunities presented by a changing external environment. Addressing these opportunities depends on the scope to invest in new resources. Examples include patents, reputation and unique knowledge.

OA theorises that to improve performance, organisations need to both simultaneously pursue both explorative (discontinuous) and exploitative (incremental) innovation (O’Reilly and Tushman, 2004). This is the notion of balancing the need to deliver both incremental and radical change simultaneously within an organisation to secure survival and long term performance. Exploration is described as a focus on organisation search, discovery, autonomy, learning new things, and innovation, whereas exploitation is described as a focus on efficiency,
control, certainty and variation reduction (March, 1991), in other words, putting existing knowledge into practice. Gibson and Birkinshaw (2004) indicate that there are always trade-offs to be made between exploitation and exploration, and whilst these trade-offs can never entirely be eliminated, the most successful organisations reconcile them to a larger degree, and in so doing enhance their long-term performance.

The DCV indicates that superior and sustained performance depends on the organisational capacity to purposefully create, extend and modify its resource base through bundles of organisational routines, which must be sustained over time (Su et al., 2014; Helfat et al., 2007). Capabilities and routines differ across and between organisations, as they have different levels of resources or may have created routines differently (Hitt et al., 2016). It is argued that organisations with more dynamic capabilities will outperform organisations with less, and that dynamic capabilities both mediate and underpin high performance (Felin et al., 2015). This is stated to particularly be the case in dynamic environments where there is ongoing uncertainty through changing technology, competition or political mandates, and organisations need to adapt to these changing conditions (Felin et al., 2015).

Whilst each theory has emerged from different research streams, there is considerable theoretical overlap and similarity in the levels of evidence. Vogel and Güttel (2013) confirm the findings from Di Stefano et al. (2010) that there are similar theoretical foundations for DCV, RBV and OA within management research. These three theories were developed within the private sector, and there is less support for these theories within the public sector, including healthcare.

The three theories are critiqued similarly in five main areas, and they are criticised for insufficient conceptualisation, and using vague and inconsistent definitions (Kraaijenbrink et al., 2010; Birkinshaw and Gupta, 2013; Vogel and Güttel, 2013). In addition, these theories place a focus and emphasis on macro perspectives rather than micro-elements and their assembly (Molina-Azorín, 2014; Turner et al., 2013; Felin et al., 2015). Inadequate measurement and prediction (Hinterhuber, 2013; Junni et al., 2013; Pavlou and El Sawy, 2011) hinders the development of empirical evidence, and there has been a lack of research into understanding the role of managers and their role in decision making (Turner et al., 2013; Sirmon et al., 2007; Eggers and Kaplan, 2013). Finally, there has been little research completed within
the public sector (Burton and Rycroft-Malone, 2014; Easterby-Smith et al., 2009; Smith and Umans, 2015).

There is considerable overlap across the three resource-based theories reviewed in this paper, and there is a large body of literature about the DCV. The DCV has a focus on how routines bundle, orchestrate and interact, and OA has been described as a dynamic capability (Helfat and Winter, 2011; O’Reilly and Tushman, 2008), as has improvement capability (Bessant and Francis, 1999). The RBV is criticised for being static and insufficiently accounts for changes in the external environment for organisations (Teece, 2012; Helfat et al., 2007), whereas the DCV takes a process view of performance and is helpfully used in this research study to understand how the improvement capability dimensions are configured.

Table 7.3: Theory comparison

<table>
<thead>
<tr>
<th>Theory</th>
<th>Resource based view</th>
<th>Organisational ambidexterity</th>
<th>Dynamic capabilities view</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principles</td>
<td>Sustained superior performance depends on organisational strategic resources and strategic decision making. Resources must be valuable, imperfectly inimitable, rare and exploitable (VRIN) (Barney, 1995).</td>
<td>Defined as the ability of an organisation to simultaneously pursue both explorative (discontinuous) and exploitative (incremental) innovation (O’Reilly and Tushman, 2004).</td>
<td>Emphasises that superior and sustained performance depends on the organisational capacity to purposefully create, extend and modify its resource base through a bundle of organisational routines which must be sustained over time (Su et al., 2014; Helfat et al., 2007).</td>
</tr>
<tr>
<td>Primary focus</td>
<td>Resources</td>
<td>Knowledge</td>
<td>Routines</td>
</tr>
<tr>
<td>Components</td>
<td>Organisations need to structure, bundle and leverage organisational resources synchronously to achieve a superior performance (Sirmon et al., 2007).</td>
<td>Organisations need to explore and exploit knowledge (Benner and Tushman, 2003; Benner and Tushman, 2015).</td>
<td>Organisations need to sense, seize and reconfigure organisational routines (Teece, 2007).</td>
</tr>
</tbody>
</table>
A dynamic capabilities view of improvement capability

The DCV is used to explore how improvement capability can be understood and is used to review the improvement capability dimensions detailed in Table 7.2. This section considers how the DCV contributes to the understanding of improvement capability.

Dynamic capabilities build from three constituent parts or ‘microfoundations’: sensing, seizing and reconfiguring (Helfat and Martin, 2014; Teece, 2012). This allows collective concepts to be unpacked into individual factors in order to understand their impact. Sensing includes the skills and processes to detect and process emerging opportunities before they fully materialise (Denrell et al., 2003), for example research and development, while seizing is required to ensure strategic choices and associated investments are made in these emerging opportunities. Reconfiguring enacts the decisions made by adapting established routines or acquiring new ones. Orchestration is needed to synchronise the capabilities needed for implementation with the strategy employed (Helfat et al., 2007; Sirmon et al., 2011), and organisational conflicts between the need to control and the need to innovate can emerge and need ‘orchestrating’ to ensure balance (Sirmon et al., 2011). Barney and Felin (2013) describe microfoundations as a pragmatic and important approach for examining collective constructs. This is important given the conceptual inconsistency within the literature and the need for operational definitions to support development plans, measurement and evaluation. This research study uses microfoundations and the DCV to develop the dimensions of improvement capability.

Using this theoretical perspective, the dimensions of improvement capability identified in the literature (Table 7.4) are reviewed. The literature descriptions for each microfoundation are compared with each improvement capability dimension and inductively categorised. Giudici and Reinmoeller (2012) state that dynamic capabilities research needs to strive for clarity in definitions in order to prevent reification and to build incremental knowledge. Table 7.4 shows that the improvement capability dimensions can be viewed with microfoundations.
Table 7.4: Improvement capability framework
(adapted from Teece, 2007 and Furnival et al., in development-a)

<table>
<thead>
<tr>
<th>Microfoundations</th>
<th>Microfoundation examples</th>
<th>Improvement capability dimension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensing</td>
<td>Customer needs</td>
<td>Service-user focus</td>
</tr>
<tr>
<td></td>
<td>Research and development</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Technology and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>industry developments</td>
<td></td>
</tr>
<tr>
<td>Seizing</td>
<td>Culture</td>
<td>Employee commitment</td>
</tr>
<tr>
<td></td>
<td>Leadership</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Communication</td>
<td>Leadership commitment</td>
</tr>
<tr>
<td></td>
<td>Developing business</td>
<td>Organisational culture</td>
</tr>
<tr>
<td></td>
<td>models</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Understanding markets</td>
<td></td>
</tr>
<tr>
<td></td>
<td>and boundaries</td>
<td></td>
</tr>
<tr>
<td>Reconfiguring</td>
<td>Decentralisation</td>
<td>Data and performance</td>
</tr>
<tr>
<td></td>
<td>Knowledge</td>
<td>Process improvement and</td>
</tr>
<tr>
<td></td>
<td>Management</td>
<td>learning</td>
</tr>
<tr>
<td></td>
<td>Co-specialisation</td>
<td>Strategy and governance</td>
</tr>
<tr>
<td></td>
<td>Governance</td>
<td></td>
</tr>
</tbody>
</table>

*Sensing*

Two improvement capability dimensions of service-user focus and stakeholder and supplier focus were categorised as ‘sensing’ microfoundations. This focuses on the organisation identifying ideas and changes within the ecosystem that need responding to. This includes viewpoints, opinions, technological advances, and external requirements, such as regulations that change continuously and ongoing developments from stakeholders and suppliers, as well as changing service-user requirements.

*Seizing*

The three dimensions of organisational culture, leadership commitment, and employee commitment, were categorised as ‘seizing’ microfoundations. These three dimensions represent the internal environment of an organisation and the decision-making processes within to (dis)assemble capabilities in response and anticipation of opportunities identified. This includes the decisions to take part in making improvements, such as those that respond to service-user complaints or improvement suggestions; these decisions potentially indicate the main link between the dimensions. Commitment to a particular strategic thrust by both the leadership and
employees of an organisation is critical, and commitment is considered the prerequisite for sustained performance (Schreyogg, 2007).

**Reconfiguration**

Finally, the three dimensions of process improvement and learning, data and performance, and strategy and governance, were categorised as the ‘reconfiguring’ microfoundation. This includes implementing new processes and policies, whilst incrementally making changes to existing processes and policies. This encompasses methods and processes used to generate and monitor improvement activities, including the use of improvement approaches such as lean, together with the use of measurement systems and practices to develop and review plans and strategies.

**Inter-relationships**

This categorisation process illustrates that the three microfoundations that make up a dynamic capability are present in the identified improvement capability dimensions. The concept of orchestration (Sirmon et al., 2007) may be useful in explaining why some organisations are less successful in performance improvement than others. Orchestration is required to ensure that excessive focus on specific microfoundations does not lead to an imbalance or isolation by focusing on one microfoundation or dimension at the expense of another. For example, many organisations provide training for improvement tools and techniques, and this could be categorised within the process improvement and learning dimension, as part of the reconfiguration microfoundation. However, the service-user focus dimension is needed to inter-relate with the process improvement and learning dimension to ensure that service user requirements inform the improvement training given that most improvement approaches emphasise the role of the service user (or customer) (Boaden and Furnival, 2016). An organisation without inter-relationship, between dimensions categorised within sensing and reconfiguration microfoundations would be ineffective at solving service-user needs, potentially leading to a ‘cosmetic’ organisation. This is where an organisation is actively sensing and seizing new ideas and knowledge, and developing plans and investments for their use, and is unable to put these new ideas and plans into practice. This may lead to an organisation giving a false impression and a sense of assurance to external agencies, service-users and stakeholders, and leading to a delay in the reconfiguration of routines.
Without sensing, an organisation may appear arrogant, insular and fortress-like, seemingly unwilling to seek ideas and knowledge from outside the organisation and focused on internally generated ideas for improvement based on an incomplete view of the opportunities and threats facing that organisation. This is where an organisation is actively seizing and developing improvement plans, strategies and measuring their outputs, but the improvements fail to meet external stakeholder, supplier and service-user needs. For example, a focus on improving the quality of a product and service when the external stakeholders and service users want improvements such as lower priced products or services that are delivered more quickly, and are content with the current quality.

An organisation may become bureaucratic and apathetic, unable to make decisions for investment, and at risk of groupthink without seizing. This is where an organisation is actively seeking new ideas and can put them into action; however, a lack of decision making may mean that this never occurs due to internal inertia. For example, an organisation might be well known for its technological, design and production processes and its ability to seek out opportunities for their use (reconfiguration and sensing), yet it may have an institutional reluctance to transition and invest in new technologies or settings. This may lead to a slow development of change, leading to a long time-lag between the identification of a potential opportunity and the reconfiguration of routines to enable its exploitation.

Conclusions

This framework views improvement capability through the lens of the microfoundations of dynamic capabilities, conceiving it as a combination of eight dimensions which all play an important role in its formation and development. This paper has discussed the application of the DCV to analyse improvement capability, and has contributed to a more nuanced understanding of its configuration and how it may influence variations in organisational performance, and thereby how to improve organisational performance. The framework has developed a more fine-grained understanding of improvement capability and its configuration, and enables avenues for further research to be identified using the DCV literature.

Further research on the configuration of improvement capability is now required to understand in detail how the dimensions are arranged and aggregated at the micro
level. This would examine how the dimensions in this framework inter-relate to each other within and across each microfoundation. Furthermore, the implications of this framework are that ‘sensing’ is important for researchers focusing on organisation context and processes for a wide range of stakeholders, and there are already existing calls for more research on organisational context (Kaplan et al., 2013; Øvretveit, 2011). Similarly, ‘seizing’ is important for researchers who focus on the role of people within organisational settings, and empirical research points to the importance both leadership and employee commitment for the development of improvement capability across an organisation (Babich et al., 2016; McGrath and Blike, 2015; Godfrey, 2013). When considering reconfiguration, there is a need to understand more about the specific routines to enact changes for improvement and to examine how reconfiguration works across differing sectors. Particularly, there is insufficient empirical research in non-market situations, particularly from sectors outside of manufacturing and technology (Hogan et al., 2011; Easterby-Smith et al., 2009), including the public sector and healthcare.

Further research is also required to understand how the microfoundations and associated dimensions of improvement capability are orchestrated. The strength of this framework is that it views improvement capability as an interdependent bundle of routines that may lead to improved performance. It moves from a direct cause and effect understanding of each dimension to one which indicates more nuanced relationships in the configuration of the dimensions. This allows managers to adapt and orchestrate the dimensions based on local conditions and requirements. Thus, further research concerning improvement capability is called for to strengthen the understanding of orchestration. This would strengthen the prospective assessment of organisations and help indicate the level, type and strength of development that organisations require in order to improve their performance across the dimensions. A more detailed understanding of the microfoundations of improvement capability is important for both employees, leaders, organisations and external bodies, such as regulatory agencies.

This theoretically based framework provides a richer and more complete depiction of how improvement capability develops within an organisation. In addition, breaking improvement capability into its component parts enables managers to identify the areas that are most in need of attention.
References


Section 3
Chapter 8 - Discussion and conclusions

The aim of the final chapter is to review and discuss the research study, provide a summary of the findings, and demonstrate how the research question has been addressed. The chapter highlights the contribution to knowledge and the limitations of the research. In addition, it considers implications for research, policy and practice from the findings of the research study and concludes with recommendations for future research.

The purpose of this research study was to understand the regulatory conceptualisation and assessment of improvement capability within healthcare organisations. It aimed to answer the following research question and the associated research objectives:

- How do regulatory agencies assess improvement capability within healthcare organisations?

Objectives:

  a) To understand and define improvement capability
  b) To understand similarities and differences in how improvement capability is currently conceptualised and assessed in practice
  c) To develop a conceptual framework for assessing improvement capability

This research question and associated objectives implicitly assumed that regulatory agencies might assess improvement capability. The research study has argued that its assessment will support the development of more responsive models of regulation, thereby allowing more tailored regulatory enforcement interventions and better use of regulatory resources.

The research study was completed in three phases linked to the three research objectives. Phase 1 involved conducting a detailed integrative literature review (Whittemore and Knafl, 2005) on the assessment of improvement capability, while Phase 2 (parts a and b) involved collecting and analysing empirical data regarding the current regulatory environment, strategies, methods and approaches for
improvement across the UK. Finally, Phase 3 involved the development of a conceptual framework for improvement capability.

This chapter reviews the findings for each research objective in turn. The microfoundations of dynamic capabilities (Teece, 2007) are then used to provide a theoretical framework for the discussion. Section 8.4 highlights the contribution and practical implications of the research study to the understanding of healthcare regulation and its role in the assessment and development of improvement capability in response to the research question. The limitations of the research study are discussed in Section 8.5, which also reflects on the generalisability of the findings. Finally, the chapter concludes by discussing potential research avenues.

8.1 Background to the research study

Regulatory theory emphasises the three aims of regulation, namely accountability, assurance and improvement, yet acknowledges that each organisation places these aims as different priorities and enacts them with different methods. Early regulation was used as a form of social control requiring punitive intervention for divergent behaviour. Later contributions suggested that deterrence models do not necessarily lead to improved healthcare and alternative persuasive regulatory models were developed to ensure ‘compliance’ with standards. Further developments have argued for a combination of both extremes, responsively contingent on the local circumstances and recognising that ‘benign big guns’ may still be required to deter unacceptable organisational behaviour (Ayres and Braithwaite, 1992). However, a responsive regulatory model is more complex and requires considerable judgement and discretion, particularly vis-à-vis deterrence models. At the same time, the empirical evidence on the impact of the use of regulation and closely related accreditation remains contradictory. In their seminal theoretical contribution ‘Responsive Regulation’ (Ayres and Braithwaite, 1992), it is suggested that both regulatory agencies and regulated organisations need to collaborate in order for regulation to be most effective and successful in its aims of protecting the public; however, the achievement of this balance is challenging and contentious. In the years that have followed, research has continued to pursue understanding and knowledge to both support or refute these claims. Research has developed to understand how responsive regulatory practices have emerged as regulation has been reconceptualised beyond the state. How regulation is used to legitimise the way
society operates has been examined, and this has provoked further understanding of how regulatory design, enforcement and compliance are enacted (Parker, 2013). Furthermore, it is argued that a lack of capacity to comply is a risk to enforcement strategies, especially for organisations deemed as ‘low risk’ and who have less interaction with regulatory agencies (Black and Baldwin, 2012). However, there has been less research to understand how regulatory agencies choose enforcement interventions, and thus there remain several knowledge gaps requiring further empirical exploration.

A responsive regulatory model is increasingly complemented by a developmental perspective, which uses enforcement methods to encourage improvement through deliberate intervention within and across organisations. This includes capability interventions, which provide support and aid, and development support to organisations (Talbot, 2010). It is argued that improved performance should be delivered through the development of capability interventions, for example through the use of improvement approaches such as BPM (Hammer and Champy, 1993) and TQM (Oakland, 2003). However, the proponents of a developmental perspective tend to assume that the use of improvement approaches as alternative enforcement strategies negates the criticisms of reduced autonomy and there is a lack of evidence for improvement approaches. They tend to take the possibility of deliberate cultivation of improvement capability for granted and there is a lack of consensus as to how improvement capability is conceptualised. Whilst the literature on healthcare improvement is long standing and builds on a substantial body of performance research from industrial and healthcare sectors (D’Andreamatteo et al., 2015; Nicolay et al., 2012; Shortell et al., 1995; Berwick, 1989), little is known about the regulatory perspective of improvement capability, and further research is required to understand regulatory enforcement actions, including capability interventions (Black and Baldwin, 2012).

Davidoff et al. (2015) argues that improvement research makes insufficient use of theory and conceptual frameworks, while Talbot (2010) outlines several resource-based theories to support capability led approaches, which are argued to have considerable theoretical overlap (Vogel and Güttel, 2013). The DCV (Teece and Pisano, 1994) was used to provide stronger theoretical framing for this research because it takes a process view of performance and emphasises that improved
performance is contingent on the organisational capability to purposefully create, extent and modify its resources through routines over time.

In summary, regulatory agencies are altering the balance of deterrence and compliance approaches within healthcare organisations, and agencies are increasingly focusing on improvement capability. Nevertheless, there is little theoretically informed research about how regulatory agencies conceptualise improvement capability, how they assess and develop it, and the impact on the way they work together. To respond to these calls for research this study has examined in detail how regulatory agencies in UK healthcare make assessments about improvement capability within organisations in order to inform enforcement strategies. Van de Ven (2007) argues that measurement and assessment are fundamentally conceptual issues, which necessitates the definition of theoretical constructs, their associated variables, and the development of appropriate valid and reliable measurement instruments. Therefore, this research study was informed through an integrative literature review of how improvement capability is conceptualised and assessed, which led to the development of a framework drawn from the DCV (Teece, 2007; Teece et al., 1997).

8.2 Research findings

The research used a qualitative comparative case study design using interviews and regulatory agency documents for data collection and then content and thematic analysis of the data. This design is particularly suited to research studies dealing with complex social issues and promotes several forms of data collection to develop explanatory accounts. Six organisational regulatory agencies within the UK were chosen as the research setting, with interview participants representing a cross-section of roles and backgrounds within each regulatory agency, including front-line inspectors, administrators and board level executives, both from clinical and non-clinical professions.

8.2.1 Phase 1: Understanding improvement capability

Paper 1 (Furnival et al., in development-a) provides a comprehensive and detailed integrative literature review of the conceptualisation and assessment of improvement capability across sectors, including healthcare. It reviews a range of assessment instruments and frameworks, both qualitative and quantitative that could be used to
assess improvement capability at the departmental and organisational level. This draws attention to a wide range of measurement constructs and themes with limited commonality. The wide variety of assessment instruments and frameworks can partly be explained by the heterogeneity in the conceptualisation of improvement capability. The review also details the lack of validity and reliability of assessment instruments and frameworks for improvement capability. Finally, 80% of the instruments and frameworks used 22 constructs, which following thematic analysis and a detailed review of measurement items led to the development of a synthetic framework of eight dimensions of improvement capability.

8.2.2 Phase 2: Understanding current improvement capability assessment practices

A comparative analysis of the regulatory arrangements in the four countries of the UK is presented in paper 2 (Furnival et al., under review), which was developed from a review of 90 policy documents and 48 interviews with staff from six regulatory agencies. This paper compares the different regulatory agencies across the UK, and discusses their regulatory aims, methods and approaches. It identifies a developmental trend whereby regulatory agencies are using a hybrid approach. This trend takes both deterrence and compliance regulatory approaches in unison, revealing that regulatory agencies have differing approaches towards delivering effective oversight and diverse hybrid forms of enforcement strategies are emerging. Nevertheless, the diversity in approaches used to balance requirements to assure and improve care face common problems which are related to the clarity of regulatory roles, the level of resources they have, and the strength of their relationships with those they regulate.

The assessment of improvement capability by healthcare regulatory and improvement agencies in the UK is presented in paper 3 (Furnival et al., in development-c). A sample of five inspection and assessment reports from six regulatory agencies, totalling 30 reports, is used to explore how improvement capability is currently assessed in practice compared with documentary policies and stated intentions collated through participant interviews. The eight dimensions of improvement capability identified through the integrative literature review in paper 1 (Furnival et al., in development-a) are used as a coding framework. The analysis finds that whilst regulatory agencies seek to assess improvement capability to
support the development of tailored interventions, the term is used inconsistently. Two dimensions of improvement capability dominate the assessment process: process improvement and learning, and strategy and governance. This indicates the deliberate choices, potential challenges or omissions in regulatory access to data, and regulatory practices in operationalising regulatory intentions to assess improvement capability.

### 8.2.3 Phase 3: Conceptual framework for the assessment of improvement capability

A conceptual framework for improvement capability is presented in paper 4 (Furnival et al, in development-b) which builds on the literature review and the empirical data presented in the previous papers. It draws on the DCV to frame the eight dimensions identified in paper 1 into three microfoundations, namely sensing, seizing and reconfiguring (Teece, 2007), and describes how each contributes to the development of dynamic capability and considers the implications for improvement capability. Finally, it describes how absent, weak or excessive dimensions within each microfoundation may cause misalignment and inadequate configuration of improvement capability (Teece, 2007).

### 8.3 Discussion

This section uses the conceptual framework and the empirical findings from papers 1-4. To support the discussion, the content analysis from the regulatory assessment reports in paper 3 (Furnival et al., in development-c), is summarised for all regulatory agencies in Table 8.1 (in paper 3 the data is presented by regulatory agency only, rather than in summary). A comparison of the summary of the content analysis and the conceptual framework shows that the improvement capability dimensions that are used more frequently in regulatory agency assessments can be viewed as part of a ‘reconfiguring’ microfoundation of a dynamic capability.
The following sub-sections discuss possible explanations for why regulatory agencies use the improvement capability dimensions classified as reconfiguring microfoundations more frequently than others. Next, the implications for increased regulatory focus on improvement capability are considered for different regulatory models, and the risks of using improvement capability dimensions that can be viewed as reconfiguring microfoundations more frequently than others are discussed.

To simplify the text for the remainder of this chapter, the improvement capability dimensions that can be viewed as a reconfiguring microfoundation will be referred to as ‘reconfiguring dimensions’, similarly improvement capability dimensions that can be viewed as a sensing or seizing microfoundation will be referred to as ‘sensing dimensions’ and ‘seizing dimensions’, respectively.

### 8.3.1 Why do regulatory agencies focus on reconfiguring dimensions?

There are several possible explanations for the more frequent use of reconfiguring dimensions, which include the dimensions strategy and governance, process improvement and learning, and data and measurement. A possible explanation for this may be connected to the ease of availability of data for assessment. Reconfiguring dimensions include strategic intentions, measures and goals, as well for example the number of employees attending improvement approach training courses or improvement tracking information within a report. This type of information is easily available from organisations via their websites and board reports, and therefore is easy to use within regulatory agency assessments.

Another possible explanation for this may be connected to the regulatory remit. Regulatory agencies have three aims to fulfil: accountability, assurance and improvement (Nunes et al., 2009; Walshe, 2003). Reconfiguring dimensions may

<table>
<thead>
<tr>
<th>Microfoundation (Teece, 2007)</th>
<th>Improvement capability dimension</th>
<th>Total</th>
<th>Total per microfoundation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensing</td>
<td>Stakeholder and supplier Focus</td>
<td>10%</td>
<td>12%</td>
</tr>
<tr>
<td></td>
<td>Service-user focus</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>Seizing</td>
<td>Organisational culture</td>
<td>6%</td>
<td>23%</td>
</tr>
<tr>
<td></td>
<td>Leadership commitment</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Employee commitment</td>
<td>12%</td>
<td></td>
</tr>
<tr>
<td>Reconfiguring</td>
<td>Process improvement and learning</td>
<td>23%</td>
<td>65%</td>
</tr>
<tr>
<td></td>
<td>Data and performance</td>
<td>19%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Strategy and governance</td>
<td>23%</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 8.1: Content analysis compared to the improvement capability framework
have greater utility for regulatory agencies in the achievement of the regulatory aims of accountability and assurance; this might explain why they are used more frequently. For example, organisational policy documents and data indicating current organisational performance would fit within the reconfiguring dimensions, specifically strategy and governance, and data and performance. Whilst these dimensions are important for the regulatory aim of improvement, this data can also be used to provide evidence of compliance with regulatory standards for customers, service-users or patients, or could be used as evidence to hold organisations to account if the evidence indicates non-compliance with regulatory standards. In contrast, there are fewer sources of data and evidence for sensing and seizing dimensions, such as organisational culture or service-user focus, making it more difficult to use data within these dimensions for accountability and assurance purposes.

A final possible explanation considers that there may be relatively less resources and skills within regulatory agencies to assess all dimensions of improvement capability, particularly for those who have not moved, or are less advanced in moving towards a responsive regulatory model. It could be argued that existing skills and resources assess reconfiguration dimensions more frequently, as these dimensions have been assessed under previous compliance and deterrence models of regulation, and therefore processes, procedures, experience and training to assess reconfiguration dimensions are more developed.

8.3.2 What are the implications for regulatory models?

There are three main regulatory models outlined within this research study: deterrence, compliance and responsive, which includes the emerging hybrid models described in paper 2 (Furnival et al., under review). Deterrence models assume that organisations are amoral and will try to break rules if they believe it possible to escape the consequences of non-compliance (Bardach and Kagan, 1982), while compliance models assume organisations will try to comply with rules, but may be unable to and require support (Parker, 2000). Both the deterrence and compliance regulatory models view organisations as non-compliant when regulatory standards are not met regardless of local circumstances or the potential to improve. Therefore, regulatory agencies using deterrence and compliance models have less need to understand organisational context and consider organisational performance as a-
contextual. This is partly because organisational context does not impact on detection and enforcement processes. These assumptions can be argued to lead to the use of a conceptualisation of improvement capability which uses reconfiguration dimensions more frequently, rather than sensing and seizing, which provide a greater understanding of organisational context.

Responsive models aim to balance both deterrence and compliance models contingent on the specific circumstances. Paradoxically, this means that by being able to escalate to tough enforcement, most regulation can be collaborative and encouraging (Braithwaite, 2011). Responsive regulatory models recognise that there will be a range of performance within organisations, and their regulatory response needs to be tailored to specific circumstances (Ayres and Braithwaite, 1992).

Therefore, the implications from this research study suggest that regulatory agencies developing hybrid and responsive models of regulation need to further develop their diagnostic processes in order to understand local circumstances and to develop regulatory responses, including the tailored provision of improvement support. However, responsive regulatory models may be challenging to execute by regulatory agencies, as greater regulatory effort and resources are needed to understand local circumstances and to ensure that enforcement approaches can be sufficiently flexible for each organisation.

8.3.3 How can regulatory agencies use improvement capability to be more responsive?

The argument detailed in this research indicates that responsive regulatory models depend on the assessment of existing organisational circumstances and performance to ensure appropriate tailoring and balancing of the regulatory response. However, responsiveness may be challenging to enact, and requires considerable discretion and effort from regulatory staff. This is needed to ensure that the organisational circumstances and performance are accurately and appropriately diagnosed and understood, in order to inform a tailored and responsive regulatory response. For example, an organisation could report an area of poor performance and non-compliance to a regulatory agency. A responsive regulatory model requires that further information is shared with the regulatory agency to understand the reasons for the poor performance, for instance an organisational decision to not implement agreed actions that would have prevented the poor performance, an unanticipated
extended time-period to implement previously agreed actions to improve performance, or an unusual and rare event causing non-compliance. Each of these scenarios may require a tailored regulatory response; deliberately failing to complete actions may require an organisation to be escalated up the regulatory enforcement pyramid, while slow action implementation by an organisation may require ongoing monitoring and encouragement, and an unusual or rare event may not necessitate a regulatory response.

Understanding organisational improvement capability offers a way for regulatory agencies to improve responsiveness by differentiating organisations. Figure 8.1 shows how different combinations of improvement capability and performance could be used to segment organisations into four quadrants. This shows the potential different regulatory response for each quadrant (highlighted in bold).

![Figure 8.1: Potential responses to regulatory assessments](image)

The lower left hand quadrant shows that for organisations viewed as having a relatively lower performance and lower improvement capability compared to their peers, they may need help and may require formal regulatory enforcement action. The lower right hand quadrant shows that for organisations with a relatively high performance but relatively low improvement capability compared to their peers, a regulatory response such as a designed intervention and the provision of support...
including resources, may be needed to reduce the risk of a declining performance.
The upper left hand quadrant shows that for organisations viewed as having relatively high improvement capability but lower performance compared to their peers, regulatory agencies may choose to encourage these organisations to ‘keep going’ through a light touch and the provision of guidance, expertise and encouragement, as organisations may be assumed to be on an upwards trajectory. Finally, the upper right hand quadrant shows that for organisations viewed as having a relatively high improvement capability and performance compared to their peers, regulatory agencies may choose to note their performance and not intervene or support these organisations, as these organisations are likely to improve anyway.

Further consideration could be given to how improvement capability could be assessed over time. It might be expected that improvement capability development would precede performance and there would be a time lag between the development of improvement capability and improved performance. Similarly, it might be expected that should investment in the development of improvement capability slow or halt then performance may subsequently dip. Therefore, organisational investment in the development of improvement capability may also be an indication of an organisation’s future performance trajectory and may need to be considered when developing a regulatory response.

### 8.3.4 Risks of focusing on improvement capability

This research study has explored the potential to assess improvement capability in order to support the development of responsive regulatory models within healthcare and to improve healthcare performance. It is suggested in the research study that an improvement capability assessment would support the development and tailoring of regulatory enforcement suitable for local circumstances. It is argued in this research that an improvement capability assessment may be useful to organisations who wish to self-assess their improvement capability and use such an assessment to identify which dimensions need further development within their organisation. This could also be used to identify if development strategies were successful over time.

However, there may also be several risks of the assessment of improvement capability which need to be considered. One risk is that measures of improvement capability are used to hold organisations to account, rather than being used for
determining appropriate regulatory responses, because the act of quantification in an assessment instrument is judgement forming. The quantification of improvement capability would help organisations and regulatory agencies to know if their development efforts have been successful and where they need to focus their next developmental attempts; however, should organisational improvement capability developmental attempts prove futile or slow, an assessment instrument could be used to hold organisations to account for failing to develop improvement capability. Such action may undermine relationships between organisations and regulatory agencies, hindering the development of improvement capability by using this information for accountability, rather than performance improvement. This may reduce trust and hinder relationship development between regulatory agencies and organisations and could lead to a reduction in information sharing between organisations and regulatory agencies or to ritualistic development of improvement capability.

Regulatory agencies could use the assessment of improvement capability to assist them in targeting the use of their limited resources. This could mean, for example, that organisations with similar performance outcomes but less improvement capability receive more improvement support than those assessed with greater improvement capability. However, this poses another risk as it could be considered unfair. It could be perceived that organisations who have failed to invest in the development of improvement capability are being rewarded by receiving help and support from regulatory agencies with little cost to the organisations at the expense of organisations that have made investments to develop improvement capability. This type of situation could paradoxically discourage organisations to invest in the development of improvement capability.

Alternatively, regulatory agencies could use the assessment to reward organisations who have invested in improvement capability through the provision of access to special rewards or funding. However, this too could have several unintended negative effects, as it could exacerbate the differences between the organisations with and without improvement capability, strengthen organisational path-dependency, whereby organisations who have already invested in the development of improvement capability receive more resources to invest further, and paradoxically, organisations without improvement capability could find
improvement capability even more difficult to develop, through a lack of resources and support.

Finally, there is variation in the local approaches and experiences used when making assessments and regulatory judgements (Boyd et al., 2016) which poses a further risk. Different assessors will interpret each improvement capability dimension with some degree of discretion and propose solutions based on these judgements. Therefore, a responsive approach is more complicated than a deterrence or compliance approach, both to design and enact. Even with the use of a framework and a broad set of expected standards, there will be variation in the assessment of improvement capability, the development of improvement capability, and the tailored enforcement approach selected. This level of complexity may be difficult to manage and justify, and runs the risk of being viewed as biased and unfair if seemingly similar organisations, based on their performance, are subject to different assessment judgements and enforcement actions because they have been assessed to have different improvement capability and perceived potential to improve.

Despite the need for the assessment of contextual circumstances required to inform a responsive regulatory model, the assessment of improvement capability poses the risk of several inadvertent consequences. These include the risk of using improvement capability information for accountability and regulatory judgements, the paradoxical exacerbation of differences between those with and without improvement capability, and other organisational developmental needs may be deprioritised.

This research has highlighted the tensions and risks faced by regulatory agencies whilst moving towards more responsive models including roles, resources and relationships (Furnival et al., under review), which may not be available or sufficient to ensure successful execution of these models. These tensions and risks may mean that some regulatory agencies may decide, perhaps due to cost or political pressure, to revert to compliance or deterrence regulatory models.

8.3.5 How do regulatory agencies assess improvement capability?

This research study set out to explore how regulatory agencies assess improvement capability. This research identifies that there are plural conceptualisations of improvement capability within the literature, with many heterogeneous assessment
instruments and frameworks. The constructs from the assessment instruments and frameworks were synthesised thematically into eight dimensions of improvement capability. This research also shows that healthcare regulatory agencies in the UK are developing new regulatory models to support the assessment and development of improvement capability, but face tensions linked to their role, resources and relationships. This research study also finds that regulatory agencies use a limited conceptualisation of improvement capability during assessments, and that two of the eight dimensions of improvement capability are used more frequently. Drawing from the microfoundations of the DCV (Teece, 2007), a conceptual framework of improvement capability is proposed using the eight improvement capability dimensions. This framework indicates that the two dimensions used more frequently can be viewed as reconfiguring dimensions. Regulatory agencies can strengthen improvement capability assessments by using the proposed conceptual framework to inform their conceptualisation and understanding of improvement capability. This may reduce the tensions faced by regulatory agencies, bolster improvement capability assessment, and inform regulatory responses. This is important because, drawing on the microfoundations of the DCV (Teece, 2007), all eight dimensions of improvement capability, representing the three microfoundations, play an important role in the formation and development of improvement capability.

8.4 Contribution to research and practice

This research study enhances the understanding of how improvement capability is conceptualised and assessed from a healthcare regulatory perspective. The theoretical contribution and practical implications of the research study are now discussed.

8.4.1 Contribution to research

The research study contributes to research in three main ways, the first being by reviewing the healthcare and non-healthcare improvement capability literature and discussing the key themes that arise for its assessment. The research study aimed to understand how improvement capability is conceptualised and assessed in practice in order to answer the call for more studies to focus on new ways for regulatory assessment to be undertaken and enforcement patterns, particularly those that encourage improvement to care delivery (Hovlid et al., 2015; McDermott et al.,
This research study builds on the existing literature through the development of an improvement capability conceptual framework drawing on the DCV. This differs from existing frameworks by taking an explicit theoretical perspective to inform its development. The conceptual framework contributes to research by clarifying what constitutes a specific dynamic capability and articulating the dimensions of improvement capability to inform measurement approaches. The research study was developed based on the likelihood that it would discern something new, warranting a revision of existing theories. Its use of the DCV to review improvement capability in this way contributes theoretically.

The research study analyses the competing roles of regulatory agencies in delivering accountability, assurance and improvement goals (Walshe, 2003), and demonstrates that regulatory agencies can develop mutually supportive regulatory strategies, including detection and enforcement, in order to meet all three goals. Paper 2 describes how this is emerging across the regulatory agencies within the UK. Enforcement strategies based on responsive regulation (Ayres and Braithwaite, 1992) can be designed to encourage behaviour change within organisations through both deterrence and compliance models concurrently, through the widening of inspection, detection and enforcement processes, including that encouraging the development of improvement capability. Drawing on the empirical findings presented in papers 2 and 3, regulatory agencies are blending detection and enforcement to deliver selective regulatory goals. The empirical findings revealed three tensions facing regulatory agencies, namely roles, resources and relationships. This research study makes an empirical contribution by presenting these tensions and discussing their implications through a comparison of different regulatory agencies and their associated regulatory designs, as called for by Nielsen and Parker (2009).

Regulatory agency assessment strategies, intentions and practices are compared using the improvement capability dimensions identified in the literature (paper 1). Through a synthesis of the empirical papers 2 and 3, the conclusion can be formed that regulatory agencies have major roles in incentivising the formation of improvement capability through their roles, yet the focus of assessments is predominately on only some of the identified dimensions of improvement capability: process improvement and learning, strategy and governance, and data and performance. These three dimensions can be identified as areas that are part of the
reconfiguring microfoundation, and may be easier to operationalise and use during assessments, as discussed in paper 3. Applying this framework further to the findings detailed in paper 3, identifies that agencies assess the micro-foundations of sensing and seizing to a much lower extent, and that ‘sensing’ is biased towards supplier and stakeholder perspectives rather than patient/end user-perspectives, and that this may reflect previous regulatory models and assumptions.

**8.4.2 Implications for policy and practice**

From the literature, this research has identified that improvement capability can be conceptualised across eight dimensions. Furthermore, this research study has identified that regulatory agencies are increasingly encouraging the development of improvement capability. However, despite this encouragement the content and thematic analysis of the empirical data collected from the regulatory agencies shows that regardless of size, scope or remit, most assessments focus on improvement capability dimensions that are argued in this research to be reconfiguring microfoundations. Agencies appear to use reconfiguring dimensions for several reasons, including ambiguous conceptualisation of improvement capability, the ease of operationalisation and access to data for reconfiguring dimensions, coupled with the difficulty of assessing sensing and seizing dimensions. This analysis suggests that regulatory agencies that use deterrence or compliance models have less need to focus on the other dimensions due to their underlying assumptions of organisations (i.e. that performance is a-contextual), whereas agencies using responsive regulatory models require more information about context, which is incorporated within sensing and seizing dimensions, to tailor their enforcement actions to organisations.

This research finds a disconnect between regulatory policy intentions and the assessment practices in use by regulatory agencies when assessing for improvement capability. If regulatory agencies wish to move to more responsive models of regulation incorporating a hybrid of deterrence and compliance models, then understanding existing motivations and associated improvement capability of organisations is important in order to inform enforcement policies and development plans. The empirical findings show that because assessments are dominated by reconfiguring dimensions, including data and performance, process improvement and learning, and strategy and governance, less attention and emphasis is placed on the sensing and seizing dimensions. Therefore, there is less regulatory incentive for
organisations to develop sensing and seizing dimensions, potentially impacting the development of improvement capability. This is because a capability is made up of the three microfoundations (Teece, 2007), thus for an organisation to develop improvement capability, three microfoundations are required, rather than only one or two microfoundations. Therefore, if regulatory agencies want to develop improvement capability within organisations to improve services and inform enforcement strategies, it follows that increased use of sensing and seizing dimensions is also needed in assessments.

This research suggests that tentative steps to develop improvement capability by regulatory agencies needs ongoing development and faces tensions related to the regulatory role, resources and relationships. These developmental steps require assessment systems to adapt and focus on both motivational intentions and improvement capability in order to detect the type of regulatory enforcement required. This is important because it will ensure that inadequate improvement capability is identified and appropriate enforcement actions for the specific circumstances are implemented to support the ongoing development of improvement capability and organisational performance.

8.5 Limitations of the research study

This research has comprehensively reviewed existing assessment instruments and frameworks for improvement capability, collated and analysed regulatory documents including strategies, plans and inspection reports or reviews, and conducted qualitative interviews with 48 participants from six regulatory agencies within the UK, with a variety of roles. However, there are several limitations to this research study which are detailed in two parts relating to the methodological and research design.

8.5.1 Research design limitations

There are several limitations concerning the research design used. The research study was cross-sectional and not longitudinal, and thus did not consider subsequent changes in regulatory policy, including developments in organisational enforcement policies and organisational change after the interview period (2014-2015), such as the operational merger of Monitor and the TDA in April 2016. A longitudinal research study could have examined regulatory perspectives of improvement
capability given the path dependencies of dynamic capabilities and the period over which change and improvement capability develops, which would have supported attempts to identify causality. However, this approach was not practical as this was a PhD research study with a limited timeframe over which it could be conducted. To ensure the dynamic nature of improvement capability was included, the research study examined the development and history of the regulatory agencies through document analysis, and sought clarifications via the interviews in order to understand why particular enforcement or inspection policies were being pursued given this history.

Another limitation was that the research study viewed improvement capability from the perspective of UK regulatory agencies, rather than from other groups or stakeholders, including those of patients or commissioners or regulated organisations, as well as those from other countries. This limits the conclusions that can be drawn from the analysis by excluding perspectives from other groups, particularly those from regulated organisations. This may have created a blind-spot in the conceptualisation of regulation and improvement capability in this research study. Nevertheless, whilst any of these areas would have been fascinating further areas of study, these would have been very different research studies. Furthermore, such a focus would have resulted in a significantly larger study requiring additional resources and thus was beyond the scope of a PhD. However, this would be a fruitful area for further research. This research has reviewed regulation and improvement capability in the context of UK healthcare, and therefore it may have limited generalisability to other contexts (Lincoln and Guba, 1985). Generalisation in most qualitative studies cannot be seen in probabilistic terms that would make general claims about a population from a sample (Eisenhart, 2009). For this research study, generalisability is theoretical and is used to make sense of the particular situation studied and is based on the assumption that this theory is useful for other similar situations (Yin, 2013), rather than a sample to population or case to case generalisation (Firestone, 1993; Kennedy, 1979).

Whilst this research study tentatively suggests eight dimensions of improvement capability that have been inductively developed from the integrative literature review, the relationships and interconnections between the dimensions have not been examined. Furthermore, the dimensions have not been tested for validity, nor have
they been developed into robust valid and reliable measurement scales. Such an extension to the research would have resulted in a significantly larger study requiring additional resources and thus was also beyond the scope of a PhD. However, again this would be an interesting area for further research.

Finally, this research study was conducted independently by an individual researcher as part of the requirements of a PhD thesis. The research would have been strengthened through the involvement of a wider and more experienced team, particularly for data analysis, including coding and theming (Saldaña, 2013), which would mitigate against individual coding biases. However, methods to strengthen validity and mitigate researcher bias were taken, including reflecting on and paying attention to the researcher’s assumptions and beliefs through using reflexive practices, such as the writing of journal notes and through the development of analytic memos (Nadin and Cassell, 2006), as well as through the supervisory process. The external validity of the research was also strengthened by the triangulation of the findings from different data sources and through interview participant feedback of both interview transcripts and research study findings as draft papers were shared. The use of triangulated data across the six regulatory agencies strengthens the findings’ reliability and validity, and mitigates against bias resulting from sample selection.

8.5.2 Methodological limitations

There are three methodological limitations, namely data collection bias, respondent bias, and selection bias. This research employed three methods of data collection: a detailed literature review of instruments and frameworks; qualitative interviews; and document analysis of strategies, policies and plans, together with inspection and assessment reports and reviews. Overall, more documents were reviewed (30 inspection and assessment reports and 90 policy documents) compared to 48 interviews and 70 instruments and frameworks identified from the literature on the assessment of improvement capability. This may have led to an over dependence on documentary evidence to support the research study. However, on reflection the larger number of documents did not seem to impact the findings disproportionately and triangulation of findings was used to mitigate the risk of this potential bias.
Qualitative research is suited to explore experiences and perceptions, and local based information that is not available through documentation (Robson, 2011). However, potential errors and inaccuracies may arise due to potential bias from respondents, for example through describing processes as they should be used, rather than as they are, in order to give a better image, and poor memory or fact distortion. Moreover, interview data is inherently subjective and based on participant opinion. Interviews are inherently time-limited and data collection may also be limited due to the questions asked, and important information may not be shared during an interview. These potential biases were mitigated through interviews involving multiple-respondents from each regulatory agency, using open ended questions within the semi-structured interview process, and triangulation with the documentary data sources.

There was the potential for the selection bias of documents and participants during this research via the nomination process used. However, there was only one participant who declined to take part in the research study, and a similar cross-section of roles across the agencies limited this potential issue. Given that the research questions required interviews to take place with participants who have some knowledge of the agency policy with respect to assessment, improvement and standard setting, this may have resulted in the selection of participants who had more strategic roles within the agencies. The validity of the findings was strengthened through research reflexivity and through the interviewing of operational inspectors, assessor and project managers to reduce this bias, although this was not evenly spread across the six agencies. To reduce bias from document and assessment/inspection report selection, a template of typical documents with selection criteria was used to consistently identify the documents for review or alternatively they were suggested by interview participants as being important.

8.6 Future research

The findings from this research study have several implications for future research and regulatory policy. This research study is one of few empirical studies focussed on improvement capability from a regulatory perspective. Building on the findings from this study, future research could contribute further to the understanding of the development of improvement capability both within and across organisations, and
relationships with regulatory agencies and other external stakeholders. Six specific research avenues are proposed.

The dimensions of improvement capability identified in this research study could be subject to further validation and testing, initially through qualitative case studies. This could be completed with several different types of organisations across sectors and could test the dimensions’ appropriateness, comprehensiveness and usefulness during assessments.

Whilst a framework may be useful at guiding both regulatory and organisational activity to develop improvement capability, following validation and testing, research could take place to develop a prototype assessment instrument prior to the full development of a valid and reliable instrument for the assessment of improvement capability. However, there are several issues with measurement approaches, including a lack of validity and unreliability (Bardsley, 2016; Tuijn et al., 2011), the increased propensity of gaming (Hamblin, 2008), and the dependence on value-judgements of inspectors and surveyors (Jaafaripooyan, 2014), which may mean that the development of an assessment instrument leads to unforeseen outcomes.

Further research could focus on understanding the relationships and interconnections between the improvement capability dimensions in detail, with a specific focus on how microfoundations change and are influenced by orchestration, where the capability needed for implementation is synchronised with the strategy employed (Sirmon et al., 2011).

Case studies could explore if other regulatory agencies from other countries or sectors face similar problems when moving to more responsive regulatory models, as identified in this research study of UK healthcare. The solutions proposed to mitigate these problems through improved assessment and differing enforcement strategies could be tested.

Longitudinal studies are needed to observe and evaluate enforcement strategies that aim to develop improvement capability. This could support calls for further longitudinal research to evaluate dynamic capabilities by providing empirical evidence and understanding about how improvement routines change over time, and
to examine causal links between improvement capability and performance (Pezeshkan et al., 2016; Giudici and Reinmoeller, 2012).

Finally, this research study identified that the dimension service user focus was used less frequently in assessment processes, and further research is needed to understand why there was less use of some dimensions and how service user voices could be amplified in assessments, including understanding how service user involvement could strengthen assessments and subsequent enforcement strategies with regulatory agencies.

8.7 Conclusions

Regulatory agencies continue to seek new ways of ensuring high quality care and improved performance. This research study focuses on healthcare organisation regulatory agencies in the UK and explores their perspectives on how improvement capability is conceptualised and assessed. The research finds that there are multiple conceptualisations of improvement capability in the literature, which have been synthesised into eight dimensions of improvement capability. The research also reveals ambiguous conceptualisations of improvement capability within regulatory agencies, which may partly explain why two improvement capability dimensions are used more frequently during assessments. This research study also shows that regulatory agencies face tensions in operationalising new regulatory designs to support the assessment and development of improvement capability, including confusion regarding regulatory roles, a lack of improvement skills and experience, and maintaining regulatory relationships with organisations.

A theoretically based conceptual framework, drawn from the literature, is proposed to reduce the conceptual ambiguity, strengthen regulatory agency assessment, and support appropriate tailoring of the regulatory response. The framework can be used as an evaluative framework for regulatory programmes which seek to develop improvement capability. This research concludes that regulatory agencies can strengthen their assessment of improvement capability by using the proposed conceptual framework. This will inform and clarify regulatory conceptualisation and understanding of improvement capability, and strengthen regulatory responses to support the development of improvement capability within healthcare organisations.
References


Appendix A: Literature reviews of improvement approaches in healthcare

Table A.1 details a non-exhaustive search for literature reviews of different improvement approaches, such as lean, six-sigma and the use of PDSA. The table summarises the findings.

Table A.1: Literature reviews of improvement approaches in healthcare

<table>
<thead>
<tr>
<th>Author</th>
<th>Journal</th>
<th>Research method</th>
<th>Improvement approach</th>
<th>Healthcare field</th>
<th>#studies</th>
<th>Findings</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andersen et al. (2014)</td>
<td>BMJ Open</td>
<td>Systematic review of reviews</td>
<td>Lean</td>
<td>Hospital</td>
<td>18</td>
<td>The review does not find substantial evidence for effective lean interventions in healthcare. However, findings are limited due to the immaturity of the research field. Calls for a shift from cause-effect to conditional attributions in research to the context-dependant and social nature of a lean intervention.</td>
<td>Lack of evidence. Poor research quality.</td>
</tr>
<tr>
<td>Costa and Godinho Filho (2016)</td>
<td>Production Planning and Control</td>
<td>Literature Review</td>
<td>Lean</td>
<td>Healthcare</td>
<td>107</td>
<td>Finds that few studies articual critical success factors to support application and that there are few failure cases to learn from.</td>
<td>Lean in healthcare is applied in a superficial way.</td>
</tr>
<tr>
<td>Author</td>
<td>Journal</td>
<td>Research method</td>
<td>Improvement approach</td>
<td>Healthcare field</td>
<td>#studies</td>
<td>Findings</td>
<td>Overall</td>
</tr>
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<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Daultani et al. (2015)</td>
<td>Global Business Review</td>
<td>Selective Literature Review</td>
<td>Lean</td>
<td>Healthcare</td>
<td>63</td>
<td>Finds that benefits during different stages of lean execution can vary depending on the sequence in which various departments are considered. Indicates that there is limited research on how to guide practising managers in choosing the appropriate projects and there is a need to have a capability-maturity model for implementing lean.</td>
<td>Results show that different healthcare services, with different service characteristics pose unique challenges to lean.</td>
</tr>
<tr>
<td>DelliFraine et al. (2010)</td>
<td>Quality Management in Healthcare</td>
<td>Comprehensive literature review</td>
<td>Lean and six sigma</td>
<td>Health Sector</td>
<td>177</td>
<td>Weak evidence of a relationship between the use of lean or six sigma and performance improvement. A focus in the studies on processes rather than clinical and financial outcomes. An absence of articles detailing unsuccessful lean or six sigma programmes.</td>
<td>Lack of evidence.</td>
</tr>
<tr>
<td>Author</td>
<td>Journal</td>
<td>Research method</td>
<td>Improvement approach</td>
<td>Healthcare field</td>
<td>#studies</td>
<td>Findings</td>
<td>Overall</td>
</tr>
<tr>
<td>--------------------</td>
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<td>--------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>D’Andreamatteo et al. (2015)</td>
<td>Health Policy</td>
<td>Comprehensive literature review</td>
<td>Lean</td>
<td>Healthcare</td>
<td>243</td>
<td>Theoretical works have been focused mainly on barriers, challenges and success factors. Sustainability, framework for measurement and critical appraisal remain underestimated themes.</td>
<td>There is a lack of evidence of sustained results, and a lack of system wide focus in research.</td>
</tr>
<tr>
<td>Glasgow et al. (2010)</td>
<td>Joint Commission Journal on Quality and Patient Safety</td>
<td>Systematic Review</td>
<td>Lean and six sigma</td>
<td>Hospital</td>
<td>47</td>
<td>Lean and six sigma are used widely across different project areas in areas. More focus on organisational culture, and developing staff with expertise and experience needed</td>
<td>Lack of rigorous evaluation or clearly sustained improvements.</td>
</tr>
<tr>
<td>Leggat et al. (2015)</td>
<td>Public Money &amp; Management</td>
<td>Systematic review</td>
<td>Lean and six sigma</td>
<td>Hospital</td>
<td>41</td>
<td>HRM practices are central to improvement approaches.</td>
<td>Lack of evidence.</td>
</tr>
<tr>
<td>Mason et al. (2015)</td>
<td>The Surgeon</td>
<td>Systematic review</td>
<td>Lean and six sigma</td>
<td>Hospital (Surgery)</td>
<td>23</td>
<td>Unable to provide recommendations due to inconsistencies in research studies.</td>
<td>Inconsistent evidence Poor research quality.</td>
</tr>
<tr>
<td>Author</td>
<td>Journal</td>
<td>Research method</td>
<td>Improvement approach</td>
<td>Healthcare field</td>
<td>#studies</td>
<td>Findings</td>
<td>Overall</td>
</tr>
<tr>
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</tr>
<tr>
<td>McIntosh et al. (2014)</td>
<td>International Journal of Health Care Quality Assurance</td>
<td>Systematic review</td>
<td>Lean</td>
<td>Health Sector</td>
<td>100</td>
<td>The literature does not support the position that Lean can be successfully adapted for extensive use in the health sector to achieve several strategic objectives.</td>
<td>Inconsistent evidence. Poor research quality.</td>
</tr>
<tr>
<td>Moraros et al. (2016)</td>
<td>International Journal for Quality in Health Care</td>
<td>Systematic Review</td>
<td>Lean</td>
<td>Healthcare</td>
<td>22</td>
<td>Finds that Lean interventions have no statistically significant association with patient satisfaction and health outcomes; a negative association with financial costs and worker satisfaction and potential, yet inconsistent, benefits on process outcomes like patient flow and safety.</td>
<td>Lack of evidence. Poor research quality.</td>
</tr>
<tr>
<td>Nadeem et al. (2013)</td>
<td>Milbank Quarterly</td>
<td>Systematic Review</td>
<td>IHI-QI</td>
<td>Healthcare</td>
<td>24</td>
<td>Limited some support for the effectiveness of collaboratives in improving patient outcomes and provides little insight into which collaborative attributes are most likely to produce the desired change.</td>
<td>Some evidence. Poor research quality.</td>
</tr>
<tr>
<td>Nicolay et al. (2012)</td>
<td>British Journal of Surgery</td>
<td>Systematic Review</td>
<td>Various, TQM, lean, PDSA, IHI-QI, six Sigma</td>
<td>Hospital (Surgery)</td>
<td>34</td>
<td>Quality Improvement methodologies from industry can have significant effects on improving surgical care, from reducing infection rates to increasing operating room efficiency.</td>
<td>Inconsistent evidence. Poor research quality.</td>
</tr>
<tr>
<td>Author</td>
<td>Journal</td>
<td>Research method</td>
<td>Improvement approach</td>
<td>Healthcare field</td>
<td>#studies</td>
<td>Findings</td>
<td>Overall</td>
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<tr>
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</tr>
<tr>
<td>Schouten et al. (2008)</td>
<td>British Medical Journal</td>
<td>Systematic Review</td>
<td>IHI-QI</td>
<td>Healthcare</td>
<td>72</td>
<td>The evidence underlying quality improvement collaboratives is positive but limited and the effects cannot be predicted with great certainty.</td>
<td>Some evidence. Poor research quality</td>
</tr>
<tr>
<td>de Souza (2009)</td>
<td>Leadership in Health Services</td>
<td>Systematic Review</td>
<td>Lean</td>
<td>Healthcare</td>
<td>90</td>
<td>Lean is in an early stage of development in healthcare. There are little inter-organisational examples of where lean is applied in healthcare.</td>
<td>Further evaluative research studies required.</td>
</tr>
<tr>
<td>Taylor et al. (2014)</td>
<td>BMJ Quality and Safety</td>
<td>Systematic Review</td>
<td>PDSA (including lean, IHI-QI)</td>
<td>Healthcare</td>
<td>47</td>
<td>Inadequate compliance with use of PDSA cycles which may compromise effectiveness. Reporting guidelines may be useful.</td>
<td>Poor quality implementation and research.</td>
</tr>
<tr>
<td>Vest and Gamm (2009)</td>
<td>Implementation Science</td>
<td>Systematic review</td>
<td>Lean, six sigma, TPS</td>
<td>Hospitals</td>
<td>9</td>
<td>Lack of valid studies, those that exist suggest positive effects though given validity issues alternative explanations cannot be ruled out.</td>
<td>Poor quality research.</td>
</tr>
</tbody>
</table>
Appendix A: References


Appendix B: Briefing note

Introduction

This research is examining the interaction between internal and external forms of quality improvement in healthcare and is particularly focused on healthcare within the four countries of the UK. The research is funded by the Health Foundation.

Research outline

This research is examining quality improvement within the NHS. In particular, it is interested in exploring how regulators are able to support more, and more successful, improvement in NHS organisations (and other healthcare bodies) in order to deliver best possible care standards for patients. There is limited evidence that quality improvement approaches (such as clinical audit, lean, six-sigma, IHI Model for Improvement, etc.) within organisations are both adopted successfully on a wide scale and when they are adopted often don’t deliver the improvements in quality and performance as initially desired, perpetuating variations in the quality of patient care. Barriers to sustainable improvement successes include, amongst others, improvement skills, leadership support and the external context in which the organisation is working, suggesting that regulators have a significant role in leading and encouraging quality improvement within and between organisations in order to mitigate these barriers.

As one of the barriers to successful improvement is improvement skills, one of the areas where this may be possible for regulators to support improvement, is through the examination of improvement capability. The working definition for improvement capability is the ability of an organisation to sustain current performance and keep improving (if they are already a high performer), or their ability to adapt and deliver the change plan to meet regulatory (and patient) expectations if performance is less than desired. With more focus on capabilities, including improvement skills, practice, methods and routines, as well as outcomes, regulators could have more confidence in the likelihood that organisations can deliver care will meet requirements prospectively as well as retrospectively, recognising there may also be risks of taking a regulatory approach.
However, there are many other definitions of improvement capability creating ambiguity and initial literature review suggests several differing perspectives on how this could be measured and assessed across different contexts. This research intends to examine through documentation analysis, interviews and template analysis, different regulatory perspectives on what improvement capability is, and how it is currently assessed or measured to develop a conceptual framework for the assessment of improvement capability within healthcare organisations and to understand the potential consequences of doing so for stakeholders internally and externally.

**For discussion**

Would research in this area be of benefit?

Has regulatory work taken place in this area previously?

What ideas or concerns would you have with respect to this research?

Would you be interested in collaborating in this research and assisting in both interviews and reviewing research findings later?

**J Furnival**

**Summer 2014**
Appendix C: Research information sheet

Regulation for Improvement?

Participant Information Sheet

You are being invited to take part in a research study in to regulation and improvement in healthcare. It is particularly interested in the assessment of improvement capability within healthcare organisations.

Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

Who will conduct the research?

Joy Furnival, PhD Candidate, Manchester Business School, University of Manchester, Manchester.

Title of the Research

Regulation for Improvement? A study of the interaction of external and internal quality improvement systems in acute healthcare in England

What is the aim of the research?

This research is examining healthcare quality improvement in the UK and is funded by The Health Foundation, a national charity. Healthcare in the UK has improved tremendously during the last 15 years or so however, problems remain as highlighted in the Mid Staffordshire inquiry and unacceptable variation of care persists across many measures. Regulation of healthcare organisations have also grown within the UK during the same period, charged with assuring and inspecting various aspects of healthcare including quality in order to maintain and improve standards, but can be criticised for being slow to act and not preventing care scandals and only inspecting present and past performance.

This research examines the role of improvement capability as a key aspect of improvement that shapes improvement outcomes and suggests that variation in improvement capability affects variation in performance outcomes. Taking a resource based view, barely used in healthcare, this research seeks to understand how improvement capability is currently defined, and assessed and developed within
healthcare and will develop a framework for examining improvement capability within healthcare organisations in order to inform the development of a more proactive approach for external organisations such as regulators to assess prospective performance. The research will also consider the potential consequences of measuring 'improvement capability'. The research will examine different approaches taken across the UK.

Why have I been chosen?

You have been chosen as a key interviewee, knowledgeable about healthcare improvement as suggested by your organisation or other key individual.

What would I be asked to do if I took part?

You are being asked to consent to taking part in an interview regarding your views and experiences of quality improvement and improvement capability. Your responses will be stored securely and anonymously and only accessed for research purposes. You will have an opportunity to see the field notes of the interview in order to be able to clarify any inaccuracies.

What happens to the data collected?

The data will be stored securely and anonymised. Following this the data will be transcribed and coded for analysis and used for the purposes of research. Only the research team will have access to the full interview transcripts.

How is confidentiality maintained?

Following the interview, they will be transcribed and then anonymised. This anonymity will be maintained throughout. In the first instance the interview will be stored digitally on a password protected recording device, following transcription and development of agreed field notes, the recording will be destroyed.

The interview transcript will be stored on the researcher secure and password protected University of Manchester laptop and secure data storage devices, e.g. the University of Manchester P:Drive and backup secure storage.

What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time.

Will I be paid for participating in the research?

Participation in the research is on a purely voluntary basis. It is not expected that there will be any out of pocket expenses resulting from participation.
What is the duration of the research?

The interview is expected to take up to two hours, and reviewing the field notes for accuracy or clarification following the interview is estimated to take up to 30 minutes.

Where will the research be conducted?

The research is intended to be conducted at your organisation.

Will the outcomes of the research be published?

Criminal Records Check (if applicable)

N/A

Who has reviewed the research project?

This research has been submitted and agreed through the Manchester Business School PhD Ethics processes.

Contact for further information

Researcher Contact Details:

Joy Furnival
Manchester Business School
The University of Manchester
Booth Street West
Manchester M15 6PB
U.K.

E-mail: joy.furnival@postgrad.mbs.ac.uk
Mobile Tel: +44 (0)7944897436

Supervisor Contact Details

Professor Kieran Walshe
Manchester Business School
The University of Manchester
Booth Street West
Manchester M15 6PB
U.K.

E-mail: kieran.walshe@mbs.ac.uk
Tel: +44 (0)161 275 3852
What if something goes wrong?

If there are any issues regarding this research that you would prefer not to discuss with members of the research team, please contact the Research Governance and Integrity Team by either writing to 'The Research Governance and Integrity Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester M13 9PL', by emailing: Research.Complaints@manchester.ac.uk, or by telephoning 0161 275 7583 or 275 8093.
Appendix D: Consent form

Regulation for improvement?

If you are happy to participate please complete and sign the consent form below

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>1.</td>
<td>I confirm that I have read the attached information sheet on the above project and have had the opportunity to consider the information and ask questions and had these answered satisfactorily.</td>
</tr>
<tr>
<td>2.</td>
<td>I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving a reason and without detriment to any treatment/service.</td>
</tr>
<tr>
<td>3.</td>
<td>I understand that the interviews will be audio-recorded</td>
</tr>
<tr>
<td>4.</td>
<td>I agree to the use of anonymous quotes</td>
</tr>
<tr>
<td>5.</td>
<td>I agree that any data collected may be passed as anonymous data to other researchers</td>
</tr>
</tbody>
</table>

I agree to take part in the above project

Name of participant | Date | Signature
--- | --- | ---

Name of person taking consent | Date | Signature
--- | --- | ---

Please initial box
Appendix E: Interview questions framework

Table E.1: Initial semi-structured interview questions and prompts

<table>
<thead>
<tr>
<th>Question</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong> How would your existing regulatory processes examine quality</td>
<td>improvement?</td>
</tr>
<tr>
<td>improvement?</td>
<td>What are the typical things you would be looking for? Governance</td>
</tr>
<tr>
<td></td>
<td>processes, leadership issues, methods, skills.</td>
</tr>
<tr>
<td></td>
<td>How does this fit into / relate with the broader regulatory</td>
</tr>
<tr>
<td></td>
<td>processes?</td>
</tr>
<tr>
<td><strong>2.</strong> If you found good examples of improvement work, what would</td>
<td>happen, &amp; similarly for not so well?</td>
</tr>
<tr>
<td>happen, &amp; similarly for not so well?</td>
<td>What are the typical good/not so good things you might highlight?</td>
</tr>
<tr>
<td></td>
<td>What would make it ‘good’ (or bad), what determines that?</td>
</tr>
<tr>
<td><strong>3.</strong> What do you think ‘improvement capability is’?</td>
<td>Do you feel the regulatory process now would look for this? Why?</td>
</tr>
<tr>
<td></td>
<td>Would this be helpful/hinder?</td>
</tr>
</tbody>
</table>

Table E.2: First revision of interview questions and prompts (after first interview)

<table>
<thead>
<tr>
<th>Question</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong> What is the aim and purpose of this organisation?</td>
<td>How do you achieve it?</td>
</tr>
<tr>
<td><strong>2.</strong> What methods of assessment do you use and in which area?</td>
<td>Why? How do you define and share what good looks like? What</td>
</tr>
<tr>
<td></td>
<td>does improvement capability mean to you? (Introduce concept if</td>
</tr>
<tr>
<td></td>
<td>not already used by participant during discussion).</td>
</tr>
<tr>
<td><strong>3.</strong> Following assessment, what interventions do you use / plan to</td>
<td>What problems do you have / foresee with this?</td>
</tr>
<tr>
<td>use with organisations to achieve your aims and why?</td>
<td></td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Theme</th>
<th>Question</th>
<th>Prompts</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Deter</td>
<td>What do you think improvement is? What does improvement mean here?</td>
</tr>
<tr>
<td>2</td>
<td>Detect</td>
<td>How would your existing regulatory processes examine quality improvement?</td>
</tr>
<tr>
<td>3</td>
<td>Enforce</td>
<td>If you found good examples of improvement work or compliant practice, what would happen, &amp; similarly</td>
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<td>Theme</td>
<td>Question</td>
<td>Prompts</td>
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<td>for not so good or non-compliant?</td>
<td>Would there be differences in how you do this across departments, professions? Resources</td>
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<tr>
<td>4 Improvement</td>
<td>What do you think ‘improvement capability’ is”?</td>
<td>Do you feel the regulatory process now would look for this? Why? How could this be identified more, what might help/hinder?</td>
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Appendix F: Example interview and coding

Appendix F includes an example interview conducted with a regulatory agency as part of the research study. This is used to show a typical interview and provide information about how each interview was coded. The interview has been sanitised and anonymised through redaction to ensure confidentiality and anonymity of the interview participant. The letter ‘R’ indicates the interview participant (respondent) in the interview, and the letter ‘I’ indicates the researcher (interviewer).

F.1: Anonymised interview transcript

R: So essentially, I was responsible for our regulatory position [in X] and then also working with the other major bodies that have a responsibility for healthcare in [X]. I had various other responsibilities in the [Regulatory agency]. So, I am fairly involved but probably don’t have technically an explicit responsibility for interactions with other oversight bodies, so the, ombudsman, those kind of people. My primary role essentially is to ensure that [organisations] were complying with the […] minimum standards that they’re expected to achieve. [I am now working to support improvement with organisations]

So, I suppose the most direct relationship with improvement of that particular role was about where [organisations] were failing to deliver certain minimum standards and therefore the quality of the care or service to patients was not what we expected, then it was my job to work with those [organisations] to ensure that they improved their position and restored themselves to at least that minimum standard. It is worth emphasising that we’re talking about a minimum standard, not necessarily some people’s idea of an ideal. So, although we have expectations on [organisations] that they should aspire to be the absolute best they can be from a regulatory authority point of view we can only work on minimum standards, and that’s exactly the same as any other regulator, […].

I: So, you just used the words we have to ensure that they do meet the standards. How do you do that?

R: So, there are a number of ways, to some extent depending on how bad it’s got. The most simple way is really to verbalise the expectation. So, it’s quite hard sometimes to explain to people who aren’t in the organisation to fully appreciate, but [organisations] really listen to [us], and sometimes they listen to us when we’ve not technically got any legal authority but just our general authority is recognised. So, at the very simplest level it’s pointing out to [organisations] that they are not performing as they should be, they are below
our expectations, and we expect them to resolve that, and if they don’t then it escalates from there.

The more substantive roles are that we effectively issue notices of intent that we’re going to take action with an [organisation] it doesn’t resolve its situation. We will work with organisations in a more informal way to identify support and expertise that they may benefit from that will help them to improve. We do quite a lot of work essentially diagnosing what the root cause of the problem is. So, most of what we see and most of what our regime is responsible for are symptoms. So, for example – it’s a little bit of an unfair example at the moment because of the pressure the system’s under – traditionally when most [organisations] were achieving the standards, where somebody wasn’t that did stand them out. It was usually a symptom of something more than just a failure to achieve [the standards], so a lack of clinical leadership […] a lack of engagement […]. That’s just as examples. So, diagnosis is usually fairly powerful.

As we sort of go through the levels we have the power and authority once certain steps have been breached to consider [escalating]. So, we have the power to [escalate], but the more kind of positive power is that we then put in additional capability and capacity. I’ll talk about that in a bit.

I: Okay. That’s interesting words that you’ve just used, put in additional capability and capacity. What do you mean by that?

R: Well, capacity is almost the slightly easier one for me to reflect on. There is I think a fair reality that most hospitals, certainly the kind of… I’m sorry, when I talk about hospitals I could reflect on any aspects of [organisations], so it could be ambulances, it could be a community services, it could be a mental health, it’s just it has tended to be acute hospitals where [I’ve] done most work.

I: Okay, that’s fine.

R: But I’m not meaning to focus on them. So, [organisations] are set up and staffed to manage the status quo, to manage the way that they deliver services today, and on the assumption to some extent that those services are running at least to a minimum standard. That’s my assertion. Whether it’s backed up by scientific evidence or not is hard to say, but my experience is that people do not generally easily have available the capacity or can’t make available the capacity to deal with situations where things go significantly wrong, particularly when they go wrong then over protracted periods, and they don’t have a significant capacity for change, by which I mean the sort of resource available to help people make change. So, that’s the capacity point.

The capability point is really, although it’s related to some extent. Sometimes we find that institutions don’t have within their ranks the skill sets required for certain situations, which are often the same sort of things, which is skill set to
I: And how do you make the assessment that those skills are there or not there? Just by the outcome results or through some other assessment?

R: Some of it is testing, by asking them to make things right. If they’re unable to make things right that is a… It’s not scientific evidence, but it’s an indication that there is an inability within the organisation to return to the position it should be at. We also have reviews [and work with partners]

R: [paragraph removed, to ensure anonymity]

I've been working with the [Regulatory agency] for five years, so I guess you’d say I’ve had five years’ experience from within the [Regulatory agency] and then my experience before I joined the [Regulatory agency] of understanding the way in which people approach improvement or change to the way they plan to make that change. Experience has given us some indications of some of the things that work and some of the things that don’t work. It’s a slightly odd place being a regulator because there are often times when I desperately want to jump in and tell people what I think they should do, and there is a point in time where you’re able to do that. But we aren’t responsible for running the organisations. We’re responsible for the oversight of them. So, you do need to give the boards and the staff of the organisation the opportunity to demonstrate that they do have the capability of sorting things out, and many organisations do.

It’s not the case that the whole health service is incapable by any stretch. But we do come across particular organisations where they’re unable to demonstrate that they can improve things, and through a combination of experience and external assessment and the symptoms we’re able to identify that actually on their own they can’t.

I: So a combination really of do they deliver when you ask and what other governance frameworks tell you, is that…?

R: Yeah, absolutely.

I: That’s really interesting. Thank you very much. Is that the same when you’re working with high performing organisations? Do you assess capability in the same way?

R: It’s one of the slightly less satisfactory aspects of my working life, which is I spend less time working with the really good organisations because the nature of regulation is if people are doing well generally we leave it alone. Which is right. It’s exactly what we should do. You’ve probably already spoken to them, but I could point you to people who within the [Regulatory agency] are better able to speak to the better performing organisations. The things I would say to
you about them are more happenstance than deliberate, as in I have had the opportunity but it’s not been deliberate.

[paragraph removed, to ensure anonymity]

I: That’s the challenge, isn’t it? [You talked about working to provide improvement support for organisations at the beginning…can you tell me more]

R: So, I think there are two elements to it., I’m trying to remember where I started so I know what the rationale is now. I think the key things are it’s clear to us as a [Regulatory agency] that the traditional methodology, it’s performance management but it comes in different forms, and regulation is a form of performance management in that you set out what you expect of people and if they meet those expectations you leave them alone, if they don’t then there are consequences. We don’t feel it’s sufficient anymore, given the pressures on the health service, to simply be a [Regulatory agency] who says, you need to sort this out and if you don’t then we’ll do something. We believe that we need to invest more in supporting people to be able to make the changes that we’re asking them to make.

I: And has that just emerged over time or was there a definitive thing…?

R: Yeah. Well, there’s always been an element of it. [So, we have a] team that have responsibilities for longer term aspects of development. So, it’s not that the [Regulatory agency] has never had a connection to this sort of way of thinking, it’s just we’ve always been very clear that it’s one thing to work on the long term […], it’s a slightly different thing to seek to provide more support to individual organisations. But the main reason being there is a danger of conflict, that we mark our own homework if we get too involved in the on the ground resolving of issues. It’s quite possible for an organisation to turn round and say, but you’ve been working with us on this so the failure is also partly yours. That could create some conflict. We think we’re moving towards a position where we understand how those can best be managed and still provide some value.

The other thing, which I’ve mentioned and its sort of linked, is the pressures on health services at the moment are very, very significant, and are very different to the pressures that existed when the [Regulatory agency] was set up, so it is an important evolution that the [Regulatory agency] is prepared to change the way it approaches things in response to a different kind of landscape that we regulate.

I: [Is there] a tension there between short term approaches around not meeting the minimum standards at the moment, versus creating, enabling, your word, capability, isn’t there?

R: Absolutely.
I: So, what challenges do you see in that?

[paragraph removed, to ensure anonymity]

R: [We recognise] that we [have choice of] a more of a big stick kind of do it or we’ll shout at you type way of working [or we need to become] more sophisticated in the way that we work with [organisations]. The other element of this as well is about not just helping to improve [organisations] but also helping to improve [ourselves]

I: Okay, that’s very interesting.

R: We [have] four main responsibilities [for improvement]. One is [improvement approach] There’s an element which is around […] leadership talent, that’s people with skills in change management and improvement, that’s people with specialist expertise, […] We want to make sure that we have real understanding of who’s out there.

I: So, that implies a little bit you see capability as an individual element, like a skill that people have as opposed to organisations have, would that be fair?

R: Yes, absolutely. […] we also want to over time understand who are the kind of rising stars. Not just the next chief executives, but who are the rising stars in specialties, who are the rising starts in support functions who possibly might be either interested in making a move in the future or might be available to be seconded out when there’s a particular need. So, at this stage we are focused on […] talent. But we’re branching out. That just purely reflects where we’re starting from. The vision is…well, I think it’s quite broad. There are elements of this in other organisations. We’d like to try and bring it together working with those other organisations.

I: Who do you mean by that, other organisations?

R: So [other regulatory agencies, stakeholders and partner organisations], […]. So, it’s one of the conversations we’re having with the equivalent people in [partner organisations] is can we share our lists. No one’s trying to be parochial. We want to try and make sure there’s a reasonable map of skills and expertise that ultimately could be shared broadly across the health service. To some extent our initial focus is of course on [organisations]. In fact that’s my remit. But ultimately other parts of the system benefit, usually [organisations] do as well. So as we develop this I would hope it would roll out to provide support beyond just [organisations]. […] It’s trying to put the right people together, those people in need with those people who have the skills to supply that need.

The second element is what you’d probably call a performance and insight team, which is making sure we have a really good understanding of what is causing people to get into difficulty, to […] able to report really clearly […] what the problems are and what’s being done about it, […]
I: Yeah, I understand. It’s all in your experience, that’s an interview.

R: But most people seem to have a similar view. But the more important bit of it is for us to understand that both in support of [organisations] but also in support of the way in which we undertake our regulatory regime, because our regulation still continues. So, if we really understand and are able to better diagnose the pressures and the reasons for poor performance, and, again, just to be clear, when I talk about performance I mean quality as well as targets and finance and all those sorts of things.

I: Do you mean quality as in…

R: A whole range of responsibilities that healthcare organisations have. […] It’s absolutely broader than that. So, it should be. Those are indicators, they’re not the whole picture. […] They’re not all the things that would be of interest to us as patients or family members or things like that. […]. And then [policy and intelligence expertise]. So, I have a simple example I use whenever I talk about this internally, which is looking at a [particular problem], as well as being something that senior people and politicians talk about a lot. It’s also something that has a huge amount of variability. So, it’s not as simple as saying the whole health service [has this problem] because at an individual organisation level the variation’s enormous.

So, I’ve got two [very similar organisations – one has double the problem as the other]. So, we would like to be able to get greater insight into what causes those sorts of variations, and as a result of that what could be done either locally, [or] nationally in support of helping people to improve that situation. That’s probably something you would imagine would lead to good practice examples, case studies, and hopefully tools that people might be able to roll out. We have quite a lot of answers in that particular example, but that’s the principal of what we’d like that team to try and do.

Then the third element is […] an internal pool of expertise, which undoubtedly will need to draw on external people for specific skills, that can work with [organisations] primarily to help them enhance their improvement capability. This isn’t about showing people how over a two-year period they might be able to bring the right people in, it’s about saying, [organisation X] right now has a major problem with […], and they need to have a plan or a programme of how they’re going to tackle that. What we often find in organisations is they don’t know where to start. It’s the classic old joke, I wouldn’t start from here if I were you. You find they’ve started on tracks with no particular reason why they started that way, and they’ve ended up in all sorts of tangents and muddles, and it doesn’t really deliver what anyone hoped it to be. If it helps, I could talk you through how we got to this view of how we might do it.

I: Yeah, sure.
R: The essential principal is we’ll have a combination of these in a team, some of whom will have some more subject expertise, so people who have a really good understanding of urgent care, of elective care, mental health, cancer, quality in its kind of broader sense as examples.

I: So subject matter experts.

R: And [...] people who have clear and proven skills and training improvement methodologies. Using a combination of those people we would provide on the ground support to trusts to either get improvement programmes going, get them motoring again if they’ve stalled, and to help keep them on the straight and narrow as they deliver. So, an example might be urgent care.

I: No, it’s all right. I know emergency care very well.

R: It’s just so topical. But we’ve got a trust who has problems with their [urgent care] that aren’t simply caused by the general pressures on the health system …who haven’t seen actually any great increases, but are still struggling or failing to deliver their standards and even the quality of care that we would expect along their urgent care pathway. So, we would be saying to them, look, you need to have a plan and a programme in place of how you’re going to address this. If we do it for you it probably won’t work, and when we withdraw you’ll be back in the same place again. So, what we want to do is provide you with direct support to help you get that programme motoring, but there’ll be a contract between us and yourselves that you will ensure that you dedicate appropriate people to work with us on this. And depending on the degree of severity of the problem. We could be talking about reasonably significant resource. So, one scenario that we’ve got would be potentially having a member of our team on the ground in the [organisation].

[Paragraph removed to ensure confidentiality]

R: [Organisations are] not technically forced. But of course, the pressure’s only put on [organisations, where they have got] into a position where [they] don’t seem to be able to do it for [themselves]. So [we need to ensure there is sufficient] capacity and, to some extent, capability to do, [that there is] good capability in diagnostics, they can help people to understand where the gaps are, what they’re not doing, and to some extent they can help people in putting a plan together on how they might address it. What [we don’t want] is then hold your hand along the way as you deliver that change. As an example, we [plan to] provide that kind of support and resource.

I: The holding the hand part.

R: Yeah. But not doing it for them. And some of that reflects experience and some of it reflects literature, that if you go in and do something for somebody then unless you’ve done it very, very well and simultaneously boosted their capability, you walk away and it all falls apart.
I: So how are you making that judgement that people have got the skills and the capability to deliver the plan as opposed to write it?

R: Sorry, say that again, I missed the first bit.

I: Well, you’re suggesting that the interventions thus far in the health service that a lot of the help can be the analysis and the diagnosis of what needs to be done, and…

R: Yes. But not the how.

I: But not the how, and you’re suggesting that you might put people in from the [Regulatory agency] to at least walk alongside whilst the how is going ahead. But how are you going to have the assurance that that organisation or wider have got the skills to do the how part as well?

R: Take an unscheduled pathway as an example, if [there has been] a kind of confident diagnostic and we feel reasonably confident that there’s an understanding of what’s going wrong in that particular pathway, then we would hope that we could focus our diagnostic on what are the skills gaps within the organisation and why prevent them from making the changes, or what are the issues with clinical engagement perhaps that means that when the surgical consultants are called to A&E they don’t come for four hours. Some of that kind of cultural and capability gap. There’s a big challenge for us to make sure that we’re able to bring in the right people who are able to do this, because these skills aren’t in constant supply.

I: Can you be more specific? Give some examples?

R: I’m going to default to some of the paperwork because I can express this much better in writing than I will from memory. So in the improvement side of things we are talking about people who through basic experience and training have proven expertise in delivering change programmes. We’re talking about operational efficiency, who have experience with lean six sigma or equivalent principals, who can demonstrate that they have delivered change, but more importantly that they’ve supported other people to deliver change. Undoubtedly, we would look at whether there are people within [support organisations] for example, who are actually capable of doing more than just pointing out what’s wrong, but the way in which those organisations are set up means they haven’t been given the opportunity to do it.

There are quite a few organisations that do demonstrate some of this capability both inside and outside the health service. Start from another perspective […] we’re absolutely unafraid to being people in with the right skills, I think actually there’s a benefit to the [Regulatory agency] to bring in a few more of the people [with different backgrounds] that we would normally do to broaden our own understanding and our own skill set. […]

I: Yeah. That’s fine.
R: But it’s worth me saying, and on record, that this is an emerging…

I: Yeah, that’s fine. It’s very interesting to me.

R: Yeah. The other thing that I think is really exciting about it is most of the improvement functions I’ve seen in recent times, [...] are a little bit different to this, but most of the improvements that I’ve seen this time have either been looking quite specifically at one issue.

I: Yeah, the one topic areas.

R: And they tend to look at the performance of that. They ignore the workforce and the finance…

I: Yes

R: So, they almost act like if everything else is fine then this is what you should do to sort it out. Nursing care particularly. So, one of the things we want to make sure is that we have a more holistic team. [...] So, I mentioned the specialty leads or specialty experts, as well as the quality and operational performance people, we’d also seek to have at least one person with really good operational understanding of finance and workforce, and even more importantly… Because I think for me one of the things that experience tells me is most lacking in healthcare institutions is information and intelligence as opposed to data.

I: Yes, totally agree.

R: It’s commonly said [healthcare organisations are] awash with data, but the amount information and intelligence available tends to be much more limited. So, we want to have some practical analysts, if you know what I mean. People who can apply their understanding of what’s useful information from the available data and help the analytical teams within trusts look at how they may translate one into the other to the benefit of outcomes. But I have to admit that this at the moment is the big idea…on paper.

I: And what are you hoping that’ll be different later when this team is in? How do you expect your relationship with trusts to change, with other scrutiny bodies, and also with government? How are you expecting it to change?

R: Obviously, our intention is that it should be possible for all of those relationships to be more [...] if we’re able to give government a much clearer understanding of what the issues are and what’s being done about it, if things are still being failed of course they won’t be delighted. They’ll be more positive about the depth of understanding. One of the big struggles at the moment, and again it’s in urgent care, is…exactly why is it that this year we’re having a particular problem as to any other year. So we all understand lots of individual causes of the difficulties of this year in terms of aging populations, demographics, transient populations, more attendances, probably the 20 somethings having a more retail view of accessing healthcare than their
forbearers, weather, the recent temperature drop. Lots of symptomatic things. But why wasn’t that a problem two years ago? Why is it this year that that combination of things has caused us problems?

I: So, it’s an assumption, a demand cause. All of those things are demand related.

R: They all assume they’re a demand cause. I mean, you and I, I expect, could have another couple of hours...this is one of my favourite subjects. But actually, if we could give a more coherent, joined up explanation to government of all the things that are true but we haven’t necessarily joined together in a comprehensive way, even that understanding would improve their view of the level of trust they can place in us and our other organisations.

I: Yeah, totally understand that.

R: If we’re able to support that understanding with our colleagues in other national organisations that then also improves probably our relationship with them, [...] which aren’t bad relationships at heart, but obviously, they have tension, as you would expect. And they are also struggling to provide that kind of cohesive description. So, everybody will welcome anybody helping to drive that planning. So, I think that would improve.

Our relationship with [x] will improve, [...]. If we’re better able to help trusts to kind of respond to the concerns [other stakeholders] will also be happy, and obviously if [organisations] find themselves in a better position that they’re not firefighting all the time or just even, I’ve got to be realistic, if we can help [organisations] even remove one of their headaches they’d be delighted is the feedback I’ve got. And also, that sense that we’re not just always against them, we’re with them. We’re recognising in a more sophisticated way that they’re not all incompetent, they just need more help, and that’s got to improve the relationship.

The danger of course in all of this is if we fail – and one of the big challenges is how you measure success – if we’re perceived to fail in this our level of competence could be questioned. [...] The other thing that I do think is really important, which is the point I made earlier on, is the improvement within the [Regulatory agency], and one of the things I think this team of people can help do is improve the understanding of the [Regulatory agency] staff about the way the health system works, help us come to more sophisticated diagnosis of underlying problems and help us be more sophisticated in what we ask or require of [organisations] in putting them right. So, if I give you an example. [Previously] if there was an [organisation] failing a standard, the [Regulatory agency’s] response would be to put in place a regulatory [recommendation to meet it within a designated timeframe].

I: Yeah, I was in [an organisation] in that type of situation three years ago.

R: Lovely. So, apologies if it was one of mine.
I: No… but interesting that you feel the need to apologise.

R: […] But now, so if you look at some of, not all of them, and there’s still been the odd bit of that conflict through, but we are more likely actually not to put a particular requirement on [an organisation now] and we’re more focused on the [organisation] delivering its plan and demonstrating to us through various ways the confidence that we can have that the [organisation] has done everything within its power to improve […] for patients.

I: Okay. That sounds positive.

R: It’s a step forward, and I think there’s probably another layer of sophistication. Don’t ask me what it is because I’m still trying to work it out, but we’ve got another layer of sophistication that we could layer on top, particularly if we have greater access to expertise in the development field. The other thing I think is very clear is […] we have spent a lot more time working with medical directors, nursing directors, COOs, workforce OD, HR directors […] which in retrospect seems obvious, but [we used to be focused on] governance and leadership.

I: Would you work with internal improvement teams now?

R: Not yet. So, that’s one of the things that what I’m building will help to do. Don’t get me wrong, there are both gaps but also there’s just a resource constraint to some extent of how far we can […] Ideally, we would look all the way down the chain if we could. But we are at the end of a day a regulator, […], and the ultimate responsibility for that does sit with the board. So, there’s still some logic in what we do, but I think we need to support our teams to be better able to have those conversations and challenge medical directors, nurse directors, divisional directors even of their various kinds, be they medical, nursing, management or another […]

We have an emerging [programme] which is focused on patient and clinical engagement, […] so a lot of the clinical input [to] provide advice and support into the system [with] specialist skills, including, for example, frail elderly as a very important and increasingly topical kind of area for change. So, they also provide support and advice.

But I think it’s almost as important that we get the [Regulatory agency] to be more sophisticated than it is that we work within [organisations] to help them become more sophisticated. Because people, whether they like it or not, listen to us and often people do what we say. The danger in that is if we say the wrong thing without meaning to, because we still expect [organisations] to think for themselves, send them down a path, so there’s two ends, that we want them to become more sophisticated both to challenge us and help themselves, and us to become more sophisticated so we’re actually helping and challenging people to do things in the right way. But that’s all very positive about the vision. In reality, still developing.
I: Yeah, of course. So, in terms of improvement expertise, do you have those skills in house now? Are you going to be practicing improvement internally as well as externally?

R: I do hope so. That is the intention. We don’t have lots of people who are in the organisation at the moment who are technically expert in improvement. We do have some people with real change expertise, and we have as an organisation fairly recently gone through a massive change programme … [we have] taken on a number of functions that we had no responsibility for before, so there is quite a lot of legacy expertise in change in its broadest sense, not necessarily change in the health system, and we’re totally aware that we need to bring more of that capability inside.

R: So, the closest we’ve got to this to date, with undoubtedly mixed results. There are organisations in the system at the moment [who need specific help on quality]. Our initial efforts certainly intended to focus more on how we might provide support, albeit some of that support is provided by the challenging way in which organisations run themselves, change, and those other things.

But there are two major elements of that that are probably worth… So, the first one is to have individuals who go into those organisations to challenge them, and through that challenge support them in addressing whatever the problems are to help them really understand the diagnosis of what’s going wrong. Is it simply that the cardiac department is totally dysfunctional, or is it in fact that there’s a total lack of clinical engagement across the [organisation] and no one really understands what’s expected of them, as examples. They’re there to challenge the plan and the programme put in place in response, and they’re there to support the [Regulatory agency] to understand whether change is really happening. Are we being fed a pack of rubbish or actually is the [organisation] genuinely making the change that they’re verbalising to us.

[paragraph removed, to ensure anonymity]

R: More latterly we’ve started to lean slightly more towards clinical executives, so people who have been nurse directors or AHPs who’ve ended up in an executive position, CEOs or some chief executives who come from a more clinical background originally who therefore also have a bit more of the confidence of what good nursing care looks like or what good on the ground might look like in specific areas, as opposed to broadly across the [organisations]. I’m sure that that will develop again. I suspect where it will head to in those circumstances there’ll be more of a focus on teams.

I: Okay. That’s fine.

R: The other element of improvement, which I personally think has been considerably less successful and I still struggle with a little bit, is the idea of buddying organisations with another organisation. The difficulty to some
extent grows from… The description that I think primarily government people would like to use is buddying somebody with a high performing organisation. Now, both of our experiences I’m sure would tell us that every organisation I’ve ever worked in has had some areas that are not so good. There is no such thing as a universally high performing NHS organisation in my personal experience. […] The other issue is that, it tends to be bigger organisations that might have capacity to provide the support, but often they have the capacity to sort themselves out, but whether they really have the capacity to also help sort someone else out, I’m quite dubious about that. So, there’s a question of whether you end up diluting a more successful organisation’s ability to improve.

I: I totally understand that, yeah.

R: There are some good things about this. The third problem is, because it tends to be larger or more specialist organisations that have the capacity, and maybe to some extent the capability to help people sort out, they’re often quite far removed in the way they work to the organisation they’re supporting. So for example [a small rural organisation] and a [very large urban organisation].

I: Yeah, I understand what you mean.

R: Therefore, it’s really questionable to me whether they’re actually the right buddy.

I: Yeah. You mean the context is so different.

R: Yeah. There was a really good [bidirectional] relationship formed between [two organisations]. It became more of a mutual kind of relationship that was quite positive, but it wasn’t aiming to be a kind of holistic hospital relationship where [organisation A] en-masse was helping others en-masse. So, I think there’s probably a bit more specificity required as to what support is actually being provided.

I also think we shouldn’t be afraid to look beyond just other NHS organisations. […] There are some smaller organisations, many of which contain some good people who came out of the health service in various forms who might be able to provide really good support to organisations. And given that the buddying programme provides some financial incentives to the buddy organisation I don’t see personally how it’s that different. But, as ever, there are some bits of bureaucracy to be worked through to work on that.

I: So, are you saying the people providing the expertise, the buddies, they have some financial incentive to do that? Do they have some payment for it?

R: Well, I say incentive, that’s probably not a fair reflection. There is money available to pay them for their time for freeing up staff.
I: Oh right, I didn’t know that.

R: [It is for] sort of back filling. So, they would understandably say it covers their expenses. There is some facility to provide… It’s not an incentive payment, because an incentive payment would say if you do really well we’ll give you this amount of money. It’s more a kind of thank you payment.

I: Yeah. Well, historically there’s not been that around, has there? If people have wanted to share good practice they’ve just gone and done it without the money, haven’t they? So, it’s been more voluntary.

R: Exactly. And I worry a little bit about the financial incentive anyway just for the reasons you imply, which is if people have to be paid to help other organisations do the best for their patients you’ve lost a bit of the soul of the health service. But I think it’s perfectly understandable that people can’t just lend all their resources for free.

I: Yeah. Because they have their own organisation.

R: And there is some work going on, but, forgive me, I can’t for the life of me remember who’s doing it, looking at the relative successes of some of these different interventions or mechanisms to support people.

R: The other thing […] is we started to undertake reviews either internally or led by external people looking at the success of the things we do. So, we are currently investigating the success of some of our interventions.

I: Okay. So, your own evaluation.

R: Yeah. So, while they don’t necessarily have any improvement label attached, as I said at the beginning, the main intention is for people to improve by anything that we do. So we are looking at case studies of organisations that [we have been working with] and see whether we can see evidence of, A, whether they improved, and, B, whether we can see evidence that our intervention helped that improvement or whether it did nothing. I’ve no doubt there are some things we’ve done that actually are probably detrimental.

I: Can you think of any examples of that?

R: I sort of gave it early on, but even just the very standard, of ‘we expect you within [timeline] to meet the [standard]’. So, focused on [the standard] that it’s an absolute possibility that it could be detrimental to the way in which people go about achieving [the standard]. Does it become performance at all costs? I just think it can’t be beyond the realms of possibility that we [have that] impact. We took regulatory [steps in X] – all of this is in the public domain – who were failing just about every standard going. Bearing in mind this was at a point in time where, bizarre as it seems now, quality wasn’t on most people’s agendas really. True quality. They were failing nearly every national standard going. There were grave concerns about their leadership. Lots of people have moved on, but that’s in the background rather than in the public eye. We
essentially required them to achieve all the standards within a set period of time.

In [X] we intervened again […] But there is just a question in the back of my mind of, […] was the [unsuccessful] approach that they took to some extent led by the pressure from [us] previously to achieve standards? I just don’t know. It’s one of the things I’d personally like to understand so that it doesn’t happen again if it’s the case. But I think we would be very naive to believe we’ve always had a positive impact. Bearing in mind I think we really can only go so far to say [we ensured measurable] improvement and can we through stakeholder interviews and any objective measures available make an assertion that we had a positive impact.

We’re not necessarily going to find out the unmeasurable impact on things like culture. […] if the [Regulatory agency] came to your door and said we are deeply unimpressed it created all sorts of ripples through an [organisation], and inevitably some of those won’t have been entirely positive because they will have been borne out of nervousness, fear, whatever it might be. And I’m not sure we’ll fully get under the skin of that kind of thing.

[paragraph removed, to ensure anonymity]

End of transcript

F.2: Example coding

Table F.1, details the codes used for an extract of the anonymised interview transcript in section F.1. It shows the coding for the first two pages of the transcript.

<table>
<thead>
<tr>
<th>Text extract</th>
<th>Codes used</th>
</tr>
</thead>
<tbody>
<tr>
<td>So essentially, I was responsible for our regulatory position [in X] and then also working with the other major bodies that have a responsibility for healthcare in [X].</td>
<td>Suppliers, stakeholders and partnership; Relationships</td>
</tr>
<tr>
<td>I had various other responsibilities in the [Regulatory agency].</td>
<td>Relationships</td>
</tr>
<tr>
<td>So, I am fairly involved but probably don’t have technically an explicit responsibility for interactions with other oversight bodies, so the, ombudsman, those kinds of people.</td>
<td>Relationships; Roles and responsibilities</td>
</tr>
<tr>
<td>My primary role essentially is to ensure that [organisations] were complying with the […] minimum standards that they’re expected to achieve.</td>
<td>Roles and responsibilities; purpose</td>
</tr>
</tbody>
</table>
So, I suppose the most direct relationship with improvement of that particular role was about where [organisations] were failing to deliver certain minimum standards and therefore the quality of the care or service to patients was not what we expected…

…then it was my job to work with those [organisations] to ensure that they improved their position and restored themselves to at least that minimum standard.

It is worth emphasising that we’re talking about a minimum standard, not necessarily some people’s idea of an ideal.

So, although we have expectations on [organisations] that they should aspire to be the absolute best they can be from a regulatory authority point of view we can only work on minimum standards, and that’s exactly the same as any other regulator, […].

So, there are a number of ways, to some extent depending on how bad it’s got. The most simple way is really to verbalise the expectation.

So, it’s quite hard sometimes to explain to people who aren’t in the organisation to fully appreciate, but [organisations] really listen to [us]…

… and sometimes they listen to us when we’ve not technically got any legal authority but just our general authority is recognised.

So, at the very simplest level it’s pointing out to [organisations] that they are not performing as they should be, they are below our expectations, and we expect them to resolve that, and if they don’t then it escalates from there.

The more substantive roles are that we effectively issue notices of intent that we’re going to take action with an [organisation] it doesn’t resolve its situation.

We will work with organisations in a more informal way to identify support and expertise that they may benefit from that will help them to improve.
<table>
<thead>
<tr>
<th>Text extract</th>
<th>Codes used</th>
</tr>
</thead>
<tbody>
<tr>
<td>We do quite a lot of work essentially diagnosing what the root cause of the problem is.</td>
<td>Measurement information and benchmarking</td>
</tr>
<tr>
<td>So, most of what we see and most of what our regime is responsible for are symptoms.</td>
<td>Measurement information and benchmarking</td>
</tr>
<tr>
<td>So, for example – it’s a little bit of an unfair example at the moment because of the pressure the system’s under – traditionally when most [organisations] were achieving the standards, where somebody wasn’t that did stand them out.</td>
<td>Process design and non-conformance; Measurement, information and benchmarking</td>
</tr>
<tr>
<td>It was usually a symptom of something more than just a failure to achieve [the standards], …</td>
<td>Process design and non-conformance; Standards</td>
</tr>
<tr>
<td>…so a lack of clinical leadership […] a lack of engagement […].</td>
<td>Leadership: Role specific leadership; Employee involvement</td>
</tr>
<tr>
<td>That’s just as examples. So, diagnosis is usually fairly powerful.</td>
<td>Measurement information and benchmarking</td>
</tr>
<tr>
<td>As we sort of go through the levels we have the power and authority once certain steps have been breached to consider [escalating].</td>
<td>Process design and conformance; Leadership; Follow up action</td>
</tr>
<tr>
<td>So, we have the power to [escalate], but the more kind of positive power is that we then put in additional capability and capacity. I’ll talk about that in a bit.</td>
<td>Follow up action; Improvement capability; Leadership</td>
</tr>
</tbody>
</table>
Appendix G: Selection criteria for assessment documents

The following table, G.1, details the selection criteria used to choose the assessment and inspection reports from each agency used in the analysis detailed in paper 3 (Furnival et al., in development-c).

Table G.1: Assessment report selection criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>Five reports per agency</td>
</tr>
<tr>
<td>Date period</td>
<td>Report produced within the period of 2013-2015</td>
</tr>
<tr>
<td>Sector</td>
<td>Report to include review content of acute NHS hospital care at a minimum. May include integrated services such as acute and community provision.</td>
</tr>
<tr>
<td>Accessibility</td>
<td>The reports need to be publicly available from either regulatory agency websites or NHS organisation websites.</td>
</tr>
<tr>
<td>Performance type</td>
<td>Range of performance to be reviewed including those described as meeting standards or ‘high’ performers or those non-compliant or ‘low’ performing.</td>
</tr>
<tr>
<td>Sample</td>
<td>Selected purposely if interview participant mentioned report as an example of high or low performance or improvement capability. Otherwise selected at random to meet the above criteria.</td>
</tr>
</tbody>
</table>

References

Appendix H: Coding framework

H.1 A priori codes

Table H.1 details the a priori coding framework used for content and thematic analysis in the research study. This is shown in the left-hand column. The a priori framework was developed from the extraction of measurement constructs and domains from the integrative literature review of instruments and frameworks for the assessment of improvement capability detailed in paper 1 (Furnival et al., in development-a). The right-hand column indicates the group the construct is part of when inductively analysed into the dimensions of improvement capability. The inductive analysis followed detailed review of the construct definitions, and measurement items.

Table H.1: A priori codes used (research study phase 2, parts a and b)

<table>
<thead>
<tr>
<th>A priori constructs</th>
<th>Improvement capability dimension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Culture</td>
<td>Organisational culture</td>
</tr>
<tr>
<td>Innovation or willingness to take risk</td>
<td></td>
</tr>
<tr>
<td>Safety</td>
<td></td>
</tr>
<tr>
<td>Mindset</td>
<td></td>
</tr>
<tr>
<td>Ways of working</td>
<td></td>
</tr>
<tr>
<td>Urgency for results</td>
<td></td>
</tr>
<tr>
<td>Measurement, information and benchmarking</td>
<td>Data and performance</td>
</tr>
<tr>
<td>Results and outcomes</td>
<td></td>
</tr>
<tr>
<td>Anticipated benefits</td>
<td></td>
</tr>
<tr>
<td>Emphasis of effectiveness</td>
<td></td>
</tr>
<tr>
<td>Employee involvement</td>
<td>Employee commitment</td>
</tr>
<tr>
<td>Empowerment</td>
<td></td>
</tr>
<tr>
<td>Distributed power</td>
<td></td>
</tr>
<tr>
<td>Reward and recognition</td>
<td></td>
</tr>
<tr>
<td>Teamworking</td>
<td></td>
</tr>
<tr>
<td>Degree of conflict</td>
<td></td>
</tr>
<tr>
<td>People and human resources management (HRM)</td>
<td></td>
</tr>
<tr>
<td>Leadership</td>
<td>Leadership commitment</td>
</tr>
<tr>
<td>Role specific commitment</td>
<td></td>
</tr>
<tr>
<td>Resources and investment</td>
<td></td>
</tr>
<tr>
<td>Organisational configuration</td>
<td></td>
</tr>
<tr>
<td>A priori constructs</td>
<td>Improvement capability dimension</td>
</tr>
<tr>
<td>--------------------------------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Continuous improvement practices and tools</td>
<td>Process improvement and learning</td>
</tr>
<tr>
<td>Statistical process control (SPC)</td>
<td></td>
</tr>
<tr>
<td>Organisational learning and knowledge</td>
<td></td>
</tr>
<tr>
<td>Skills and training</td>
<td></td>
</tr>
<tr>
<td>Problem areas</td>
<td></td>
</tr>
<tr>
<td>Barriers to change</td>
<td></td>
</tr>
<tr>
<td>Process design and conformance</td>
<td></td>
</tr>
<tr>
<td>[Improvement] Infrastructure</td>
<td></td>
</tr>
<tr>
<td>Product and service design</td>
<td></td>
</tr>
<tr>
<td>Implementation scope</td>
<td></td>
</tr>
<tr>
<td>Customer focus</td>
<td>Service-user focus</td>
</tr>
<tr>
<td>Patient or customer involvement</td>
<td></td>
</tr>
<tr>
<td>Patient or customer satisfaction</td>
<td></td>
</tr>
<tr>
<td>Environment</td>
<td>Stakeholder and supplier focus</td>
</tr>
<tr>
<td>Suppliers, stakeholders and partnerships</td>
<td></td>
</tr>
<tr>
<td>Environmental context</td>
<td></td>
</tr>
<tr>
<td>Sales</td>
<td></td>
</tr>
<tr>
<td>Supplier quality management</td>
<td></td>
</tr>
<tr>
<td>Supply chain</td>
<td></td>
</tr>
<tr>
<td>Strategy and policy</td>
<td>Strategy and governance</td>
</tr>
<tr>
<td>Communication</td>
<td></td>
</tr>
<tr>
<td>Documentation</td>
<td></td>
</tr>
<tr>
<td>Priorities, timescales and goals</td>
<td></td>
</tr>
<tr>
<td>Quality management and governance</td>
<td></td>
</tr>
<tr>
<td>Accountability</td>
<td></td>
</tr>
</tbody>
</table>

**H.2 Final codes**

Table H.2 details the final coding framework used in the thematic analysis. This is shown as nodes and branches of the coding framework within NVivo10. The three main themes of relationship, roles and resources identified as tensions for regulatory agencies whilst moving to a hybrid approach can be identified in the first left hand column. The sub-codes attributed to this theme are branched to the right.
### Table H.2: Final codes for thematic and content analysis (research study phase 2, parts a and b)

<table>
<thead>
<tr>
<th>Final codes for thematic analysis</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Relationships</strong></td>
<td></td>
</tr>
<tr>
<td>Relationships / partnerships</td>
<td></td>
</tr>
<tr>
<td>Communication</td>
<td></td>
</tr>
<tr>
<td>Customer focus</td>
<td></td>
</tr>
<tr>
<td>Customer or patient involvement</td>
<td></td>
</tr>
<tr>
<td>People and HRM</td>
<td></td>
</tr>
<tr>
<td>Degree of conflict</td>
<td></td>
</tr>
<tr>
<td>Employee involvement</td>
<td></td>
</tr>
<tr>
<td>Role specific commitment</td>
<td></td>
</tr>
<tr>
<td>Suppliers, stakeholders and partnerships</td>
<td></td>
</tr>
<tr>
<td>Teamworking</td>
<td></td>
</tr>
<tr>
<td><strong>Culture</strong></td>
<td></td>
</tr>
<tr>
<td>Trust</td>
<td></td>
</tr>
<tr>
<td>Transparency</td>
<td></td>
</tr>
<tr>
<td>Accountability</td>
<td></td>
</tr>
<tr>
<td>Environmental, political and historical context</td>
<td></td>
</tr>
<tr>
<td>Organisational configuration</td>
<td></td>
</tr>
<tr>
<td>Flexibility and responsiveness</td>
<td></td>
</tr>
<tr>
<td>Empowerment</td>
<td></td>
</tr>
<tr>
<td>Innovation and willingness to Experiment</td>
<td></td>
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<tr>
<td>Values, ethics and behaviour</td>
<td></td>
</tr>
<tr>
<td>Mindset</td>
<td></td>
</tr>
<tr>
<td>Ways of working</td>
<td></td>
</tr>
<tr>
<td>Leadership</td>
<td></td>
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<tr>
<td>Resources</td>
<td></td>
</tr>
<tr>
<td>Assessment process and method</td>
<td></td>
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<tr>
<td>Assessment tool</td>
<td></td>
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<tr>
<td>Bias</td>
<td></td>
</tr>
<tr>
<td>Frequency of assessment</td>
<td></td>
</tr>
<tr>
<td>Final codes for thematic analysis</td>
<td></td>
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<td>----------------------------------</td>
<td></td>
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<tr>
<td><strong>Non-compliance</strong></td>
<td></td>
</tr>
<tr>
<td>Fear and threats</td>
<td></td>
</tr>
<tr>
<td>Follow up action</td>
<td></td>
</tr>
<tr>
<td><strong>Emphasis of effectiveness</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Regulatory methods</strong></td>
<td></td>
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<tr>
<td>Standards</td>
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<tr>
<td>Thematic review</td>
<td></td>
</tr>
<tr>
<td>Accreditation</td>
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<tr>
<td>Evaluation</td>
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<td>Inspection</td>
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<tr>
<td>[Anonymised organisation] review</td>
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<td>Developmental approach</td>
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<td><strong>Reward and recognition</strong></td>
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</tr>
<tr>
<td><strong>Improvement capability</strong></td>
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<tr>
<td>Self-regulation and governance</td>
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<td>External support</td>
<td></td>
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<td>Projects and programmes</td>
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<td>Improvement capacity</td>
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<td>Continuous improvement practices</td>
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<td>Complaints</td>
<td></td>
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<td>Variation</td>
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<td>Measurement</td>
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<td>Safety</td>
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<tr>
<td>Skills and training</td>
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<td><strong>Organisational learning and knowledge</strong></td>
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<td>Maturity</td>
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<tr>
<td><strong>Quality management and governance</strong></td>
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<tr>
<td>Documentation</td>
<td></td>
</tr>
<tr>
<td>Infrastructure</td>
<td></td>
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<tr>
<td><strong>Roles</strong></td>
<td></td>
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<tr>
<td>Strategy and policy</td>
<td></td>
</tr>
<tr>
<td>Purpose</td>
<td></td>
</tr>
<tr>
<td>Conflict of role</td>
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</tr>
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</table>
Final codes for thematic analysis

<table>
<thead>
<tr>
<th></th>
<th>Highlighting good practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Language and terminology</td>
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<tr>
<td>Segmentation</td>
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</tr>
<tr>
<td>Roles and responsibilities</td>
<td></td>
</tr>
<tr>
<td>Priorities, timescales and goals</td>
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<tr>
<td>Barrier removal</td>
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<td>Barriers to change</td>
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<td>Sustainability</td>
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<td>Implementation scope</td>
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<td>Resources and investment</td>
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<tr>
<td>Results and outcomes</td>
<td></td>
</tr>
<tr>
<td>Urgency for results</td>
<td></td>
</tr>
</tbody>
</table>

Appendix H: References

Appendix I: List of instruments and frameworks for the assessment of improvement capability

Appendix I details the instruments and frameworks found in the integrative review of improvement capability. This is shown in table I.1.

Table I.1: Instruments and frameworks for the assessment of improvement capability

<table>
<thead>
<tr>
<th>Lead author</th>
<th>Method</th>
<th>Sector</th>
<th>Country</th>
<th>Final sample size</th>
<th>Response rate</th>
<th>Number of areas of interest</th>
<th>Summary</th>
<th>Reliability (Cronbach’s alpha)</th>
<th>Validity tests</th>
<th>Improvement capability group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adam et al. (1997)</td>
<td>Survey</td>
<td>Manufacturing</td>
<td>Firms in 9 countries worldwide</td>
<td>977</td>
<td>Unstated</td>
<td>9 factors</td>
<td>Survey of multiple global manufacturing companies’ improvement practices to identify key factors and to assess geographical variation. Found that whilst quality improvement predicts quality performance in any region. Quality improvement practices alone are insufficient to change financial performance.</td>
<td>0.74-0.89</td>
<td>Not reported</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Adam (1994)</td>
<td>Survey</td>
<td>Manufacturing</td>
<td>USA</td>
<td>187</td>
<td>46%</td>
<td>20 items</td>
<td>Factors were identified to identify quality and productivity improvement approaches and indicates that the improvement approach may depend on which measures are selected for quality and financial performance.</td>
<td>Not reported</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Lead author</td>
<td>Method</td>
<td>Sector</td>
<td>Country</td>
<td>Final sample size</td>
<td>Response rate</td>
<td>Number of areas of interest</td>
<td>Summary</td>
<td>Reliability (Cronbach’s alpha)</td>
<td>Validity tests</td>
<td>Improvement capability group</td>
</tr>
<tr>
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<td>-----------------------------</td>
</tr>
<tr>
<td>Adebanjo and Kehoe (1999)</td>
<td>Survey and interviews</td>
<td>Manufacturing</td>
<td>UK</td>
<td>166</td>
<td>25%</td>
<td>7 areas</td>
<td>Survey and interviews showed that teamwork as least developed across organisations regardless if a TQM programme was in train. Main observations indicated that organisations lacking a comprehensive and structured approach to quality development were more likely to have inconsistent success with culture change.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Ahire et al. (1996)</td>
<td>Survey</td>
<td>Automotive</td>
<td>USA</td>
<td>371</td>
<td>37%</td>
<td>12 constructs</td>
<td>Identifies 12 constructs for integrated quality management strategy and tests developed scale in one industry. Concluded that quality management strategies act in synergy and influence each other to different degrees, pointing to inter-related determinants of QM. Suggests further studies needed to assess the extent of TQM implementation.</td>
<td>&gt;0.6</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Anand et al. (2009)</td>
<td>Case study and interviews</td>
<td>Manufacturing and Healthcare</td>
<td>USA</td>
<td>5 cases</td>
<td>Not applicable (n/a)</td>
<td>8 constructs</td>
<td>Development framework through grounded theory for continuous improvement infrastructure based on dynamic capabilities. Developed with five USA firms.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Improvement models</td>
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<tr>
<td>Lead author</td>
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<tr>
<td>Anderson et al. (1995)</td>
<td>Survey</td>
<td>Electronics, Machinery and Transportation</td>
<td>USA</td>
<td>41</td>
<td>60%</td>
<td>7 constructs</td>
<td>Describes quality management and tests theory based on Deming's 14 points using seven constructs based on Delphi survey. Indicates through path analysis that there are large unexplained effects suggesting the theory is not exhaustive.</td>
<td>0.6</td>
<td>Indicated</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Baidoun (2003)</td>
<td>Survey</td>
<td>Small ISO 9000 Industry and Service</td>
<td>Palestine</td>
<td>78</td>
<td>100%</td>
<td>19 factors</td>
<td>Identifies important quality management factors from the literature develops instrument and tests and indicates that these are relevant in the Palestinian context.</td>
<td>Consensus approach</td>
<td>Consensus approach</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Batalden and Stoltz (1993)</td>
<td>Case studies</td>
<td>Hospital</td>
<td>USA</td>
<td>n/a</td>
<td>n/a</td>
<td>4 themes</td>
<td>Case study example to demonstrate developed framework.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Benn et al. (2012)</td>
<td>Survey</td>
<td>Hospital</td>
<td>UK</td>
<td>284 (19 organisations)</td>
<td>52%</td>
<td>22 factors</td>
<td>Development of a survey to predict changes in safety climate and capability as part of the UK safer patients’ initiative. Suggests that scores did improve, over one year, but that context and hospital size and type were not significant factors.</td>
<td>0.952</td>
<td>Not reported</td>
<td>Change models</td>
</tr>
<tr>
<td>Lead author</td>
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<tr>
<td>Benson et al. (1991)</td>
<td>Survey</td>
<td>Manufacturing and service</td>
<td>USA</td>
<td>152 (20 organisations)</td>
<td>unstated</td>
<td>8 critical factors</td>
<td>Merges 2 existing instruments linked to quality management and organisational quality context, and indicates that context moderates the effectiveness of quality management. Most significant factor is identified as management knowledge, accounting for 40% of the variance. In the service sub sample only internal factors correlated with quality management.</td>
<td>0.7-0.9</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Berlowitz et al. (2003)</td>
<td>Survey</td>
<td>Nursing homes</td>
<td>USA</td>
<td>106 (35 organisations)</td>
<td>60%</td>
<td>42 items</td>
<td>Examined quality improvement implementation within USA nursing homes and culture and results were impacted. Focused on pressure ulcer care and found that there was significant variation of quality improvement implementation and this was not linked to size, status or location. However, it also found that organisations with a developmental culture were more advanced in implementing improvement practices and that there were indications that this linked to improved results.</td>
<td>0.89 - 0.92</td>
<td>Not reported</td>
<td>Change models</td>
</tr>
<tr>
<td>Lead author</td>
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<tr>
<td>Bessant and Francis (1999)</td>
<td>Assessment framework</td>
<td>Manufacturing and Financial Services</td>
<td>UK</td>
<td>3</td>
<td>n/a</td>
<td>6 levels</td>
<td>A 6-level scale is described ranging from 0 - 5 describing differing levels of strategic improvement capability implementation from none to fully embedded. Indicates that both incremental and disruptive improvement needed and should link into organisational strategic goals and measures. Designed to be used as an assessment tool.</td>
<td></td>
<td></td>
<td>Maturity models</td>
</tr>
<tr>
<td>Black and Porter (1996)</td>
<td>Survey</td>
<td>EFQM members</td>
<td>Europe</td>
<td>204</td>
<td>44%</td>
<td>10 factors</td>
<td>An empirical framework for designed to identify critical total quality management factors using experience of practitioners and Baldrige Award. Study offered a simple, reliable and valid approach for examine TQM practices and systems which can be used to improve quality award criteria and other similar self-assessments.</td>
<td>&gt;0.6</td>
<td>Yes</td>
<td>Improvem ent models</td>
</tr>
<tr>
<td>Bobiak et al. (2009)</td>
<td>Interviews and observation</td>
<td>Primary Healthcare</td>
<td>USA (Ohio)</td>
<td>15 practices</td>
<td>n/a</td>
<td>25 items</td>
<td>Suggests that 'capacity for change' or the 'ability and willingness to undertake change' is an organisational characteristic for healthcare quality improvement and describes measurement approach designed and tested within healthcare to support capacity building.</td>
<td>0.94</td>
<td>Yes</td>
<td>Change models</td>
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<td>Bou-Llusar et al. (2009)</td>
<td>Questionnaire</td>
<td>Manufacturing and Service</td>
<td>Spain</td>
<td>446</td>
<td>Not stated</td>
<td>13 constructs</td>
<td>Review of total quality management instruments to empirically test EFQM frameworks. Suggests that ‘enabler excellence’ is key and the study found strong evidence of a causal relationship between enablers and results when TQM is implemented and systematically and with a firm commitment to TQM principles.</td>
<td>&gt;0.7 excl. 1</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Software Engineering Institute (2006)</td>
<td>On site observation</td>
<td>Unstated</td>
<td>NA</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>A framework to examine for five levels within practices, from fully implemented to not yet for each process. This is aggregated into goal satisfaction and organisational ratings. There must be full consensus from the team for the scores given. Areas addressed are not exhaustive and can be tailored as required.</td>
<td>Consensus reported</td>
<td>Not reported</td>
<td>Maturity models</td>
</tr>
<tr>
<td>Claver et al. (2003)</td>
<td>Survey</td>
<td>ISO 9000 companies</td>
<td>Spain</td>
<td>154</td>
<td>76%</td>
<td>8 factors</td>
<td>A literature review to develop an assessment model using EFQM as starting point. Compares instrument with other models, identifies factors that assess TQM results and validates instrument for use in firms of variable sizes. Indicates this instrument can be used to evaluate TQM programmes.</td>
<td>&gt;0.55 except 5 factors</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
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<td>Criado and Calvo-Mora (2009)</td>
<td>Survey</td>
<td>ISO 9000 companies</td>
<td>Spain</td>
<td>103</td>
<td>19%</td>
<td>37 variables</td>
<td>Development of a Reformed Excellence Predictor (REP) based on the critical factors for implementing, developing and improving a quality management system (QMS). Found that experience of QMS implementation is a critical factor in achieving results together with management commitment.</td>
<td>Indicated</td>
<td>Yes</td>
<td>Improvemnt models</td>
</tr>
<tr>
<td>Cronenmyr and Danielsson (2013)</td>
<td>Maturity model</td>
<td>Manufacturing</td>
<td>Scandinavia</td>
<td>1</td>
<td>n/a</td>
<td>5 levels</td>
<td>A maturity model called Process Management 123, suggests that many improvement programmes fail as organisations try to start advanced work too early and an assessment of maturity would be helpful. 6 assessment levels are proposed and tested across 8 categories.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Maturity models</td>
</tr>
<tr>
<td>Dahlgaard et al. (2011)</td>
<td>Self-assessment</td>
<td>Manufacturing</td>
<td>Denmark</td>
<td>1</td>
<td>n/a</td>
<td>97 statements</td>
<td>A model designed to assess and improve healthcare organisations using a simple methodology based on a simplified excellence model. This can be used for cultural assessment and to identify improvement areas. It is a self-assessment approach encouraging all employees to participate and claims to measure both intangible systemic factors and logical tangible factors.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Improvemnt models</td>
</tr>
<tr>
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<tr>
<td>Douglas and Judge (2001)</td>
<td>Survey</td>
<td>Hospitals</td>
<td>USA</td>
<td>193</td>
<td>38%</td>
<td>7 areas</td>
<td>Study trying to identify if degree of TQM implementation can be measured and how. Clarified the relationship between the degree of implementation of TQM and performance, and thus indicates that for successful adoption of TQM is required.</td>
<td>0.9</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>European Foundation for Quality Management (2014)</td>
<td>Framework</td>
<td>All</td>
<td>Europe</td>
<td>n/a</td>
<td>n/a</td>
<td>9 criteria</td>
<td>The EFQM model provides a framework with which to conduct a holistic review of an organisation and its approach to quality management. This model is targeted at European companies. It claims to be able to be used regardless of the improvement methodology utilised in the company and for identifying improvement areas. It aims to promote and recognise sustainable success.</td>
<td>n/a</td>
<td>n/a</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Flynn et al. (1994)</td>
<td>Survey</td>
<td>Machinery, transportation and electronics</td>
<td>USA</td>
<td>75</td>
<td>60%</td>
<td>7 dimensions</td>
<td>Valid and reliable scales to measure quality management practices were tested in USA manufacturing. The use of such scales is important for organisational self-assessment and can support planning and decision making. The analysis shows that the instrument is a valid predictor or quality performance at plant level.</td>
<td>&gt;0.6</td>
<td>Yes</td>
<td>Improvement models</td>
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<td>Gagliardi et al. (2010)</td>
<td>Survey and interviews</td>
<td>Hospital</td>
<td>Canada</td>
<td>97</td>
<td>79%</td>
<td>3</td>
<td>A study to evaluate improvement infrastructure as this important for improved outcomes. Found that acute care does not adequately resource quality improvement and investment are needed to develop capacity.</td>
<td>Indicated</td>
<td>Not reported</td>
<td>Change models</td>
</tr>
<tr>
<td>Hammer (2007)</td>
<td>Self-assessment</td>
<td>Automotive and chemicals</td>
<td>US</td>
<td>4</td>
<td>n/a</td>
<td>9</td>
<td>Development of a process and enterprise maturity model to assess process based transformation efforts. Identified two process enablers, which include the abilities of the people who operate the process and enterprise wide capabilities.</td>
<td>n/a</td>
<td>n/a</td>
<td>Maturity models</td>
</tr>
<tr>
<td>Ismail et al. (2009)</td>
<td>Maturity model</td>
<td>ISO 9000 companies</td>
<td>Iran</td>
<td>8</td>
<td>n/a</td>
<td>33</td>
<td>Paper outlines the development of a self-assessment framework based on 33 criteria linked to ISO 9001 which has been tested in 8 Iranian companies. A radar logic is used as a measurement tool and maturity is also assessed with 8 dimensions.</td>
<td>0.933-0.943</td>
<td>Not reported</td>
<td>Governance models</td>
</tr>
<tr>
<td>Ivanovic and Majstrovic</td>
<td>Survey</td>
<td>Manufacturing</td>
<td>West Balkans</td>
<td>55</td>
<td>unstated</td>
<td>4</td>
<td>Research to identify quality management practices and potential improvement in the Balkans. Identifies four levels of evolution, inspection, quality control, quality assurance and TQM, proposes 5th level of integrated management system.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Governance models</td>
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<tr>
<td>Jochem et al. (2011)</td>
<td>Maturity model</td>
<td>Small manufacturing enterprises</td>
<td>Germany</td>
<td>2</td>
<td>unstated</td>
<td>7 areas</td>
<td>Paper describing how to measure maturity of knowledge businesses through integration of disciplines such as quality management, process management and knowledge management.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Maturity models</td>
</tr>
<tr>
<td>Joly et al. (2012)</td>
<td>Survey</td>
<td>Public health organisation</td>
<td>USA (16 states)</td>
<td>116</td>
<td>60%</td>
<td>4 domains</td>
<td>Describes the development of an instrument to measure quality improvement maturity within public health agencies. Incorporates 10 items that measure skills, functions, and the approach used within organisations.</td>
<td>&gt;0.76</td>
<td>Yes</td>
<td>Maturity models</td>
</tr>
<tr>
<td>Judge and Douglas (2009)</td>
<td>Survey</td>
<td>Manufacturing and service</td>
<td>USA</td>
<td>327</td>
<td>Unstated</td>
<td>8 dimensions</td>
<td>Development of a multi-dimensional scale to measure the construct of ‘organisational capacity of change’ (OCC).</td>
<td>Not Reported</td>
<td>Yes</td>
<td>Change models</td>
</tr>
<tr>
<td>Lead author</td>
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<td>Deming Prize Committee (2014)</td>
<td>Framework</td>
<td>All</td>
<td>Japan</td>
<td>n/a</td>
<td>n/a</td>
<td>6 categories</td>
<td>Set up to promote the teachings of Deming in Japan in 1951. Organisations can apply for the prize and must demonstrate firm commitment to Deming principles and continuous improvement and be open to scrutiny. Most emphasis of the prize is on top management commitment and leadership.</td>
<td>n/a</td>
<td>Not reported</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Kaplan et al. (2013)</td>
<td>Cross-sectional survey</td>
<td>Healthcare</td>
<td>USA</td>
<td>74 improvement projects</td>
<td>55%</td>
<td>25 factors</td>
<td>An analysis of the Model for Success in Quality (MUSIQ), looks for relations between different constructs including team QI skills, and microsystem QI capability. Study showed that microsystem QI capability was one of several factors that had significant effect on QI project performance outcomes, with the most significant being that of QI resourcing. Further information within Kaplan et al. (2012).</td>
<td>&gt;0.8</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Kianto (2008)</td>
<td>Cross-Sectional survey</td>
<td>Unstated</td>
<td>Unstated</td>
<td>258 (from 4 organisations)</td>
<td>Unstated</td>
<td>6 factors</td>
<td>An instrument to measure organisational renewal capability using index called ORCI (Organisational renewal capability inventory). Found that organisational renewal capability directly influenced organisational performance and it was a reliable instrument.</td>
<td>&gt;0.7 excl. 1</td>
<td>Yes</td>
<td>Change models</td>
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<tr>
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<td>Klemenc-Ketiš et al. (2013)</td>
<td>Survey</td>
<td>Primary care practices</td>
<td>Slovenia</td>
<td>100</td>
<td>60%</td>
<td>6 domains</td>
<td>Development of a self-assessment questionnaire for QI competences in primary care in Slovenia based on the quality improvement competency framework for family medicine in Slovenia.</td>
<td>&gt;0.9</td>
<td>Not reported</td>
<td>Change models</td>
</tr>
<tr>
<td>Lakhal et al. (2006)</td>
<td>Survey</td>
<td>Manufacturing (plastics, transforming)</td>
<td>Tunisia</td>
<td>92</td>
<td>Unstated</td>
<td>7 practices</td>
<td>Examines how different improvement practices interact and link together to identify the most critical. Uses multidimensional construct for TQM, rather than single which many earlier ones do.</td>
<td>&gt;0.8 (Joresko g's coefficient)</td>
<td>Yes</td>
<td>Improvement models</td>
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<tr>
<td>Lammers et al. (1996)</td>
<td>Survey</td>
<td>Healthcare</td>
<td>USA</td>
<td>204 (36 sites)</td>
<td>89%</td>
<td>4 domains</td>
<td>Development of a quality improvement survey within Veterans Health Association to understand commitment at team leader level. Found that age of the quality council, overall organisation commitment and physician commitment are the most critical variables for predicting improvement activity.</td>
<td>&gt;0.62</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Lead author</td>
<td>Method</td>
<td>Sector</td>
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<td>Lee et al. (2002)</td>
<td>Survey</td>
<td>Healthcare</td>
<td>Korea</td>
<td>67</td>
<td>73%</td>
<td>4 domains</td>
<td>Research to review the extent of clinical quality improvement implementation in Korean hospitals and to identify the influencing factors. It was observed that larger hospitals tended to have more successful improvement activity. Information technology and the systematic problem solving approach used were significant predictors of improvement success.</td>
<td>0.75-0.93</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Lobo et al. (2012)</td>
<td>Survey</td>
<td>Manufacturing</td>
<td>Australia (New South Wales)</td>
<td>60</td>
<td>4%</td>
<td>6 constructs</td>
<td>Development of the QMAF model (quality management assessment framework) to developed focused methodology for low performing organisations to reapply strategies from higher performing organisations. Results showed that in this study most organisations had few continuous improvement initiatives and reward systems, and a 'dismal' use of TQM.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Governance models</td>
</tr>
<tr>
<td>Lombarts et al. (2009)</td>
<td>Survey</td>
<td>Hospitals</td>
<td>Europe</td>
<td>349</td>
<td>Unstated</td>
<td>7 domains</td>
<td>Development of an index and maturity classification scheme for quality management in European hospitals. Plan-Do-Check-Act (PDCA) was used as frame to assess maturity level. The index helped to differentiated between different hospital systems and it is</td>
<td>&gt;0.69-0.89 excl. 1</td>
<td>Yes</td>
<td>Maturity models</td>
</tr>
<tr>
<td>Lead author</td>
<td>Method</td>
<td>Sector</td>
<td>Country</td>
<td>Final sample size</td>
<td>Response rate</td>
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<tr>
<td>Mohanty and Lakhe (1998)</td>
<td>Survey</td>
<td>Process, textiles, automotive and electronics</td>
<td>India</td>
<td>175</td>
<td>62%</td>
<td>18 items</td>
<td>Suggested that the index be adapted into a ‘quick’ scan of the organisation.</td>
<td>&gt;0.7</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Morris et al. (1999)</td>
<td>Survey</td>
<td>Manufacturing</td>
<td>Australia</td>
<td>330</td>
<td>94%</td>
<td>7 sections</td>
<td>A survey designed to measure dynamic organisational capability. Tested in Australian manufacturing. Found that successful transitions to a quality culture required a clear vision and strategy, supported by leadership action and team work, detailed planning and resources and time.</td>
<td>0.71-0.87</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Nightingale and Mize (2002)</td>
<td>Self-assessment</td>
<td>Aerospace</td>
<td>USA &amp; UK</td>
<td>10</td>
<td>n/a</td>
<td>3 sections</td>
<td>Outlines the development of LESAT (Lean enterprise self-assessment toolkit) for organisations that can be used to assess capabilities. Assessment is done as group consensus process to identify current and desired capability.</td>
<td>Consensus</td>
<td>Qualitative</td>
<td>Maturity models</td>
</tr>
<tr>
<td>Lead author</td>
<td>Method</td>
<td>Sector</td>
<td>Country</td>
<td>Final sample size</td>
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<tr>
<td>National Institute of Standard s and Technology (2013-14)</td>
<td>Framework</td>
<td>All</td>
<td>USA</td>
<td>n/a</td>
<td>n/a</td>
<td>7</td>
<td>Within the USA many performance programmes use the Baldrige framework and criteria to improve their results and many accreditation systems are based on the criteria, approximately 100 excellence models are derived from Baldrige including EFQM.</td>
<td>Consensus</td>
<td>Qualitative</td>
<td>Improvem ent models</td>
</tr>
<tr>
<td>Olsson et al. (2003)</td>
<td>Survey</td>
<td>Primary care practices and hospitals</td>
<td>Sweden</td>
<td>231 3</td>
<td>46%</td>
<td>6</td>
<td>Used an organisational capabilities perspective. Swedish healthcare managers were surveyed on their views of improvement activity. Results indicated that most improvement work is localised and introverted with few programmes being strategic, measurable and systematic or externally driven.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Change models</td>
</tr>
<tr>
<td>Parker et al. (1999)</td>
<td>Survey and site visits</td>
<td>Hospitals</td>
<td>USA</td>
<td>135 48 (16 2 sites)</td>
<td>68%</td>
<td>5</td>
<td>This paper collected empirical evidence from Veteran's Healthcare in the USA about quality improvement to assess the relationship between organisational commitment to improvement and implementation abilities. Found that managers need to be committed to improvement and it needs to be central to their strategy and aligned with corporate strategy.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Improvem ent models</td>
</tr>
<tr>
<td>Lead author</td>
<td>Method</td>
<td>Sector</td>
<td>Country</td>
<td>Final sample size</td>
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<tr>
<td>Peng et al. (2011)</td>
<td>Survey</td>
<td>Electronics, machinery and transportation</td>
<td>8 developed countries</td>
<td>238</td>
<td>65%</td>
<td>4 constructs</td>
<td>Examined the strategic impact of improvement and innovation capabilities and their level of fit. The study found that differing competitive priorities require different levels of these capabilities and thus can have varying impact on performance.</td>
<td>&gt;0.57</td>
<td>Yes</td>
<td>Improvement Models</td>
</tr>
<tr>
<td>Powell (1995)</td>
<td>Survey</td>
<td>Industry</td>
<td>North-east USA</td>
<td>54</td>
<td>33%</td>
<td>12 variables</td>
<td>Indicates that TQM is pervasive and yet has rarely been researched from a strategic management perspective despite it being an approach for gaining competitive advantage and thus the empirical evidence is reviewed and new study conducted. Findings suggests that 'tools' such as quality training, and benchmarking do not produce advantage however the climate encouraged through TQM such as open culture and empowerment can produce advantage.</td>
<td>0.78 - 0.9</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Lead author</td>
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<td>Prybutok and Ramasesh (2005)</td>
<td>Survey</td>
<td>Defence</td>
<td>USA</td>
<td>100</td>
<td>21%</td>
<td>5 factors</td>
<td>Empirical data has been collected through an action research study including a questionnaire, within a site in US manufacturing. Identifies critical factors underlying clinical quality improvement implementation.</td>
<td>&gt;0.7</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Pun (2002)</td>
<td>Self-assessment</td>
<td>Government</td>
<td>Hong Kong</td>
<td>10</td>
<td>42%</td>
<td>6 criteria</td>
<td>Development of integrated total quality management self-assessment method through an empirical study in Hong Kong. Found that TQM capabilities are increasingly important to boost competitiveness and this will become a strategic necessity. Indicates that management commitment and people well-being are factors that facilitate the integration of TQM into organisations.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Rao et al. (1999)</td>
<td>Survey</td>
<td>Manufacturing</td>
<td>USA, India, China, Mexico, Taiwan</td>
<td>780</td>
<td>24%</td>
<td>13 constructs</td>
<td>A conceptual study to develop quality management measures and an instrument that could be used internationally which when tested has good validity and reliability.</td>
<td>&gt;0.83</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Lead author</td>
<td>Method</td>
<td>Sector</td>
<td>Country</td>
<td>Final sample size</td>
<td>Response rate</td>
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<tr>
<td>Robert et al. (2011)</td>
<td>Mixed methods</td>
<td>Hospitals</td>
<td>Europe</td>
<td>10</td>
<td>n/a</td>
<td>8 dimensions</td>
<td>QUASER study outlined how a European investigation of how hospitals implement, spread and sustain quality improvement. Has 3 features: quality definition of clinical effectiveness, patient safety and patient experience, conceptualised quality as technical, human, social and organisational accomplishment and seeks to provide guidance within Europe. Further information within Burnett et al. (2015).</td>
<td></td>
<td>Consensus approach</td>
<td>Consensus approach</td>
</tr>
<tr>
<td>Saraph et al. (1989)</td>
<td>Survey</td>
<td>Manufacturing and service</td>
<td>USA</td>
<td>162 (20 companies)</td>
<td>91%</td>
<td>8 factors</td>
<td>Suggests a way of measuring critical factors for quality management based on the work of Deming, and sets about reviewing their essentials to develop survey. Found that there are 8 critical factors and instrument proposed with good reliability and validity.</td>
<td>0.71-0.94</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Lead author</td>
<td>Method</td>
<td>Sector</td>
<td>Country</td>
<td>Final sample size</td>
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<tr>
<td>Schilling et al. (2010)</td>
<td>Internal benchmarking and assessment</td>
<td>Healthcare</td>
<td>USA</td>
<td>n/a</td>
<td>n/a</td>
<td>6 capabilities</td>
<td>Outlines measurement of key domains within quality dashboard used within Kaiser Permanente in the USA. This performance improvement system addresses 6 capabilities, including improvement capability. Indicates that a barrier to sustainability is that some leaders wish to change direction or perceive that subsets of skills such as change management are more important than the whole improvement system.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Governance models</td>
</tr>
<tr>
<td>Schwartz et al. (2010)</td>
<td>Survey</td>
<td>Healthcare</td>
<td>USA</td>
<td>214 2 (7 organisations)</td>
<td>38%</td>
<td>4 sections</td>
<td>Summarises survey of organisational and quality factors linked to quality improvement through testing employee perceptions. Suggested that organisations direction, simplified care processes and communication all significant for quality. Training, resources, intergroup co-ordination were perceived as less significant.</td>
<td>&gt;0.7 excluding 1 factor</td>
<td>Yes</td>
<td>Change models</td>
</tr>
<tr>
<td>Lead author</td>
<td>Method</td>
<td>Sector</td>
<td>Country</td>
<td>Final sample size</td>
<td>Response rate</td>
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<tr>
<td>Secanell et al. (2014)</td>
<td>Survey</td>
<td>Hospitals</td>
<td>7 countries in mainland Europe</td>
<td>259 (18 organisations)</td>
<td>87%</td>
<td>13 constructs</td>
<td>DUQuE study: A cross sectional study across the EU to understand relationship between quality management and outcomes. The first study of its kind. Assessed areas included quality management systems, compliance and implementation, culture, professionalism and involvement in QM.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Governance models</td>
</tr>
<tr>
<td>Shortell et al. (1995)</td>
<td>Survey</td>
<td>Hospitals</td>
<td>USA</td>
<td>733 (61 organisations)</td>
<td>72%</td>
<td>9 areas</td>
<td>Found that a participative, flexible, risk taking organisational culture was significantly related to quality improvement implementation, that this in turn was positively associated with patient outcomes and human resources development. Larger hospitals had more bureaucratic and hierarchical cultures serving as a barrier to quality improvement.</td>
<td>&gt;0.7 excluding 1 factor</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Simperi et al. (2002)</td>
<td>Framework</td>
<td>Healthcare</td>
<td>Latin America and Africa</td>
<td>12</td>
<td>n/a</td>
<td>8 elements</td>
<td>Describes 'capacity building' as critical to the institutionalisation of quality improvement. The framework designed can be used at system or organisational level and describes the development phases, as awareness, experiential, expansion and consolidation leading to a state of maturity, although this is not a linear process.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Governance models</td>
</tr>
<tr>
<td>Lead author</td>
<td>Method</td>
<td>Sector</td>
<td>Country</td>
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<tr>
<td>Solberg et al. (2008)</td>
<td>Survey</td>
<td>Primary care practices</td>
<td>USA</td>
<td>41</td>
<td>100%</td>
<td>16 factors</td>
<td>Development of survey called Change Process Capability Questionnaire to assess medical group capability to improve care in the USA. Findings were that improvement was related to organisational factors and heterogeneity. Improvement also depended on priorities and wider infrastructure of care support.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Change models</td>
</tr>
<tr>
<td>Terziovs ki and Dean (1998)</td>
<td>Survey</td>
<td>Service sector (medium to large firms)</td>
<td>Australia</td>
<td>130</td>
<td>23%</td>
<td>14 outcomes</td>
<td>Cross sectional study to examine quality management practices on quality outcomes including productivity, competitive advantage, customers and morale. Results show importance of strategically planning for quality, and both involving customers and workers.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Governance models</td>
</tr>
<tr>
<td>Ulrich and Lake (1991)</td>
<td>Case study</td>
<td>Service and manufacturing</td>
<td>USA</td>
<td>2</td>
<td>n/a</td>
<td>4 elements</td>
<td>Argues that three mainstream capabilities for competitiveness, technological, strategic and financial are insufficient and there is fourth complementary one, which is organisational, directly related to people. Critical areas within this capability are mindset, management practices, capacity for change and managing organisational systems and empowerment.</td>
<td>n/a</td>
<td>Not reported</td>
<td>Change models</td>
</tr>
<tr>
<td>Lead author</td>
<td>Method</td>
<td>Sector</td>
<td>Country</td>
<td>Final sample size</td>
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<tr>
<td>Valmohammadi (2011)</td>
<td>Survey</td>
<td>Manufacturing</td>
<td>Iran</td>
<td>65</td>
<td>82%</td>
<td>7 factors</td>
<td>Development of instrument for use in total quality management, found significant relationship between TQM practices and performance, and that some of these practices need development.</td>
<td>&gt;0.7 excluding 1 factor</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Wagner et al. (1999)</td>
<td>Survey</td>
<td>Healthcare &amp; social care, 1182 orgs</td>
<td>Netherlands</td>
<td>1182</td>
<td>74%</td>
<td>5 factors</td>
<td>Developed a survey instrument for organisations to measure and compare quality systems in healthcare provision. Used measures linked to quality assurance and quality improvement. Found that the instrument was valid and reliable for use in health and social care settings and applicable to these different groups. This instrument would complement other audits.</td>
<td>&gt;0.75</td>
<td>Yes</td>
<td>Governance models</td>
</tr>
<tr>
<td>Wali et al. (2003)</td>
<td>Survey</td>
<td>ISO 9000 companies</td>
<td>India</td>
<td>114</td>
<td>22%</td>
<td>12 factors</td>
<td>Develops critical success factors for TQM implementation based on survey of Indian companies and review of mainstream literature, adds factors not included in others and in awards, e.g. congeniality of atmosphere.</td>
<td>&gt;0.91</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Lead author</td>
<td>Method</td>
<td>Sector</td>
<td>Country</td>
<td>Final sample size</td>
<td>Response rate</td>
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<tr>
<td>Warwoo d and Antony (2003)</td>
<td>Survey</td>
<td>Manufacturing and non-manufacturing</td>
<td>UK</td>
<td>10 (survey 1); 54 (survey 2)</td>
<td>30% (survey 1); 54% (survey 2); 30% (group 1); 30% (group 2)</td>
<td>9 factors</td>
<td>Results of a self-assessment survey for TQM for industry. Found that the most significant factors in successful TQM implementation in the UK included leadership, impact of other improvement programmes, measurement and culture.</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Improvem ent models</td>
</tr>
<tr>
<td>Wu et al. (2010)</td>
<td>Survey</td>
<td>Non-manufacturing based.</td>
<td>USA</td>
<td>62 (group 1) and 160 (group 2)</td>
<td>30% (group 1) and 6.5% (group 2)</td>
<td>10 constructs</td>
<td>A paper describing the construct of operational capabilities and the challenges of imitation and measurement, as they are tacit and embedded and context dependent. A taxonomy with six capability areas is articulated including operational improvement with associated measurement scales.</td>
<td>Indicated</td>
<td>Yes</td>
<td>Improvem ent models</td>
</tr>
<tr>
<td>Yen-Tsang et al. (2012)</td>
<td>Case study</td>
<td>Transport, metals, Foundry</td>
<td>Brazil</td>
<td>3 cases</td>
<td>n/a</td>
<td>8 areas</td>
<td>A study using a behavioural theoretical lens to investigate the antecedents of continuous improvement capability based on operational routines. Suggests the ‘will to improve’ also critical to capability although the data only partially supports this hypothesis.</td>
<td>Consensus approach</td>
<td>Consensus approach</td>
<td>Maturity models</td>
</tr>
<tr>
<td>Lead author</td>
<td>Method</td>
<td>Sector</td>
<td>Country</td>
<td>Final sample size</td>
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<tr>
<td>Yeung et al. (2003)</td>
<td>Survey</td>
<td>Electronics</td>
<td>Hong Kong</td>
<td>225</td>
<td>75%</td>
<td>17 areas</td>
<td>Development of a classification system to identify different types of quality management systems (QMS). 3 classes identified as: undeveloped, frame, accommodating and strategic. Article found that QMSs develop at different maturity levels/speed depending on the prevailing view of quality management. Top level described as strategic quality system and an 'aggressive long term strategic weapon'</td>
<td>0.7</td>
<td>Yes</td>
<td>Governance models</td>
</tr>
<tr>
<td>Zeitz et al. (1997)</td>
<td>Survey</td>
<td>Various</td>
<td>USA</td>
<td>886 respondents</td>
<td>&gt;95%</td>
<td>12 dimensions</td>
<td>A realisable and valid instrument with 23 dimensions is proposed for measuring TQM and has been tested with respondents from several sectors. This can be used to evaluate improvement and organisational development interventions through use of information and analysis.</td>
<td>0.65</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
<tr>
<td>Zhang et al. (2007)</td>
<td>Survey</td>
<td>Manufacturing</td>
<td>China</td>
<td>212</td>
<td>24%</td>
<td>11 constructs</td>
<td>Develops an instrument to measuring TQM with high external validity for Chinese manufacturing for evaluating and improving TQM programmes.</td>
<td>0.8377-0.9245</td>
<td>Yes</td>
<td>Improvement models</td>
</tr>
</tbody>
</table>
Appendix I: References


