A scientific approach to improvement: the use of Plan-Do-Study-Act cycles in healthcare

A thesis presented for the degree of Doctor of Philosophy (PhD)

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Declarations

I hereby declare that the work within this thesis is my own, except where it is referenced or carried out in collaboration with others who are duly acknowledged.

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Date: 31/05/2016
Abstract

This thesis contributes further understanding on how to pursue improvements in healthcare and informs the academic growth of improvement science. Derived from manufacturing industries, QI methods are common approaches to structure the process of making improvements in healthcare, however, questions over their scientific legitimacy and application have arisen due to their varied effectiveness.

A review of how QI methods are associated with science identifies the prominent theoretical role of QI methods in facilitating change and improvement by supporting the local application of the scientific method. The Plan-Do-Study-Act (PDSA) cycle method is identified as playing a central role in this and a theoretical framework is developed to assess the use of the method in published and local team's accounts. This demonstrates that the method is commonly not used with high fidelity; a key novel addition to the research literature.

Studies are presented to further understand the reality of PDSA cycle use. These provide a novel identification and empirically grounded description of the social dimensions of applying the PDSA cycle method including negotiating through a single PDSA cycle and navigating the iteration and scale up of change and complexity of learning. A novel association between understanding, intentions and process of applying the PDSA cycle method and the fidelity of the methods use is also presented as well as the views of teams using the method which demonstrate different conceptual views of the PDSA cycle method and the wider social benefits of using the method.

Overall, this thesis provides clarity in regards to the technical and social elements of PDSA cycle use. It demonstrates research approaches to open the “black box” of PDSA cycle use and investigate the use of QI methods more widely. It calls for continued exploration of applying science to improve the quality of healthcare for patients.
Research Structure and Questions

Figure 1. Diagrammatic research structure of chapters within thesis

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<th>Title</th>
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<td>Improvement Science Practice and Research: A systematic narrative review of the associations between science and QI methods</td>
<td>What associations have been made between science and QI methods?</td>
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<tr>
<td>2</td>
<td>Development and application of criteria to assess fidelity: Systematic Review of PDSA Cycle Conduct</td>
<td>What principles need to be adhered to for high fidelity PDSA Cycle conduct and to what extent is the conduct reported in line with this in published healthcare literature?</td>
</tr>
<tr>
<td>3</td>
<td>Assessment of PDSA Cycles conduct in prospectively documented healthcare improvement teams: updating a framework to guide the application of PDSA cycles and assess their use</td>
<td>In documented QI team accounts, how are PDSA Cycles conducted and reported?</td>
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<td>What is the fidelity of QI teams’ PDSA cycle conduct? How did this fidelity change over time? What factors may have influenced change in fidelity of PDSA cycles over time?</td>
</tr>
<tr>
<td>5</td>
<td>PDSA perspectives: International case studies of the perceived principles and benefits of PDSA cycles</td>
<td>What are healthcare QI team members’ perceptions of the principles and benefits of PDSA cycles?</td>
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Abbreviations

QI - Quality Improvement
PDSA - Plan-Do-Study-Act
NHS - National Health Service
NIHR – National Institute of Health Research
RCT – Randomised Control Trial
CFIR – Consolidated Framework for Implementation Research
PARIHS - Promoting Action on Research Implementation in Health Services
MFI - Model For Improvement
SPC - Statistical Process Control
TQM - Total Quality Management
CQI - Continuous Quality Improvement
DMAIC - Define, Measure, Analyse, Improve, Control
SQUIRE - Standards for QUality Improvement Reporting Excellence
PDCA – Plan-Do-Check-Act
FOCUS – Find, Organise, Clarify, Understand, Select
CLAHRC – Collaboration for Leadership in Applied Health Research and Care
NWL – Northwest London
WISH – Web Improvement System for Healthcare
IHI – Institute for Healthcare Improvement
BMJ – British Medical Journal
PRISMA - Preferred Reporting Items for Systematic Reviews and Meta-Analyses
MUSIQ – Model for Understanding Success In Quality
RAA – the Reasoned Action Approach
List of Peer-Reviewed Publications and Presentations

Peer-Reviewed Publications

Published


To be submitted

- McNicholas, C., Bell, D., and Reed J.E. Improvement Science Practice and Research: A systematic narrative review of the scientific connotations of Quality Improvement methods.
- McNicholas, C., Lennox, L., Woodcock, T., Bell, D. & Reed, J. E., A framework for the application, reporting and analysis of Plan-Do-Study-Act cycles: a guide to drive improvement in scientific and pragmatic standards
• McNicholas, C., Lennox, L., Bell, D. & Reed, J. E., Supporting the use of PDSA cycles: application of an assessment framework and exploration of contextual factors that influence conduct
• McNicholas, C., Bell, D., and Reed J.E. PDSA perspectives: principles of PDSA use and social benefits
• McNicholas, C., Bell, D., and Reed J.E. Reality of using PDSA cycles: Negotiation, Navigation and Narration.

Conference Presentations
• McNicholas, C., Bell, D., and Reed J.E. "Opening the “black box” of plan-do-study-act cycles: achieving a scientific yet pragmatic approach to improving patient care." International Forum for Quality and Safety, Paris 2014
• McNicholas, C and Reed J.E. "Global perspectives: Mastering the use of PDSA cycles." Scientific Symposium, Institute for Healthcare Improvement National Forum, Orlando 2014
• McNicholas, C., Lennox, L., Bell, D., & Reed, J.E. “Assessing the fidelity of an iterative approach to learning and improvement in healthcare: a retrospective analysis of documented Plan-Do-Study-Act cycle conduct” Health Service Research Network Symposium, Nottingham 2014
• McNicholas, C and Reed J.E. "Mastering the use of PDSA cycles." International Forum for Quality and Safety, London 2015
• Reed J.E and McNicholas, C “Conquering PDSA cycles”. International Forum for Quality and Safety, Gothenburg 2016
• Reed J.E and McNicholas, C “Navigating Local Context to Influence Change: An International Comparative Study of Plan-Do-Study-Act Cycle Conduct” Health Service Research Network Symposium, Nottingham 2014

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**Teaching**

• Public Health Masters – Imperial College London
• Healthy Policy Masters – Imperial College London
• Improvement Leader Fellowship – National Institute for Health Research, Collaboration for Leadership in Applied Health Research and Care Northwest London
• Improvement Science Masters – National Institute for Health Research, Collaboration for Leadership in Applied Health Research and Care Northwest London
1. Chapter 1 - Theories and Approaches to Improving Quality in Healthcare

Chapter overview - This introductory chapter provides narrative and rationale to the development of the academic field of Improvement Science in healthcare and the research conducted within this thesis.

1.1. Introduction

“To improve: to make or become better” (Oxford Dictionary of English 2010)

Harnessing scientific principles to support the process of making improvements is an important focus of the developing academic field, Improvement Science. (Perla et al. 2013) Applicable to any industry or walk of life in which improvement is desired, the field has gained particular traction in healthcare with the focus on improving people’s health and wellbeing and healthcare services.

This thesis adds to the continued development of the field of Improvement Science with a focus on healthcare. To position the field, a historical overview of mechanisms that have attempted to improve healthcare is first presented. It draws on relevant literature and theoretical frameworks to outline approaches to improve healthcare. This includes: improving the quality of health and healthcare by considering outcomes, process and structures; identifying evidence-based practices; implementing these practices; and the use of specific “Quality Improvement” (QI) methods that originated from manufacturing industries.

1.2. Improving quality in healthcare

The ultimate aims for those working in the healthcare industry are to improve the health of a person or population and to improve the quality of healthcare that enables this to happen. (Batalden & Davidoff 2007; Berwick 2008a) Variations in the quality of healthcare patients receive (Right Care 2015), however, combined with a prolonged time gap between
research findings being published and then delivered routinely, mean those that require healthcare do not consistently receive the highest quality care. (Institute of Medicine 2001; Cooksey 2006; Burnett et al. 2012) In addition, reports have highlighted on-going challenges to delivering high quality healthcare (Mid Staffordshire NHS Foundation Trust 2013; Keogh 2013; Berwick 2013) and this is set against a backdrop of continued economic pressures on healthcare systems. (House of Lords 2011) All indicate that effective and efficient approaches to improve healthcare quality, and subsequently health of a person, are required and are an important subject for further research.

The notion of quality in healthcare can apply to three interrelated areas: outcomes, processes and structures. (Donabedian 1988) From a patient perspective, healthcare quality is assessed by health outcomes: measures of the quality of one’s health. These can include recovery from or the prevention ill health or injury, enhancement of quality of life, receiving a positive experience of care or being protected from avoidable harm when being cared for. (Department of Health 2013)

The quality of delivering healthcare can be viewed as related to processes and structures which refer to how healthcare is provided and organised respectively. Processes refer to the transactions between healthcare providers and patients whereas structures refer to the organisation of care such as staff, financing, buildings and equipment. Quality measures for processes and structures can be considered across several recognised domains including: safety, effectiveness, efficiency, patient-centeredness, timeliness and equity. (Institute of Medicine 2001). Ultimately, the processes and structures of delivering healthcare are also measured by their impact on the health outcomes of a person.

All three terms, outcomes, processes and structures, will be revisited in this chapter to provide an overview of improvement in healthcare by drawing on a range of literature and theoretical lenses. This includes identifying and implementing evidence-based interventions to change processes and structures to improve outcomes (Damschroder et al. 2009; Rabin
et al. 2008; Kitson et al. 1998; Grol & Grimshaw 1999) and using QI methods to help change processes and structures to improve outcomes. (Boaden et al. 2008; Langley et al. 1996)

1.3. Identifying evidence-based healthcare practices

In the 19th century, early pioneers of improving quality in healthcare, such as Florence Nightingale and Louis Pasteur, sought to develop evidence-based practices by linking the processes and structures of healthcare with health outcomes of patients.

Florence Nightingale led a group of nurses to care for soldiers during the Crimean war in 1854. Within six months of her arrival the death rate from disease dropped from 42.7% to 2.2%. (Sheingold & Hahn 2014) Nightingale had identified a link between hospital sanitation and mortality and introduced new practices such as hand washing, sanitising surgical tools, changing bed linen, good nutrition and fresh air. (Meyer & Bishop 2007) This knowledge was developed through documenting, and subsequently linking all aspects of quality; outcomes, structures and processes. (Henry et al. 1990)

Louis Pasteur also linked healthcare processes and structures with health outcomes; linking morbidity and mortality rates with lack of sanitisation and low hygiene standards. Pasteur’s discovery, that disease was caused by microorganisms, helped contribute to wide-scale adoption of antiseptic practices and also “pasteurisation” (utilising heat to destroy harmful microorganisms) to improve health outcomes. (Sheingold & Hahn 2014)

To continue this approach in the 20th century and the present day, research methodologies have been developed and deployed to systematically link health outcomes with healthcare processes and structures. (Naylor 2002; Berwick 2005; Glasgow et al. 2012) They often involve “controlling” all potential factors that may influence an outcome except the process or structure that is desired to be understood. By doing this and making discrete changes to the process or structure in question and comparing this to a change in outcome, the quality of the process or structure can be determined.
The gold standard for controlled evaluation is the Randomised Control trial (RCT). (Moher et al. 2010) RCTs are experiments in which a sample in question is randomly allocated to one or other of the different practices being investigated. (Chalmers et al. 1981) Most commonly this involves randomly assigning half of the sample to receive the healthcare practice that is wanted to be studied and the other half to the healthcare practice that is currently delivered (Figure 2). (Kendall 2003) This latter group is known as the “control group”. Through random assignment it is assumed that the outcomes of both groups will be equally affected by any external environmental factors. The influence of the healthcare practice in question is therefore controlled as it is the only differentiating factors between the groups. Its quality can therefore be measured and evidenced.

![Figure 2. Conceptual design of a Randomised Control Trial (Kendall 2003)](image)

Once identified, processes and structures are then advocated to those providing care. The translation of knowledge can occur passively, with individuals or organisations delivering care seeking out the knowledge in academic publications or being informed by peers and mentors. Alternatively, and increasingly so, it occurs in the form of “packaged” information, such as clinical guidelines, systematic reviews gathering and presenting outcomes from multiple studies, or through formal training and continuing education. (Scott 2007)
1.4. Challenges to implementing evidence-based healthcare practices

The process of identifying and communicating evidence-based based practices has led to vast improvements in health and healthcare quality throughout the 20th century, however, challenges still remain. (Berwick 2008a; Naylor 2002) As previously discussed, wide variation in the quality of care patients receive exists. This includes variation between countries (Hussey et al. 2004), within countries (Burnett et al. 2012; Right Care 2015) and within organisations. (Weiner & Alexander 2006) In addition, there is a gap between what is known through controlled evaluations identifying high quality, evidence base practices and what is delivered in routine healthcare practice. In the U.K this is known as the “second translational gap” (the “the first translational gap refers to the gap between transferring basic and clinical research findings into the development of new products, technologies and approaches to the treatment of disease and illness) (Figure 3). (Cooksey 2006)

![Figure 3. First and Second Translational gap of health research in relation to health outcomes and healthcare practices (processes and structures)](image)

Influential reports have highlighted the second translational gap as a significant problem for healthcare in the UK (Cooksey 2006) and the USA. (McGlynn 2004) A key reason suggested for this persisting problem is the over reliance on focusing on identifying best practices (1st translational gap) rather than ensuring the practices are routinely delivered by people and organisations that commission and provide healthcare. (Berwick 2008a) Developing the knowledge of effective healthcare is highly important and great cultural changes have been
made by the evidence based medicine movement to make it a norm to robustly link health outcomes with healthcare practices. (McClellan et al. 2008) However, identifying the process or structure is not the only aspect of improving quality. (Berwick 2008a) Focus must also be directed on the ability to organise healthcare to ensure it is sustainably delivered at the recommended evidence based standard. (Bate et al. 2008)

Improving the quality of care by implementing new practice entails changing the established systems or routines of healthcare delivery. (Dopson & Fitzgerald 2006) Controlled evaluations to identify the best quality practices can often be “atheoretical, aprocessual, acontextual and/or ahistorical”. (Bate et al. 2008) They do not necessarily take into account the personal, organisational and external factors required to ensure good quality healthcare practices are able to be delivered consistently. (Davies et al. 2008) For improvements to be made systematically, the improvement effort itself must be a dynamic approach, attentive to the complex and socially and contextually dependent environment of healthcare delivery. (Plsek & Greenhalgh 2001) Focus must include “how” to implement and adapt a practice, not just “what” worked. (Walshe 2007)

It is this challenge that the field of Improvement Science aims to address. It aims to extend the focus of improving quality from identifying best practice to understanding how to implement it and make adaptions to ensure improvements are delivered.

1.5. Principles of implementing change

With the past focus on identifying high quality healthcare processes and structures, few research studies described the actual process of implementing these within healthcare. As a result, less was known about how to translate good ideas into practice in healthcare. (Cohen et al. 2008) In the last 20 years this has changed leading to the development and study of an evidence-base for implementation, often termed as ‘Implementation Science’. (Grol & Grimshaw 1999; Bero et al. 1998; Foy et al. 2015) Whilst the field dominantly refers to the scientific study of implementing research findings in healthcare, and hence improving care,
the principles identified can apply to the implementation of any new healthcare process or structure. (Foy et al. 2001) These principles are outlined below to frame the development and consideration of improvement as a science. ‘Implementation’ and ‘Improvement’ are related terms but are distinguished by different end goals: achieving implementation of a practice regardless of whether it results in improvement or not; or achieving improvement regardless of implementing a specific practice or not. (Reed & Bell 2011)

Implementation can be considered as the constellation of processes intended to put a practice (process or structure) into use within an organisation. (Rabin et al. 2008) Numerous literature reviews and theoretical frameworks have been published that identify and present integral mechanisms that can support effective implementation. (Greenhalgh et al. 2004; Damschroder et al. 2009; McCormack et al. 2002) There are also a number of different models that outline the principles of implementation science. (Rycroft-Malone 2004; Greenhalgh et al. 2004; Carroll et al. 2007; Kitson et al. 1998) Whilst the reviews and models consist of similar content, there are some differences.

“They overlap considerably in the constructs included in individual theories, and a comparison of theories reveals that each is missing important constructs included in other theories” (Damschroder et al. 2009)

To draw together the literature of implementation, a comprehensive literature review of implementation research studies and theories has been conducted: The Consolidated Framework for Implementation Research (CFIR). (Damschroder et al. 2009) It presents an overarching framework to consider the principles of implementing new practices and provides an overview of five broad domains to be considered:

1. **Characteristics of the intervention;** recognising the need for an intervention and it to be adaptable and “fit” in local context

2. **The implementation process;** the active change process aimed to achieve individual and organisational level use of the intervention
3. The outer setting: economic, political, and social context within which an organisation resides

4. The inner setting: structural characteristics, networks and communications, culture, climate, and readiness all interrelating and influencing implementation

5. Individuals: people involved with the intervention and implementation process

Combining the outer, inner and individuals domains of the CFIR as a representation of the overall context in which the implementation of change takes place, the authors state that the five domains align with other existing frameworks. This includes the Promoting Action on Research Implementation in Health Services (PARIHS) framework which outlines the role of the evidence for an intervention, the context in which it is implemented and the process by which implementation is facilitated (Figure 4). (Rycroft-Malone 2004) It also includes factors suggested to influence successful business change management outlined within management sciences. (Pettigrew & Whipp 1993) The model developed by Pettigrew and Whipp distinguishes three dimensions of change management: content (the change, objectives, purpose and goals); process (implementation of change); and context (internal and external environment). They describe this as the “what”, the “how” and the “where” of change respectively.
Interpretation of Consolidated Framework for Implementation Research

<table>
<thead>
<tr>
<th>Interpretation of Consolidated Framework for Implementation Research</th>
<th>Promoting Action on Research Implementation in Health Services (PARIHS) framework</th>
<th>Factors influencing successful change management</th>
</tr>
</thead>
</table>

From the commonality across the range of theories it is clear that the implementation of change involves three key domains: an intervention, a process by which this intervention is implemented, and the context in which the intervention is implemented. Detail within these three domains may differ depending on the academic area of interest; however, these three areas are consistent.

An intervention is regarded as the change to the *processes or structures* of healthcare service delivery. It can include either a new aspect of care or a modification of a current aspect to achieve a desired *outcome*. In healthcare, interventions may be implemented to address processes or structures at different levels: the individual health professional, healthcare groups or teams, organisations providing healthcare (e.g. Hospitals, General practices), or the system or environment in which the organisations are embedded. (Ferlie & Shortell 2001) Whilst the healthcare a patient receives (the process) is often at the forefront of considerations for an intervention, the organisational mechanism required (the structure) to ensure the care occurs reliably can also be part of an intervention.
Any intervention introduced must “fit” with other related processes and structures. This means that, to be successful, an intervention must influence the process or structure necessary to achieve the improvement desired but also be able to function within the wider system of care made up of other processes and structures. Both are dependent on the people involved in them. (Damschroder et al. 2009)

Implementation theories state the importance of adapting and iteratively developing an intervention to ensure it achieves the desired outcome and “fits” within a given setting. In regards to the principles of implementation, this purposeful iterative approach to implementing an ‘intervention’ is part of the ‘implementation process’ domain and occurs in light of the ‘context’ in which the intervention is implemented (Figure 4). Pettigrew and Whipp emphasise that implementation of change is an “iterative, cumulative and reformulation” process and success is a result of this interaction between the change, the process and the context. (Pettigrew & Whipp 1993) In healthcare, it has been demonstrated that changes to practice are more likely to succeed if they are allowed to develop in this evolutionary fashion. (Øvretveit 2004) Iterative changes can occur to adaptable aspects of the intervention or to aspects of the context that the intervention is being implemented in. (Kaplan et al. 2011; Kirsh et al. 2008) These steps are accomplished in a “spiral, stop-and-start or incremental approach to implementation” (Figure 5). (Ven et al. 1999)

Figure 5. Example of iterative change process (Ven et al. 1999)
The recognition of iteration as an enabler of the implementation of change is echoed widely across implementation research. It is a key addition to extend the focus on improving quality from just identifying best practice and promoting it and suggests that an active process of implementation and adaption should occur. As outlined in the remainder of this chapter, mechanisms to support iteration are a key focus of this thesis.

A further theoretical model outlining the factors that play a role in the implementation of change defines “trial-ability” as a necessary feature of an innovation and “reinvention/development” and “feedback on progress” necessary features of the implementation process. (Greenhalgh et al. 2004) Similarly, a study by Cohen et al (2008) demonstrates that interventions used to translate evidence into practice often require changes as they are integrated into practice. They specifically identify three broad categories that iterations must accommodate:

- **Existing Practices** – to ensure interventions fits with existing processes and structures
- **Patients** – to ensure patient’s circumstances and reactions to interventions are taken into account
- **Personnel** – to ensure the time and costs to fund key personnel to deliver the intervention are considered

The implementation, including iteration, of change in healthcare is influenced by multiple stakeholders: the team conducting the implementation, the team using the change in routine practice and the patients receiving the change. To drive iteration, the role of the individuals and teams involved is important. Cohen et al (2008) emphasise the importance of the project teams in fostering the intervention implementation through teaching, assistance, personal influence and motivation. They conclude that “the translation of evidence into practice will be improved when research designs and reporting standards are modified to help QI teams...”
understand both these adaptations and the effort required to implement interventions into practice”.

The implementation science field provides an academic platform to conduct research on and present factors that facilitate the implementation of change as outlined above. Whilst useful to consider, a potential limitation of the current theoretical frameworks in supporting the improvement of health and healthcare quality is that they can result in being complex, too academically driven and time-consuming for practical use when attempting to improve healthcare.(Glasgow et al. 2012) Practical tools and techniques for those on the frontline of healthcare delivery and improvement are required to support the achievement of the key success factors of implementation outlined, such as iterating an intervention.(Glasgow et al. 2012)

1.6. The Development of Quality Improvement Methods

The need for practical, user-led approaches to improving patient care has led to the increasing popularity of utilising industry developed Quality Improvement (QI) methods in healthcare.(Shojania & Grimshaw 2005; Walshe 2009) Led by the staff responsible for delivering improvements, the methods seek to structure and facilitate the process by which a change to healthcare practice is introduced, iterated and embedded.(Boaden et al. 2008) Whilst not derived from implementation science research, the tools align with the principles identified in the previous section by addressing the need to consider the intervention, the implementation process and the context. They are not a new process or structure of healthcare delivery (an intervention) but tools which can be used to facilitate the ‘implementation process’ of an intervention in light of the ‘context’.

Different QI methods exist including specific tools for specific tasks or approaches to be used for the totality of an improvement effort. Boaden’s (Boaden et al. 2008) broad review of QI methods in healthcare refers to the following key QI methods: Model for Improvement, Plan-Do-Study-Act (PDSA) cycle, Statistical Process Control (SPC), Six Sigma, Lean,
Theory of Constraints, Mass Customisation, Total Quality Management and Continuous Quality Improvement (Table 2). Broadly, they are systematic in nature yet receptive of contextual factors. Their use extends from identifying and executing change to monitoring and iterating these changes. (Powell et al. 2009)

<table>
<thead>
<tr>
<th>QI method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan-Do-Study-Act</td>
<td>PDSA cycles are a four staged cycle to structure learning and change aimed at improvement. Users develop a “plan”, execute this plan in the “do” stage, “study” the outcome of this and “act” to determine next steps and repeat the cycle. The Model for Improvement provides three questions to precede use of PDSA cycle to identify aims, measures and changes to make.</td>
</tr>
<tr>
<td>(PDSA) cycle and Model for Improvement</td>
<td></td>
</tr>
<tr>
<td>Statistical Process Control (SPC)</td>
<td>SPC is used to identify between natural variation (“common cause”) and that which could be controlled (“special cause”). Using control charts (time series run charts with statistically derived control limits depicting natural variation limits) SPC monitors data over time to identify significant changes. It is a tool for measurement and is often used alongside other QI methods.</td>
</tr>
<tr>
<td>Six Sigma</td>
<td>Six sigma is a process/ product improvement or redesign approach. It uses structured steps of define, measure, analyse, improve and control (DMAIC) to facilitate improvements and reduce defects.</td>
</tr>
<tr>
<td>Lean</td>
<td>Lean is an approach to organise production processes. It includes principles of: identifying customer value; managing value streams; flow production; using “pull” mechanisms to support flow; and pursuing perfection by reducing waste.</td>
</tr>
<tr>
<td>Theory of Constraints</td>
<td>Theory of constraints represents an overall theory for running an organisation. Basics concepts includes: every system has at least one constraint (anything that limits the system from achieving higher performance); and the existence of constraints represents opportunities for improvement.</td>
</tr>
<tr>
<td>Mass Customisation</td>
<td>Mass customisation focuses on the ability to produce product or services in high volume with the needs of individual customers or type of customer in mind. It is focused on process and system design.</td>
</tr>
<tr>
<td>Total Quality Management (TQM)</td>
<td>Additional terminology to describe QI. It is often described as a management philosophy and business strategy with the common view: Success is dependent on meeting customer needs; Quality is an effect caused by the processes within the organisation which are complex but understandable; Most people at work are intrinsically motivated to try hard and do well; and simple statistical approaches, linked with data collection, can yield powerful insights. TQM often includes application of other QI methods.</td>
</tr>
</tbody>
</table>
Continuous Quality Improvement (CQI) Additional terminology to describe QI. Similar to TQM in terms of acting as management philosophy and business strategy. Often includes application of other QI methods.

Table 2. Selected Quality Improvement Methods (Adapted from Boaden et al. 2008)

The roots of these QI methods stem from the early 1920’s and attempts to control the quality of product in manufacturing industries. Walter Shewhart and his trainee Edward Deming are renowned to be the “fathers” of QI methods and applied statistical techniques to monitor and improve quality. (Gabor 1992)

1.7. QI methods use in healthcare

QI methods became well established in other industries during the second half of the 20th Century. The introduction to healthcare did not develop until the 1990’s, however, their use is now widespread. (Marshall & Bamber 2011) Despite the increased utilisation of QI methods the evidence base for their effectiveness is poor and under-theorised. (Walshe 2007; Shojania & Grimshaw 2005; Auerbach et al. 2007) Some QI methods have demonstrated significant improvements in the delivery of care and patient outcomes (Pronovost et al. 2006) whilst others have demonstrated no improvements. (Landon et al. 2004)

Boaden (Boaden et al. 2008) and Powell (Powell et al. 2009) suggest it is possibly an absence of evidence of effectiveness in outcomes rather than ineffectiveness itself that have contributed to the mixed impact of QI methods. Evaluation of QI methods have tended to be drawn from descriptive case studies of single sites using a method rather than analytical reviews of the methods themselves. (Walshe et al. 2011) A particular problem is that many are before and after studies which make it difficult to determine whether success is directly attributable to the QI methods. As with developing an understanding of the impact of improvement efforts in general, evaluating the effectiveness of QI methods is similarly complex. Like with implementation, understanding “how and why” a QI attempt works has
been argued as perhaps of greater use than simply stating whether they worked or not. (Walshe 2007)

The complexity of evaluating the effectiveness of QI methods is perhaps best outlined by comparing the three domains previously described relating to the implementation of change; *Intervention, Implementation process* and *context*, (Damschroder et al. 2009) and the conceptual model presented by Bate (Bate et al. 2002) in their evaluation of a “QI collaborative” (Figure 6). A “QI collaborative” is a term coined by the Institute of Healthcare Improvement (IHI) and refers to a set structure for frontline healthcare staff to make change and improvement by receiving training and support in using QI methods. Bate proposed that the success of the “QI collaborative” in question was influenced by three interrelated areas: the use of the QI methods by project teams, the way in which the QI methods were introduced and taught to the teams (the implementation of the QI methods) and the surrounding context in which all of this occurred. These factors presented by Bate (Bate et al. 2002) have been reinforced in a recent systematic review of the use of “QI collaboratives”. (Nadeem et al. 2013)

![Figure 6. Conceptual framework explaining impact and effectiveness of a UK collaborative from Bate et al. 2002](image)

There is similarity between the principles of successful use of QI methods and the three areas outlined as factors contributing to success through implementing change by
Damschroder (Damschroder et al. 2009) (Figure 4, Page 28). The factors influencing implementation and QI method use recognise the influence of context and an implementation process; however, in place of a focus on implementing an intervention, the model described by Bate is focussed on implementing the use of a QI method.

The two models actually overlap (Figure 7) and subsequently present the complexity faced by efforts to evaluate the use of QI methods. In the case of the intervention from the implementation science frameworks, the use of QI methods can be considered as the implementation process, and thus the point at which the models overlap. The multiple dimensions and interconnections are all aspects that need to be understood to deliver and reliably understand the success of using QI methods. This is in addition to the question of measuring a quality outcome, be in a health outcome or change in process or structure of healthcare provision.
Figure 7. Overlap of Interpretation of Damschroder et al 2009 Consolidated Framework for Implementation Research and Bate et al. 2002 Conceptual framework explaining impact and effectiveness of a UK collaborative.
1.8. The development of Improvement Science

The provision of practical tools for those conducting improvement has been a key driver in the increasing popularity of QI methods. Challenges, however, persist in relation to their use with recognised variation in outcomes and the inability to reliably reproduce successful improvements in quality (Walshe 2007), as well as complexities in effective evaluation of their use in practice. It is these challenges that have directly contributed to the recent development of a healthcare Improvement Science discipline. (The Health Foundation 2014a) Academic conferences (BMJ quality & safety 2014; Institute for Healthcare Improvement 2014), groups (Improvement Science Research Network 2014; The Health Foundation 2014b) and fellowships (The Health Foundation 2014c) now exist contributing to the field with a growing presence in the academic literature. (Berwick 2008a; Marshall et al. 2013; Perla et al. 2013; Reed & Bell 2013; Pearson 2010)

The focus and definition of “Improvement Science” continues to evolve. (The Health Foundation 2011) Definitions range from considering the process of making improvement and the use of QI methods as scientific practices (Perla et al. 2013) to focussing on the scientific evaluation of improvement. (Marshall et al. 2013) Perla (Perla et al. 2013) have called for the continued examination of the philosophical foundations of improvement science methods, including QI methods, to ensure its continued progress. It is on this grounding that this thesis is built.

The original descriptions of QI methods are based on a clear scientific method (Deming 1986; Box & Bisgaard 1987), however, partly due to their varied effectiveness, questions over their scientific validity and application have arisen. (Vos et al. 2010) In healthcare many perceive that improvement attempts, including QI methods, are not scientific as they do not meet the research standard of controlled evaluations to identify best practice, the predominant paradigm within healthcare research. (Auerbach et al. 2007) This view of conducting rigorous evaluation to inform the selection of a change often takes precedence as the favoured scientific view of improvement in comparison to developing and testing
changes iteratively. As such there is a need for QI methods to be conducted rigorously and act within a research framework to complement and broaden this currently favoured view. (Shojania & Grimshaw 2005) This is a complex undertaking, however, that is still in its early stages of understanding and application. (Ting et al. 2009) To develop and apply the field of Improvement Science, with the aim of reliably supporting the improvement of health outcomes and practices, further research is required to understand the potential and the application of QI methods in a scientific manner. This is a key enquiry in which this thesis aims to pursue.

As with any developing academic discipline, language and definitions are a common cause for disagreement and misunderstanding and are also required to be theorised to develop a common agreement. (Parry 2014) “Quality Improvement”, for example, is often used as a global term regarding everything and anything surrounding an improvement attempt or for a variety of different aspects relating to improvement including the aim, the intervention, the outcome and the process or approach. (Berwick 2012) As such, distinct messages trying to be conveyed can often be misinterpreted. Further clarity is required in regards to the nomenclature of QI, in particularly in relation to its scientific grounding in comparison to other research approaches.

1.9. **Summary and Thesis Research Enquiry**

Mechanisms to improve healthcare have evolved overtime; from the individual efforts of early pioneers understanding links between health outcomes and healthcare practices to identify evidence based practice, to the use of principles and tools to support teams to implement interventions. The success of deliberate attempts to improve healthcare are influenced by an intervention, the context and the implementation process. QI methods seek to facilitate the process of implementation to ensure improvement is achieved. They are sensitive to context and guide the iteration of an identified intervention. Further
understanding on how to apply and evaluate QI methods is required to support both the conduct and evaluation of improvement efforts.

This thesis sets out to continue the development of Improvement Science as an academic discipline. The field at present is susceptible to a variety of interpretations as it uses two commonly used terms, *improvement* and *science*. To contribute to the field's development, this thesis will explore the scientific nature of QI methods. This is a valuable area to dedicate research focus as it will help inform understanding and application of systematic approaches to effectively and efficiently improve healthcare processes and structures and the associated health outcomes.

The thesis will investigate the extent to which, and how, the range of QI methods are considered scientific. As identified and outlined in the next chapter, Plan-Do-Study-Act cycles are identified as a method most closely represents the scientific method of induction and deduction in local improvement efforts. They therefore become a specific focus of the research in this thesis. Studies are presented that aim to determine the extent and how the method is applied scientifically in real-world healthcare QI efforts. The studies will use the theoretical framing outlined in Figure 7 (Page 36) to consider the context and implementation processes that influence the use of PDSA cycles, recognising that the use of the QI methods represents the implementation process for an intervention aimed at improving quality.
2. Chapter 2 - Improvement Science Practice and Research: A systematic narrative review of the associations between science and QI methods

Chapter Overview - This chapter presents a systematic narrative review of the literature to identify the articulated associations between QI methods and science. Data analysis was conducted by two reviewers: myself (CM) and PhD supervisor, Julie Reed (JR).

2.1. Introduction

“The epistemological foundations and theoretical basis of the science of improvement and its reasoning methods need to be critically examined to ensure its continued development and relevance.” (Perla et al. 2013)

The recognition of the need for a systematic approach for improvement which is more socially and contextually attentive has led to an increasing popularity of the use industry derived QI methods in healthcare. (Walshe 2009; Damschroder et al. 2009; Greenhalgh et al. 2004) These methods have been described as scientific by their founders (Shewhart 1986; Deming 1986; Moen & Norman 2006), however, whilst the field of improvement science has received increased attention, debate over the scientific nature of QI methods exists. (Vos et al. 2010; Marshall et al. 2013; Perla et al. 2013; Moen & Norman 2010) As outlined in Chapter 1, the reasons for debate relate to two main areas. Firstly, QI methods have resulted in varying levels of success. (Boaden et al. 2008; Ting et al. 2009) Secondly, their epistemological approach does not compare to traditionally used research methods to develop evidence-based interventions. Further examination and theoretical justification of the methods is therefore required. This will help gain greater understanding and ensure further development is relevant to the field of improvement science. (Perla et al. 2013). This will support their application to systematically facilitate improvements to patient care.
This chapter describes a literature review which presents the extent and manner to which QI methods are considered and theorised as scientific in academic literature. Specifically, it develops a scientific description of QI methods to guide those using the methods and researchers.

2.1.1. Science

Combined with the background to the concept of QI and QI methods provided in Chapter 1, it is helpful to consider an overview of the conceptual nature of science to frame this study. This will help inform the discussion and positioning of the scientific associations of QI methods.

“Science - The intellectual and practical activity encompassing the systematic study of the structure and behaviour of the physical and natural world through observation and experiment” (Oxford Dictionary of English 2010)

Considered as the systematic study of the physical and natural world (Oxford Dictionary of English 2010), science refers to an approach by which knowledge is pursued. This approach of study abides to a method: the scientific method.

The information that is gathered from this systematic study of the physical and natural world is categorised by subject matter. These collections can be considered “branches of science”. (Feynman & Leighton 1965) They range from traditional physical and life sciences such as chemistry, physics and biology to social sciences such as sociology and psychology. Developing areas of academic interest can often also be referred to as sciences such as sport science, political science and, accordingly, improvement science.

2.1.2. Development of the scientific method

The concept of science, including branches of science and the scientific method, has evolved over time. Since the development of the scientific method as understood today, many branches of science have seen rapid progress.(Chalmers 1999) Historically, the
development of scientific method, can be attributed to a number of influential individuals such as Aristotle, Ibn Al-Haytham, Galileo, Bacon, Pierce and Popper. An overview of their roles in developing our understanding of science and the scientific methods is presented below.

*Aristotle’s scientific theorising*

The scientific method stems from the method of induction; a process of gaining knowledge through the observation of instances, also known as empirical evidence. It was built upon the practice of philosophy; the study of the fundamental nature of knowledge, reality, and existence. (Oxford Dictionary of English 2010) Aristotle (384 BC- 322 BC) brought inductive thinking to the forefront of the philosophical study. He saw reality as physical observations through the five senses (Prior to this, led by his teacher, Plato, the study of the natural world had been driven by ideas, reflection and inspiration. (Dunn 2006) In doing so, Aristotle instigated the theory of empiricism in which knowledge is developed from sensory experiences. Much of natural philosophy, what became known as science, was driven by this notion of observation for the next 1,000 years.

*Ibn Al-Haytham’s method of experimentation*

Ibn Al-Haytham (965 – 1040) is attributed as the first to formulise a process of experimentation. (Gorini 2003) His approach included the following steps (Perla et al. 2013):

- Explicit statement of problem, linked to observation and proof by experiment
- Testing and/or criticism of a hypothesis using experimentation
- Interpretation of data and formulation of a conclusion
- Publication of findings

His worked combined observations with experimentation and he was the first to systematically vary experimental conditions to gain knowledge. Whilst Ibn Al-Haytham did
not articulate his work as “science”, he is regarded as the first to consistently apply an approach that resembles the scientific method accepted today.

**Galileo’s and Bacon’s initial formulisation of the scientific method**

Galileo (1564-1642), often referred to as the “father” of modern science, was at the forefront of the scientific revolution in the 16th century. This was driven by the separation of science from philosophy and religion. He advocated the process of experimentation to gain knowledge through induction. He specifically contributed to the formulisation of the scientific method by combining experimentation with mathematics.(Sharratt, 1994) Typically, science until then had commonly been a qualitative practice based on observation and subsequent theorising.

In the same period Francis Bacon (1561-1626) added to the field by explicitly articulating a procedure for scientific investigation.(Jardine 1974) His thinking can be described by his articulation of science as “light” and “fruit”: The “light” of science provides observations and insight into the workings of a particular phenomenon of interest, the “fruit” of science refers to the practical application of a particular phenomenon of interest to advance knowledge and improve quality of life in general.(Mathews 1996) This is perhaps the earliest reference linking science to the concept of improvement. Experiments of light refer to those of discovery. Experiments of fruit refer to that of invention. Bacon argued that light must precede fruit. In doing so he drove the formulisation of practical approach to the scientific method.

**Pierce and Popper’s additions to the scientific method**

Although Galileo, Bacon and others had proposed a scientific method, it was largely an applied inductive process in theory and practice. As outlined, the foundations of the method were based on inductive methods that sought to draw knowledge from observations, either through observing the natural world or conducting experiments and observing the outcomes. In the 20th Century, Charles Pierce and Karl Popper developed the concept of placing
inductive and deductive thinking in a complementary cyclic state (Figure 8). (Chalmers 1999; Box et al. 1978) The cyclical process proceeds through deduction (the formulation of a hypothesis based on current knowledge, designing an experiment to test this theory, executing the experiment and collecting data) to induction (analysing and interpreting the data to make observations, and modifying or reinforcing the existing knowledge base to inform the formulation of future hypothesis).

“An initial hypothesis leads by a process of deduction to certain necessary consequences that may be compared with data, when data and consequences fail to agree, the discrepancy can lead, by a process called induction, to modification of the hypothesis. A second cycle in the iteration is thus initiated. The consequences of the modified hypothesis are worked out and again compared with data (old or newly acquired) that in turn can lead to further modification and gain of knowledge” (Box et al. 1978)

Linked to the inductive and deductive process was Popper’s proposal of falsifiability: that for a theory to be considered scientific it must be testable. (Popper 1934) To be falsified was for a theory to be conclusively proven to be false by experiment or observation. It argues that a theory cannot be proven through only observing its occurrence as a complete sample may not have been used and there therefore may be cases where the theory is not true. A theory, however, can be disproved through observations of negative instances: if the theory is
shown to be incorrect it supports progress of knowledge because it means a theory must be adapted or abandoned. This process of falsification supports critical and rigorous science by testing for ways in which a currently held or proposed claim might be false or inaccurate.

2.1.3. Improvement Science

The brief description of science and the development of the scientific method is provided to frame the consideration of improvement as a science. On the one hand it could be considered as the scientific branch that objectively studies and collects knowledge around improvement efforts. On the other hand it could be considered the application of the scientific method which is actively deployed to pursue improvement.

This study aims to explore the associations between science and QI methods and develop a shared understanding and appreciation of the associations between the scientific method and common QI methods. It aims to add to the continued understanding of improvement as a science, and specifically, provide clarity as the scientific role of QI methods.
2.2. Method

A systematic narrative review was designed and conducted to identify and analyse published articles referring to both QI method(s) and science. The definition of a systematic review as a review of the literature according to an explicit, rigorous, and transparent methodology was used. (Greenhalgh et al. 2004) However, unlike some traditional systematic reviews the aim was not seek to judge evidence based or effectiveness of a phenomenon of interest, instead analysis was designed to provide a narrative of findings. (Powell et al. 2009)

2.2.1. Sample and data collection

The search strategy used a Boolean AND/OR search to identify any articles referencing specific QI methods and the terms “science” or “scientific”. The range of methods outlined and described in Chapter 1 (Table 2, Page 33) were used as the search terms for QI methods:

- Plan-Do-Study-Act (PDSA) cycle
- Model for Improvement
- Statistical Process Control (SPC)
- Six Sigma
- Lean
- Theory of Constraints
- Mass Customisation
- Total Quality Management (TQM)
- Continuous Quality Improvement (CQI)

Empirical literature was identified from searches of databases (Cochrane Library, Embase, Medline, Science Direct, Web of Knowledge) that contained one of the QI method terms, including acronyms, and the terms “science” or “scientific”.

46
Two authors (CM and JR) independently reviewed the retrieved abstracts and selected studies if the QI method and science terms were associated together. This included a spectrum of linkages from providing a description of how the terms link, simply linking the words alongside one another or demonstrating uses of the term that implicitly suggested they may be associated. Disagreements, often with this latter example of association, were resolved through discussion until consensus was reached. This process was repeated for the full text of included abstracts to provide a final set of included articles for analysis. Inclusion of full text articles was restricted to English Language peer-reviewed journal articles.

When reviewing the abstracts it was evident that whilst a QI method was mentioned it was not always a specific QI method that was related directly to science. Instead the broader concept of “quality improvement” was linked to science. While recognising that the term “quality improvement” can refer to other aspects relevant to improvement other than a QI method, such as an output, aim or intervention, the term was added to the search terms so that a broad view of the link between QI methods and science could be gained, and the article selection process repeated as above for newly identified articles. The final search was dated 22nd August 2014.

2.2.2. Data analysis

The full texts of the selected articles were reviewed and codes developed by identifying the types of associations made between QI methods and science. This included statements linking the terms and discussions of these associations. Whilst definitions of QI methods, science and improvement science have been outlined so far to frame the research problem and provide a basis to compare findings with, data analysis was conducted inductively: no pre-identified theory was used to guide analysis. This was to ensure all links between QI methods and science were driven by the content of the selected articles and biases of reviewers was limited. (Bernard & Ryan 2009)
The analysis followed an inductive qualitative approach through the constant comparative method of (1) read transcripts, (2) identify themes (codes, concepts, categories) (3) compare and contrast themes, identifying structure among them, and (4) build theoretical models, constantly checking them against data. (Bernard & Ryan 1998) This method prescribes analysis that identifies, constantly compares and iterates codes, concepts and categories to develop a theory (Glaser 1965): ‘Codes’ refer to the initial identification of aspects that allow the key points of the data to be gathered; ‘Concepts’ refer to collections of similar codes to group the data; ‘Categories’ refer to collections of similar concepts that are used to generate theory; and ‘Theory’ refers to the collection and organisation of categories that present theory regarding the data and subject of the research.

Linkages were coded by a single reviewer (CM) and an initial description of the codes created. The initial codes were then discussed with the second reviewer at the abstract selection stage and common concepts identified and merged; categorising themes into a hierarchical coding structure. Definitions were given to the high level categories. Further articles were subsequently reviewed following a similar process and codes, concepts and categories iterated and continually discussed.
2.3. Results

After removing duplicates the search returned a total of 1136 abstracts for review. From these abstracts, 187 were selected for full text review of which 95 were included in the final analysis (Figure 9). No articles referenced Theory of Constraints and only 1 referenced Mass Customisation but the article did not relate it to science and was therefore not included for full review. Of the 95 included articles many mentioned more than one of the QI method search terms.

![Diagram showing the selection process for QI methods/Science review study selection](image)

Figure 9. QI methods/Science review study selection

Three high level categories describing the different ways in which QI/QI methods were linked to the concept of Science were identified:

- Articulation that QI methods are scientific methods to facilitate change and improvement (84/95);
- Debate on whether QI methods are appropriate scientific methods to evaluate a change’s impact on an outcome and build a body of generalisable knowledge (11/95);
- Calls for science to be applied to study the use of QI methods to facilitate change and improvement (9/95).
The relationship between the three categories are presented in a theoretical model in (Figure 10). The first category represents the role that QI methods can play to facilitate a change made to a process or structure achieve improvement against a desired outcome; they can help identify, iterate and implement the change in a facilitatory role that mirrors the scientific method. The second category collates discussions as to whether QI methods are appropriate methods to scientifically evaluate the link between a change made and the outcome in question. Finally, the third category proposes that greater scientific investigation is required to understand the use of QI methods to facilitate or evaluate change.

Figure 10. Model to demonstrate the three categories associating QI methods and science – centred on the notion of introducing a change to achieve improvement

Detailed descriptions of the categories are presented below with specific examples and quotes from selected articles. They outline the collective viewpoints and arguments derived from the included articles. All references made within the results are directly attributed to articles reviewed in the study. Some articles described connections between QI and science in a way that was fully consistent with a single category, others covered more than one
category. Appendix 1 presents each article included in the review, the QI method they refer to and the link(s) to science they outline.

2.3.1. Articulation that QI methods are scientific methods to facilitate change and improvement

The most common category associating QI methods and science was that QI methods were or applied scientific methods to facilitate change and improvement. 88% (84/95) of articles referenced this link. This was indicated to varying extents: from simply adjoining the two concepts such as QI or a QI method and, “...is a scientific approach”, “… applies the scientific method”, or “is built on Science”, to explaining the link further; outlining how conduct of QI or a QI methods is scientific or includes the application of the scientific method in detail. Table 3 presents the observed articulations of how individual QI methods were considered scientific.

<table>
<thead>
<tr>
<th>QI method</th>
<th>How is it considered scientific?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Model for Improvement and Plan-Do-Study-Act (PDSA) cycle</strong></td>
<td>The Model for improvement “consists of three questions which address intention, measurement and the identification of well-founded ideas based on the literature, solid theory or experience before employing the scientific method to test these ideas in the clinical environment.” (Kilo et al. 1998) Plan-do-study-act (PDSA) cycles are “the application of the scientific method to implement and test the effects of change ideas on the performance of the healthcare system”.(Speroff et al. 2004) They are used to define a hypothesis to improve work (plan), test the hypothesis (do), collect and analyse relevant data (study), and draw conclusions for action regarding the tested hypothesis (act). (Cleghorn &amp; Headrick 1996)</td>
</tr>
<tr>
<td><strong>Statistical Process Control</strong></td>
<td>“SPC is a scientific approach to QI in which data are collected and used as evidence of the performance of a process, organization or set of equipment.”(Yi et al. 2006)</td>
</tr>
<tr>
<td><strong>Six Sigma</strong></td>
<td>Six sigma is “the application of the scientific method to quality improvement”. (Impellizzeri et al. 2009) It represents a form of scientific method which is empirical, inductive and deductive, and systematic, which relies on data, and is fact-based.(Cloete &amp; Bester 2012) Problem solving can been seen as a scientific activity in DMAIC through a fact finding mission in the Measure stage.(Mast &amp; Bisgaard 2007) The “Improvement” phase includes the employment of a scientific experimental design technique.(Rowlands &amp; Antony 2003)</td>
</tr>
<tr>
<td><strong>Lean</strong></td>
<td>Lean is application of scientific method (Pattanaik &amp; Sharma 2009) which is empirical, inductive and deductive, and systematic, which relies on data,</td>
</tr>
</tbody>
</table>
and is fact-based. (Cloete & Bester 2012) Using the scientific method to problem solve is part of the approach (Staats & Upton 2011) which “empowers staff to investigate process problems and to develop, test, and implement countermeasures using a scientific method” (Mazzocato et al. 2012)

### Total Quality Management

TQM reflects a scientific cycle (Aziz 2006) and includes use of scientific methods to support data collection and analysis and action on data (Botticelli 1995) It fosters the scientific method of inductive and deductive approaches, through Statistical quality control by using a control/ run chart, both to make changes and observe impact. (Amasaka 2003)

It’s scientific methodology includes use of Deming’s seven management tools of flow-charts, cause-and-effect diagrams, histograms, pareto charts, run charts, scatter diagrams and control charts. (Spanbauer 1995)

### Continuous Quality Improvement

Continuous Quality Improvement, or just Continuous Improvement in some cases, reflects the science of “studying, dissecting and acting”. (Little 1993) It uses scientific method used to test ideas in the clinical environment (Kilo et al. 1998) through the application of the Deming/ Shewhart/ PDSA cycle and the scientific nature it provides. (Erturk et al. 2005)

The scientific method requires careful and rigorous gathering of data and interpreting it before proposing solutions or responses. (Jones & Ziegenfuss Jr. 1993)

The process of CQI includes “investigating phenomena and developing knowledge that involves the identification of a problem, development of a hypothesis and methods of testing the hypothesis, evaluating the observable results of the testing methods, and reaching conclusions” (Nolte et al. 2008)

<table>
<thead>
<tr>
<th>Table 3. The scientific conduct of QI methods – identified from articles in this review</th>
</tr>
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</table>

In general, QI methods were described as scientific methods of observation and experimentation. (Bisgaard & European Org 1997) This included: the identification of a change aimed at improvement; testing a change iteratively; and measuring a change and it’s impact reliably:

- **Identification of a change aimed at improvement:** Testing and measuring change is preceded by the development of hypotheses, collection of baseline data, and identification of cause and effect relationships within the system to identify a change. (Predpall 1994; Vogelsang 1999; Buchmann et al. 2008; Gordon W 1997)

- **Testing a change iteratively:** Scientific learning cycles of induction and deduction are used to experiment when testing changes aimed at improvement. (Bisgaard &
European Org 1997; Cloete & Bester 2012; Amasaka 2003) This was most commonly referred to through the use of PDSA cycles (also referred to as PDCA, Deming cycle, and Shewhart cycle).

- **Measuring a change and it’s impact reliably:** Testing change is supported by scientific measurement to inform action through statistical analyses, including the use of SPC. (Jiang 2013; Rozman & Robida 2014)

The PDSA cycle method was most closely aligned with the scientific method. A number of articles described it as a direct application of the scientific method (Figure 11). (Speroff et al. 2004; Cleghorn & Headrick 1996; Bisgaard & European Org 1997) It is used to define a hypothesis to improve work (plan), test the hypothesis (do), collect and analyse relevant data (study), and draw conclusions for action regarding the tested hypothesis (act). (Cleghorn & Headrick 1996)

![Figure 11. PDSA cycle as the application of the scientific method (Based on Speroff et al. 2004; Cleghorn & Headrick 1996; Bisgaard & European Org 1997)](image)

The benefit of the scientific nature of QI methods was articulated by a number of articles. It was argued that the use of the scientific principles (identifying a change, testing iteratively and measuring reliably) within QI methods helps counteract tendencies to operate improvement efforts on hunches without the rigorous gathering and interpretation of data. (Gordon W 1997; Jones & Ziegenfuss Jr. 1993) It also supports a conscious and continual attempt to problem solve and learn within a team setting and cautions against
assuming an idea for a change, even when carefully considered and evidence based, will automatically work resulting in the intended effect in healthcare practice. This view of QI methods as scientific learning methods subsequently allows the rigor of inductive and deductive learning to be applied in a pragmatic manner where action and adaptations can be made. (Cleghorn & Headrick 1996)

“Scientific practice is used to provide a better approach to improvement than just intuition.” (Ellrodt 1993)

"Ignoring data and not having the discipline to use a scientific method is a failure to learn." (Predpall 1994)

“Only by continually learning about the system can we achieve continuous improvement.” (Kilo et al. 1998)

Other sciences were also linked to the conduct of QI or QI methods to facilitate change and improvement. A clinical scientific evidence base was suggest to be utilised when identifying a change to be introduced. (Dowla & Chan 2010) “Reliability sciences” can also be drawn on when identifying a change and learning in regards to its success. (Berry et al. 2009; Kaminski et al. 2014) This refers to methods of evaluating, calculating, and improving the overall reliability of a complex system.

Social sciences were also positioned as being supported by QI methods. “Complexity science”, including the social process of learning within the context of relationships and interactions among individuals, was argued to be harnessed by using QI methods. (Anderson et al. 2012) Additionally, “team training sciences” were suggested to be applied in the use of QI methods: They help inform the process of making change and the social interactions necessary to influence team’s attitudes, behaviours, and cognitions. (Weaver et al. 2010)

2.3.2 Debate on whether QI methods are appropriate scientific methods to evaluate a change’s impact on an outcome and build a body of generalisable knowledge
The second category identified articulations in regards to the use of QI methods as research methods to evaluate the outcome of an improvement effort and build evidence for a change to healthcare and its effect on health outcomes (12% (11/95) of articles). Unlike the previous category which clearly attributed the conduct of QI methods to the conduct of science, this category included a debate between the science of traditional research methodologies and the science of QI methods as research methods.

The key point of debate centred on the scientific rigour of evaluation. Whilst QI methods, as already alluded to, reflect the scientific method to solve problems and make changes, the debate discussed was whether they follow the rigors of traditional research methodology to provide convincing evidence of impact and build a body of specific and generalisable knowledge. (Vogelsang 1999) QI methods were not seen contributing to this type of research method as they aim only to produce local knowledge rather than generalizable knowledge. (Cheung & Duan 2014)

The internal validity, the extent to which a causal relationship between a change and an outcome can be concluded, was argued as source of difference between QI methods and traditional research methodology as evaluation approaches. (Speroff et al. 2004) With Randomised Control Trials perceived as the gold standard for experimental design to evaluate internal validity (Chapter 1), QI methods diverge from this as they do not normally propose the use of a control group to make comparisons against. (Ovretveit & Gustafson 2002) This brings criticism as an evaluation approach to identify causal attribution between a change and an outcome. Another contributing factor includes the failure to sufficiently measure outcomes. (Ovretveit & Gustafson 2002) Without stringent protocols in place to make controlled comparisons, the validity, reliability and generalisability of findings to other settings in regards to the effect of a particular change to healthcare facilitated by QI methods is suggested to be at risk. (VanCleave et al. 2011)
Rather than stating that because QI methods do not follow the rigour of other research methodologies they are not scientific, others argued it was important to consider the scientific nature of QI methods and other research methodologies in relation to their primary aims. (Lynch-Jordan et al. 2010) They may share the same ultimate goal of improving patient outcomes, however, traditional research methodologies, in terms of controlled trials, seek to apply the scientific method to provide confirmatory evidence and build a body of evidenced based care. QI methods, in comparison, use scientific method to solve local problems, iterate change and make improvements against desired metrics. As such they may stray from a pure evidence-based change to make an intervention work in practice and achieve improvement. (Vogelsang 1999)

“Each side in this debate has been guilty of caricaturizing the position of their opponent, making it appear that one side rejects any study that is not a randomized clinical trial, while the other will accept any evidence that supports their favourite QI intervention.” (Atkins 2009)

“RCTs are considered optimal in most intervention research because, if done well, they control for threats to internal validity. However, as typically implemented, they do not allow for rapid changes in the intervention in response to lessons learned.” (VanCleave et al. 2011)

From this balanced view, it was suggested that research and QI methods should not be seen as competing methodologies with users choosing one approach or another. Their strengths can be combined, clinical research providing the evidence for an improvement intervention and QI methods determining how to best deliver this in practice. QI methods were also proposed as being at the end of a spectrum of research approaches in healthcare from “basic science research, translational research, comparative effectiveness research, implementation sciences, and quality improvement” (Figure 12). (Hudson 2013)
As discussed in the first category, QI methods as scientific methods to facilitate change and improvement, statistical process control (SPC) can contribute to the scientific evaluation of an improvement effort by providing analysis of quantitative data collected regularly over a defined time period. (Yi et al. 2006) The method is often used to determine the deployment of an intervention and/or its impact. Rather than aiming to determine internal validity between an intervention and outcome, it aims to determine whether a change observed in data is due to inherent variation within a system ('common-cause variation') or something different ('special-cause variation'), such as the intervention. This is helpful as the complex nature of healthcare means inherent variation is often present but also because it provides information to guide iterations made within an improvement effort.

Additionally, however, if desired, study designs other than RCTs were proposed as ways of generating useful information with internal validity, such as interrupted time series, multifactorial designs, and mixed qualitative and quantitative approaches. (VanCleave et al. 2011) It was further proposed that there is clear importance of the ability to share the narrative, knowledge and outcomes of improvement attempts that use QI methods. (Atkins 2009) Continued clarification on how to ensure evidence for a change is valid and applicable, and balancing a desire to foster timely improvements in care with the need to protect against promoting ineffective or even harmful changes was called for.
2.3.3. Calls for science to be applied to study the use of QI methods to facilitate change and improvement

The two categories presented represent and discuss QI methods applying the scientific method: firstly, to facilitate change and subsequent improvement and, secondly, science to evaluate change and subsequent improvement. The third category, rather than consider QI methods applying the scientific method, explores the need to apply scientific research to investigate the use of QI methods themselves to facilitate change and improvement (9% (9/95) of articles). Specifically, they indicate the need to understand the practical application and effectiveness of QI methods in the reality of healthcare improvement.

Practical efforts to improve quality of healthcare have moved from simply identifying best practice to the use of QI methods to facilitate delivery of change. However, evaluation of improvement efforts mostly continues to focus on whether an intervention to healthcare delivery has resulted in improvement, rather than how the process of making improvement, including the use of the QI methods themselves, contributes to overall success. (Brennan 2002) More recent research has considered the relationships between favourable contextual elements, such as leadership and clinician involvement, and outcomes of implementing a change by using QI methods, however, specific attention to the application of the methods is lacking. (Ovretveit & Gustafson 2002) As such, empirical evidence that QI methods are implemented as intended and the link between this and positive outcomes is needed. (Alemi 1999)

They are complexities in identifying causality between using a QI method and a successful outcome. (Ovretveit & Gustafson 2002) In the “uncontrolled” nature of a QI effort, many contextual factors may influence the outcome of an improvement effort which means that causality is difficult to identify. Even if context was controlled, clear criteria to measure the extent to which QI methods are used as intended are not evident. To address this and evaluate adherence to QI methods, researchers must engage in the development and
validation of empirical measures for assessing conduct of QI/ QI methods. (Rungtusanatham et al. 2003) This type of research will allow the exploration of links between QI method conduct and success plus help improve structures, training and support to use them and terminology for scientific communication. (O’Neill et al. 2011)

Two examples of this type of research were identified in this review. (Riley et al. 2012; Taylor et al. 2014) The first study prosposed a taxonomy to accumualte evidence regarding the extent to which certain aspects of QI methods were used within QI projects. (Riley et al. 2012) These included creation of aim statement, use of process mapping and use of process control methodology to review data. The second outlined key principles of Plan-Do-Study-Act cycle method and reviewed academic publications for the extent to which these principles are reported. (Taylor et al. 2014) (This paper was published as part of this thesis – see N.B) Neither of the two studies aimed to determine the effectiveness of QI methods or PDSA cycles, instead they outlined the variation in their use and proposed structures to inform future conduct, research and education.

(N.B. This review was originally conducted in the early stage of my PhD to base future work. The original findings informed the initiation of a systematic review of PDSA cycle which is presented in the next chapter and has been published. The search in this current review in this chapter has since been updated for publication submission. The new articles are returned and included in the results, including the PDSA cycle systematic review)
2.4. Discussion

“The quality improvement field is littered with words and concepts poorly understood, varying in meaning or lost in translation when interacting with research, academic, or practitioner communities.” (Parry 2014)

To progress the science of improvement, this review aims to contribute to a shared understanding and appreciation of the different associations between science and common QI methods. In doing so, it presents three categories linking a number of QI methods and the concept of science: articulation that QI methods are scientific methods to facilitate change and improvement; debate on whether QI methods are appropriate scientific methods to evaluate a change’s impact on an outcome and build a body of generalisable knowledge; and calls for science to be applied to study the use of QI methods to facilitate change and improvement. The large majority of articles returned in the search referred the first category.

2.4.1. Limitations

The data collection approach was taken to identify a broad range of articles referencing science and QI methods and to not rely on the authors own awareness. Only academic articles that refer to QI or a QI method in their abstract were considered in the review and it is therefore not exhaustive. For example, other examples of articles that discuss the scientific nature of QI that were not identified by the review are used in Chapter 1 and this discussion section. By searching for articles that articulate both QI methods and science terms it could be argued that the search inclines towards identifying articles that positively consider QI methods as scientific. However, the search terms allowed for articles to state that QI methods are not associated with science. These articles were identified and appear in the review in relation to the debate between QI methods and traditional research methods, minimising concerns over positive bias.

2.4.2. QI methods as a reflection of scientific methods
The three categories outlined demonstrate that there is not a single consideration associating QI methods and science. However, from the articles reviewed the dominant consideration of QI methods and science relates to the application of scientific principles when facilitating change and improvement. This centres on iterative cycles of testing supported by approaches to identify a change (develop a hypothesis) and measure impact which mirrors Popper’s deductive-inductive scientific method. This recognition of the similarity of principles has been previously noted, including a recent comparison between Lean and the Model for Improvement approach, including PDSA and SPC. (Scoville & Little 2014) Whilst the specific tools of QI methods are termed differently with different focuses, considered broadly, they come together to apply scientific principles. The application of these principles, is believed to be of greater importance than the use of a specific QI method itself. (Berwick 2012)

These scientific principles overlap with Perla et al’s (2013) propositions for the science of improvement including the use of prior and existing knowledge to develop changes aimed at improvement (including systems knowledge), testing and adapting change using scientific learning cycles, measuring reliably through use of operational definitions and understanding variation to help inform adoptions and monitor success. (Perla et al. 2013) Perla et al 2013, also proposed the combination of psychology and scientific logic when conducting improvement efforts. This was identified in the studies returned in this review, in relation to “complexity science” and “team training science”, however the role of psychology was not substantially addressed by the categories identified for the scientific nature of QI methods. Improvement efforts are made up of social interactions such as engagement, dialogue and motivation which QI methods can facilitate. (Walshe et al. 2011) There is opportunity for further definition and exploration of the role of QI methods and psychological and sociological factors they require or influence.

A final proposition from Perla et al (2013), that the science of improvement includes both the science of discovery and science of justification, links to the second category identified: a
debate in using QI methods as research methods to evaluate improvement efforts. *Discovery* refers to the use of scientific methods to discover and test theories, *justification* refers to the use of scientific methods to evaluate outcomes and confirm the validity of these theories.

It is useful to point explore this debate further: QI methods can play a role as a justification research method, evaluating outcomes and confirming the validity of associated theories, however, are often limited to justification in local settings rather than producing more generalisable knowledge. Other methods are perhaps better suited to do this rigorously and in a way which can build generalizable knowledge across settings, such as the randomised control trial. The aim of QI methods is not necessarily to prove the validity of a causal connection between an intervention and outcome. Instead their key role is in discovering how an intervention can best result in improvement. This is achieved through sequential learning cycles to create and adapt changes in a local setting. The application of QI methods is by no means isolated from other research methods and it could learn from them to support the justification of knowledge including attempts to control or influence some aspects of context; focus on the reproducibility of improvement efforts and the development of generalisable knowledge through the experimental learning cycles. (Ovretveit & Gustafson 2002; Provost 2011) Their overall aim of supporting learning and discovery within local improvement efforts must remain at the forefront, however, if they are to facilitate iterative change and improvement.

### 2.4.3. Scientifically understanding the conduct of QI methods

The future challenge for the use of QI methods is perhaps not a question of whether they are theoretically scientific or not, but instead whether they are actually being used scientifically in practice and contributing to learning, informing action to adapt changes in a given context and helping achieve desired improvements.
QI methods are known to have variable outcomes and are highly dependent on the context in which they are used. (Walshe & Freeman 2002) As identified by the third category in the review, a more rigorous approach to the evaluation of the use QI methods is required to determine if QI methods are used “well”. (Walshe 2009) In other words, are they being used scientifically (as intended) to support improvement? Addressing this question will help build generalisable knowledge about how the scientific method is applied in improvement efforts.

Methods to investigate the effectiveness of QI methods have long been debated. From one perspective, methods designed to minimise the influence of context, such as RCTs, are not relevant as the use of QI methods are often a complex social intervention that relies on contextual influence. (Berwick 2008a) From another, as identified in this review, designs such as RCTs are perceived as necessary to draw internal validity links between an outcome and an intervention. This is from the viewpoint of evaluating the change that is introduced to healthcare, not to evaluate the effectiveness of the QI method itself.

To address the evaluation challenge of understanding QI conduct, a staged approach to evaluation, applying different research methods at different stages, has been suggested; treating the use of QI methods as a complex intervention. (Campbell et al. 2000; Campbell & Murray 2007) For this type of research the QI method would be viewed as part of a complex intervention to improve healthcare delivery that also includes the actual change to healthcare delivery and the context of the setting they were being implemented within. These link to the three areas previously identified in Chapter 1: the intervention, the context and the implementation process.

Evaluations to understand the use of QI methods, either individually or as a complex intervention, would benefit from the ability to understand the extent to which the QI method are conducted as they are intended. As Rungtusanatham et al (2003) suggests, to understand this better, attention must be paid to the actual use of the methods and assess if they are used with high fidelity compared to their original descriptions. Knowledge of this will
allow targeted action to better use the methods, including education and adapting them. This will enable the development of better evidence for the use of QI methods by linking the fidelity of use with the development and deployment of an intervention and an improvement in quality outcomes. This has been described by two articles returned in this Chapter. (Riley et al. 2012; Taylor et al. 2014) Other examples include whether Six Sigma is being used to its full potential (DelliFraine et al. 2014) and how Lean is applied in frontline clinical settings. (Waring & Bishop 2010) Further studies of this nature are needed to build the understanding of and evidence base for QI methods, with a focus on measuring fidelity of use. Findings can then be used by those implementing the methods and to also build evaluation models to scientifically review, and develop, the application of the science of improvement when using QI methods.

2.4.4. Implications for Improvement Science

Reflecting on the view of science as either groupings of knowledge in the form of branches of science or the approach of science in the form of scientific method, it is clear that QI methods are dominantly seen as scientific mechanisms in which improvement can be pursued. In other words, they embody the scientific method. They are practical tools to invoke science in both a deductive, hypothesis driven manner through steps to identify and test change and an inductive manner through reliable measurement and acting as a broader research method. A branch of science referring to knowledge surrounding the conduct of improvement is also developing. This refers more broadly to the knowledge in regards to what changes to healthcare result in improvement (the second category identified in this study) and also the knowledge of applying QI methods (the third category).

The different links between QI methods and science, whether a method or a branch of science, link to the existing views of improvement science: there is a distinction between trying to deliver improvement (Perla et al. 2013) and trying to study improvement. (Marshall et al. 2013) On one hand, science is applied to facilitate change and improvement with
learning applied immediately by adopting, adapting or abandoning a change aimed at improvement. On the other hand, science is applied to confirm and develop generalisable knowledge that a particular change, in a particular context, causes improvement. In addition, generalisable knowledge can be developed, and is called for, for the role in which the use of QI methods facilitates the process of delivering improvement.

2.5. Conclusion

It has been argued that in the developing field of improvement science terminology, similar in wording yet different in nature, must be further defined and understood. (Parry 2014) Understanding the different links between QI methods and science can help develop this understanding and, subsequently, advance a more sophisticated discussion through supporting dialogue. Whilst the categories have been articulated in relation to QI or a specified QI methods, they also reflect three key areas for the improvement science field to consider: facilitating change and improvement (local application of the scientific method); conducting research on the outcome of change (building generalisable knowledge); and conducting research on facilitating change and improvement through the use of QI methods (building generalisable knowledge about how scientific method applied). Scientific principles can be applied to all three areas.

2.6. Contribution to overall thesis

This review has identified three associations between science and QI methods. Based on the predominant view within the study, the remainder of the thesis presents research conducted on the first category: QI methods as scientific methods to facilitate change and improvement. This also reflects research as defined by the third category: calls for scientific research to study the use of QI methods to facilitate change and improvement.

The research studies presented will focus on the PDSA cycle method as it is the QI method that most closely reflects the stages of the scientific method. This therefore enables the
development of knowledge about how the scientific method is applied in local efforts to
deliver improvements, using the PDSA cycle method as a surrogate to do so.

Chapter 3 explores the extent to which the application of PDSA cycles in healthcare is
conducted with fidelity and adheres to the principles of the scientific method through a
systematic review of published articles.

Chapter 4 and 5 explore the fidelity of PDSA cycles documented by local improvement
teams and the influence of context on their conduct through document analysis and
interviews.

Chapter 6 and 7 explore the reality of conducting PDSA cycles in practice through a
qualitative observational study where the principles, benefits, challenges and enablers to
PDSA cycle conduct are explored.
3. Chapter 3 - Development and application of criteria to assess fidelity:

Systematic Review of PDSA Cycle Conduct

Chapter overview – This chapter presents a novel study into the reported conduct of PDSA cycles in healthcare. The study uses a systematic review to apply a theoretically informed framework to peer-reviewed publications.

The findings presented in this chapter have been published in the BMJ Quality and Safety Journal (Taylor et al. 2014) My role in the published article was to lead on the development of the framework to assess PDSA cycle fidelity, to act as a duel reviewer on a first review of articles, lead a second review of articles prior to publication and co-write the paper.

3.1. Introduction

From the previous chapter, Plan-Do-Study-Act (PDSA) Cycles were identified as a direct application of the scientific method in improvement efforts in healthcare: The theoretical grounding and rational of PDSA as an application of the scientific method to structure learning, and therefore inform iterations of an intervention aimed at improvement, were outlined. The chapter presented the need to study and understand the use of QI methods further to contribute to the development of Improvement Science. The remainder of this thesis explores this with a focus on the use of PDSA cycles.

This chapter outlines the development of a framework to systematically evaluate the conduct of the PDSA cycle method based on its guiding literature. The framework is then applied to peer-reviewed publications reporting the use of the PDSA method to determine the extent to which key principles of the method are adhered to.

3.1.1. The rational for PDSA cycles

Chapter 1 identified the importance of an iterative process to support improvement. This was articulated within the broader theoretical consideration of improvement with an iterative
approach part of the implementation process to support the adaptation and implementation of an intervention in light of the context in which the intervention is implemented. The PDSA cycle method was identified as a QI method that structured this iterative process and Chapter 2 demonstrated how the cyclic nature of the method mirrors the scientific process of induction and deduction. Further background on the method is now provided to frame investigation into its scientific application in practice.

The PDSA cycles prescribe a four stage cyclic learning approach to test and adapt changes aimed at improvement. In the "plan" stage a change aimed at improvement is identified, the "do" stage sees this change tested with the "study" stage examining the success of the change and "act" identifying adaptations and next steps and inform a new cycle (Figure 13). (Deming 1986; Langley et al. 1996)

![Figure 13. The Plan-Do-Study Act Method](image)

The ability to adapt and iteratively develop a change is widely regarded as an important trait when attempting to make improvements. (Damschroder et al. 2009; Greenhalgh et al. 2004; Rycroft-Malone 2004; Øvretveit 2004) Cycles of learning allow a change to be tested and adapted to ensure it is fit for purpose within a given context and consequently improving healthcare for patients. Without adaptation, a change may not overcome system problems and may be resisted by individuals or organisations influential in achieving improvement.
Of all QI methods used in practice, many can be considered as predominantly either planning or evaluation tools: facilitating the use of evidence or system knowledge to identify changes or measurement to inform and guide change. In doing so, they inform iterative development rather than directly guide it. The PDSA cycle is the main exception to this and is the central method that directly structures change. (Moen & Norman 2010) In this light, it can be seen as the crux of making improvements: without change, improvement cannot occur. (Goldratt 1990)

"Every improvement is a change but not every change is an improvement." (Goldratt 1990)

3.1.2. Application in healthcare

The PDSA cycle method has been widely used in healthcare either as a standalone method, as part of wider QI methods such as the Model for Improvement (MFI), Total Quality Management, Continuous QI, Lean, Six Sigma or ‘Quality Improvement Collaboratives’ (Schouten et al. 2008; Nicolay 2012; Boaden et al. 2008) or with specific tools such as process mapping and cause and effect diagrams. (Plsek 1999; Reed et al. 2014)

Despite increased utilisation of PDSA cycles, like many QI methods, evidence for their effectiveness is varied with examples of both successful (Brock et al. 1998; Buckley et al. 2010) and unsuccessful achievement of improvement. (Benning et al. 2011a; Landon et al. 2004; Vos et al. 2010) This mixed evaluation of effectiveness is also seen for “QI collaboratives” (Schouten et al. 2008) and other QI methods (DelliFraine et al. 2010) which recommend the use of PDSA. Whilst a number of sources advocate and comment on the method (Institute for Healthcare Improvement 2013; NHS Institute for Innovation and Improvement 2013), there are no overarching objective evaluations of their effectiveness or conduct. (Ting et al. 2009)

As previously discussed, if the PDSA cycle method is to facilitate the improvement of healthcare delivery by providing a structure to test and adapt change, its use must be
effectively understood and those using the method must be educated and supported accordingly. It is insufficient to only understand whether use of the method has resulted in improvement or count the number of cycles conducted in determining the effectiveness of the method. Neither provides generalisable learning which can be applied in different settings at different times. The PDSA cycle method is a structure to support learning; its success not driven by the number of cycles carried out but by the quality of learning process and the decisions and actions taken subsequently. (Langley et al. 1996)

The functions that inform and facilitate PDSA cycle’s support of iteratively developing an intervention must be recognised and evaluations conducted with these in mind. In this sense, by understanding the functions that support good quality application, a better understanding of whether an effective approach to learning through iterative development has occurred and thus generalisable knowledge can be created to inform further use and increase the likelihood that changes successfully result in improvement.

Prior to this PhD, no formal criteria for evaluating the use of PDSA cycles existed. Guidelines for the publication of QI projects, the Standards for QUality Improvement Reporting Excellence (SQUIRE) guidelines (Davidoff et al. 2008) existed but did not present criteria for conducting and reporting PDSA cycles, or any other QI method, specifically. (Davidoff et al. 2008) In addition, whilst guidance for those conducting PDSA cycle is very clear with each stage cycle having individual instructions (Langley et al. 1996), it does not readily translate into evaluation criteria to assess the fidelity of the method. To develop an evaluation framework to assess the conduct of PDSA cycle it is necessary to consider guidance from the founders and contributors of the method’s development.

3.2. Plan-Do-Study-Act Cycle Fidelity Framework Development

3.2.1. Development from industry

PDSA cycle originates from the efforts of W.A Shewhart and Edward Deming in the mid-20th century. The early use of the cycle was aimed at understanding "production as a
In his book, *Statistical Method from the Viewpoint of Quality Control*, Shewhart presented the idea of a learning cycle to guide mass production process (Figure 14). The cycle is the evolution of a three step process: specification, production and inspection. From the outset the cycle was primed as the application of the scientific method:

"These three steps must go in a circle instead of in a straight line, as shown. It may be helpful to think of the three steps in the mass production process as steps in the scientific method. In this sense, specification, production, and inspection correspond respectively to making a hypothesis, carrying out an experiment, and testing the hypothesis. The three steps constitute a dynamic scientific process of acquiring knowledge" (Shewhart 1986)

The deductive-inductive scientific method informed Walter Shewhart's original cycle to conduct improvement work. Specification, production and inspection were 3 stages to conduct in a cyclic nature and constituted a dynamic scientific process of acquiring...
knowledge. Corresponding to the scientific method of making a hypothesis, carrying out an experiment and testing the hypothesis, the cycle allowed learning to occur from successes and failures and fed this into a new cycle.

Edward Deming, the editor for Shewhart’s book, continued developing the concept while teaching in Japan between 1950s and 1980s. In doing so he adapted the terminology, added a fourth step to the cycle and emphasised the need to use the cycle iteratively (Figure 15). The terminology now focussed on testing a change and learning from it and this format was illustrated in his book Out of the Crisis.(Deming 1986) The cycle, at this stage, was still termed the Shewhart cycle.

![Shewhart Cycle Diagram](image)

**Figure 15. Deming’s proposal of Shewhart Cycle**

In the 1990s the cycle took form of how it appears today. Deming specifically outlined the 4 stages, Plan, Do, Study, Act and specified concise guidance for each (Figure 16). During its adaption from the Shewhart steps to the PDSA cycle the applicability of the cycle expanded. Shewhart’s initial outline aimed the use of the cycle at mass production. Deming outlined the wider applicability of the method to all types of learning and improvement.
The terminology, Plan-Do-Check-Act (PDCA), has also been used to describe the method following Deming’s early teaching in Japan. (Imai 1986) Deming didn’t actually propose the acronym PDCA, instead his teaching of what at the time was referred to as the Shewhart Cycle was rebranded as the Plan-Do-Check-Act cycle after he had visited the country. In fact, Deming was actually against the use of “Check” as it may be interpreted as “to hold back”. (Moen & Norman 2010) The terms PDSA and PDCA are often used interchangeably in reference to the method. For the purpose of this study PDSA and PDCA are both included and referred to as ‘PDSA’ cycles unless otherwise stated.

Whilst the origins of PDSA cycles were informed from Shewhart’s and Deming’s QI work in organisations, their thinking was largely informed by philosophers, including C.I Lewis and John Dewey, in the early twentieth century who link science with the philosophical views of pragmatism. (Moen & Norman 2010) The conduct of experiments is central to the scientific method and it is this that reflects the role that PDSA cycles seek to play in learning and improvement. Critical to this concept is the advancement of knowledge through inductive and deductive reasoning. The complementary role of pragmatism refers to the notion that learning is guided by an overarching aim and understanding is the gained by the testing and modifying beliefs, not just proven theories. PDSA cycles are not about building knowledge in isolation, but importantly, to deliver improvement, by re-applying knowledge gained in

Figure 16. Deming’s proposal of the Plan-Do-Study-Act Cycle (Deming 1993)
practice. Importantly this viewpoint emphasises the benefits of learning from failure and then taking action to rectify actions.

“the scientific experimental method is…a trial of ideas; hence even when practically – or immediately – unsuccessful, it is intellectual, fruitful; for we learn from our failure when our endeavours are seriously thoughtful” (Dewy, 1925, the development of American pragmatism).

Modern day application of PDSA cycle has been driven by the Associates in Process Improvement. (Associates in Process Improvement 2015) in their book, The Improvement Guide (Langley et al. 1996) In this, the PDSA cycle method further evolves with the addition three questions to supplement the PDSA cycle:

1. What are we trying to accomplish?
2. How will we know that a change is an improvement?
3. What changes can we make that will result in improvement?

The questions help define the aim, measures and changes of an improvement effort. These questions and the PDSA cycle form the Model for Improvement (Figure 17). Alternatively, in the case of the terminology PDCA another preceding framework has been developed called FOCUS (Batalden 1992) The acronym provides five steps to address prior to using the PDCA cycle (Figure 17)
3.2.2. Identification of key principles

Using this overview of the PDSA cycle method and the sources referred to, five key principles of the method have been identified. They are outlined below and will form the domains of a framework to evaluate the method's use:

- Use of iterative cycles
- Prediction based tests of change
- Initial Small scale testing
- Use of regular data over time
- Documentation
**Iterative cycles**

The central feature of iterative development is achieved through sequential iterative cycles testing and adapting change (Figure 18). (Deming 1986; Langley et al. 2009; Brock et al. 1998) The PDSA cycle can be considered as an evolved cyclic version of the traditional scientific method of deduction and induction (creating hypothesis and comparing with data) (Speroff & O'Connor 2004) with multiple linked cycles of induction and deduction providing the key facilitator for learning and iteration of a change. This approach also reflects learning cycles used in education and organisational development. (Schon 1988; Kolb 1984)

Depending on the knowledge gained from a PDSA cycle, the following cycle may seek to modify, expand, adopt or abandon a change that was tested.

![Figure 18. Iterative PDSA cycles](image)

**Prediction based test of change**

Informing the process of testing change requires an understanding and utilisation of existing knowledge to select an aim and change concept aimed at achieving this aim. (Langley et al. 1996; Plsek 1999) These may be developed from the external existing research base but also internal knowledge through understanding the national or local healthcare system and performance and/or the engagement and empowerment of the people that are involved in the improvement effort. The capture of knowledge created from testing a change loops back to inform both external and internal knowledge sources and subsequent cycles.
As part of developing and adapting a change and in line with the scientific method, a prediction is developed in the ‘plan’ stage of a cycle. This change is then tested and examined by comparison of results with the prediction.

*Initial small scale testing*

To support iteration, small samples and short experimental cycles are used to learn quickly and cumulatively. (Berwick 2005; Langley et al. 1996) Initial small scale testing ensures a change is adapted or removed if it is not having the intended effect and, if the change is provoking a negative response, effects are minimised. The small scale nature of PDSA cycles additionally ensures a pragmatic approach to the analysis of change by providing a middle ground between a large scale evaluation of a change to healthcare or no evaluation at all. (Kilo 1998) It is suggested the scale of the test be decided on the evidence supporting the change and risks of a failed test. (Brock et al. 1998) As certainty of success of a test grows so does the scale of the test (Figure 19). (Langley et al. 1996)

*Figure 19. Increasing of PDSA cycle scale over time*
Use of regular data over time

Tracking data over time is necessary to also support iterations. The notion of “just enough data” links scale and the use of data over time. Measurement should be proportional to the certainty of success which will in turn inform the scale of the test of change. Measurement over time allows temporal relationships to be identified with the changes tested and builds evidence of improvement. Ideally this would be documented in time series of regular intervals. (Lynn et al. 2002)

Statistical process control can be used to support this monitoring of data over time. (Carey & Staker 2003; Langley et al. 1996) Throughout both Shewhart’s and Deming’s development of the cycle it was closely linked to the use of statistical process control charts to monitor data over time. (Best & Neuhauser 2006) This data over time increases understanding regarding the variation inherent in a complex healthcare system. Accompanying qualitative measurements of the change further supports understanding and learning.

Documentation

Documentation of all four stages of the PDSA cycle, including the reflections on both quantitative and qualitative information is crucial. This not only demonstrates if improvement is achieved but ensures learning is cumulative, informing future cycles and avoiding repetition, and provides a scientific rigour to the method (Speroff & O’Connor 2004)

3.2.3. Theoretical framework to assess PDSA cycle conduct

The five principles of PDSA conduct outlined above are presented in Table 4. Drawing on the guidance used to inform these principles, questions are also outlined to assess the extent to which reported PDSA conduct adhere to the principles: the fidelity of PDSA cycle conduct. This theoretical framework will be used as the basis of the systematic literature to assess the reported conduct of PDSA cycles in peer-reviewed literature.
<table>
<thead>
<tr>
<th>Feature of PDSA</th>
<th>Description of feature</th>
<th>How can this be measured</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iterative cycles</td>
<td>To achieve an iterative approach, multiple PDSA cycles must occur. Lessons learned from one cycle link and inform cycles that follow. Depending on the knowledge gained from a PDSA cycle, the following cycle may seek to modify, expand, adopt or abandon a change that was tested.</td>
<td>Were multiple cycles used? Were multiple cycles linked to one another (i.e. does the Act stage of one cycle inform the Plan stage of the cycle that follows)? Where isolated cycles were used were future actions postulated in the ‘act’ stage?</td>
</tr>
<tr>
<td>Prediction-based test of change</td>
<td>A prediction of the outcome of a change is developed in the ‘plan’ stage of a cycle. This change is then tested and examined by comparison of results with the prediction.</td>
<td>Was a change tested? Was an explicit prediction articulated?</td>
</tr>
<tr>
<td>Small-scale testing</td>
<td>As certainty of success of a test of change is not guaranteed PDSA cycles start small in scale and build in scale as confidence grow. This allows the change to be adapted according to feedback, minimises risk and facilitates rapid change and learning.</td>
<td>What was the sample size/duration/ number of changes tested per cycle? Did sequential cycles increase scale of testing?</td>
</tr>
<tr>
<td>Use of data over time</td>
<td>Data over time increases understanding regarding the variation inherent in a complex healthcare system. Use of data over time is necessary to understand the impact of a change on the process or outcome of interest.</td>
<td>Was data collected over time? Were statistics used to test effect of changes and/or understand variation?</td>
</tr>
<tr>
<td>Documentation</td>
<td>Documentation is crucial to support local learning and transferability of learning to other settings.</td>
<td>Was each stage of the PDSA cycles documented?</td>
</tr>
</tbody>
</table>

Table 4. PDSA Cycle principles and criteria to measure them
3.3.  Methods

3.3.1.  Values

This study takes a post-positivist, critical realist view. (Trochim & Donnelly 2001; Colin 2002) Realism is a branch of epistemology which is similar to positivism in that it assumes a scientific approach to the development of knowledge. (Saunders 2011) This assumption underpins the collection of data and the understanding of those data. However, the post-positivist, critical realist view is a progression in the application of a positivist view and is “critical” of our ability to know reality with certainty. (Trochim & Donnelly 2001)

This study aims to deductively assess the conduct of PDSA cycles; however, it recognises that the study will not reveal the full reality of the method’s use. It aims to describe how the PDSA cycle method is reported to be used which can then help inform the further development of theory to support users of the method and researchers.

3.3.2.  Sample and data collection

The systematic review was conducted in adherence to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. (Moher 2009)

The search was designed to identify empirical accounts of the use PDSA cycles published in peer-reviewed literature. Taking into account the different terms for the PDSA cycles the following search terms were used: “Plan Do Study Act”; PDSA; “Plan Do Check Act”; PDCA; Deming cycle, Deming circle; Deming wheel; Shewhart cycle. No year of publications were imposed on the search.

The following databases were searched: Allied and Complementary Medicine Database (AMED; 1985 to present), British Nursing Index (BNI; 1985 to present), Cumulative Index to Nursing and Allied Health Literature (CINAHL; 1981 to present), Embase (1980 to present), Health BusinessTM Elite (EMBESCO Publishing, Ipswich, Massachusetts, USA), the Health Management Information Consortium (HMIC), MEDLINE from PubMed (1950 to present)
and PsychINFO (1806 to present) using the NHS Evidence online library, and the Cochrane Database of Systematic Reviews. Two searches were conducted, with the second conducted to update the review prior to publication. This search was dated 25th September 2012.

All returned abstracts were reviewed for inclusion independently by three reviewers (CM, MT, and CN). Abstracts were reviewed to determine whether PDSA cycles were referred to. Full texts of articles were then reviewed to determine whether the articles were describing the empirical use of PDSA cycles in healthcare. Full criteria for including articles were: published in peer-reviewed journal; reporting the empirical use of PDSA cycles in a healthcare setting; and published in English. Editorial letters, conference abstracts and opinion articles were not included. Disagreements were resolved by consensus.

3.3.3. Data analysis

Each included article was assessed against the criteria outlined in the theoretical framework for PDSA cycle fidelity. This reflected a classical content analysis approach. (Weber 1990; Krippendorff 2004) Face validity of the framework was achieved through discussions between reviewers, with supervisors and at local research meetings.

Unlike the previous chapter which focussed on exploring data, this study took a deductive confirmatory approach. This refers to a hypothesis-driven approach that derives theories and codes in advance of data analysis and then seeks to confirm them in the data. (Guest et al. 2011) A theory of PDSA cycle conduct has been developed and the selected publications were analysed to seek to confirm whether their reported conduct of PDSA cycles adheres with this theory. Using content analysis quantitatively involves establishing categories and identifying the frequency at which the categories are prevalent in collected data. (Joffe & Yardley 2004) It provides numerical output to qualitative data (Figure 20). This complements the research objective as it allows the presentation of the extent to which PDSA cycles are conducted in alignment with guiding theory.
Figure 20. Qualitative and Quantitative data and analysis framework (Guest et al. 2011)

Two reviewers assessed each included article independently (CM and MT). To do so the articulation of PDSA cycle conduct was identified within the article and a proforma outlining the criteria from the framework completed. Disagreements (which occurred in less than 3% of data items) were resolved through discussion. The frequencies of which the included articles adhere to the identified principles were recorded and ratios and means are presented.
3.4. Results

942 articles were returned in the search. After removal of duplicates 409 articles remained. 216 articles were excluded following abstract review. 120 were discarded following initial full text review. 73 articles remained and were included for full analysis against the framework (Figure 21)

![Diagram showing the selection process of articles](Figure 21. PDSA cycle systematic review articles selection process)

3.4.1. PDSA/ PDCA terminology

Of the included articles, 42 used “PDSA” terminology and 31 used PDCA terminology. 8 and 20 articles used the preceding Model for Improvement (MFI) and FOCUS frameworks respectively. One article used both MFI and FOCUS. Over time there was an increased use of PDSA terminology (Figure 22)
Figure 22. Prevalence of PDSA and PDCA terminology over time

3.4.2. Documentation (n=73)

Four categories were identified to group the thoroughness of PDSA documentation: 41/73 (56.2%) articles provided details of each stage (P, D, S and A) for the cycles reported; 8/73 (11.0%) articles provided details of individual cycles but did not specify the stages explicitly; a further 8/73 (11.0%) articles reported the themes of cycles were addressing but not detail; finally, 16/73 (21.8%) articles reported the use of PDSA cycles but provided no details or indication of the themes (Figure 23).

Figure 23. Thoroughness of PDSA cycle documentation
As the application of the theoretical framework is reliant on the reported use of PDSA cycles, the articles that provide no details or only themes of cycles were insufficient for further analysis. These articles were excluded from the remainder of the articles leaving 49 articles (those that provided details of each stage or individual cycles) for review. A full breakdown of the results for each article is provided in Appendix 2.

3.4.3. Iterative cycles (n=49)

Of the 49 articles reviewed, 14 (28.6%) reported the use of iterative cycles. This is defined as 2 or more cycles linked together; the learning from one cycle informing the next. 33 (67.3%) articles described isolate cycles that are not linked to another. A final 2 (4.1%) articles described the use of PDSA cycles but use the stages in a different order that P, D, S, A. One of this reported the following sequence of stages: PDACACA. The second article only described 3 of the stages: P, D, and A. These 2 articles were excluded from further review.

Of the 33 articles that describe isolated cycles, 4 described multiple cycles however the cycles are not linked to one another and are therefore not categorised as iterative cycles. The remaining 29 described just a single cycle. Whilst many suggest further actions, only 3 of these articles describing single isolated cycles suggest the possibility of future PDSA cycles.

11/ 25 articles (44%) using PDSA terminology described iterative cycles whereas only 3/ 22 (13.6%) of the articles using PDCA terminology did so (Figure 24)
3.4.4. Prediction-based test of change (n=47)

To review the fidelity of testing change, the PDSA cycles are split between single isolated cycles and iterative cycles. 30/33 articles reporting isolated cycles used the cycles to structure a test of change. The remaining 3 used the cycles to structure the collection or review of data only (with no change tested). Of the 14 articles describing iterative cycles, 8 describe cycles testing change only. 5 describe an initial cycle collecting or reviewing data followed by cycles testing change. A final article describes a mix of cycles testing change and collecting data.

For the use of predictions, of all the 47 articles describing iterative or isolated cycles, only 4 (8.5%) contained an explicit prediction within the PDSA cycle descriptions. All 4 of these described cycles testing change.

3.4.5. Small scale testing (n=47)

As outlined in the framework, the scale of cycles was assessed through the sample size of cycles, their duration and the number of changes tested.
Defined as reporting the number of observations used to test change or collect information, for example the number of patients a change was tested on or number of staff that provided feedback, 27/ 47 (57.4%) articles reported a sample size for at one PDSA cycle or more PDSA cycles they described. For iterative cycles, 6/14 articles reported sample size but only 2 studies reported an increase in sample size over cycles. The sample size for the first cycles in these iterative chains ranged from 1 to 34 (Mean=16.75, Standard Deviation 11.47). The remaining 21 articles reporting sample size used isolated cycles. Sample size for these ranged from 7 to 2079 (M=16.8, SD=11.5).

Similarly for the reporting of duration of a PDSA cycle, it is helpful to split findings between isolated and iterative cycles. 13/ 14 (92.9%) articles with iterative cycles reported duration. This could be by reporting individual cycle duration or the duration for all cycles collectively. Using the duration of individual cycles and estimating individual cycle duration for articles that only reported the duration of all cycles collectively, by dividing the total duration by number of cycles, individual cycle duration of iterative cycles ranged from 3 cycles in 1 day to 1 cycle in 16 months (M=5.4 months, SD=4.8 months). The total duration of all cycles in a series of iterative cycles (first to last in one series) ranged from 1 day to 4 years (M=20.4, SD=20.4). Of the isolated cycles, 27/ 33 (81.8%) reported duration of cycles. This ranged from 2 weeks to 5 years (M=11.9 months, SD=12.8 months).

For the final measure of scale, number of changes tested within a cycle, 22/ 47 (46.8%) articles reported more than one change being tested within a single cycle.

3.4.6. Data over time (n=47)

All 47 articles reported quantitative or qualitative data in their descriptions of PDSA cycle use. 39/ 47 (82.9%) articles reported quantitative data which was in turn categorised into 3 types: 15 /47 (31.9%) reported the used of regular data (defined as 3 or more data points at consistent time intervals); 16/47 (34.0%) reported the use of non-regular data (defined as
before and after data, data points per PDSA cycle or data at inconsistent time intervals); and
8 (17.0%) reported a single data point after PDSA cycles use.

Of the 15 articles reporting regular quantitative data, 7 used monthly or more frequent time
intervals between data points. 11/ 47 (23.4%) articles reported analysis of data using
inferential statistical tests, however, none reported the use of statistical process control
(SPC).

6/ 47(12.8%) articles did not report quantitative data but used qualitative data only to inform
PDSA cycles. This included informal staff or patient feedback and structured focus groups.
The final 2/ 47 (4.3%) articles reported that quantitative analyses had taken place but did not
present the results.
3.5. Discussion

PDSA cycles intend to support improvement efforts by providing a combined scientific and pragmatic approach. The framework developed in this study draws on the historic development and theory of PDSA cycles and is used to review the extent to which peer-reviewed publications reporting their use adhere to the methodology. The review demonstrates variability in the use, description and reporting of the PDSA method with inconsistent approaches to the conduct and reporting of the method and a lack of adherence to these key facilitating functions that underpin its design as a pragmatic scientific method. Only 2.7% (Lynch-Jordan et al. 2010; Varkey & Sathananthan 2009) of all included articles demonstrate compliance with criteria in all five principles suggesting that the full benefits of the PDSA cycle method to contribute to learning and improvement are likely not to have been realised in the remaining studies.

Of the articles in the review that documented details of the PDSA cycles, less than a third report the conduct of multiple linked cycles of change and, of these, less than a sixth used incremental testing scales. Without an iterative approach to learning it is unlikely that changes will be adapted and optimised effectively which limits the chance of achieving an improvement to patient care. By not starting on a small scale time there is greater risk that time is wasted on ineffectual change ideas. Starting on a small scale supports the ability to learn rapidly what works and what doesn’t with a change idea and make the necessary adaptations or introduce a new change completely. Linked to this, only 14% (7/47) of articles reported the use of monthly or more frequent regular data over time to inform the iteration of change. Using infrequent data has two potential negative effects: firstly it inhibits the ability to learn and adapt a change quickly, secondly, it inhibits the ability to review the impact of a change within the normal variation of the system it is being tested within.

An assumption made in the development of the theoretical framework to review PDSA fidelity was that all cycles would test a change as the mechanism to learn. This proved not to
be the case. Whilst most cycles were used to structure the testing of a change, there were a number of examples in which the four stage process was used to structure the collection of data with no change tested.

The increasing use of PDSA as a term as opposed to PDCA cycles in recent years appears to align with a move towards improved use of the method as observed with an increased compliance with some key principles such as the use of iterative cycles. Deming, was cautious over the use of the ‘PDCA’ and warned it referred to a quality control circle for dealing with faults within a system, rather than the PDSA process which was intended for iterative learning and improvement of a product or a process. This subtle difference in focus, and therefore intentions in use, may explain this better compliance with key methodological principles in studies that refer to the method as ‘PDSA’.

3.5.1. Limitations

Assessment of adherence to the principles was difficult due to the marked variation in the documentation of the PDSA cycle method, reflecting a lack of standardised reporting structure.

Even with full documentation, results are limited as the reported accounts of PDSA cycles in publications have the potential to be retrospectively recorded. It has been assumed that the documentation reflects the process of learning achieved in the cycle, however, retrospective documentation is at risk of positive bias or omitting key observations. Although the value of using documentation to make inferences about behaviour may be limited; at the early stage on developing a mechanism to inform and evaluate conduct it is arguably sufficient. To further understand the use of PDSA cycles and supplementing analysis of documentation, it is necessary to observe the use of the method in practice and to understand the perspective of its users.

Despite the review being focussed upon reported application, rather than success of interventions, it may still be possible that publication bias affected results of this study.
Research that used the PDSA method, but did not yield successful results may be less likely to be published than reports of successful PDSA interventions.

3.5.2. Implications

This study directly addresses the call identified in Chapter 2 for further investigation into the actual application of QI methods. As an approach that it is proposed to be based upon the scientific method, this study has demonstrated that, based on reported accounts of using the method, the principles that contribute to its scientific application are not routinely followed.

The findings highlight the need for caution in interpreting results from studies which treat the PDSA method as a “black box”. (Dückers et al. 2009) This is the case in a number of studies identified within this review with little or no recognition of the content of the cycles or the functions that support good quality conduct. This is also a feature of some “QI collaboratives”. (Dückers et al. 2009; Knight, Caesar, et al. 2012; Benning et al. 2011a)

The review did not attempt to compare effectiveness of using PDSA cycles to reported outcomes and hence cannot conclude whether better conduct of the PDSA method results in improvement. Instead it drew on theoretical principles of PDSA cycles to rationalise why this would be expected. PDSA cycles are intended to support learning about change made to the delivery to healthcare in light of context and adapt, adopt or abandon the change as a consequence. Conducting the method in line with the identified principles ensures a change to healthcare delivery is made and documented and this change is iterated according to the learning achieved through using data over time and increasing scale with risk and inefficiency also minimised. Achieving improvement is a cascade effect of using PDSA cycles: the use of PDSA cycles will invoke learning which in turn will help adapt a change, the change is more likely to be successful due to this adaptation and therefore its intended effect is more likely to occur. A number of other factors will influence the overall success of an improvement effort on patient outcomes and direct casual relationships between PDSA conduct and outcome improvements may always be difficult to determine.
3.5.3. Future Research

This study builds on the research inquiry highlighted in Chapter 1 and 2 and sets the foundation for the future studies presented within this thesis. There is a clear need to explore the impact of PDSA cycles fidelity and how it may be related to variable outcomes of QI attempts. To initiate this there is first a need to understand the fidelity of the method in greater detail, the factors that support high fidelity usage and how it is applied in practice. This remaining studies in this thesis aim to do this.

Healthcare is a complex social system and many individuals and groups will often be involved in and influence the conduct of each PDSA cycle. Understanding how knowledge and learning is communicated between individuals and groups between cycles and between each stage of a cycle is critical to understand how the PDSA method is applied in practice. Recognition of these social features in further studies of the method is necessary to reflect the facilitatory role of engaging and empowering the people using the method.

Whilst guidance on PDSA cycles depicts the iteration of cycles to occur in a smooth progression, one article identified in the review argued that the reality of using PDSA cycles should be “more realistically represented” (Figure 25),(Tomolo et al. 2009) They state that as ineffective cycles can be abandoned early on it is not necessary to go through all four stages. This idea is interesting on two levels. Firstly, they may provide insight into a potential misunderstanding of the PDSA cycle method; that a successful PDSA always results in improvement. Whilst ineffectual changes may not result in desired improvement, they do result in learning that can be passed on to future cycles. However early on a change is identified as ineffective, the process can still be useful described as a whole PDSA cycle. Secondly, it signals that further research efforts are needed to understanding the reality of using QI methods. Whilst learning cycles may be continual, the progression of an iteration of a change or an increase in the scale of testing is not necessarily as the introductory guidance makes out. As Tomolo et al point out the “false starts, miss firings, plateaus,
regrouping, backsliding, feedback, and overlapping scenarios within the process” means that the navigation of change aimed at improvement is complex.

Figure 25. Tomolo et al 2009 representation of PDSA cycle reality

As part of the investigation into the reality of improvement initiatives, recognition of the enabling or disabling contextual factors is important. Understanding how high fidelity usage can be achieved needs to be addressed if QI methods are going to be an avenue for effectively and efficiently improving patient care.

With the inherent complexity of improvement recognised, further efforts can still be beneficial to support the systematic reporting and conduct of PDSA cycles. Such guidelines are necessary to drive scientific rigour in the application of the method. The SQUIRE guidelines make reference to PDSA cycles further support to those that wish to report the use of PDSA cycles seems necessary. Using the framework outlined in this study is perhaps a starting point.
3.6. Conclusion

This study is the first to provide an objective assessment of a range of PDSA cycles. It systematically assessed the fidelity of the method and revealed that the application and reporting of PDSA cycles does not comply with the principles that underpin the methods design as a scientific and pragmatic method. This varied practice cautions against studies that merely view PDSA cycles as a “black box” intervention and seek to link success with only a statement of whether the method has been used or not. Future users should attempt to ensure that the method is conducted with greater accordance to guidelines provided by its founders and developers. (Deming 1986; Langley et al. 1996)

3.7. Contribution to overall thesis

This study has identified that the fidelity of PDSA cycles, and therefore the application of the scientific method by using them, is low.

The predominant view articulated in Chapter 2 was that QI methods mirror the scientific method to facilitate change and improvement. The review of the background theory and guidance on the method in the introduction confirms and adds detail to this to develop a theoretical framework of the method’s intended use. However, the application of this framework to assess published accounts of PDSA indicates that the method is not conducted with high fidelity. This therefore suggests the method is not used in a scientific manner.

The subsequent chapters seek to continue explorations into the use of PDSA cycles in healthcare. They seek to assess the fidelity of use in other examples of the methods use and to understand what influences fidelity of PDSA use.

Chapter 4 and 5 seek to further develop a theoretical evaluation framework to assess the fidelity of PDSA cycles and apply it to improvement teams’ documented PDSA cycle accounts rather than publications. Chapter 5 specifically sets out to explore whether fidelity
can be improved and what contextual factors may influence this. This reflects the relationship of QI conduct and context present in Chapter 1, Figure 7 (page 36).

Chapter 6 and 7 conduct qualitative studies to identify the interpretations and social reality of using PDSA cycles and therefore understand reasons why fidelity may be low. For both, the role of context and how it influences PDSA cycle conduct is also investigated. Chapter 6 seeks to determine whether those using the method perceived the functions of the method in line with the developed framework and the benefits they associate with these functions. In addition, it seeks to link these perceptions to the organisational QI context. Chapter 7 seeks to explore the challenges and enablers to actually using the method.
4. Chapter 4 - Assessment of PDSA Cycles conduct in prospectively documented healthcare improvement teams: updating a framework to guide the application of PDSA cycles and assess their use

Chapter overview – This chapter presents a study that seeks to update the theoretical framework to improvement team’s documentation of PDSA cycle. Data analysis was conducted by two reviewers: myself (CM) and research programme colleague, Laura Lennox (LL).

4.1. Introduction

The PDSA method is commonly used in healthcare improvement, however, the systematic review in Chapter 3 demonstrated poor adherence to the method’s key principles suggesting the full intended benefits are not being realised (Table 5). (Taylor et al. 2014) Individual studies reviewing improvement efforts using the PDSA method have also previously indicated problems in completing cycles, for example a failure to initiate tests of change rapidly at a small scale; (Vos et al. 2010; Walley & Gowland 2004), a failure to execute appropriate cycles and increase testing scale following initial tests; (Baxley et al. 2011; Tomolo et al. 2009) and a lack of detail when reporting the cycles. (Nadeem et al. 2013)

<table>
<thead>
<tr>
<th>Principle (Based on previous chapter)</th>
<th>Intended benefit (Drawn from Langley et al. 2009)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prediction based test of change</td>
<td>Testing change is central to learning whether an idea for improvement works or not. It allows improvement teams to understand whether the change is having its intended effect or whether adaptations are necessary. Learning is aided by the articulation of prediction. During the planning stage it provides clarity on the intended effects of a change and allows team members to uncover any assumptions. It can also help reflect on challenges that may be encountered and whether it is possible or desirable to mitigate against them during the test. It enhances the study stage by acting as a comparison to actual outcome and prevents hindsight bias (“I knew it all along”).</td>
</tr>
</tbody>
</table>
Iterative cycles ensure the learning from one cycle is applied in a subsequent cycle in the pursuit of improvement. It is a key part of the scientific method in doing so with the learning from one cycle informing the generation of the hypothesis for the next. It allows for scale of testing to increase over time and for learning to be informed by the use of longitudinal data over time.

Small scale testing

Initial small scale testing facilitates rapid change and minimises risk and waste. Learning occurs quickly and adaptions to change can be made sooner rather than later. Users are provided with the freedom to act and have the opportunity to build evidence of benefit and engage others as confidence increases.

Regular data over time

Regular data over time reliably guides learning and action and prevents reliance on impulses and inclinations. Used in conjunction with statistical process control (SPC) (Provost 2011) it helps understand the impact of a change and make comparisons with predictions. It helps understand variation inherent in a complex healthcare system. Qualitative data is used to gain feedback and can be triangulated with quantitative data to make sense of test results.

Documentation

Documentation supports prospective management of a PDSA cycle and records learning. It provides qualitative enrichment to quantitative data monitoring improvement and supports understanding of why improvements were or were not made.

Table 5. Intended benefits of PDSA cycle principles

Evaluations of improvement efforts have historically focused on the linear relationship between changes in processes of care and their impact. However, increasingly research is starting to explore the "black box" of improvement. This includes seeking a more in-depth understanding of interventions and their effective use,(Dixon-Woods et al. 2011; Hoffmann et al. 2014) the role of context,(Kaplan et al. 2011; The Health Foundation 2014d) and the extent to which adaptations are made to implement interventions in a specific settings.(Damschroder et al. 2009; Cohen et al. 2008) Analysis to determine the extent to which a QI method is used as intended has received less focus.(Riley et al. 2012; Walshe 2009) As such there is a need to explore the fidelity of application of QI methods, such as PDSA cycles, to better understand their effective deployment in practice.(Taylor et al. 2014; Walshe 2009)

Attribution between using a particular QI method, in this case PDSA cycles, and effective improvement in outcomes cannot be determined simply by stating whether the method was
used or not. Instead, the development and validation of empirical measures for assessing
the extent to which the method is used as intended, its fidelity, is necessary.
(Rungtusanatham et al. 2003) In doing so, this offers a formative mechanism to drive
scientific standards for the use of the method and highlights areas for improvement.(Walshe
2009)

To realise the full potential of applying PDSA in QI initiatives it is helpful to set clear
standards for its use which can also support and highlight areas where the use of the
method can be improved.(Walshe 2009) This could accelerate learning at a local level and
support sharing of learning between improvement efforts about how to use the PDSA cycle
method in practice. Such a structure would also support meta-evaluation and systematic
reviews of how to use the method effectively and help identify factors that influence high
fidelity use of the method.

The systematic review in the previous chapter was a first step in doing this through the
development of a framework to assess fidelity of PDSAs in peer-reviewed literature.(Taylor
et al. 2014) This framework identified key theoretical principles of the method and posed
open questions to assess whether published accounts of use of the method adhered to
them.

Further development of the original framework is required to elicit its full potential in guiding
and assessing PDSA conduct. As well as taking into account findings from the previous
chapter, the framework must be adapted to guide and assess the application and
documentation of PDSA cycles in active QI initiatives, not only summaries included in
academically published accounts. There is also further opportunity to provide greater
clarification to assess the fidelity of the method. The framework in the previous chapter used
open questions to guide assessment but more specificity could be established to support
consistent and objective assessment. This study therefore seeks to update the framework to
guide the application of PDSA cycles and assess their use.
4.2. Methods

4.2.1. Values

This study continues the post-positivist, critical realist view. (Trochim & Donnelly 2001; Colin 2002) Instead of aiming to provide a quantified view of PDSA cycle fidelity, it aims to qualitatively assess its use to further develop theory which will be positioned within an updated assessment framework for the method. It is recognised, however, that this will not be the complete reality of using the method and the framework and reality of using the method must be continued to be investigated. The further development of a framework helps to do this.

4.2.2. Approach

To develop a practical framework the study qualitatively explored documented PDSA cycles from a cohort of projects supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Northwest London (NWL). (Curcin et al. 2014) This regional programme supports research and improvement teams to translate evidence into practice by using a suite of QI methods including PDSA cycles. (Howe et al. 2013; Doyle et al. 2013; Reed et al. 2012)

4.2.3. Sample

The project teams supported by CLAHRC NWL included a breadth of clinical initiatives across a range of local healthcare settings within the Northwest London National Health Service (NHS) system. Whilst teams were provided with education and support to use and document PDSA cycles in real-time, they devised, conducted and documented PDSA cycles on their own accord.

4.2.4. Data collection

In total 421 PDSA cycles were documented by CLAHRC NWL project teams, all were included in the analysis. This included data from 39 teams across 11 healthcare
organisations. Documented PDSA cycles were exported from the CLAHRC NWL Web Improvement Support (WISH) tool (Figure 26) (Curcin et al. 2014) in ‘comma separated values format’. Documentation fields included free text title, plan, do, study, and act stages as well as a date for each. All fields were retrieved for initiated PDSA cycles (defined by the presence of a documented “Plan” stage).
4.2.5. Data analysis

An deductive qualitative content analysis approach (Elo & Kyngäs 2008) was used to review the CLAHRC NWL project teams' documented PDSA cycles and inform the update and refinement of the framework originally used to assess fidelity of PDSAs in peer-reviewed literature. (Taylor et al. 2014) The ability of the framework to support structured fidelity assessments was considered and areas for modification (improvement/improved specification and description) identified.

Prior to analysis, an initial update to the framework was made based on learning from the systematic review. (Taylor et al. 2014) The single principle of “Prediction-based test of change” was divided into two: “prediction” and “test of change” (Figure 27). “Test of change” was then relabelled to “Learning activity” to reflect the observation that not all cycles framed a test of change as some were used to structure the collection of information only. This resulted in six principles of the method that were investigated: Learning Activity, Prediction, Iterative cycles, Incremental testing scale, Regular data over time and Documentation.
Figure 27. Updated principles of PDSA cycle fidelity (#1-6)

Building on this, additional types of learning activity ("collecting information", "testing change" and "implementing change") articulated in existing guidance on the use of PDSA cycles (Langley et al. 1996) were also included as an initial subset of the principle to guide the analysis. These had not been included in the initial higher-level framework. "Collecting information" refers to cycles used to collect information only with no change tested; "Testing change" refers to cycles structuring the early stage piloting of a change; and "Implementing change" refers to cycles that structure learning once a change is being used regularly in routine practice.

With these initial updates made, two reviewers (CM and LL) assessed the CLAHRC NWL PDSA cycle data. A first review of the data identified references to the identified principles of PDSA cycle conduct based on the theoretical framework or any other additional areas of conduct not covered by the principles. The data was attributed to initial broad codes and was then analysed, based on the constant comparative approach,(Charmaz 2014) to refine a hierarchy of more detailed codes to describe PDSA cycle conduct. The hierarchy levels of the codes were refined, labelled and used directly to develop the updated framework.
4.3. Results

Across each of the six principles in the framework, the study identified areas which could be enhanced by providing greater detail and clarity to support assessment of PDSA cycle fidelity.

The updated framework following the qualitative inductive analysis is presented in Table 6. Within each principle, specific areas of conduct were identified. Assessment against these themes either provided indication as to whether the principle of PDSA cycle was adhered to (representing fidelity of use) or helped described the methods’ use in greater detail. The fidelity assessments indicated whether the method was used as guidance outlines. The descriptive assessments outlined other general themes of conduct and could either help describe an aspect of fidelity or conduct more broadly. Specific questions are posed to assess against each area of conduct and multiple choice classifications are proposed to provide consistency for assessment where possible.
<table>
<thead>
<tr>
<th>Principle of PDSA cycle conduct</th>
<th>Area of PDSA cycle conduct</th>
<th>Assessment</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Documentation</strong></td>
<td>Complete documentation</td>
<td>Which stages of the cycle were documented?</td>
<td>Plan; Do; Study; Act</td>
</tr>
<tr>
<td></td>
<td>Study stage documented in past tense – indicating that the PDSA Cycle was executed</td>
<td>Was the “Study” stage documented in the past tense?</td>
<td>Yes; No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>In what tense were other stages documented?</td>
<td>Past; Future</td>
</tr>
<tr>
<td><strong>Learning Activity</strong></td>
<td>Learning activity presence</td>
<td>Was the cycle describing a learning activity?</td>
<td>Collecting information (no change tested); Testing change; Other</td>
</tr>
<tr>
<td></td>
<td>Learning activity type</td>
<td>What learning activity was the PDSA cycle used to structure?</td>
<td>Collecting information</td>
</tr>
<tr>
<td></td>
<td>Learning activity sub-type</td>
<td>What was the specific learning activity of the cycle?</td>
<td>• Collecting information on: current service; a change being tested; data collection.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Testing/ implementing change:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Simulation change and learning about its potential</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Testing change in practice and learning about: functionality; direct impact; indirect impact</td>
</tr>
<tr>
<td><strong>Prediction</strong></td>
<td>Explicit prediction articulated</td>
<td>Was an explicit prediction articulated?</td>
<td>Yes; No</td>
</tr>
<tr>
<td></td>
<td>Implicit prediction articulated</td>
<td>If no explicit prediction, was an implicit prediction made?</td>
<td>Yes; No</td>
</tr>
<tr>
<td></td>
<td>Positivity of prediction</td>
<td>What was the positivity of the predicted outcome?</td>
<td>Positive; Negative</td>
</tr>
<tr>
<td></td>
<td>Prediction of influencing factors</td>
<td>What type of, if any, influencing factors were predicted?</td>
<td>Facilitator; barrier; none</td>
</tr>
<tr>
<td><strong>Iterative cycles</strong></td>
<td>Cycle within an iterative chain</td>
<td>Was the cycle within an iterative chain of cycles? (i.e. did the “Act” stage of one cycle inform the “Plan” stage of a subsequent cycle)</td>
<td>Within iterative chain of cycles; Isolated cycle</td>
</tr>
<tr>
<td></td>
<td>“Act” stage theme</td>
<td>What was the theme of the “act” stage?</td>
<td>Adopt; Abandon; Adapt (Further changes have already been made; further changes are to be made; and further information is to be collected); Repeat testing with no adaptations; Learning summarised with no explicit actions documented.</td>
</tr>
<tr>
<td></td>
<td>Change in learning activity across a chain</td>
<td>How did learning activity change over an iterative chain of cycles?</td>
<td>(Use Learning activity types)</td>
</tr>
<tr>
<td><strong>Small scale testing</strong></td>
<td>Increasing testing scale</td>
<td>For iterative cycles, did scale size of testing scale increase over cycles?</td>
<td>Yes; No</td>
</tr>
<tr>
<td></td>
<td>Duration of cycle</td>
<td>What was the reported duration of the PDSA cycle?</td>
<td>#</td>
</tr>
<tr>
<td></td>
<td>Size of test</td>
<td>What was the reported size of the test of change or collection of information?</td>
<td>#</td>
</tr>
<tr>
<td></td>
<td>(the number of times a change was tested or the number of subjects the change was tested on/ information was collected from)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Quantity of tests</td>
<td>For cycles testing change, how many changes were tested?</td>
<td>#</td>
</tr>
<tr>
<td><strong>Regular data over time</strong></td>
<td>Regular data used across a chain</td>
<td>For iterative cycles, was a regular data source used over cycles?</td>
<td>Yes; No</td>
</tr>
<tr>
<td></td>
<td>Data source type</td>
<td>What data source was used to inform learning?</td>
<td>Quantitative (identify type); Qualitative (observation, person, group (identify who); no data</td>
</tr>
<tr>
<td></td>
<td>(Quantitative considered as numerical data, qualitative as any non-numerical data)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frequency of data</td>
<td>What was the frequency of data used?</td>
<td># data points/# period of time</td>
</tr>
<tr>
<td></td>
<td>Analysis of data</td>
<td>Was Statistical Process Control (SPC) referenced?</td>
<td>Yes; No</td>
</tr>
</tbody>
</table>

* Fidelity of conduct assessment | Description of conduct assessment

Table 6. Assessment framework for the application, reporting and analysis of Plan-Do-Study-Act cycles
4.3.1. Documentation

Fidelity of documentation was assessed as full documentation of all stages (P, D, S and A) and documentation of the “Study” stage in the past tense. Analysis identified that the tense used for documentation varied across and within stages of cycles. Cycle documentation may have captured the “Study” stages in future tense, referring to plans of what was going to be studied rather than what had been studied (Table 7). If documented in real-time, “Plan” would be documented in future tense, “Do” in past tense following execution, “Study” in past tense and “Act” in future tense. Documenting the “Study” stage in past tense confirms that the “Do” has been executed and studied. If “Study” stages are documented in future tense it suggests that cycles were planned but not executed, executed but not “studied” or documentation was not revised and updated regardless of actions.

<table>
<thead>
<tr>
<th>Plan</th>
<th>To run 4 education sessions over the month on the intervention for new members of the team;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do</td>
<td>Physician and Nurse to show new members how to use the intervention, which patients it applies to and where documentation is kept;</td>
</tr>
<tr>
<td>Study</td>
<td>Look to see if compliance with intervention improves;</td>
</tr>
<tr>
<td>Act</td>
<td>Acknowledge improvement if occurs and review if there is no improvement or deterioration.</td>
</tr>
</tbody>
</table>

Table 7. Example of future tense “Study” documentation – suggesting the cycle was planned but not executed, executed but not “studied” or that documentation was not revisited.

4.3.2. Learning Activity

Learning activity fidelity was assessed as whether an activity to create knowledge was described or not.

Descriptive assessment within the principle indicates the type of learning activity used. Seven classifications were identified, three regarding collecting information and four regarding testing or implementing change. Whilst “collecting information”, “testing change” and “implementing change” were useful to consider when reviewing use of PDSA cycles (Langley et al. 1996), “testing” and “implementing” change were difficult to differentiate between as documentation often did not provide enough detail to do so. As such, the
classifications identified reflect the relationship between the aim of a cycle and the activity to achieve that aim, were identified to provide descriptions of the types of learning activities that occur during PDSA conduct (Table 8) (Further examples are presented in Appendix 3).

<table>
<thead>
<tr>
<th>Learning activity classification</th>
<th>Learning activity sub-classification</th>
<th>Description</th>
<th>Example: Developing and testing “Intervention X”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collecting information (no change tested)</td>
<td>Current service</td>
<td>Collect information on the provision of a current service</td>
<td>Identify number of patients who would be eligible for “Intervention X” in the last year</td>
</tr>
<tr>
<td>An ongoing change</td>
<td>Collect information on a change already being tested</td>
<td>Identify the number of “Intervention Xs” that have been initiated in the last month</td>
<td></td>
</tr>
<tr>
<td>Data collection</td>
<td>Collect information on data collection processes</td>
<td>Examine accuracy of data collection</td>
<td></td>
</tr>
<tr>
<td>Testing Change</td>
<td>Potential suitability of a change</td>
<td>Testing change by simulation: receiving feedback from others prior to testing in healthcare practice</td>
<td>Presenting current version of “Intervention X” at a nursing meeting to receive feedback</td>
</tr>
<tr>
<td>Functionality of a change</td>
<td>Testing a change in healthcare practice and learning about the functionality of the change</td>
<td>Testing “Intervention X” for first time on one ward in one morning and asking staff how it was to use.</td>
<td></td>
</tr>
<tr>
<td>Direct Impact of a change</td>
<td>Testing a change in healthcare practice and learning about the direct impact of the change</td>
<td>Reduce “Intervention X” from two to one side of paper and see if completion rate improves</td>
<td></td>
</tr>
<tr>
<td>Indirect Impact of a change</td>
<td>Testing a change in healthcare practice and learning about its indirect impact</td>
<td>Testing an iteration to “Intervention X” and seeing whether an increase in referrals to a downstream service is observed (assumes completion rate of “Intervention X” has improved)</td>
<td></td>
</tr>
</tbody>
</table>

Table 8. Learning activity classifications, descriptions and examples

A distinction between cycles structuring a test of change was whether testing occurred in “real-life” routine healthcare or whether it was a simulated change. Simulated change is a
change tested by asking individuals or groups for opinions on a potential change or simulating its use in a “dry-run”.

For changes tested in practice, three sub-classifications were identified. The first was learning about the functionality of a change; whether it was usable or applicable in a certain setting. The second was learning about the direct impact of a change; measuring the consequence of a change, or its modification, on an identified outcome. The third was learning about the indirect impact of a change. This could either have been an additional activity to influence the uptake of an original change being tested, or measuring an indirect outcome of a change.

4.3.3. Prediction

Inductive analysis identified both explicit and implicit predictions. To ensure there is a conscious attempt to support learning explicit predictions were included as an assessment of fidelity. Further descriptive assessments of the principle were whether a positive outcome (i.e. predicting the change will have the desired effect) or a negative outcome (predicting the change will not have the desired effect) was predicted, or whether influencing factors were predicted. This latter theme reflects predictions of other factors that would aid the success of a change, a facilitator, or impede it, a barrier.

4.3.4. Iterative cycles

The fidelity assessment for iterative cycles was whether a PDSA cycle was linked within a chain of cycles with each informing another sequentially. Cycles that were neither informed by a past cycle nor informed a future cycle were classified as “isolated” cycles.

Traditionally the “Act” stage has three classifications: adapt, adopt or abandon. Analysis identified the need to expand the “adapt” classification to include: Future PDSA cycles specifically outlined; Further changes have already been made; further changes are to be made; and further information is to be collected (an indication of moving from testing change to collecting information). The new classifications identified were "repeat testing" (if
something prevented the test occurring as planned or more data was needed) and "learning summarised" with no further action indicated.

4.3.5. Incremental scale of testing

Fidelity to incremental scale of testing assesses whether the scale of testing increased over the cycles.

Scale was described either as the sample size of testing (the number of times a change was tested or the number of subjects the change was tested on/ information was collected from), duration of testing or number of different changes tested. As these assessments were on a continuous scale no further classification was necessary.

4.3.6. Regular data over time

Fidelity to regular data over time was defined as a consistent data source used across two or more cycles.

For the descriptive assessments, data was classified as quantitative or qualitative. Different types of data were identified for both. For qualitative this included observations reported by the individual documenting the PDSA, feedback from the improvement team, healthcare staff external to the improvement team (ranging from clinical staff to management), patients receiving care at the time of the cycle, or patient and public representatives.

Quantitative data ranged from measuring aspects of current service provision, measuring the number of times a new change was used, measuring the impact of a change such as a referral to a service, figures regarding patient or staff attendance (including recruitment to research trials) and survey feedback. Frequency of quantitative data included timeframes such as daily, weekly and monthly data but also before and after data or just a single data point after the “do” stage with no preceding comparator data.
4.4. Discussion

4.4.1. Summary

This chapter presents a more specific structured framework to guide the advanced application, reporting and analysis of PDSA cycles and a novel classification system to reflect the variety of ways in which the method is used in practice. It is intended to drive high quality use of the method which in turn will improve the quality of and accelerate learning and the ability to achieve desired improvements. Specifically, it aims to support the conduct of PDSA cycles across three areas:

1. Act as guide to users of the method to conduct PDSA cycles with high fidelity
2. Help educators and supporting programmes to assess the QI ability of an improvement team and to target further education and/ or support
3. Allow evaluations of improvement efforts to assess whether PDSA cycles are used with high fidelity and contribute this assessment to broader evaluation of improvement success, context and process by which a change to practice was made

It is the last point that will inform and support the remainder of this thesis.

This is the first study that has reviewed a large number of PDSA cycles documented in real-time by frontline QI teams across a range of improvement areas. This allowed an in-depth exploration of how PDSA's are documented and applied in practice against key principles of Learning Activity, Prediction, Iterative cycles, Incremental testing scale, Regular data over time and Documentation. Assessments of fidelity are proposed for each principle (Figure 28). Assessments to help describe PDSA cycle conduct are also included. For both, where possible, nominal classifications are identified to aid clear and consistent assessment.
Figure 28. Presentation of updated principles and specific areas of conduct for assessment within them
An important addition from this work is the attention to the tense of documentation and using it as a proxy to determine whether the cycle has actually been completed or not. When using PDSA cycle, and healthcare improvement in general, there may be a tendency to Plan and Do a test of change but never pause to study and act on how it went. (Baxley et al. 2011) In addition to this update of key indicators of fidelity, assessments of the principles are presented in the framework. This is particularly useful for instance such as reviewing the type of data used to drive PDSA cycle conduct: is it regular quantitative data or regular qualitative data?

4.4.2. Implications

This more detailed description of PDSA cycle conduct helps to better classify different aspects of how PDSAs are used in practice. For example, through the identification and classification of the range of learning activities that are structured by the use of PDSA cycles. The language of PDSA is often used interchangeably with the phrase ‘test of change’ and is considered as limited to rapid, small scale tests of change. However, it is evident that the full advanced application of PDSA has potential to be much broader than this. It is the versatility of the method and how it can be adapted from large scale change to small scale local based problem solving (Langley et al. 1996) that is both part of its appeal and part of challenge in using it. The updated framework presented shines a light on the detailed aspects of this versatility.

All the principles, assessments and classifications proposed in this framework can help with the prospective planning and application of PDSA cycles and will benefit those aiming to advance the use and teaching of PDSA cycles. Further, this framework will support the evaluation of use of PDSA cycles, either formatively to drive improvement in the quality with which PDSA cycles are applied, or summative to assess the extent and nature of how PDSAs were deployed in a particular initiative (explored in next chapter).

One key benefit of the PDSA cycle method is it accessibility to all users. As a beginner or expert in QI, it is a useful concept to loosely frame any learning or improvement. The
pragmatic elements of the PDSA cycle method ensure individuals and groups are able to tackle their local problems in a manner that fits their need. This freedom comes through the selection of a change or data collection mechanism, interpretation of data, and decision on subsequent actions and is informed by the learning achieved from the PDSA cycles as well as subject matter expertise. (Parry 2014) This conceptual and pragmatic use should not be discouraged; however, it should occur with adherence to the basic scientific principles, the fidelity, of the method which is distinguished by this framework.

As well as articulating the basic scientific principles associated with the PDSA method this framework recognises the flexibility the method allows users when pursuing improvement. Understanding the nature of these variations is critical to mastering the use of PDSA. For instance, the different types of learning activity, ranging from collecting information to simulation of a change to testing changes in practice, reflect the diverse nature of tasks required to inform improvement efforts. Combining the different types of learning activity with the different scales of study and rigour of data collection reflect the pragmatic nature of the PDSA method; aiming to accelerate learning by ascertaining areas for improvement as soon as possible.

Key to the ability to learn from the use of PDSA is the quality with which they are documented. Documentation is an essential component of scientific rigour. High quality documentation of PDSAs should be the equivalent of the diligent maintenance of a lab book in the basic sciences. Documentation provides clarity of thinking for individuals or teams conducting an experiment and allows others to learn from previous experiments and ultimately meta-analysis to be undertaken to support the production of generalizable knowledge. All components of this PDSA conduct framework should inform the quality with which PDSAs are applied and their content documented.

4.4.3. Limitations and Future research

This framework provides a useful foundation for future research into the use of the PDSA method in practice. Evaluation of improvement work in which PDSA cycles are used often
treat its conduct at face value; stating the method is used but with little further detail on how it is used. (Benning et al. 2011a; Power et al. 2014; Knight, Ford, et al. 2012) The literature shows that little attempt has been made to explore the actual conduct of the PDSA cycles. (Ting et al. 2009) It provides a granular level of detail pertaining to the methods conduct; enabling the identification of areas for improvement in PDSA cycle conduct and providing a platform to contribute to broader evaluations of improvement initiative success. (Walshe 2009; Rungtusanatham et al. 2003)

Reviewing documentation offers a practical approach for improvement teams, educators and researchers to “open the black box” of PDSA cycle conduct. (Grol et al. 2002) Developing this framework from reviewing documented PDSAs as opposed to observation in practice is a limiting factor in proposing all relevant classifications and considerations for use and documentation of PDSA, however. Whilst reviewing improvement team documentation offers a more instantaneous and realistic account of conduct in comparison to limited details reported in peer-review publications, it remains dependent on documentation and is subject to documentation bias. Implicit intentions and any actions decided upon after documentation are also missed. With this in mind, future users of the framework are encouraged to add to and expand the proposed classifications.

In addition, prospective qualitative studies, described for other QI methods, (Waring & Bishop 2010; Nembhard 2009; Chakrabarty & Chuan 2013) would be useful to determine the reality of using the PDSA cycle method, the benefits it delivers and the challenges to achieving high fidelity conduct. These studies can use the framework proposed in this paper to shape investigations and also consider the social and contextual features that influence conduct (Chapter 6 and 7 follow this research enquiry). (Berwick 1998; Walley & Gowland 2004; Parand et al. 2010; Lipshutz et al. 2008)

4.5. Conclusion

In the complex nature of healthcare, PDSA cycles support teams to act pragmatically and scientifically to learn, make change and pursue improvement in patient care. The ability to
assess the fidelity of PDSA cycles is necessary to drive scientific standards of the method’s conduct, support further exploration in the reality of using the method and consider effectiveness. This study presents an approach to achieve this and in doing so calls for an increased focus on applying, reporting and analysing key principles of the method.

4.6. Contribution to overall thesis

This chapter presents a key output from this thesis, a framework to assess the conduct of PDSA cycles.

The framework produced within this chapter provides a mechanism to conduct the research called for by the third category identified in Chapter 2: study of the use of QI methods to facilitate change and improvement. It does so by including assessments of fidelity for each principle of the method, to determine whether the method is applied scientifically, as well as further assessments to help describe PDSA cycle conduct more generally.

The framework provides a more systematic approach for others to conduct a similar review to that conducted in Chapter 3. By encouraging further assessment of fidelity of PDSA cycles in raises the profile of the method as a scientific approach to improvement and encourages others to use as such.

Chapter 5 will apply the framework quantitatively to the same cohort of QI teams’ documentation of the method to investigate any changes in fidelity over time. In addition it will qualitatively explore contextual factors that may have influenced any change.

Chapter 6 and 7 do not seek to directly apply the framework to quantify fidelity but instead use the content within it to guide thematic analysis within research studies into the perceptions and reality of using the method.
5. Chapter 5 - Investigating the change in PDSA cycles fidelity and influencing factors

Chapter overview – This chapter presents a study to assess PDSA cycles conducted across a range of QI projects and teams. It seeks to determine change in fidelity over time and investigates factors that may have influenced this. Data analysis was conducted by two reviewers: myself (CM) and research programme colleague, Laura Lennox (LL).

5.1. Introduction

Chapters 3 and 4 presented the development and application of a novel framework to review the fidelity of PDSA cycles; a method considered central to acting scientifically in healthcare improvement. By applying the framework to academic publications reporting the use of PDSA cycles, Chapter 3 revealed that fidelity of conduct was low. Subsequently, in the Chapter 4, the clarity and detail of the framework to assess conduct of PDSA cycles was developed further. This provides the ability to review the degree and extent of QI team’s documented conduct of PDSA cycles to gain a detailed assessment of their fidelity and a description of use.

This chapter investigates the fidelity of PDSA cycles documented directly by front-line local improvement teams. It assesses the change in PDSA cycle fidelity over time and investigates the factors that may have influenced any change in fidelity including the associated approaches of an overarching QI collaborative support team to implement and improve the use of the method.

5.1.1. Application of QI methods in healthcare

To advance the science of improvement, greater attention must be paid to the “black box” of improvement efforts. (Grol et al. 2002; Düékers et al. 2009) This refers not only to understanding the outcome of an improvement effort and the change made to a system or
process to cause this, but also the use of QI methods to support facilitate change and improvement.

Derived from manufacturing industries, and now commonly used in healthcare, QI methods provide approaches for teams to develop and deploy interventions aimed at delivering improvement. Previous healthcare research has, however, demonstrated low levels of engagement with the methods (Davies et al. 2006; Parand et al. 2010; Waring & Bishop 2010; Audet et al. 2005; Dixon-Woods et al. 2012) and low fidelity against key principles of their use (Chapter 2) (Taylor et al. 2014; Waring & Bishop 2010; Riley et al. 2009) This suggests that the full benefits of these methods may not have been realised.

The use of QI methods has been proposed to be influenced by the way in which they are introduced and taught to the teams using them (the implementation of the QI methods) and the surrounding context in which their use occurs. (Bate et al. 2002) These factors presented by Bate et al have been reinforced in a recent systematic review of the use of “QI collaboratives”. (Nadeem et al. 2013) To use QI methods more effectively the relationship between fidelity, the surrounding context, and the implementation process of using the method must be better understood. (Bate et al. 2002)

To date no studies have been conducted to assess factors that may influence the fidelity of PDSA cycle method use. (Ting et al. 2009) Understanding the contextual factors that influence the fidelity of PDSA cycle conduct can help inform future conduct, future support and education on the method, and ultimately achieving desired improvements in healthcare. (Walshe & Freeman 2002)

5.1.2. **Aim of study**

The study follows three lines of inquiry to determine whether the fidelity of PDSA cycles conducted by range of QI projects improved over time and the factors that influenced any change:
• What was the fidelity of conduct of all PDSA cycles against core principles of the method?
• How did PDSA cycle fidelity change over time?
• How did the QI method implementation process and context influence change in fidelity of PDSA cycles over time?

These questions are addressed by first applying the framework developed in Chapter 4. Change in fidelity over time is then investigated as well as the deliberate actions taken by a QI support team to influence context and improve fidelity. To achieve this, the NIHR CLAHRC for NWL programme is revisited.

To frame this study, further detail in regards to the role of a QI support team and the broader role of context in QI is discussed below.

5.1.3. Role of a QI support team - QI method implementation process

To introduce and support the use of QI methods, overarching QI support teams are often put in place to provide education, facilitation and feedback to QI project teams. One commonly used in healthcare is a ‘QI collaborative’ where a central team supports multiple project teams and community of improvement is developed. (Nadeem et al. 2013) The calls to open the “black box” of improvement applies to the functioning of these support teams, as well as the functioning of any improvement intervention. (Grol et al. 2002; Dückers et al. 2009) From a theoretical perspective, QI support teams have been proposed to directly impact the use of the method and also provide a supportive context in which QI efforts can be carried out. (Bate et al. 2002) Further understanding of how their role is necessary however. (Nadeem et al. 2013)

The challenges that QI support teams face in engaging people in QI and the use of the methods in healthcare are well documented. (Davies et al. 2006; Parand et al. 2010; Waring & Bishop 2010; Audet et al. 2005; Dixon-Woods et al. 2012; Bate et al. 2002) Factors influencing this include: limited knowledge and understanding of the concepts and methods, time constraints in conducting QI efforts, scepticism towards the effectiveness of QI methods
including beliefs that efforts will be ineffective, a waste of resource and even detrimental to quality of care, and beliefs that high quality care is already being provided. (Davies et al. 2006) This can beaccentuated when the use of QI methods is new. (Benning et al. 2011a)

5.1.4. Influence of context in Quality Improvement

The challenges that a QI support team may face are linked with the context in which an improvement effort takes place, which also plays pivotal role in success more broadly. (Kaplan et al. 2010; Bate et al. 2002) Improvement initiatives in healthcare rarely act in a controlled environment. Contextual factors are therefore a variable that will influence success. From an delivery perspective, improvement initiatives must be receptive of context; learning and taking iterative actions in light of the local environment. (Greenhalgh et al. 2004)

From a research perspective, evaluations cannot only examine whether improvement initiatives were successful or not, but instead, aim to understand why, when, and where they work most effectively; the influence of context. (Walshe 2007)

An increasing amount of research has focused on the influence of the context in QI, and, as such, a more detailed overview is provided here. (Robert & Fulop 2014; The Health Foundation 2014d; Kaplan et al. 2012) There have been increasing calls for further research into the influence of context in quality improvement (The Health Foundation 2014d; Øvretveit 2011; Dixon-Woods et al. 2012; McDonald 2013) including a recent report from the Health Foundation. (The Health Foundation 2014d) In the report, leading authors in the field outline the challenge of understanding context including the need to define aspects of context better and understand their impact on delivering improvements in healthcare. The report argues that “more research should steadily help clarify what context factors help in the success and spread of innovations and service improvements”.

To do so, it is helpful to revisit the interdependent nature of factors that influence improvement success (Figure 7, page 36). In relation to QI methods, and this study, it is useful to distinguish the influence of context from two perspectives. Firstly, that context can influence a QI intervention made to a system or process delivering an outcome; for example,
how local practices influence the uptake of an intervention. Secondly, context can influence the use of QI methods. These were both discussed in Chapter 1 which displayed the role of context in the implementation of an intervention and the use of QI methods.

5.2. Context influence on an QI intervention

From the broad healthcare improvement perspective, context can be considered as anything that is not directly part of the change to a healthcare delivery or the specific approach by which this change was developed and deployed. (Kaplan et al. 2010) It can be categorised into different influencing factors crossing macro, meso and micro levels. These include political factors, organisational factors, team and individual traits and capabilities, and factors relating to the specific system or process in question. (Øvretveit 2011; Damschroder et al. 2009; McCormack et al. 2002; Schouten et al. 2008; Kaplan et al. 2010; Robert & Fulop 2014)

Based on a systematic review and subsequent Delphi exercise, the Model for Understanding Success in Quality (MUSIQ) (Kaplan et al. 2011) identifies a range of contextual factors influencing the success of a QI intervention (Figure 29). The factors cover the microsystem in which an improvement effort takes place, the specific team responsible for the improvement effort, the support and capacity provided by organisation to conduct improvement efforts and other macrosystem organisational factors.
Figure 29. Model for Understanding Success In Quality (Kaplan et al. 2011)
5.3. Influence of contextual factors on PDSA cycle use

With a view to support better the use of QI methods, this study takes a more specific focus on the role of context; viewing its influence on the use of PDSA cycles. Calls have been made for an increase in theoretical and empirical attention to how contextual factors influence the conduct of QI methods, such as Plan-Do-Study-Act (PDSA) Cycles (Ting et al. 2009; Reed & Card 2015), Statistical Process Control (Thor et al. 2007) and Lean (Waring & Bishop 2010; Joosten et al. 2009). Further developing an understanding of the relationship between context and QI method conduct will inform how high quality application can be achieved. (Walshe 2009)

Whilst empirical studies may have not directly considered the influence of context on the fidelity of PDSA cycles, previous suggestions that contextual factors influence QI or principles of PDSA cycle use can be identified from other studies. Below is an outline of such factors, grouped into three areas, which are suggested to influence PDSA cycle conduct:

Organisational capacity and capability for improvement

Firstly, the organisational capacity and capability for improvement is suggested to influence the fidelity of PDSA cycle conduct. Many studies have discussed the influence of different technical and social contextual factors inherent to an organisation that impact improvement initiatives using the PDSA cycle method. Many of these align with the factors outlined in MUSIQ framework. They include the data infrastructure to inform and monitor improvement, leadership attributes of those involved, specific training provided by organisations and the maturity and past experience in conducting improvement work. (Lundberg & Boonprasabhai 2001; Vos et al. 2010; Benning et al. 2011a; Kilo et al. 1998; Benn et al. 2009; Parand et al. 2010)

MUSIQ outlines how contextual factors influence one another and how they influence system and process change and overall improvement outcomes. Whilst it does not directly represent how context influences on QI methods fidelity, in this case PDSA cycles, factors
such as “QI skill”, “prior QI experience”, “QI workforce” are outlined which implicate an impact on PDSA cycle conduct. “QI skill”, defined as “Team’s ability to use improvement methods to make changes” directly links to fidelity of a QI method but does not represent the actual fidelity, rather the ability to use the methods.

Initial exploratory analysis of the MUSIQ model has assessed the strength of the hypothesised contextual relationships by evaluating improvement team member’s perception of the different factors and overall success. (Kaplan et al. 2011) This preliminary validation demonstrated that most factors were related to at least one perceived QI success factor. The improvement team’s and microsystem’s QI capability was amongst a group of six factors that showed significant effects on two measures of QI success.

**Socio-cultural attitudes towards QI methods (including choice whether to use)**

Secondly, socio-cultural attitudes towards QI methods are suggested to influence PDSA cycle use. Experience and training in improvement initiatives not only influence the ability to use QI methods but also the attitude towards using them. Individual’s perceptions and wider professional and organisational traits in healthcare means that choosing to conduct PDSA cycles, and to the discussed quality, can often be counter-cultural to users. (Berwick 1998; Dixon-Woods et al. 2009) With experience and education in other fields of science, conducting QI can represent a new way of thinking for healthcare professionals and is a potential barrier to the use of the methods. (Batalden & Davidoff 2007; Davies et al. 2006) Potential issues that could hinder the use of the PDSA method in healthcare include (Berwick 1998):

- Being perceived as insufficiently rigorous In comparison to traditional large sample sizes and randomized trial design approaches;
- Constraining attitude towards failure, not seeing the benefit of learning from not succeeding on first attempt;
- Perceived lack of time, energy or resources to conduct the cycles;
- Ethical issues with “testing changes” in routine care.
Finally, in addition to specific factors of the organisations and individuals, the complex nature of healthcare may influence PDSA cycle fidelity. The process of making change requires the consideration of social interactions and team’s attitudes, behaviours, and cognitions. (Weaver et al. 2010) PDSA cycles and the changes they introduce are dependent on communication and knowledge transfer within and between different settings. However, due to the often fragmented nature of healthcare, with poor channels of communication between wards, departments and organisations, knowledge transfer is often complicated. In addition to these organisational complexities, many different professional groups who belong to different communities of practice and learn and make sense of knowledge in different ways are involved in improvement (Wenger 2000), adding another layer of complexity to the social team learning process and communication of change. (Anderson et al. 2012) Furthermore, the traditional hierarchical nature of healthcare systems may mean that staff feel disempowered to make changes in their local setting. It may be difficult for individuals to raise concerns, share ideas for improvement or to test changes in practice.
5.4. Method

5.4.1. Values

This study takes the critical realist view (Colin 2002) taken so far in this thesis further by deliberately attempting to understand why we may observe a certain level, or change in level, of fidelity. It continue to recognises that observations are fallible and theory is revisable (Colin 2002), however attempts to further the theory in regards to PDSA cycle conduct; particular how a QI support team and other contextual factors may influence this.

5.4.2. Sample - National Institute of Health Research (NIHR) Collaboration for Leadership in Applied Heath Research and Care (CLAHRC) Northwest London (NWL)

Tasked with accelerating the translation of evidence into practice, the CLAHRC NWL programme supports a range of QI project teams consisting of frontline NHS teams, patients and academics to improve the quality of healthcare through the delivery of research evidence into practice. (Howe et al. 2013; Doyle et al. 2013) Using a QI collaborative structure, project teams are supported by a central team within the programme to use a suite of QI methods, including PDSA cycles.

Team size ranged between 5-20 people and included multidisciplinary healthcare staff, patients and public representatives and academics. Team membership varied, but typically included a clinical lead (usually a medical consultant or general practitioner (GP)), a project manager, an executive sponsor (usually someone working at or near Board level) and frontline staff delivering care in that clinical area.

Three rounds of 18 months long projects were supported during the first five years of the CLAHRC NWL programme (2008-2013) (Figure 30). The first round started in April 2009 with two further annual rounds. (NIHR CLAHRC for NWL 2013) The initiation of projects in annual rounds aimed to provide the CLAHRC NWL programme the ability to be receptive to change including local health needs, political direction or the availability of new evidence. It further provided a mechanism for the education and support for QI provided by the CLAHRC.
NWL core team to develop iteratively informed by an inbuilt programme of evaluation, hereafter referred to as “QI support”.

Figure 30. “Round” project initiation approach of NIHR CLAHRC NWL for NWL

Over the three rounds of funding, 39 project teams were initiated. Each project documented their use of PDSA cycles of an online tool, the Web Improvement Support for Healthcare system. (Curcin et al. 2014) A total of 421 PDSA cycles were documented and are included in the study.

5.4.3. Data collection and analysis

A mix-methods approach was taken to investigate the research questions.

What was the fidelity of conduct of all PDSA cycles against core principles of the method?

The framework developed in the previous chapter, outlining six key principles of PDSA cycle use (Documentation, Learning activity, Prediction, Iterative cycles, Incremental testing scale and Regular data overtime), was used (Table 6, Page 104). (Taylor et al. 2014) The framework contains measures to assess the fidelity of conduct against the principles and also measures to help describe conduct more generally. The documented PDSA cycles of
the CLAHRC NWL project teams were assessed by deductive content analysis against this framework. (Krippendorff 2004; Weber 1990) The summative output identified counts of adherence for all principles regardless of project initiation year.

Two reviewers (CM and LL) first coded a third of the 421 cycles against the principles in Microsoft Excel. Intercoder reliability, as indicated by Cohen’s Kappa, ranged between 1 and 0.77 with percentage agreement between 100% and 82%. Discrepancies were resolved by discussion and consensus and a shared understanding was developed. The remainder of cycles were then coded by 1 reviewer (CM).

How did PDSA cycle fidelity change over time?

The quantitative outputs for the measures of fidelity from the first stage of analysis were divided by the year the project teams were initiated (Table 9). A one-way ANOVA and post-hoc t-tests were firstly used to determine change in the mean number of PDSA cycles conducted per project overtime.

Secondly, each variable was arranged in a dichotomous manner in relation to fidelity; whether the principle was adhered to or not. Only fidelity measures were assessed over time. Using a Chi-square test and a subsequent trend test, the Marascuilo procedure, the observed adherence to each measure was compared to the expected adherence based on the proportion of projects teams initiated in each year. (Levine et al. 1999)

<table>
<thead>
<tr>
<th>Principle</th>
<th>Measure assessment (Yes/ No)</th>
<th>PDSA cycles included in analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documentation</td>
<td>Were all cycle stages of the PDSA cycle documented?</td>
<td>All initiated PDSA cycles (PDSA cycles with a documented “Plan”)</td>
</tr>
<tr>
<td></td>
<td>Was the “Study” stage documented in the past tense (indicating that the PDSA Cycle was executing)?</td>
<td>All fully documented PDSA cycles</td>
</tr>
<tr>
<td>Learning Activity</td>
<td>Was the PDSA cycle use to structure a learning Activity (Cycle documenting a test of change or collection of information)?</td>
<td>All fully documented PDSA cycles</td>
</tr>
<tr>
<td>Prediction</td>
<td>Was an explicit prediction documented?</td>
<td>All fully documented PDSA cycles describing a learning activity</td>
</tr>
</tbody>
</table>
Iterative cycles | Was the PDSA cycle within an iterative chain of PDSA cycles? | All fully documented PDSA cycles within an iterative chain of PDSA cycles
---|---|---
Incremental testing scale | Was the PDSA cycle within an iterative chain of PDSA cycles increasing scale? | All fully documented PDSA cycles within an iterative chain of PDSA cycles
Use of data over time | Was the PDSA cycle within an iterative chain of PDSA cycles using regular data over time? | All fully documented PDSA cycles within an iterative chain of PDSA cycles

Table 9. PDSA cycle measures of fidelity

**Chi-Square**

Pearson’s Chi-square test for independence evaluates how likely it is that any observed differences between categorical data sets arose by chance. (Levine et al. 1999) It is used in this case to determine change in fidelity between PDSA cycles documented by improvement teams of the three rounds.

Chi-square tests the null hypothesis and indicates whether it can be rejected or not. If it is rejected it indicates that observed differences between the fidelity of PDSA cycles across Rounds is not due to chance. In this study the Null hypothesis, across any principle reflecting an aspect of PDSA cycle conduct fidelity, was that the fidelity of PDSA cycle principles is the same across each Round of projects.

Observed data for each principle was compared to the expected distribution. In this case, for the PDSA cycle principles reviewed, Chi-square tested the observed distribution figures across Rounds of projects against the expected distribution as indicated by the number of PDSA cycles based on the sample and the distribution of PDSA cycles between each Round.

*Marascuillo procedure*

Whilst rejecting the null hypothesis using Chi-square indicates that the differences between Rounds are unlikely to be due to chance, it does not indicate between which Rounds there are the significant differences. The Marascuillo procedure, a multiple comparisons test, was used to determine these trends. (Levine et al. 1999) The Marascuillo procedure allows
comparisons between all pairs of groups. If the null hypothesis is rejected for a variable the procedure was used to determine between which Round any difference is significant.

**What contextual factors influenced change in fidelity of PDSA cycles over time?**

Retrospective qualitative data collection and analysis, was conducted to gain insight into what changes were made by the QI support team to support PDSA cycle conduct over time.

Training materials on QI methods and formal project review documentation were retrieved from across each Round. In total, training material from 20 events teaching or referring to PDSA cycles and 182 project review documents (reports and minutes where available) were assessed (number of documents review per Round: R1=11, R2=80, R3=89). Each project completed two to three formal project reviews which involved submitting a report and attending a meeting with CLAHRC NWL support team to discuss the report and progress of the project. Each review included exploration of the experiences of using the QI methods, including PDSA cycles.

Interviews with three CLAHRC NWL QI support team members were also conducted. Interviewees were pragmatically selected for their direct involvement in supporting project teams to use QI methods, including PDSA cycles, and responsibility for the CLAHRC NWL programme development across all three Rounds of project funding including training material development. The interviewees were not aware of the outcome of the fidelity assessment or the statistical analysis. They were, however, provided copies of the PDSA cycle training sessions delivered to projects across the three rounds prior to and during the interview as a prompt to support reflection on what changes had been made and the rationale for doing so.

Audio recordings of interviews were transcribed and analysed using Nvivo (Version 10) software. A thematic inductive analysis using the constant comparative method was conducted for all data sources to provide a bottom-up approach to identify potential
contextual themes influencing PDSA cycle conduct. Whilst contextual factors have been articulated in terms of improvement success and conduct of QI methods, their direct influence on PDSA cycle fidelity has not been investigated. This inductive analytical approach was therefore used due to the exploratory nature of the study. The primary goal was to provide a thematic descriptive account of the changes in contextual factors relating to the conduct of PDSA cycles over a specified period of time and context.

The analysis of training presentations and interview transcripts started with detailed open-coding of each line of text along with code definitions. These were grouped to high level categories before further conceptualisation within each category. Coders (CM and LL) met to discuss and refine coding in an iterative manner. Analysis of project review documentation followed the same process, however, a pragmatic step preceded it of identifying and grouping reference to PDSA cycles, the Model for Improvement or testing of change.
5.5. Results

5.5.1. Overall PDSA cycles conduct

_PDSA cycle initiation over time_

The mean number of PDSA cycles per project increased over the Rounds (Table 10). Of the 421 PDSA cycles retrieved from the CLAHRC NWL WISH tool, 30 were documented by Round 1 projects, 144 by Round 2 and 247 by Round 3. A one-way ANOVA indicated that the null hypothesis that all means are equal across Rounds can be rejected and that the differences were not due to chance (F(2,36)=4.64, p<.05).

<table>
<thead>
<tr>
<th>Groups</th>
<th>Number of projects</th>
<th>Number of PDSA cycles</th>
<th>Mean number of cycles per project</th>
<th>Variance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Round 1</td>
<td>6</td>
<td>30</td>
<td>5</td>
<td>34</td>
</tr>
<tr>
<td>Round 2</td>
<td>16</td>
<td>144</td>
<td>9</td>
<td>27.3</td>
</tr>
<tr>
<td>Round 3</td>
<td>17</td>
<td>247</td>
<td>14.5</td>
<td>82.6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Source of Variation</th>
<th>SS</th>
<th>df</th>
<th>MS</th>
<th>F</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between Groups</td>
<td>490.1</td>
<td>2</td>
<td>245.1</td>
<td>4.6</td>
<td>0.016</td>
</tr>
<tr>
<td>Within Groups</td>
<td>1902.2</td>
<td>36</td>
<td>52.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>2392.4</td>
<td>38</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SS, sum of squares; df, degrees of freedom; MS, mean square; F denotes the F statistic used with Anovas

**Table 10. PDSA cycles initiated by CLAHRC NWL project teams**

Post-hoc t-tests were conducted following F-tests for two-sample variance. The F-tests indicate the type of t-test to be used and demonstrated variances were equal between Round 1 and 2 and unequal between Round 1 and 3 and Round 2 and 3. The appropriate two-sample t-test was therefore conducted. These demonstrated significant differences between Round 3 and both preceding Rounds. Differences between Round 1 and 2 were not significant; however, there was an increasing trend of PDSA cycle initiation across all three rounds (Figure 31).
Overall, only 2% (7/421) of PDSA cycles reviewed adhered to all six measures of fidelity outlined in the framework.

Increases in fidelity against individual principles of PDSA cycle conduct were seen across Rounds except learning activity presence which was high across all Rounds (Table 11 and Table 12) (Additional results are presented in Appendix 4). Significant increases were seen for documentation (All PDSA cycle stages documented, \( p<0.001 \); “Study” documented in past tense, \( p<0.001 \)), predictions (Explicit Prediction documented, \( p=0.001 \)) and iterative cycles (PDSA cycle within iterative chain of cycles, \( p<0.001 \)). Increases were seen for incremental scale and use of regular data over time but this finding was not statistically significant. The seven cycles adhering to all indicators of fidelity were all from the final round projects. Due to the high level of learning activities observed, and the central role of testing change when using PDSA cycles, post-hoc analysis was conducted to investigate the type of learning activity, a descriptive measure, statistically.
<table>
<thead>
<tr>
<th>Principle</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall conduct</td>
<td>60% (253/421) of cycles had all stages documented and the “study” stage documented in the past tense. This was made up by 71.0% (299/421) of PDSA cycles fully documented and, of these, 84.6% with the study stage documented in past tense, indicating the cycle had been executed.</td>
</tr>
<tr>
<td>Change over time</td>
<td>Compliance with both aspects of documentation fidelity increased continuously across all three rounds. Full documentation was significantly better in Round 3 compared to Round 1 and 2. Past tense study documentation displayed significant improvements between Round 2 and 3.</td>
</tr>
<tr>
<td>Overall conduct</td>
<td>The vast majority of cycles were used to describe a learning activity (98.3% (294/299)). A small number of cycles had no explicit intention to set out on a process of learning; instead they were used to capture a specific task without measurement or reflection. Just over two thirds of learning activities were seeking to test change (70.1% (206/294)), the remainder framed learning by collecting information without testing change (29.9% (98/294)).</td>
</tr>
<tr>
<td>Change over time</td>
<td>The presence of learning activities was consistent across all Rounds. For type of learning activity, Round 2 saw significantly lower proportion of cycles testing change in comparison to collecting information than Round 1 and 3. No significant difference was noted between Round 1 and 3.</td>
</tr>
<tr>
<td>Overall conduct</td>
<td>The use of explicit predictions was low across all rounds with only 12.2% (36/294) of cycles displaying this.</td>
</tr>
<tr>
<td>Change over time</td>
<td>Predictions increased across the Rounds with significant difference in Round 3 compared to 1 and 2.</td>
</tr>
<tr>
<td>Overall conduct</td>
<td>54.5% (163/299) of all cycles were documented in series of linked cycles. In total, 64 separate iterative chains were identified (one chain represents one series of linked PDSA cycles). Whilst approximately a third of chains only documented tests of change, the remainder demonstrated a variety of transitions between different learning activities with no clear tendency for a particular transition.</td>
</tr>
<tr>
<td>Change over time</td>
<td>No iterative cycles were observed in Round 1, there was therefore a significant increase in comparison to both Round 2 and 3. Whilst an increase was seen between Round 2 and 3, it was not significant.</td>
</tr>
<tr>
<td>Overall conduct</td>
<td>33.1% (54/299) of all cycles were part of an iterative chain displaying an incremental testing scale. Of the chains of PDSAs that did increase scale, only two increased the scale of changes tested in practice. A further seven cycles moved from simulation testing to testing in practice and two from testing a single change to testing multiple changes. The remainder displayed increasing durations as documented by the date field of the documentation form, however, these cycles did not document that this increase in scale was an explicit intention.</td>
</tr>
<tr>
<td>Change over time</td>
<td>Whilst there was a slight increase, there was no significant change across Round 2 and 3 for incremental testing scale variables.</td>
</tr>
<tr>
<td>Overall conduct</td>
<td>13% (38/299) of cycles reported the use of both quantitative and qualitative data, 23% (69/299) quantitative only and 62% (184/299) qualitative only. The cycles that did not use any data were documented in the future tense and did not reference data or were not structuring a learning activity. For those cycles that did use qualitative data the majority used the observations of the individual documenting the PDSA. 30.1% (98/299) of all cycles were part of an iterative chain using regular data over time. 13% (8/64) of iterative chains of cycles reported the use of both regular quantitative and qualitative data over time. 30% (19/64) used regular qualitative data over time and 13% (8/64) used regular quantitative data over time. No reference to statistical process control was made within documentation (However, automated SPC run charts were available on the online documentation system)</td>
</tr>
<tr>
<td>Change over time</td>
<td>Whilst there was a slight increase in use of data over time, no significant difference was observed.</td>
</tr>
</tbody>
</table>

Table 11. Descriptive overview of change in PDSA Cycle conduct
<table>
<thead>
<tr>
<th>Principle</th>
<th>Measure</th>
<th>Observed data</th>
<th>Chi-Square test</th>
<th>Marascuilo Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>DoF</td>
<td>Sample size</td>
</tr>
<tr>
<td>Cycles adhering to principle</td>
<td></td>
<td></td>
<td>2</td>
<td>421</td>
</tr>
<tr>
<td>Cycle Sample</td>
<td></td>
<td></td>
<td>2</td>
<td>299</td>
</tr>
<tr>
<td>%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cycles adhering to principle</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cycle Sample</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>%</td>
<td></td>
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</tr>
<tr>
<td>Cycles adhering to principle</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Cycle Sample</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Cycles adhering to principle</td>
<td></td>
<td></td>
<td>2</td>
<td>294</td>
</tr>
<tr>
<td>Total Cycle Sample</td>
<td></td>
<td></td>
<td>2</td>
<td>294</td>
</tr>
<tr>
<td>% Cycles adhering to principle</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Documentation: All PDSA cycle stages documented

Cycles adhering to principle
Cycle Sample
%

Learning Activity present
Cycles adhering to principle
Cycle Sample
%

Testing change (vs collecting information)
Total Cycles adhering to principle
Total Cycle Sample
% Cycles adhering to principle

Note: N.A* indicates that the data is not applicable or not available.
### Table 12. Change in measures of PDSA Cycle fidelity over Round of project initiation (The table depicts three areas of results: 1) The observed data over all and each individual Round, the total cycle sample and a percentage. 2) Results from Chi-Square tests. 3) Results from Marascuillo procedure)

<table>
<thead>
<tr>
<th>Prediction</th>
<th>Cycles adhering to principle</th>
<th>Cycle Sample</th>
<th>%</th>
<th>R1-R2</th>
<th>R1-R3</th>
<th>R2-R3</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predetermined</td>
<td>0 3 33 36 100%</td>
<td>15 90 189 294</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Cycles within</td>
<td>0 48 115 163 100%</td>
<td>15 93 191 299</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>PDSA chain</td>
<td>N.A 3 16 19 100%</td>
<td>N.A 19 45 64</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increasing testing</td>
<td>N.A 3 16 19 100%</td>
<td>N.A 19 45 64</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small scale testing</td>
<td>N.A 3 16 19 100%</td>
<td>N.A 19 45 64</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of Data overtime</td>
<td>N.A 3 16 19 100%</td>
<td>N.A 19 45 64</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*As a predeterminant to running the test, Chi square test requires 80% of the expected frequencies to exceed 5 data items, in this case 5 PDSA cycles. This was the case for all categories in question except “Learning activity presence”. Frequencies were high across all Rounds and therefore the expected frequency of not having a learning activity present did not exceed 5 PDSA cycles.

**Increasing scale of testing and use of data over time categories were dependent on iterative cycles. As no iterative chains were present in Round 1 comparisons within the categories were made using Chi-square for only Round 2 and 3.
5.5.2. Change in context over time

Thematic analysis of project documentation, training materials and interviewees identified three areas by which PDSA cycle fidelity was influenced by the context of the project team: QI projects’ understanding of how to use the method, their intention to use the method and the process of application by which they went about using the method. Each area presented different barriers to the use of PDSA cycles. The improvements in fidelity of PDSA cycle conduct over rounds suggest that the CLAHRC NWL QI support team were able to positively influence these areas of context, although there were still a number of barriers remaining as indicated by the overall low fidelity.

Understanding referred to capability to use the methods and includes both knowledge of the concept of the method but also the specific principles that guide its conduct. Intention to use the method referred to whether the teams were engaged with using PDSA cycles to support their pursuit of improvement and whether they planned to use it. Understanding and intention were distinct factors but interlinked in a number of ways. Some teams may have had little intention to use the method as they did not understand it, some may have understood the method and consciously intended not to use it, and some may have intended to use but had insufficient understanding to use with high fidelity. Application of use referred to the approaches by which teams went about using the method. These could either be social processes, such as how a team is brought together to discuss its use, or the use of technology to support conduct, such as automated use of data.

Table 13 presents the barriers found in using PDSA cycles in relation to the three identified areas and is split between factors related to the QI team and factors related to the initial QI support. They are not assigned to a specific Round, however, as factors were not necessarily discrete to one or another. The strategies taken by the QI support team in light of these challenges are also presented.
Contextual barriers to PDSA cycle conduct

<table>
<thead>
<tr>
<th>QI team factors</th>
<th>Original QI support strategies</th>
<th>New QI support strategies developed in response to challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understanding of purpose of PDSA: QI methods were new to many team members. Many did not understand the appropriateness of the method. Regular data collection and analysis to inform adaptations of an intervention were viewed as contradictory to traditional before and after research designs with fixed study protocols.</td>
<td>Personnel - External experts used for training sessions: External experts provided initial training but no ongoing support. The CLAHRC QI support team had little or no practical experience in PDSA.</td>
<td>Personnel - Investment in QI support team: Recognition of importance of internal QI support staff and greater training and support for them</td>
</tr>
<tr>
<td>Understanding of principles of method: Where there was an understanding of the basic concept of PDSA, there was little awareness and understanding of the more details elements of the methods use such as what the specific stages required and that multiple linked cycles should be used to adapt a change. Teams did not consciously link project data and PDSA cycles.</td>
<td>Style - Assumption that PDSA cycles were “easy” to understand: Implicit assumption that teams would quickly understand the method and didactic training at the beginning of a project would be sufficient.</td>
<td>Style - Experiential learning: Training sessions encouraged teams to immediately practice the method. Teams learnt by experience and learning was reinforced over numerous occasions.</td>
</tr>
<tr>
<td>Preconceived project approach plans: teams had predefined ideas of how to approach the project implementation – which did not include PDSA.</td>
<td>Timing - Training not provided for whole team: Unforeseen constraints meant that Not all project team members were in place at the beginning when. training for the team was provided.</td>
<td>Timing - Staggered teaching of methods to times relevant in the project life span: Teams were introduced to the basics of the method before details how to use it.</td>
</tr>
<tr>
<td>Perception of rigour of method: Teams from clinical research background questioned the rigour of the method. PDSA was not seen as not “proper” research.</td>
<td>Examples - Examples were not perceived as relevant to healthcare setting and project timelines: Non-healthcare examples were used that were not relevant to teams and complex examples of PDSA cycles were introduced at too early a stage.</td>
<td>Examples - Peer to peer learning: Training included past team members presenting in sessions.</td>
</tr>
<tr>
<td>Perception of benefit: Teams did not believe the PDSA cycles would benefit their team. Teams felt aspects such as documentation and data collection was for the funders assurance rather than the projects learning</td>
<td>Other project priorities - Establishing team membership and project scope took priority but with was less focus on PDSAs</td>
<td>Examples - Comparative and relevant examples of PDSAs from healthcare settings: Good and bad examples of PDSA cycles were provided to provide basis for critical reflection. Relevant healthcare examples from past CLAHRC NWL projects were used.</td>
</tr>
<tr>
<td>Other project priorities - Establishing team membership and project scope took priority but was less focus on PDSAs</td>
<td>Selecting teams - Programme approached established teams: The programme originally approached project teams that had partially developed project plans and as a consequence the teams felt the use of QI methods was being imposed.</td>
<td>Selecting teams - Managing expectations: Teams were required to apply to become projects and receive support and funding. Reference to the use of QI methods, including PDSA, was required in the application form and guidance documents</td>
</tr>
<tr>
<td>Used retrospectively: PDSA method used retrospectively to frame past actions rather than prospectively plan and test changes iteratively</td>
<td>Selecting teams - Pre-application workshops: Introductory sessions were held to introduce teams to what QI methods were and why to use them</td>
<td>Selecting teams - Pre-application workshops: Introductory sessions were held to introduce teams to what QI methods were and why to use them</td>
</tr>
<tr>
<td>Allocation of responsibility to lead use of method: The use of PDSA cycle was on one person rather than a team activity.</td>
<td>Style - Assumption that teams would be willing to use PDSA cycles following training: Introductory sessions focused on what method is rather than why to use it. Didactic teaching style did not facilitate debate of why PDSA cycles may be helpful.</td>
<td>Style - Purposeful facilitation of debate: Time and space was provided for teams to discuss the pros and cons of PDSA cycle method</td>
</tr>
<tr>
<td>Ability to document: Not all team members had access to template forms.</td>
<td>Support - Assumption that PDSA cycles were “easy” to apply: QI support was not invested in to help QI teams use the method. Support was predominantly offered in an advisory form before or after using the method rather than hands-on support during.</td>
<td>Support - Greater amount of hands-on, facilitatory support: QI support was deployed and acted a part of team rather than an external advisor. They would take responsibility to lead the use of the method.</td>
</tr>
<tr>
<td>Technology - Online tool in development: An online tool to support PDSA documentation and review of data was in development but not always immediately available due to technological developments and definition of improvement measures.</td>
<td>Technology - Online tool enhanced: The online tool was enhanced so that it was easier to navigate and data was more accessible. It also automatically annotate PDSA use on charts</td>
<td></td>
</tr>
</tbody>
</table>

Table 13. Summary of contextual barriers and QI support team changes overtime
**Observed barriers to PDSA cycle conduct**

**Understanding**

Acting in a largely novice QI environment, members of QI projects across all rounds were often new and unfamiliar to the use of QI methods. Any existing knowledge, or where knowledge was built, was related to the basic concept of PDSA cycles to test a change and make an adaptation. Teams' understanding of the intuitive approach was not married with awareness and understanding of the more detailed elements of the methods or how to apply in practice.

“The PDSA is in principle a simple tool but in practice it is difficult to use.” (Project team report)

“There were problems with documentation in terms of writing bits of the analysis in the Do section and mixing up the Plan, Do, Study and Act completely.” (Interviewee 2)

A key part of the QI support was to deliver educational sessions to the QI teams. At the beginning of the programme, the CLAHRC QI support team used external experts to provide group training sessions for Round 1. Challenges to project team recruitment meant that full project team membership was not in place for the training sessions and not all team members received training.

“the big room teaching was done by someone external to the CLAHRC, so the expertise was outside of the [QI support] team” (Interviewee 1)

“clinical leads came to [the teaching on QI methods], most of our new [QI support team] were in post but no-one else” (Interviewee 3)

For those that did receive the initial training, one barrier to developing understanding effectively was the examples used to teach PDSA cycles. Training by external QI experts was based on teaching methods and content used internationally and in past national QI programmes. When reviewing past training materials, however, interviewees retrospectively
reflected and reported that some QI teams fed-back that the examples used were not relevant to the teams or their healthcare setting and project timelines: they were either too simplistic or over complicated and, either way, did not allow the individuals to engage with them readily.

*Example PDSA in training: “to establish whether the bus is a better way to get to work than my old route.”* (Training material)

*Interviewee reflecting on training materials: “Actually that looks really complicated. There’s nothing wrong with it, I’m just reflecting now whether or not that’s the right way to introduce it for the first time”* (Interviewee 3)

*Intention*

Interrelated with an understanding of the method, PDSA cycle conduct was also influenced by the intention of the QI teams members to use the method. QI teams reported that the use of the method was not instinctive for them and QI review minutes often contained actions for the QI team to conduct PDSA cycles.

*“[Doing PDSA cycles is] still not second nature”* (Project team report)

*“[QI support team member] suggested doing this as a PDSA to test whether it affects follow up rates”* (Project team report)

There was often an academic orientation to QI team membership due to the CLAHRC NWL programme being a collaboration between university researchers and healthcare professionals. This meant that traditional research methods, rather than QI methods, were the “go to” approaches. Interviewees reflected that they felt PDSA cycles were not viewed as rigorous research method and principles such as use of regular data over time or small scale incremental testing were viewed as contradictory to traditional before and after research designs with fixed study protocols.
“[the] team wanted to just do a big confirmatory study before they really looked at implementation” (Interviewee 3)

“to think about changing protocol seemed quite counter-intuitive – the more traditional, this is our protocol – we’re going to stick to it – scientific perspective” (Interviewee 2)

In hindsight, interviewees reported that they had made the assumption that teams would be motivated and intend to use the PDSA cycle method. Support did not seek to address the ‘hearts and minds’ of project teams or the reality of using it in a complex healthcare context. It focused on what the method was rather than how and why to use it. This was felt to have created a perception that the use of PDSA cycles was for the benefit of the QI support team rather than the QI team itself. Areas such as documentation and data collection were seen as a form of programmes assurance rather than as mechanism to help the team learn.

“the assumption would be that having been taught they would go away and use it” (Interviewee 1)

“there was definitely a misunderstanding by some people that the PDSAs were being done for [the QI support team]… “they thought they were collecting weekly data because we needed it rather than because we thought it would be useful for the success of their team” (Interviewee 2)

Application

Understanding and intention factors were seen to influence both the initiation of PDSA cycles and how it was used. There were also some factors that influenced how the method was used specifically: the application of its use. The method was often used retrospectively to frame past actions rather than prospectively plan and test changes iteratively. This meant that principles such as use of predictions or consideration of scale were not applied. Due to
an initial assumption that the method would be “easy” to apply there was also less focus on supporting the application.

“PDSA are currently being written up retrospectively rather than as the test is happening so the team have to guess the exact dates (to log them as)” (Project team report)

“our assumption was that it was quite straightforward – you teach people and they use the method.” (Interviewee 3)

Technology to support documentation and data analysis was also not available in the early Rounds. This meant that time and expertise was required to manually collect and analyse data to use within a PDSA cycle. Teams having time and access to document was also reported as a barrier.

“the project team do not have access to see the [online documentation tool] of PDSAs. However, it was discussed and agreed that the purpose of PDSA cycle is to do together on paper as a team and then record the cycle on the [online documentation tool]” (Project team report)

“it was down to really practical things, you know, nurses not having internet access or not prioritising, accessing, something to do with their project as part of their busy day” (Interviewee 1)

**What new QI support strategies were deployed?**

In light of the observations and the learning gained by the QI support team, deliberate actions were taken to improve the support for PDSA cycle conduct. These changes aligned with the three identified areas (understanding, intention and application) and the yearly project initiation cycle allowed an iterative approach to be taken to optimise them.
The actions centred on the introductory and continuous support provided to teams through education sessions and facilitation. An overarching element that influenced all actions was the investment in internal QI support team staff. This stemmed from recognising the importance of individual QI support staff and ensuring greater support and training for them also.

**Understanding and Intention**

In general, understanding of the method and intention to use were addressed together. Alterations included aspects such as timing, content, and the individuals and examples involved in the training and ongoing support provided.

Education sessions and support were provided throughout a project but were also introduced earlier in a project's lifespan. Teams were required to apply to become projects and receive support and funding. This meant that they were introduced to the concept of PDSA before the project idea had been fully developed and had time to develop a team. Reference to the use of QI methods, including PDSA, was required in the application form.

“[We were] actively structuring the application form around the tools and techniques to give them a head-start” (Interviewee 3)

“the pre-application stuff, the workshop, was a conscious effort to make it clearer to projects what we expected in terms of usage of methodology because we had struggled so much” (Interviewee 2)

The content delivered across training sessions was staggered with the level of detail within the training sessions related to the project life span. Teams were introduced to the basics of the method before details how to use it. Content also focussed on *why* and *how* to use the method rather than on just *what* it is with time and space provided for teams to discuss and debate the benefit of the PDSA cycle method. Teams were also encouraged to practice the
use of the method within the sessions or soon after and reflect on the benefits and challenges to its use.

“At the end of the session you will be able to… have practice-based experience of developing and undertaking PDSA cycles in generic and healthcare-based scenarios” (Training material)

“we had some quite heated debates but I think it was helpful for people to kind of explore when you wouldn’t do (PDSA), get some of their opinions out” (Interviewee 1)

Training sessions were designed to include more relevant examples of PDSA cycle use and individuals with past experience in projects were invited to present them. This included past project team members presenting their experiences of using the PDSA method and the benefits they had gained. Understanding was further supported by comparing examples of PDSAs from project teams with good and bad examples of PDSA cycles to support critical reflection.

“The opportunity to speak to and learn from others is highly valued by the [project] team members, as well as the use of real examples in the process mapping and PDSA sessions” (Project team report)

“We’d got further towards what we would describe as good practice in teaching in terms of having good examples, relevant examples and peer to peer input” (Interviewee 2)

“using examples from other people in the peer group, both good and bad in order for participants to have some form of basis for critical reflection which they could then take in to their own practice” (Interviewee 1)
**Application**

The application of the method was influenced by the intention and understanding of teams but was also addressed by strategies aimed at making it easier to use the method – either through the deployment of individuals from the QI support team with a project team or through technological advances that made it easier to use the method.

“[the deployed support staff] had the opportunity to do some of the more basic things like documenting PDSAs during meetings, for example, if they were being discussed then.” (Interviewee 1)

In addition, the online tool was enhanced so that it was easier to navigate and reviewing data was more accessible. Data entry was made easier and Statistical Process Control (SPC) run charts were automated. An automatic function to annotate the documented PDSA on run charts was also developed. Crucial to gaining the benefits of these technological advances was the earlier scoping of project aims and interventions. Teams were supported to developed measure definitions earlier so that timely data was available to inform PDSA cycles.

“We didn’t want them to rush off and change practice, we wanted them to sort their measures out and get their baselines and then test changes” (Interviewee 2)
5.6. Discussion

5.6.1. Summary

This study presents an investigation into the PDSA cycle fidelity of QI projects within a QI collaborative and how changes to training and support evolved overtime. Over three and a half years, and three QI collaborative rounds of projects, significant improvements were seen in the number of PDSA cycles conducted and the fidelity of these cycles against key principles of the method. However, across the total sample of QI projects, PDSA cycle fidelity was low with principles of articulating predictions, using iterative cycles, increasing scale of testing and using regular data over time not being achieved. Only seven cycles adhered to all assessments of fidelity. Qualitative analysis identified reasons that may have influenced the change in fidelity over time. They are linked to changes in team’s understanding, intention, and application of using the method. These changes were influenced by specific actions implemented by the QI support team.

This is the first study that provides a detailed assessment of a large range of PDSA cycles documented in real-time over a range of QI projects. The lack of fidelity against all principles of the method adds to the literature that suggests PDSA cycles (Taylor et al. 2014; Baxley et al. 2011), and QI methods in general (Riley et al. 2009; Waring & Bishop 2010), are not always applied as they are intended.

Whilst cycles were largely used to structure learning activities, one of the principles of PDSA cycles, the remaining principles to enhance learning were not. This was demonstrated by low use of predictions within a single cycle and only half of cycles applying learning within a chain of iterative cycles. This suggests that the method’s intended output, the iterative application of learning to develop and deploy an intervention, was unlikely to have been realised fully. This is important to recognise in future evaluations of PDSA cycles as it is not possible to fairly determine the benefit of the method without it being used as intended.
5.6.2. Linking fidelity, context and implementation process

Improvements in PDSA cycle fidelity are presented in parallel to analysis of context the method was used and the implementation process followed by the QI support team. The influence of both areas was grouped in regards to QI teams’ understanding, intention and application of using the method. These were all identified as areas that were likely to have influenced fidelity and link to the literature outlined in the introduction: organisational QI capability with understanding; socio-cultural attitudes with intentions; and complexity of healthcare with process of use. (Kaplan et al. 2012; Vos et al. 2010; Benning et al. 2011a; Kilo et al. 1998; Benn et al. 2009; Parand et al. 2010; Berwick 1998; Dixon-Woods et al. 2009; Weaver et al. 2010; Wenger 2000; Anderson et al. 2012) Using the approach of running sequential Rounds of projects enabled the QI support team to reflect on and iterate support to address the factors.

An increase in intention was shown by the increased mean number of PDSA cycles used by QI project teams across rounds. This increased intention may not have immediately been met by increased in understanding, however. The data suggests that Round 2 projects initiated more iterative cycles, however, they were not necessarily focussing on testing changes or using predictions. This is highlighted by the reduction between Round 1 and Round 2 in the proportion of cycles used to test change, with more cycles used to frame the collection of information only. This decrease in cycles testing change represents an increased intention to use cycles but a low level of understanding. The use of cycles testing change increased significantly between Round 2 and Round 3 when the CLAHRC NWL introduced additional direct facilitation within teams.

Of note, the measures of fidelity that did not see significant improvements were those requiring users to revisit the method; including the increasing scale and use of data overtime. Even with an adequate level of intention and understanding, these principles are
more complex and harder to achieve as they require processes of team decision making and revisiting the documentation of two or more cycles.

A further potential reason for low fidelity is the project teams’ reason for iterating cycles. The method’s guidance suggests using regular data over time and increasing testing scale across iterative cycles. However, the identification of different learning activities suggests that iterative cycles may have sought to change learning activity instead. This may have involved a different type of test or the need to collect further information. It echoes suggestions that progressing iterative chains of cycles may not be as smooth as frequently taught. (Tomolo et al. 2009) Teams may have to manage a number of unexpected occurrences and therefore increasing the scale of testing and using regular data is not possible, regardless if it was the intention, understood and attempted. Further research is needed to understand the reality of the method’s use including the decision taken when initiating new cycles.

Further to this, the observation that only 60% (253/421) of cycles had all stages documented and the “study” stage documented in the past tense represents challenges across intention, understanding and application. Documentation is an important measure as it acts as a proxy for the execution of a cycle and subsequent learning gained. With a high number of incomplete and/or future tense documentation three potential realities are suggested: (1) that PDSA cycles were planned and documented prospectively but not executed for a particular reason; (2) that PDSA cycles were completed with all stages fully utilised but documentation was not revisited and updated; or (3) that PDSA cycles are planned, documented prospectively and executed but the study and act stages not utilised. The latter scenario is a particular cause for concern because the method is used as a “just do it” approach informed by hunches rather than a mechanism to reflectively and objectively inform change. This tendency to “Plan” and “Do” a test of change but not to proceed to “Study” and “Act” has also been highlighted elsewhere. (Baxley et al. 2011; Reed & Card 2015)
Building on these specific links with fidelity, this study also provides further indications on how QI support teams can support the implementation of QI methods. It suggests that supporting the use of PDSA cycles is not easy and not helped by assumptions that just providing education on the method will be adequate. Intention and understanding can be supported by critiquing and ensuring relevance of training materials, however, even if the intention and understanding of the method can be built, the application the method also requires further hands-on support. QI support teams, in particular ones newly supporting QI teams, are likely to benefit from an iterative approach, a key implication of this work outlined further below.

5.6.3. Limitations

The study was driven by the desire to understand potential factors that influence PDSA cycle fidelity; however, it has some limitations.

A key limitation is that the factors linked to the change in fidelity are predominantly identified through a small sample size of interviewees. Whilst the project team reports and training materials gave some insight into the context and QI support team implementation process, the interviewees provided the most in-depth reflection of the time period. There is a potential for hindsight bias and it does not take into account the views of the project teams. At this initial stage of theory development, however, the small sample size does allow initial indications of context to be developed for further investigation. The sample chosen was pragmatic due to the retrospective nature of the study. As the QI projects had already been completed there was no opportunity to collect data prospectively. It has allowed insight into the viewpoint of the programme team; however, a larger study would be helpful to triangulated data further.

Linked to the interviewees viewpoint, and using the background in the introduction as a comparison, the findings focus on the micro features of QI teams and the implementation process of the QI support team, rather than more macro organisational or microsystem
contextual factors. (Kaplan et al. 2012) This does not mean they are not influential, rather that the nature of the study positioned the focus on the relationship between QI support team and QI teams.

Finally, as per the previous chapter, the study is reliant of PDSA cycle documentation which limits the knowledge of the actual use of PDSA cycles, including who was involved. As identified by the qualitative data, the documentation system used to retrieve PDSA cycles was the developed over time and there is potential that some cycle conduct in Round 1 would not have been captured.

5.6.4. Implications and future work

Rather than explicitly recommending QI support teams deploy the specific actions observed, it is the identification of interrelated areas that influence PDSA cycle conduct and the proven benefit of iterating QI support that are the most helpful learning from this study. The challenges encountered across all three factors (understanding, intention and application) suggested to influence PDSA cycle fidelity are likely to be present across many current settings where QI methods are used. Some learning about how to improve context surrounding PDSA use may be due to the QI support team working out how they best function (e.g. investing and training QI support staff), other learning may be from applying existing training materials or styles supporting PDSA cycles but revising them following feedback or reflection (e.g. using relevant healthcare examples to support teaching).

Other QI support teams implementing the use of QI methods can use the specific examples of actions taken by the CLAHRC NWL programme to use in their own setting. More so, however, future QI support teams, in collaboration with researchers, should consider implementing QI methods using a similar iterative approach used by the CLAHRC NWL. This could combine prospectively quantitative assessment of fidelity and qualitative assessment of context that this studied has used.
Harnessing behavioural sciences

The three identified factors influencing PDSA cycle conduct suggest that those supporting the implementation of QI methods should pay more attention to behavioural science theories. PDSA cycle isn’t just a form that is completed but an approach that requires behaviour change through teams discussing, agreeing and executing actions in a certain manner. One theory in particular that aligns with the findings of this study and can help consider future QI support provision is the Reasoned Action Approach (RAA) (Fishbein & Ajzen 2011). It outlines that any change in behaviour is informed by “intention” and “actual control”, the latter of which refers to understanding (skills and abilities) and other factors within the environment which link the actual application of PDSA identified in this study (Figure 32). If we take high fidelity PDSA conduct as the behaviour, the RAA can be used to consider actions to address teams’ intention to use the method and distinguishes between this and their understanding and application of the method which can be considered as “actual control”. Whilst there is often strong desire to improve healthcare quality, this does not mean that the QI methods intended to support the process of doing so are instantly accepted. Support should recognise the traits of the teams they are attempting to help use QI methods and take action to address aspects such as attitude, perceived norms and perceived control.
“Attitude towards behaviour” is defined as the tendency to respond with some degree of favourableness or unfavourableness to a given behaviour.

“Perceived norm” is defined as perceived social pressure to perform or not to perform a given behaviour.

“Perceived behavioural control” to the perceived capability to perform the behaviour.

Figure 32. The Reasoned Action Approach

**Build capability or take ownership?**

This study also highlights the need to consider the role and type of QI support provided; whether to aim to build an understanding of how to use PDSA cycles or to take ownership themselves and lead the use of the QI methods. Engaging others in QI can be challenging (Davies et al. 2006) and it may be preferable to deploy experts in QI to lead projects. This may be a more instant approach to achieving success but more resource intensive and may not build capability or spread QI initiatives.

**Applying QI to QI support**

The “Round” approach taken by the CLAHRC NWL of initiating QI projects annually and iterating QI support provided allows training and learning to develop together. If all projects had started at the same time the QI support team would have not been able to refine support for PDSA cycle use. The learning structure helped revise existing teaching material of PDSA cycles to improve it or adapt to the local setting. All iterations were driven by qualitative...
feedback and observations of the CLAHRC NWL core team. This represents a QI method applied to support QI projects with the “Rounds” acting in principle as PDSA cycles.

5.7. Conclusion

This study reinforces the literature that suggests engagement and fidelity in using QI methods is challenging. It demonstrates that PDSA fidelity improved as a result a QI support team targeting deliberate iterative actions taken by towards the intention, understanding and application of using the method. Future QI supports teams would benefit by addressing these areas iteratively. A continued research and improvement focus on the “black box” of improvement, particularly on areas that help understand and apply QI methods as they are intended is required.

5.8. Contribution to overall thesis

Chapter 2 identified the need for research into how the scientific method was applied in improvement efforts. This chapter does so and expands the assessment of fidelity by also investigating the contextual factors that influence this.

Chapters 3 and 4 develop, apply and refine an approach to assess PDSA cycle conduct, specifically the fidelity of the method. This chapter echoes the observation of low fidelity and understand reasons why this may occur and what factors and mechanisms can help improve fidelity.

Chapter 6 explores the perceptions of those using the method. It seeks to understand whether the areas of fidelity that are shown to be low are even seen as a principle by those using the method. It also seeks to understand what benefits those using the method perceive. With this chapter identifying the challenges to engaging individuals and teams to use the method, Chapter 6 seeks to identify reasons that could be promoted to help persuade others in using the method.
Finally, Chapter 7 seeks to go beyond assessing documentation and explore the reality of using the method. It does not seek to directly give an assessment of fidelity but instead explores the social factors that may help or hinder high fidelity use of the method and therefore its application as a scientific method of improvement.
6. Chapter 6 – PDSA perspectives: International case studies of the perceived principles and benefits of PDSA cycles

This chapter presents three case studies exploring how the principles and benefits of PDSA cycles are interpreted and articulated by those involved in the delivery of QI initiatives. Data analysis was conducted by two reviewers: myself (CM) and PhD supervisor, Julie Reed (JR).

6.1. Introduction

Following Chapter 3, an explicit split of research avenues was made. Chapter 4 and 5 followed the development and application of a framework to assess fidelity and demonstrated that the method is not always used as intended. In this sense, the studies can be viewed as providing a more objective view of PDSA; measuring the fidelity of PDSA cycles and using it as a proxy for reality. These studies have relied on either documented PDSA cycles or the perceptions of those that support QI teams use the method, rather than the QI teams themselves.

To continue this thesis’ contribution to a theoretical and empirical understanding of the use of PDSA cycles in healthcare, it is necessary to investigate the perceptions of improvement teams using the method (their intentions and understanding) and how the method is enacted in social practice (the application). Chapter 6 and 7 attempt to address these areas respectively. They do not deliver a measure of fidelity, instead they take an interpretivist view and attempt to understand how users of the method interpret, articulate and apply it in healthcare improvement efforts. Both chapters present relevant literature pertaining to their area of interest before presenting their respective studies.
6.1.1. Aim of this study

Based on the research conducted so far in this thesis, this chapter investigates how individuals using PDSA cycles interpret and articulate the method’s principles and benefits. The perceived principles reflect an understanding of the method and the perceived benefits reflect an intention to use the method. Understanding and intention were shown to be associated with PDSA cycle conduct as demonstrated in Chapter 5. They are also both influences of behaviour more generally as identified by the Reasoned Action Approach (Figure 32, page 150). (Fishbein & Ajzen 2011)

6.1.2. Principles of PDSA cycles

PDSA cycles are widely used in healthcare and are a popular method of choice by many conducting improvement efforts. (Walshe 2009; Marshall & Bamber 2011) Very clear guidance exists on the stages of the method (Langley et al. 1996; Deming 1993) and the principles identified in this thesis (learning activity, prediction, iterative cycles, incremental testing scale, regular data over time and documentation) are drawn from the founders of the method.

However, there is not necessarily a single or full view of PDSA cycles. Firstly, there are two terminologies of the method, PDSA and PDCA. Deming raised concerns that the use of PDCA terminology may result in the method being used as a quality control cycle rather than promoting continuous learning and improvement. (Moen & Norman 2010) The systematic review in Chapter 3 echoed this by highlighting that adherence to principles of the method were lower for those that used “PDCA”. Secondly, and building on the results from Chapter 3 and 5, the varying extent to which reports have adhered to the principles of the method in general suggests that there are differing views on how to use it.

Understanding the gap or differences in users’ perceived principles of PDSA cycles can help education on using the method, particularly for QI support teams introducing the method to new projects or teams (Chapter 5). In addition, it can help shape future updates and
applications of the developed framework to assess fidelity (Chapter 4). Whilst face validation was achieved through discussion with colleagues and the framework has been applied to published and QI team’ accounts of the method, continued refinement is required.

6.1.3. Benefits of PDSA cycles

Understanding the differences in users’ perceived benefits of the PDSA cycle method can also help education and support in using the method. Given the challenges to use with high fidelity, it is helpful to understand why people use the method and what benefits they perceive.

There has been little research that has specifically set out to develop an empirical understanding of the reasons for using or not using PDSA cycles. (Berwick 1998) The benefits of PDSA cycles are often articulated theoretically as using iterative tests of change to learn, and from this, deliver improvements (Table 5, page 97). There is little understanding of whether this benefit is perceived by those using the method, and the value attached to this compared to any other perceived benefits.

Potential detrimental views associated with PDSA cycles have been proposed but not specifically investigated. (Berwick, 2012) These include:

- Being perceived as insufficiently rigorous in comparison to traditional large sample sizes and randomized trial design approaches;
- Constraining attitude towards failure, not seeing the benefit of learning from not succeeding on first attempt;
- Perceived lack of time, energy or resources to conduct the cycles;
- Ethical issues with “testing changes” in routine care.

Whilst there is no previous research that explicitly sets out to understand the interpreted benefits of using PDSA cycles, there is research into QI collaboratives that suggest mixed perceptions of the PDSA cycle method and can help frame this study.
One example investigated individual’s perceptions of the “theory of change” of a QI collaborative. (Dixon-Woods et al. 2010) The researchers defined a “theory of change” as the process by which the QI collaborative was intended to result in the improvement of healthcare delivery. Within this, they included the use of PDSA cycles. They found broad awareness that PDSA cycles were part of the approach and reasonable descriptions of its principles, although varied precision. The method was perceived as important because it gave ownership to the improvement teams. Echoing this perceived importance, other examples of QI collaboratives’ evaluations have indicated that the PDSA cycles method was a highly valued aspect of the approaches however they provided not further detail on the reasons to this. (Benn et al. 2009; Nembhard 2009)

In contrast to the popularity of the PDSA cycles method and positive perceptions, another study has highlighted negative perceptions of the method: Frontline staff were often not aware of PDSA cycles and the scientific legitimacy of the method was debated (Benning et al. 2011b). Whilst these insights are helpful, they are high level and are drawn from QI collaborative in which the use of the PDSA method is often new. (Nadeem et al. 2013) Little research has focussed on those that use the approach as part of normal organisational processes and are experienced in doing so.

6.1.4. QI methods conduct as socially dependent practices

Understanding perceptions of QI team members helps take a step forward as recognising the use of QI methods as socially dependent practices. Despite the theoretical arguments for the benefits they provide to support learning and improvement, it is widely understood that engaging individuals and groups in QI and the use of QI methods is challenging (Siriwardena 2009; Taitz et al. 2012; Albanese et al. 2010; Davies et al. 2006; Parand et al. 2010).

Healthcare is a complex social system and many individuals and groups will be involved in and influence the conduct of each PDSA cycle. Understanding how knowledge and learning
is communicated between these people during its use is critical to understand how and why the PDSA method is applied in practice.

Investigating the interpreted and articulated principles and benefits reflect the rhetoric of those using QI methods. This notion has also been identified in previous research into the conduct of the Lean QI method. In their ‘technology-in-practice’ view, ethnographic study of Lean, Waring et al (Waring & Bishop 2010) outline key dimensions of the social practice of Lean. With this perspective, ‘technology’ is considered in its broadest sense, including management ‘technologies’ of which QI methods fit. It views the use of any ‘technology’ within a complex network of actors and social environments; recognising that conduct may vary across different contexts.(Timmermans & Berg 2003)

*Waring et al* prescribe the notions of rhetoric, ritual and resistance to describe the social facets that influence its use. These refer to the way Lean is interpreted and articulated (rhetoric), how it is enacted (ritual), and how it is influenced by the context of clinical practical (resistance). Through this lens they suggest that, whilst set guidance exists, the conduct of the approach remains reliant on and open to negotiation and influence within a local context. They indicate that individuals and teams emphasise different principles and benefits to the use of Lean and balance its use between strictly flowing the approach’s guidance and simply stating they are “doing lean” but in reality follow little rigour against guiding principles. As such, they suggest that the practice of Lean should not be considered an “easy remedy” for making improvements in healthcare as it is required to fit with social and cultural practice as well supporting the often difficult task of changing clinical practices. They call for further research into the reality of using QI methods in healthcare to broaden the socio-cultural understanding of their use.
6.2. Method

6.2.1. Values

Chapter 6 and 7 differ in comparison to Chapters 3, 4 and 5 as they take an interpretivist perspective. Stemming from ontological relativism, Interpretivism believes reality is relative and multiple. (Hudson & Ozanne 1988) The goal of interpretivist research is to understand and interpret human behaviour rather than the goal of positivist or realist research which seeks to generalize and predict causes and effects. (Lee 1989) Chapter 6 and 7 seek to follow this line of enquiry by understanding participants’ subjective interpretation, articulation and application of PDSA cycles within their given context.

6.2.2. Research approach

As used by the “Lean” study described in the introduction, this study as well as Chapter 7 outline qualitative investigations with ‘technology-in-practice’ perspectives. (Timmermans & Berg 2003; Waring & Bishop 2010) This perspective has been previously used to investigate how scientific knowledge and technologies develop and are applied within “highly contextualised” environments. (Law 1992; Latour 2005) By this it is meant that the context is largely influenced by the people and “technologies” within it. It aims to consider how people interact with the technology, how they interpreted its use and how they communicate that. It is attentive to observations that technologies may be interpreted differently in different contexts, regardless if the primary goal of the technology is well defined. (Waring & Bishop 2010) This is a relevant view to take as it allows the consideration of PDSA cycles as the technology and investigations into how different people view it.

In addition to this “technology-in-practice” view, the study in this chapter takes a case study approach to compare and contrast perceptions of different organisations using PDSA cycles. Yin (2013) defines as case study as “an empirical inquiry that investigates a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident”. (Yin 2013) It is a helpful approach to use
when understanding is at an early, formative stage and when the roles of individuals and general contexts in question are of interest. (Cepeda & Martin 2005)

6.2.3. Sample

Three organisations formed the sample of the study and were used to provide different contexts in which the method is conducted. The inclusion criteria were: (i) a healthcare organisation and (ii) with at least 3 improvement projects using the PDSA cycle method. The organisations were pragmatically sampled through existing relationships of the researchers. The organisations were from three countries: Australia, USA and UK. Each organisation was a hospital based healthcare service with between 300 to 600 beds.

From within each organisation 3-4 improvement areas and/or projects that conduct and document PDSA cycles were included in the study as well as the organisational support infrastructure for QI. The improvement projects were identified by asking a manager with an overview of improvement work to identify those currently active and using the PDSA cycle method. Individuals within these improvement teams and the organisation’s team supporting improvement work were then approached to participate in the study. The study included only members of improvement teams as it focus was on how the PDSA cycle method is perceived by those involved with using the method, not the awareness in general across an organisation.

6.2.4. Data Collection

Data collection took place through semi-structured Interviews with improvement team members and members of organisation whose roles support or influence the improvement work. Documentation of improvement team PDSA cycles and other project related items were also available and formed background material.

Semi-structured interviews were conducted with improvement team members and members of organisation whose roles support or influence the improvement (Appendix 6). Interviews with team members were used to understand current and typical PDSA conduct and the
context they were used within, as well as the perceived principles and benefits of the method. The interview questions also allowed for any perceived limitations of the method to be raised. In total, 64 interviews were conducted by 2 researchers (CM and JR) (Table 14). They were transcribed and transferred to Nvivo 10 software for analysis.

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Data collection summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The first site had a smaller sample size than planned and only 5 individuals were interviewed. All participants played a role in QI. 4 led improvement projects with the organisation (QI leads) and 1 oversaw these projects at an organisational level (QI manager).</td>
</tr>
<tr>
<td>2</td>
<td>In total 29 interviews were conducted with a range of staff including clinicians, improvement support staff and organisation managers. Interviewees were from Emergency Department, Senior Decision Making in Medicine and Tissue viability QI projects. Due to the varied roles staff members played discussions extended to include PDSA cycle conduct in other areas including Senior Charge Nurse Supervisory programme, Stroke Unit, Medical assessment unit and a Patient Safety project.</td>
</tr>
<tr>
<td>3</td>
<td>In total 30 interviews were conducted with a range of staff including clinicians, quality improvement staff and organisation managers. Interviewees were from QI projects from 4 clinical areas: the Emergency Department, Kidney Transplant, Psychiatry and Gynaecology.</td>
</tr>
</tbody>
</table>

Table 14. Perceived principles and benefits study data collection

6.2.5. Data analysis

A combination of deductive analysis and inductive thematic analysis (Guest et al. 2011) based on the constant comparative method (Glaser 1965) was conducted. For all analysis, coding was discussed between researchers through a series of meetings and coding structure was refined iteratively where necessary.

To determine participants’ perceived principles of the method, data was first grouped according the six principles within the developed theoretical framework of PDSA cycle conduct. These groupings were then distilled to determine sub categories within the principles. Articulations of principles of the method that did not fit with the framework were attributed to new categories driven inductively by the data.
To determine perceived benefits and limitations of the method, an inductive approach was first taken. Emphasis was placed on reading and re-reading transcripts, highlighting relevant text and making annotations. Codes were then identified to describe the perceived benefits and limitations. Through comparison across transcripts, these codes were then grouped into hierarchical thematic categories and subcategories.

6.2.6. Methodological quality

Methodological quality was considered using evaluative criteria appropriate for the research questions and approaches. (Roulston 2010; Tracy 2010) Purposive sampling was used to invite the most appropriate individuals, with experience relevant to the research questions. Specifically, these individuals were part of improvement efforts, organisational or smaller team based, that were involved in the use of PDSA cycles. The participants did not necessarily need to be aware of the PDSA cycle method but did need to be able to articulate their role and experiences within the improvement effort. Methodological rigor was enhanced through conducting pilot interviews with improvement team members local to the researchers to test and adapt research questions. A coding journal was developed to document reflective commentary of how codes and categories were developed. Finally, researchers presented initial findings to a group of participants at the included organisations and at local research meetings to sense check themes and act as critical friend.

6.2.7. Ethics

The study outlined over both chapter 6 and 7 was approved by a multicentre research ethics committee (REC reference: 13/WM/0436). Relevant research governance was sought and obtained at each participating organisation. All participants were notified in writing and staff briefings of the study aims and methods in advance of participation. Written consent was obtained from all interviewees (Appendix 7).
6.3. Results

Each organisation exhibited different interpretations and articulations of the principles of PDSA cycles. The first organisation presented a partial alignment to the principles and a different application of the method. In this case the organisation referred to the method as PDCA. The other two organisation’s perceptions of the principles of the PDSA cycle method aligned fully with the principles within the theoretical framework, however, the emphasis placed on different principles differed.

Analysis grouped participants’ perceived benefits of PDSA cycles into three categories: logical, ethical and social benefits. There were similar perceived benefits across all organisations; however, the extent to which they focussed on the categories differed. Logical refers to the mechanistic reasoning why using PDSA cycles will result in the preferred outcome e.g. PDSA cycles are beneficial as they help teams learn about the suitability of a change, adapt it where necessary and positively influence a desired outcome. Ethical refers to the value that PDSA cycles provide; including its credibility compared to other similar approaches that provide the same outcome e.g. PDSA cycles are beneficial as they reduce the time taken to deliver improvements. Social refers to the personal feelings and social interactions granted through the use of the method e.g. PDSA cycles are beneficial as they empower individuals to take responsibility for making improvements. Few references to limitations were raised; however, challenges to practically apply the method were raised and are discussed in Chapter 7.

The differences in perceived principles and benefits were associated with the QI maturity of the organisations (based on number of years using PDSA cycles within the organisation). The most inexperienced organisation used the method as a tool to manage QI projects, the next focused rigidly on rapid small scale cycles and the most experienced were more reflective about the role of the method a method for learning and its benefit to support dialogue.
Common themes and differences between sites are presented in Table 15. The findings for individual sites are then expanded on below, framed by the following questions:

- *Within what organisational structure/ context were PDSA cycles used?*
- *What were the perceived principles of the method (including in comparison with the PDSA cycle framework developed in Chapter 3 and 4)?*
- *What were the perceived benefits of the method?*
<table>
<thead>
<tr>
<th>Context - Within what organisational structure/ context were PDSA cycles used?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terminology</td>
</tr>
<tr>
<td>PDCA</td>
</tr>
<tr>
<td>PDSA</td>
</tr>
<tr>
<td>PDSA</td>
</tr>
<tr>
<td>Period PDSA advocated</td>
</tr>
<tr>
<td>1 year</td>
</tr>
<tr>
<td>3-5 years</td>
</tr>
<tr>
<td>20+ years</td>
</tr>
<tr>
<td>Organisation structure for QI from which PDSA cycle use was led</td>
</tr>
<tr>
<td>Quality and Safety Department which was responsible for the management of registering risks, initiating and logging QI projects and linking all to organisational policy. The department’s activities was influenced by governmental assurance of healthcare</td>
</tr>
<tr>
<td>Range of sources including clinical departments, QI support team, clinical governance, executive leadership and external funding.</td>
</tr>
<tr>
<td>Quality department, supported by executive leadership, with a team of QI support staff who were deployed within a range of clinical areas in the organisation. Improvement Teams, including the QI support member, were set up within each department to deliver improvements.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Principles - What were the perceived principles of the method (including comparison to the developed PDSA cycle framework)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary</td>
</tr>
<tr>
<td>Quality management: PDCA structured the management of QI projects</td>
</tr>
<tr>
<td>Quality Improvement: PDSA structured small scale tests of change</td>
</tr>
<tr>
<td>Quality Improvement: PDSA structured iterative learning cycles.</td>
</tr>
<tr>
<td>Learning activity</td>
</tr>
<tr>
<td>“Do” stage focused predominantly on data collection. A QI report recommending actions was produced in the “act” stage</td>
</tr>
<tr>
<td>Unanimously related to the concept of testing change Implementing change not seen as part of PDSA cycle use</td>
</tr>
<tr>
<td>Production of learning seen as key principle Learning was produced through a range of testing options and frequencies and was supported by detailed project planning stage that proceeded PDSA conduct.</td>
</tr>
<tr>
<td>Prediction</td>
</tr>
<tr>
<td>No common practice, however, rationale for an improvement project was articulated within an improvement proposal in the “Plan” stage which implied a prediction.</td>
</tr>
<tr>
<td>Not part of common practice</td>
</tr>
<tr>
<td>Common term used and different types of prediction were recognised.</td>
</tr>
<tr>
<td>Iterative cycles</td>
</tr>
<tr>
<td>Follow-on actions recommended at end of cycle but did not always lead to a new cycle</td>
</tr>
<tr>
<td>Multiple small scale tests of change linked together</td>
</tr>
<tr>
<td>Multiple learning cycles linked together</td>
</tr>
<tr>
<td>Incremental testing scale</td>
</tr>
<tr>
<td>No reference to increasing scale. Projects typically conducted on large scale</td>
</tr>
<tr>
<td>Wide recognition on start testing on a small scale “1-3-5” approach to scale up often articulated</td>
</tr>
<tr>
<td>Starting on a small scale related to small sample size and rapid conduct of cycles Increasing the scale of a test of change was referred to as “Ramping” and was common.</td>
</tr>
</tbody>
</table>
### Data over time
- One-off data collection within a QI project rather than regularly overtime
- Regular “huddles” held to gain feedback from staff
- Wide spread use of run charts and recognition of the use of qualitative feedback, particularly in early tests.

### Documentation
- Documents produced at outset (QI project proposal) and subsequent report once on project is completed
- Recognised as part of PDSA cycles but reported variation in the extent to which the principle occurred
- Documentation principle recognised and in general adhered to but mixed opinions on the process and value of it.

### Benefits - What were the perceived benefits of the method?

| Summary | Social benefits most commonly articulated: PDSA cycles help the dynamism of changes, work rapidly, participate in regular discussions and engage people. | Greater balance between the recognition of logical and social benefits: PDSA has logical benefit of supporting learning and adapting of an intervention and support to engage and empower people |
| Logical | Logical and manageable structure to approach QI efforts Supports creation of new knowledge Helps keeps teams focused on delivering improvements | Structures the production of learning Provides a manageable structure Helps information management (memory, share with others, publishing) |
| Ethical | None articulated | By testing change, time is reduced on ineffective changes | Facilitates rapid improvement and lowers risks by testing on a small scale first. |
| Social | Motivates QI leads to submit QI project proposals and reports Applicable and accessible enough to be used by the many Use of the method empowers people to pursue improvement/ to take responsibility Helps engages others in the improvement effort Supports dialogue | Helps engages others in the improvement effort Use of the method empowers people to pursue improvement/ to take responsibility Helps develop a shared understanding Accessible to all |

Table 15. Comparison of perceived principles and benefits across organisations
6.3.1. Case study 1

Within what organisational structure/ context were PDSA cycles used?

The first case study organisation used the terminology, Plan-Do-Check-Act. The method had reportedly been advocated by the organisation for one year. Some examples of its use may have occurred previously but through the efforts of individuals rather than the organisation.

The use of the method was driven through the organisation’s Quality and Safety Department. The department was required to demonstrate initiatives to improve quality within the organisation as part of governmental assurance and regulation of the quality of healthcare delivery. As such, the department was responsible for managing an integrated organisation-wide knowledge management system that connected a register of identified organisational and clinical risks to the initiation of QI activities. This was reported to provide a strong foundation to support knowledge mobilisation and connectivity across the whole organisation. The department consisted of a Quality and Safety Manger and small support team. Across clinical areas within the organisation there were “QI leads” who led QI activities within their area. These leads had responsibility within their clinical areas but also to the Quality and Safety department.

What were the perceived principles of the method?

PDCA cycles were used within the organisation to structure the management of QI projects rather than individual tests of change and learning within a project. This was driven by the documentation and submission of project proposals and subsequent project reports which acted as part of a governance structure within the department (Figure 33). Through this, the cycles played a key role in structuring the Quality and Safety department’s function but differed to the two other sites and to the guidance on the method as outlined by its founders. (Deming 1986; Langley et al. 1996)
The PDCA cycle method guided the activities required to develop an improvement project, complete it and write up at report with identified actions. The “Plan” stage referred to the completion and submission of QI Projects proposals from QI leads to the Quality and Safety department for review and approval. Once registered a QI project could commence, reflecting the “Do” stage of the cycle. This was simply noted as “Complete improvement” on the cycle guidance following which a QI report was to be produced. Seen as part of “Do” but moving into “check”, the QI report would be “checked” by the QI manager in the Quality and Safety department. The actions that are recommended within the QI report were then agreed upon and formed the “Act” stage. It identified immediate actions and follow up work for a later date, both would be added to an organisational management log. The final report and agreed actions represented the closing of the PDCA cycle. Future actions would potentially, but not necessarily, inform a “Plan” stage in a new cycle in the form of a new QI project proposal form.

The site presented a partial alignment to the principles of PDSA cycles as incremental testing scale and use of regular data over time were not perceived as principles of the PDSA method. Sample size and duration were allocated a section on the project proposal form; however, no reference to increasing scale within the project was made. The use of regular data over time
was also not a priority also. Data was collected and reported as part of the QI project but regular data over time at monthly or less intervals was not used. Instead, projects would be encouraged to perform one-off data collections per project e.g. collecting data on a process in question for the last year and summarising it as a single figure.

"12 month audits are common" (Interviewee 2, Site 1)

Other perceived principles of the method articulated by the participants did relate more closely to the principles outlined in the theoretical framework but from a different perspective. This included: the rigorous documentation of project proposals and reports rather than individual P-D-C-A stages. Documentation played a role in approving and influencing the projects carried out. Completed forms were reviewed by the QI manager to give organisational sign off for the project to commence but also feedback on any risks or policies that had not been referred to and identify where the proposed work fitted with other ongoing activities and organisational strategy. Predictions were made within documentation but not explicitly as part of PDCA cycle. Instead, they came in the form of rationale for an improvement project as outlined in the project proposal forms.

The whole cycle was used as a learning activity for the conduct of quality and safety projects in the organisation. The projects themselves, represented within the “Do” stage, were all associated with learning too. The aim of projects was often to learn through data collection rather than testing change. Changes to be made to healthcare delivery were articulated in the subsequent QI report which recommended actions. Framing this focus on data collection, the proposal required applicants to indicate the methodology they would use and gave activities such as “questionnaire”, “audit”, “focus group or “literature review”. Emphasis was on developing learning to then inform training and/ or policy development.

Iterative cycles, referred to as “closing the loop”, were achieved by the QI department ensuring learning from previous QI projects was logged and informed repeat or new QI projects. This
was rather than multiple iterative cycles used within one QI project. The actions suggested by a QI report may have been completed immediately or suggested as future actions. They tended to be training or education for staff, modifications to hospital policies or procedures or identification of potential risks. A time period for future actions was noted in tick boxes offering 3, 6, 12 months. Recommendations and timelines set out in QI reports were added to an electronic calendar by the QI managers and automated reminder emails sent to the QI project leads to ensure they follow up with the actions or re-audits they stated. These may have been initiated as a new PDCA cycle through the submission of a QI project proposal form.

Whilst the principles of the method were articulated and interpreted as outlined above, it was evident through interviewees with QI leads that smaller scale cycles of testing change were actually being conducted during the QI projects. These smaller cycles were reported to be critical for ‘testing things out’: gauging fit with local processes and reactions from staff members and adjusting plans accordingly. However, these cycles were not recognised as PDCA cycles. The conduct of these smaller cycle activities was discussed by QI leads as daily activities in their job with some evidence of documentation in the form of activity logs and training session feedback.

What were the perceived benefits of the method?

Only the QI manager was fully aware of the both the PDCA cycle terminology and its full functioning within the organisations Quality and Safety department. The QI manager used and saw the cycle as a method to help them act as a knowledge manager for organisation: distilling evidence and communicating QI efforts. This was noticed as somewhat intentional, with the QI manager stating that the QI leads “don’t see this (the PDCA cycle), it’s just part of the job” (Interviewee 1, Site 1). The QI leads reported being aware what was termed a “loose” quality cycle and the role they played within it, however, awareness of the PDCA acronym was low and reflected in statements such as “P, D – what is it?!?” (Interviewee 2, Site 3).
In terms of perceived benefits of the PDCA approached used, insights were limited with little awareness of the method. The QI manager reported that process acted as a useful reminder system and motivator for QI leads to submit QI project proposals and reports and provided governance oversight to ensure necessary actions were taken and followed up. QI leads recognised the usefulness of proposal and report forms to document and share information. The need for a structure to support tests of change within a project was evident. QI leads reported relying on their persistence and social networks to make change happen rather than problem solving and learning as a group to test and adapt change.
6.3.2. Case Study 2

Within what organisational structure/ context were PDSA cycles used?

The second case study organisation used the terminology, Plan-Do-Study-Act. The method had been used within the organisation over the last 5 years, however an organisational effort to run QI projects using the PDSA cycle methods had been underway for a “few” years. The site articulated an intention to develop as a “quality improvement organisation” with an explicit drive to build an organisational culture for improvement. Although other QI methods, such as Lean, were reported to be used previously, PDSA cycles had become a common approach to structure improvement efforts more recently and were supported by the organisational leadership.

Many interviewees reported that the organisation was developing an organisational structure for improvement; however, there was not one overarching structure to manage improvement and initiate projects. Instead, improvement efforts stemmed from a range of sources. This included individual clinical departments, an organisational QI support team, clinical governance department and external national funding sources. Use of PDSA cycles was articulated within project environments and also as part of routine operational management. A range of individuals led the use of PDSA with some projects formally supported by a designated “QI facilitator”.

What were the perceived principles of the method?

The method was unanimously related to the concept of testing change. Across the site there was a growing awareness of the method and the PDSA acronym was used commonly in conversations at meetings discussing the improvement of service quality. All interviewees were aware of the concept and “let’s PDSA it” was a commonly heard phrase. Interviewees, however, made a distinction between testing change and implementing change and it was
commonly viewed that the PDSA cycle was used to support the testing of change, not implementation.

“a PDSA is a very small test of change usually, actually thinking, drilling it down to that very small test” (Interviewee 8, Site 2)

“I’m having interesting conversations at the moment about, is it really a PDSA or are you just implementing? Is it a test of change or are you…? You find they’re not… it’s an implementation. They’ve heard a good idea and they’re just going to go for it.” (Interviewee 25, Site 2)

This linked to the majority of interviewees who did not explicitly perceive the method as a learning method. Individuals within the organisation tended to refer to the method as a way to introduce a change rather than a specific learning mechanism. Learning was recognised implicitly but it did not receive conscious reflection by many, although a small number of QI facilitators did recognise the need to see tests of change that did not succeed as learning to apply in a subsequent cycle.

“I heard that somewhere else… ‘This was one failed’ …but I regularly show people that it is learning… not a failure, it wasn’t a successful implementation. It was a learning curve” (Interviewee 25, Site 2)

The discussion of predictions was not observed or articulated as common practice across the improvement projects. Whilst there were instances of the concept discussed in conversations and when using the PDSA documentation template predictions on the success of tests of change were well captured, it was not common language like “PDSA” or “test of change”.

Good examples of multiple PDSA cycles linked together were observed in both documentation and verbal accounts of use. This iteration was often linked with an increase in the scale of testing. There was wide recognition and application of initiating PDSA cycles on a small scale. This was either by testing a change a small number of times or testing a change over a short
period of time. Subsequent iterative cycles were then conducted aiming to increase scale. A commonly articulated phrase was the desire to test change on a “1, 3, 5” basis. This referred to the scale of cycles and the number of time the change was tested (once, three times, five times).

“you do one patient, three patients, five patients. All the patients, all the days. There we go, change has happened. And then you move to another ward and you do the same thing. And then you move to another ward and you do the same thing.” (Interviewee 26, Site 2)

“basic principles, you know, around small incremental changes, not big bang… you know, having to go round the cycle several times” (Interviewee 18, Site 2)

The use of data to support improvement efforts was articulated across the organisation and was interpreted as a key part of using PDSA cycles. This included qualitative feedback from staff but also the wide spread use of run charts to review the performance of various areas of the health system. PDSA cycles were often associated with a run chart, the data often displayed at weekly time intervals. The use of run charts was articulated as providing a similar function to charts used to support patient care. In terms of qualitative data, regular meetings, either more formal “sit-down” meetings or stand-up “zones” were held to gain the views of staff members.

“it’s completely improvement minded now, so everything is, let’s do a PDSA, where’s the run chart, what’s it telling” (Interviewee 30, Site 2)

“[If I have a service chart] I can eyeball a patient and go, you’re sick, what’s your heart rate? What’s the temperature? Lovely, right, let’s do this. And that’s... this is the equivalent of our [improvement effort].” (Interviewee 19, Site 2)

“So this is why this idea about having an improvement zone that isn’t fixed in time, where you can go and look at the data, is so important. Because if someone stops you
in the corridor, you can take them to the data. And you can capture their input. And it becomes a much more dynamic process." (Interviewee 26, Site 2)

Documentation was recognised as part of PDSA cycles but there was variation in the extent to which the principle occurred: some were rigorously documented, some were documented but not revisited, and some were just verbal reports of using PDSA but with no documentation.

“I think the reason people feel it’s, like, laborious is because they think it’s a huge exercise to write up a PDSA, but it really isn’t if you make it just... it’s just, like, a few lines of your reflection on it." (Interviewee 27, Site 2)

What were the perceived benefits of the method?

Overall, the organisation’s cultural drive to make change part of day job and standardised the language for addressing changes, through the use of PDSA, was reported to help the conduct of improvement efforts. It encouraged people to work rapidly, participate in regular discussions about change and engage more people over time as scale of a change grows.

The use and discussion of PDSA cycles was common in improvement initiatives. There was growing clinician buy-in and leadership for improvement in organisation. Good relationships between QI staff and frontline staff were observed and frontline staff typically felt supported by QI staff. Many staff were aware of tests of change and aims for improvement and had been actively engaged to input ideas for change.

Specifically in regards to the PDSA cycle method conduct, social benefits were most commonly articulated. The method was seen as beneficial as it was accessible to all healthcare staff and their working environment. This included individuals leading the use of the method but also triggering engagement and involvement of a wide range of staff.

“And that’s the way I like [using PDSA cycles] because you get staff involved” (Interviewee 10, Site 2)
“So they see that and they want to do it, so if they immediately say this isn’t going to work, then why isn’t it going to work, what shall we do instead, or how about this? Can you do X, Y and Z? And then you get buy-in, yes.” (Interviewee 23, Site 2)

“It means value, it’s a way of being recognised, your contribution, or being listened to” (Interviewee 31, Site 2)

Both accessibility and engagement linked to the provision of a freedom to act and the empowerment of individuals to take responsibility for improvement, a commonly articulated benefit of the method: senior managers promoted the method for staff to have freedom to act and take ownership for improvement; improvement leaders felt they have a “finger on the pulse” in terms of testing change and monitoring regular data; and frontline staff articulated the ability to feedback on changes they have tested and feeling confident there is oversight to improvement work. The method was also viewed as a mechanism to support dialogue and facilitate conversations.

“I think for some people it means a bit of autonomy” (Interviewee 31, Site 2)

“Because it allows people to take responsibility for their ideas and go away and try them out. It’s very empowering.” (Interviewee 26, Site 2)

“[It] gives people, kind of, permission to try something and even if it doesn’t work it’s not a problem, it doesn’t matter” (Interviewee 32, Site 2)

“(For) encouraging dialogue around improvement and doing it rapidly and managing behaviours, PDSA works very well.” (Interviewee 26, Site 2)

There was also recognition of the logical and ethical benefits but to a lesser extent. From a logical perspective, the method was viewed as a structured approach that helped maintain focus on improvement.
“it brings some logic to it and in some respects that’s helping the process. When we move forward we’ll have some structure” (Interviewee 6, Site 2)

“It’s better obviously that we’re testing things so you know that, like, we’re trying to improve everything rather than just keeping everything the same, so, it is better.”

(Interviewee 14, Site 2)

Ethical benefits were articulated in relation to conducting improvement in an efficient manner: changing rapidly and not wasting time.

“this is about how you change things rapidly.” (Interviewee 19, Site 2)

“And I think the PDSA cycles really supports that idea of let’s not spend ages in a business meeting talking about what we want to do and writing a business case. Let’s just try it...” (Interviewee 27, Site 2)
6.3.3. Case study 3

Within what organisational structure/ context were PDSA cycles used?

The third case study organisation used the terminology Plan-Do-Study-Act. The method had been reported to be used within the organisation for over 10 years. There was a positive attitude towards testing change and an organisational culture to strive for improvement. Across the organisation there was high awareness of the PDSA cycle method. The acronym was used commonly in conversations at meetings discussing the improvement of service quality and all interviews were aware of the concept.

The method was used as part of day-to-day work of organisation’s quality systems department. The department had a team of QI support staff who were deployed within a range of clinical areas across the organisation. These QI support staff were responsible for coordinating and facilitating QI efforts in their respective areas. PDSA cycles were an advocated tool within all improvement efforts. Improvement teams, including the QI support member, were set up within each department to deliver improvements against identified departmental targets that were also aligned to organisational priorities.

The Quality department also orchestrated a range of internal QI training sessions, including on PDSA cycles. This included different levels of expertise and team and individual learning sessions.

What were the perceived principles of the method?

The method was unanimously related to introducing changes by testing and adaption to make improvements but with a greater association to acting as a learning activity in comparison to the previous case studies. Tests of change were common practice across all clinical areas with many staff considering it part of their normal work duties and subsequently as something that PDSA cycles could support.

“PDSA does the look, feel, size, shape of the change: the how” (Interviewee 52, Site 3)
The use of PDSA cycles was widely associated with learning. The term “learning” was used more often and iterative cycles were articulated as a key mechanism to apply learning as well as scale up.

“we are learning about the staff roles and what more we can do” (Interviewee 55, Site 3)

“the more you test, the more you learn, and hopefully you benefit from the learning… We need to learn. What are we learning? You know, it’s not just what are you testing, but what are you learning from this testing?” (Interviewee 37, Site 3)

There was broader recognition of the types of iterative testing to support learning also. This included dissecting a new process and testing different aspects at different times (including different options for the same part of a process), reflection on the frequency and timing of testing, and recognition of the importance of planning a test.

“You take a process and you break it down into components and you test components in that process, you can test them in parallel and you can test them sequentially however. But you can test little parts of it or big parts of it.” (Interviewee 35, Site 3)

“when she reviewed it the first time, (she said) “I think you could test earlier” ” (Interviewee 55, Site 3)

“We do great at executing. We just all are so busy executing things that we execute right on the fly, which sometimes you have to do, but many times it’s because we didn’t plan enough. So, sort of putting conscious time and effort into planning [is important]” (Interviewee 55, Site 3)

There was also greater recognition on using predictions to support learning and the terminology of “prediction” or “hypothesis” was common. Predictions were often discussed in conversations around improvement and typically focused on the expected outcome of a test of change, although, instances in which teams articulated predictions of challenges that may occur were also observed.
“There would be a prediction on what we had anticipated to happen, and the actual…
and then some sort of diagnosis as to why or why not that didn’t work, and if it didn’t
work, how do we fix it, or if it did work, then how do we spread” (Interviewee 53, Site 3)

“we predicted at the end of that test that the triage nurse that… would have to go back
to a team and wait a long time and they would find that both dissatisfying and not be
able to take care of patients upfront” (Interviewee 47, Site 3)

Examples of multiple PDSA cycles linked together, taking learning from one cycle forward and
informing a subsequent cycle, were observed in both documentation and verbal accounts of
use. These iterative cycles were linked with the scale of testing but also the speed of iterations
(by having more rapid tests of change it was assumed that they would be smaller scale). The
concepts of “Adapt, adopt, Abandon” were applied regularly within the “Act” stage to progress
to the next cycle.

“The whole idea about iterative learning and starting small and ramping and building is
really important” (Interviewee 35, Site 3)

“You know, try... test a change and try to test it rapidly so that we can then determine
what adjustments need to be made, or if we just need a whole new idea.” (Interviewee
57, Site 3)

“the early, sort of, cadence for any of these projects has a more heavy ramp up. And so
you have a lot of energy devoted to, okay we’re going to test a bunch of things, and
we’re going to evaluate really quickly, and so you need a lot of rapid feedback, both on
the data side and, sort of the, you know, looking at the charts, and later in the process,
you know, four to six months later, you’ll have less of that aggressive testing.”
(Interviewee 47, Site 3)

Starting on a small scale was recognised and was related to small sample size and also rapid
conduct of cycles.
“small tests of change… that’s really been the foundation of our work” (Interviewee 35, Site 3)

“I’m all about rapid testing. I think that gives people… you know, they just don’t get as bored with it. They test it, they get some answers, and they move on, and that’s what I try to encourage in my teams,” (Interviewee 57, Site 3)

Increasing the scale of a test of change was common practice across all observed uses of PDSA cycles and linked closely to learning. Learning from an initial test of change was taken forward to a subsequent cycle which not only sought to test the iteration to a change but also increase either the sample size for testing or duration of testing. Scale up would seek to result in implementing the change in question, however, learning and reflection cycles framed by PDSA would still continue at implementation stage.

“there’s a difference between if you do five PDSAs, on five different concepts, versus one PDSA, or one ramp, and you have five different PDSA, that you took that concept, and you’re really close to implementing. So, it’s not just the number of PDSAs, but how many are you really learning the system.” (Interviewee 42, Site 3)

“…if I can do that and what do I learn from that …when you've applied, you know, enough tests of change and learning then you can, you get to the point so, okay, well, can we implement, you know, full scale and then once you've done that, say, okay, well, what wasn't appropriate” (Interviewee 41, Site 3)

There was an embedded focus on producing and discussing run charts to monitor improvement across all teams the researchers engaged with. Discussions in regards to defining and collecting data placed significant emphasis on identifying and iterating a change idea. This provided a foundation to rigorously monitor success. It was articulated that data should be used proportionately to the scale of testing. Testing should also include a mix of
quantitative and qualitative data and the use of different frequency of data was recognised.

The importance of making a plan for collecting data was also recognised.

“It can’t be complex, if you’re just doing a test on a short term basis you’ve got to have a way to get the feedback from the people who are doing the test” (Interviewee 35, Site 3)

“often talk in class is that of both the story and the data, and we often hear the story in the elevator but, can you send me a run chart” (Interviewee 36, Site 3)

“We had our run chart that was looking at what’s happening monthly and looking for trends, but then I would provide another report where I would say, okay, here’s what you did in the past two weeks and not that it’s going to be statistically significant, but … you want short term data to see are you making a difference.” (Interviewee 51, Site 3)

Documentation of PDSA cycles drew the most contention with mixed opinions on the process and value of documentation. Examples reported include uncertainty over who should document PDSA cycles, the priority of documenting given limited time available and whether to document prospectively or retrospectively. When discussing documentation in more detail with interviewees the concept of the value of documentation was prominent. Some perceived that documentation ensured clarity in the test of change prior to its execution and captured the subsequent learning gained. If the latter is not utilised the value of documentation was likely to diminish in the view of users. It was widely felt that more could be done to maximise the learning from previous improvement efforts, particularly in supporting spread and scale-up to other hospital settings.

“one of the complaints that my staff has around test of change... or the PDSAs is it’s very time consuming to document” (Interviewee 35, Site 3)

“we’ve created multiple tools and multiple forms. I could go to my computer probably and pull out ten different versions, you know.” (Interviewee 42, Site 3)
What were the perceived benefits of the method?

All three groups of benefits were perceived by the site. There was a greater balance between the recognition of logical and social benefits but with many similar areas covered. In general, benefits of using PDSA were predominantly based on the provision of a structured approach that empowers staff to make local changes and accelerates learning from tests of change. This ensures that interventions are abandoned if unsuccessful, adapted based on learning or, if successful, adopted and embedded. PDSA cycles, as part of a broader suite of improvement methods, were seen as providing a common language to support communication between those testing changes including frontline staff and quality improvement support staff.

“We always learn so much by doing our tests and oftentimes that would change the direction of where we wanted to go because what we learnt about our systems and the process” (Interviewee 35, Site 3)

“you have a better basis and understanding for what didn’t work and why it didn’t work, and then can maybe make adjustments and adapt, and adaptations along the way.” (Interviewee 36, Site 3)

A range of factors were indicated to support the production of learning. This included the articulation that the method helped make the improvement effort manageable in terms of breaking down the tasks that are required and also ensuring a structure and rigorous approach was followed. The support for collecting and sharing of information from using the method was also suggested.

“You try to make things bite-size, and so that’s really hard for people to do, because most people get very… get ten steps ahead. I’m guilty of it too. I’ll say, oh, you know, all we need to do is build a new clinic… and everything will be solved!” (Interviewee 53, Site 3)
“The best use of the PDSA is actually probably time spent brain-storming of the PD… it does break things down into very digestible chunks” (Interviewee 53, Site 3)

The social benefit of empowering individuals and teams was echoed in comparison to Site 2. The method triggered and provided a mechanism by which people could take responsibility for improvement efforts.

“They have to own the PDSA, they have to own the test, they have to own making a prediction for that test before they run” (Interviewee 36, Site 3)

“You can always test. You can always be going testing. You don’t have to wait for that. You can always be doing that. If we’re just waiting for data to come in or whatever, you can always be testing something in the system. …you can just always keep it moving” (Interviewee 58, Site 3)

The role PDSA cycles played in engaging others was wide ranging. It included, getting “naysayers” on board, demonstrating success to leadership, and, most commonly, getting frontline staff involved in testing. By testing, it was viewed that this increased excitement to be involved and allowed feedback to be provided. Specific principles, such as asking people for predictions, also helped engagement as people then had a stake in the work.

“It’s a great tool to work with especially your nay-sayers” (Interviewee 47, Site 3)

“We get feedback, …no one ever says they don’t like feedback, right? You know, everyone loves feedback; of course you do.” (Interviewee 52, Site 3)

“It helps to create buy-in on the unit. So it’s like proof of concept, shows people that things will work and can work.” (Interviewee 55, Site 3)

In addition, use of the method helped individuals own the work and develop a shared understanding of theirs and others roles. It’s accessibility to all individuals and to all situations was also articulated as a benefit.
“I think part of the front-end of the whole sort of PDSA, and testing, is helping people to understand what is their role, and I think it’s been important for us because, oh, I always, I thought you did that – I do this, you know “(Interviewee 54, Site 3)

“The next one is, and probably the more important, I wish I’d thought about it in the other order, probably more important than scalability, is accessibility.” (Interviewee 36, Site 3)

The ethical benefits were the same as articulated in case study 2, that the method helped efficient improvement but also lowered the risk of harm.

“It shortens the time to come to that intervention.” (Interviewee 35, Site 3)

“there's minimal long-term impact because you're trying it on small scale” (Interviewee 52, Site 3)
6.4. **Discussion**

The study presents the rhetoric of PDSA cycles in three international healthcare sites using the method. It indicates how the method’s principles and benefits are interpreted and articulated, and highlights differences between organisations, which link to the QI maturity.

6.4.1. **Perceived principles**

All sites expressed views of principles that aligned with the theoretical framework presented in Chapter 4. However, the extent of alignment varied and can be generalised at a high level as follows:

- **Quality management** – PDCA cycle method coordinated QI projects
- **Quality improvement** – PDSA cycle method structured small scale tests of change
- **Quality improvement** – PDSA cycle method structured incremental learning cycles

The site that used the method to coordinate QI projects aligned partially with all principles but did not consider incremental scale or regular data over time. The cyclic nature of the quality management of projects is helpful but, for clarity to exist in regards to the PDSA cycle method, this use should be a conscious differentiation from the typical QI focus that the method has by testing on a small scale, increasing this scale and using regular data over time to guide this.

The second had a prominent focus on small scale tests of change. The scale up, use of data and iterative nature of PDSA was recognised, however, implicitly, the rhetoric surrounding the method focused on the initial small scale cycles, with the PDSA method detached from supporting change when it was becoming implemented more routinely. There was an implicit assumption that the scaling up of a test would happen automatically rather than an appreciation of the complexity of factors that would be required to be addressed and continued learning cycles required to do so. This under recognised view of the cycle as a method to explicitly support learning was also emphasised with little recognition of the use of predictions.
Within the second site there was also a perception that because the initial test is a small scale test, that planning for the change would also be small. This meant that some changes received little planning as there they were not considered complex enough. This links to previous observations in the literature that typical PDSA cycle training can lead to the impression that the method is used to involve “quick and dirty” tests of change rather than conducting the test rapidly but with adequate planning and studying time either side of this. (Reed & Card 2015)

The third site was most close to the full premise of the method as a pragmatic scientific learning tool. There were a greater number of articulations to the cyclic learning role of the method and the use of hypothesis to guide this learning. This was within the organisation with the longest period of time advocating the method.

6.4.2. Perceived benefits

The three groupings of perceived benefits are loosely framed on the Aristotle’s principles of rhetoric: logos (logic), ethos (ethics) and pathos (social). (Higgins & Walker 2012) They are not a direct application of these principles however because Aristotle’s principles are three mechanisms in which a persuasive argument can be made. E.g. an argument can benefit from appealing to the logic or the argument based on facts (logos), credibility of the speaker (ethos) or an audience’s emotions (pathos). Whilst these mechanisms are similar, the three categories of perceived benefits are outputs from using the PDSA cycles method. They can, however, act as a way to inform and persuade others in using the method.

The logical and ethical benefits identified in study aligned with the commonly articulated theoretical benefits of PDSA (Table 5, page 97). The study also, however, highlighted the importance placed on the social benefits that can be produced from using the method. The main factors that made up the articulated social benefits included:

- Empowers individuals to lead improvement efforts
- Is applicable and accessible for all to use
- Helps engage others with the improvement effort
- Facilitates dialogue and sharing knowledge between individuals/within a team

6.4.3. Limitations

One limitation of this study is that the perceived principles of the method are assumed as the reality of how the method is used. An assessment of fidelity is not carried out to confirm these perceptions; the study intentionally focuses on how the method is interpreted and articulated. Future studies could seek to collate perceptions, a measure of documented fidelity an actual observed fidelity to identify and investigate differences.

In addition, the benefits articulated are the areas in which are believed to be influence by PDSA, however, this must be caveated with the need to first engage individuals. This limitation links to those inherent with using a case study approach. Whilst site specific views are identified, the extent to which they can be generalised must be considered. The findings are not intended to reveal how populations using PDSA feel; instead they seek to be generalised to theoretical propositions. (Yin 2013) This study does so by developing an understanding of a sample of people involved in using the PDSA cycle method and comparing this to the theoretical principles and benefits, based on the framework developed for PDSA cycles conduct.

The participants were from organisations using PDSA cycles as part of their QI method. There is therefore a likely bias with the observed interpretations and articulations of principles and benefits. This, however, was intended so that the full potential of the method was identified but does give reason to why little limitations of the method were raised.

6.4.4. Implications

By reviewing the perceived principles of the method, this study further validates the theoretical framework for PDSA cycle fidelity developed throughout this thesis. No new principles of the method were identified through participants’ perceptions, however, varying extents to which
they were articulated were observed. These represent different applications all based on the concept of the method as an iterative structure: iterative quality management; iterative small scale tests of change; iterative learning cycles. These can be used to introduce the concept of the method in education.

The different views give potential reasons for the low fidelity observed in the systematic review (Chapter 3), and within the CLAHRC NWL (Chapter 5): those using PDSA may have been doing so from a broader quality management basis or may have focused on the initial small and quick tests only.

The study provides a richer understanding of the benefits that goes beyond the typical theoretical logical and ethical benefits by highlighting the social benefits of the method. If PDSA, and QI activities in general can help engage and empower others then this benefit must be articulated as prominently as the logical and ethical benefits of the method. This may help foster initial intentions to use the method and support the “tendency to respond with some degree of favourableness or unfavourableness to a given behaviour” as suggested in the Reasoned Action Approach (Figure 32, page 150). (Fishbein & Ajzen 2011)

The literature indicates that it is hard to engage people in QI and, if poorly introduced, the use of QI methods can negatively impact motivation to participate in improvement (Gollop 2004) and create confusion. (Brandao de Souza 2009) The benefits articulated in this study, however, suggest that, as well as being used to get over the initial hurdle of gaining intention, the method can be used to further harness intention through developing engagement in QI and more broadly engage employees in their daily work.

Specifically in regards to the additional social benefits identified, the results also align with factors that influence general employee engagement in the workplace. For example, empowerment was a commonly articulated benefit: By using PDSA cycles, individuals and teams are granted permission to take control and make improvements to the area they work...
within. This echoes other organisations with high employee engagement measures; they often have good QI structures. (Kammerlind et al. 2004; White et al. 2014) This is important to recognise as employee engagement has been demonstrated a key mechanism to help improve quality. (Ham 2014) Organisations with engaged employees perform higher than those that don’t and, in particular for healthcare, employee engagement is linked with better quality of care and patient experience. (Newman & Maylor 2002) Deming’s early thinking on QI suggested that teams needed to enjoy and be engaged with the work they do if they are to make improvements to it. (Reed 2016) This study indicated that the use of methods can help achieve this.

Linked to this, the results suggest that the use of PDSA cycles can foster “psychological safety”. Psychological safety is a persons or teams belief that they are able to speak up and take calculated risks in pursuing improvement. (Edmondson 1999) It has been shown empirically to benefit organisations and teams in many different ways including increasing the likelihood that innovation will be successful (West & Anderson 1996), increasing the ability to learn from mistakes (Edmondson 1996) and improving employee engagement. (Nembhard & Edmondson 2006) Other studies have suggested that psychological safety can foster the conduct of activities that help teams “learn-how” to implement change, including the use of PDSA cycles. (Tucker et al. 2007) The perceived benefits identified in this study suggest that the relationship is reciprocal, with team members articulating that the method empowers and engages teams and individuals, aligning with the notion of psychological safety, to pursue improvement. The reciprocal relationship between engagement and quality improvement activities has been highlighted elsewhere. (White et al. 2014)

Overall, this study paves the way for further research considering the PDSA cycle method as a socio-technical tool through the identification of both technical and social benefits. It reaffirms that researchers should take into account that the method as a complex social-technical tool and the “technology-in practice” view helps frame this.
6.5. **Conclusion**

This study presents the different perceptions of three organisations using PDSA cycles. It presents different applications of the method that align to key principles of the method derived from its original guidance. It suggests that to help engage others in using the method then the social benefits of doing so should be further articulated.

6.6. **Contribution to overall thesis**

This study again represents the conduct of investigations, identified in Chapter 2, to study the use of QI methods. Instead of investigating the fidelity of the method it seeks to provide a view of how the principles and benefits of using the method are interpreted and articulated.

With the identification of low fidelity uses in Chapter 3 and 5, this chapter suggest further reasons as to why this may be the case; differing extents to which users perceive the functioning of the method being a key reason.

The chapter suggests further investigation of the social reality of using the method which builds upon the technical elements of the methods use identified, refined and applied in Chapter 3, 4 and 5. If social benefits are perceived, then how they are realised in practice merits further investigation. The chapter also builds upon the contextual factors that are suggested to influence fidelity by providing further areas to harness when encouraging others to use method. These are identified in the form of the articulated benefits of the method, of which the social benefits are prominent.

Chapter 7, therefore, seeks to explore and understand how the method is used in the reality of social practice. It seeks to understand the person-to-person interactions that are necessary to use the method, specifically how to support knowledge interactions to progress through the method’s stages.
7. Chapter 7 - The reality of using PDSA cycles

This chapter presents a qualitative investigation into the application of PDSA cycles in healthcare improvement teams. Data analysis was conducted by two reviewers: myself (CM) and PhD supervisor, Julie Reed (JR).

7.1. Introduction

“Lecture, textbooks and review articles that teach about PDSA typically depict the cycles as a smooth progression, with each cycle seamlessly and iteratively building on the previous… However, those who have engaged in small tests of change quickly recognise that this pristine view of PDSA does not capture reality” (Ogrinc & Shojania 2014)

QI methods can help teams learn which, in turn, can help increase the likelihood of a more suitable change to a system or process. Subsequently, this can increase the likelihood of a desired outcome. PDSA cycles are popular QI method in healthcare that help this process, however, this thesis so far has shown that the method is often not used as intended. As such, the benefits of the method to facilitate learning and improvement are unlikely to have been realised to their full potential. (Taylor et al. 2014) To support better use, and therefore more effective and efficient improvement, there is a need to understand the reality of using the method; highlighting challenges and enablers to using the method as intended. Currently, clear guidance exists to conduct the method (Langley et al. 1996) but empirical research knowledge of how this is applied in practice is low. (Taylor et al. 2014)

7.1.1. Aim of this study

Gaining an empirical understanding of how challenges to PDSA cycle use permeate during a QI effort and how they can be overcome, including the way in which PDSA use is led and facilitated, can help attain good quality use of the method. This study aims to support this by
providing greater understanding of the challenges faced and solutions for teams to use when conducting cycles.

The study aims to investigate the social reality of using PDSA cycles in project teams. It aims to specifically draw on the CoP and Knowledge interactions lenses to describe the enablers and challenges of using the method, these academic areas are presented below to frame the study.

7.1.2. Continued efforts to understand and support PDSA cycle use

The need to understand the empirical reality of improvement efforts more generally has been a focus of previous research looking at changes made to the delivery of healthcare including the deployment of interventions such as checklists and care bundles. (Gillespie & Marshall 2015; Bosk et al. 2009; Borgert et al. 2015) The benefits of these interventions are well versed, theoretically and empirically. Translating these benefits into practice elsewhere has not always occurred, however. (Bosk et al. 2009) It is argued that one reason for this is that they are oversimplified and only used at face value. By this, it is meant that steps outlined on a form may have been followed but the actions or decisions they should instigate are not sufficiently understood, monitored against or engaged with culturally. By understanding the reality of what occurs when using the interventions, the process of effective use can be better described, challenges identified and facilitators shared. This notion applies equally to the conduct of QI methods and, in this case of this study, provides part of the rationale for closer inspection of PDSA cycles.

“Little is known about which conditions are most important, whether these are different for different quality interventions or whether some become less or more important at different times in carrying out an improvement. Knowing more about these conditions could help speed up and spread improvements and develop the science” (Øvretveit 2011)
Understanding the reality of using PDSA cycles is particularly important because of the role it plays in directly supporting the process of making change; the crux of any improvement.(Goldratt 1990) Whereas other QI methods focus on the planning or evaluation of a change, the PDSA method helps support the iterative testing and adaptation of change targeted at a desired outcome.(Langley et al. 1996) The method is often depicted as a smooth progression, with each cycle seamlessly and iteratively building on the previous (Ogrinc & Shojania 2014), however, concerns regarding the extent to whether the method is used as such have been raised.(Ogrinc & Shojania 2014; Taylor et al. 2014) Not applying the PDSA method as intended can lead to teams deciding to implement changes without learning whether they are appropriate for the outcome that is desired.(Vos et al. 2010)

This study aims to understand further the social reality of using PDSA cycles. To frame the research enquiry in this chapter it is helpful to summarise and draw on other existing literature: firstly, summarising the contextual factors that have been known to influence the conduct of QI, including PDSA; and secondly, introducing the social dimensions of QI and the role of communities of practice and knowledge interactions.

7.1.3. Factors that influence PDSA cycle use

A number of potential areas have been highlighted in inhibiting optimal use of the method, both in the previous chapters and past literature. Firstly, and most generally, a wide range of contextual factors are outlined in the MUSIQ framework to influence QI efforts such as the clinical engagement, resource availability and organisational/ political alignment.(Kaplan et al. 2012) The MUSIQ framework directs contextual factors influence towards the overall success of an improvement effort, however, does include factors that will directly influence PDSA cycle conduct such as “QI skill” and “prior QI experience”. The inclusion of these proxies and their interactions with other factors gives a broad overview of how organisational context may influence PDSA cycle fidelity.
Linked to specific factors in MUSIQ and as identified in Chapter 5, individuals’ understanding of and intention to use the method also play a role in the methods use. In regards to understanding, low awareness or different interpretations of the method and how it should be deployed have been highlighted elsewhere.(Moen & Norman 2006) In regards to intentions, low engagement and intentions to use QI methods have been demonstrated.(Powell et al. 2009) Specific viewpoints that can disengage people from testing change have also been articulated (Berwick 1998): Small-scale tests of change may be perceived as insufficiently rigorous; negative attitudes may exist towards learning by failure; there may be an unwillingness to commit to the time and effort required to conduct iterative tests of change; and some individuals may have an ethical problem with the notion of “testing change” within routine healthcare.

Finally, also identified in Chapter 5, the actual application of the method may face some barriers due to the complex and people dependent nature of healthcare improvement. This can mean a tendency to start using the method but not fully completing due to competing priorities.(Baxley et al. 2011) Some reasons for this have been highlighted in a study on a QI collaborative.(Vos et al. 2010) The study highlights the challenges of having multiple individuals that need to engage with a test of change. Testing a change that affects several departments requires more input beforehand which was argued to increase the possibility of resistance to change. Without gaining buy-in or developing a compromised intervention a change may not be able to be tested. Linked to this, testing on a small scale, although reduces risk, can also lower expectations of the benefits of change and therefore does not stimulate departments to engage in the change. These difficulties mean that QI teams can often implement an intervention without testing them first. They therefore do not get feedback on the work they were doing and do not experience a momentum of change.
7.1.4. Social dimensions of Quality Improvement

So far, this thesis has concentrated on the technical, scientific nature of using QI methods, specifically PDSA cycles. To understand the reality of using PDSA cycles it is also necessary to consider the social interactions required in any QI effort further.

The delivery of healthcare is predominantly a social activity involving at least two people: a patient and a healthcare provider (doctor, nurse etc.). More often than not, this individual healthcare provider is acting within a team and organisation and interacting systems and processes. To make improvements in this complex environment of healthcare delivery, multiple people are required to change the way they work. This change needs to be identified, agreed and implemented consistently (a process of which the use of QI methods supports).

To support identify, agree and implement a change it is helpful that the people changing the way they work are involved and engaged in the improvement efforts. (Davies et al. 2006; Audet et al. 2005; Siriwardena 2009; Srinivasan 2011; Albanese et al. 2010; Taitz et al. 2012) This not only ensures that relevant knowledge can be shared to identify a change, but also engages the necessary people to deliver the change once agreed. This involvement can come in a number of different forms and can consist of raising challenges to current care provision and ideas of how to improve it, carrying out experiments to determine better ways of work, agreeing how to best refine changes and, finally, working in this agreed different way and implementing it as normal routine healthcare delivery.

Gaining this involvement and engagement can be challenging, however. (Davies et al. 2006) It requires time which draws on healthcare workers primary role of delivering or managing healthcare and, in doing so, has a financial implication. It also requires bringing together people and groups that are not necessarily used to working together and may have competing ideas and priorities.
From an academic perspective, these social complexities of conducting QI can be linked to two interrelated areas: communities of practice and knowledge management.

7.1.5. Communities of Practice

The different people and groups working together within an improvement effort can be viewed as coming from different Communities of Practice (CoP). CoP is an term to describe ‘a group of people who share a concern, a set of problems, or a passion about a particular topic, and who deep their understanding and knowledge of this area by interacting on an ongoing basis’.(Wenger et al. 2002) CoPs represent the relations that exist in addition to a formal organizational structure (Brown & Duguid 1991; Lave & Wenger 1991). In healthcare, these typically refer to a profession such as medics or nurses, or a multidisciplinary team that comes together to deliver care for a patient. Since its introduction by Lave and Wenger in 1991, the concept of CoP has been widely adopted in a range of academic fields. This has been accompanied by the continuous development of the concept.(Omidvar & Kislov 2013)

There are different angles from which the role of CoP can be viewed.(Cox 2004) Firstly, and the original premised of the concept, is the role it plays in supporting individuals to learn within a community.(Lave & Wenger 1991) This is referred to as ‘situated learning’ and involves the socialisation of new-comers as they join a new community and learn about existing practices; the technical elements but also the social-norms surrounding them. Secondly, is the role CoP can play to support the generation of solutions to problems.(Brown & Duguid 1991) This refers to organisational learning and informal groups of people forming and improvising to develop solutions to problems. Thirdly, CoPs play a role to help instil meaning and identity for individuals within them.(Wenger 1998) This role focuses on the relationships and development of common understanding through a shared practice. From a theoretical perspective, whether it is learning, problem solving or development of relationships as role, each view considers the concept as a community of people coming together around a certain practice in a particular domain.(Wenger 2000)
These roles of learning, problem solving and relationships are articulations of the beneficial outcomes of CoPs. It is the observation of these benefits that has propelled the academic interest in the topic with further research focussed on how to best ‘cultivate’ CoPs. (Wenger et al. 2002) This focus represents a shift in thinking: it focuses on the concept as a management tool and, rather than seeing it as an natural observed state, seeks to understanding how a CoP can be deliberately developed. (Cox 2004) Considered in this way, CoPs have come to be seen as ways of addressing organisational knowledge management challenges and act as social instruments to create, share and store both physical and tacit knowledge. (Papargyris and Poulymenakou 2003)

“This is genuinely a different concept from that proposed in CoP, not just a change of tone or position; it is simply a different idea. Thus the prescription for management is not about making space for workers to appropriate a joint enterprise, as it was in CoP; rather the idea is to create or foster new groupings of people who work on similar or parallel not joint enterprises (practices), effectively to invent new practices.” (Cox 2004)

This move has seen the focus turn from seeing CoP as existing communities to reorganising team structures to deliberately mix individuals from different existing CoP to form new groups around a particular problem or collaborative practice. By having a mix of knowledge and experience, the same potential benefits achieved through existing CoPs can be fostered but in a heightened way. Linked to this is also the encouragement of managers to develop “horizontal” groups across typical organisational boundaries to help improve performance. (McDermott 2003)

With this focus, it has further been identified, however, that just by bringing together a group of people and calling them a CoP does not mean that they experience the benefits articulated. (Li et al. 2009) A range of factors have been suggested to influence the successes of CoPs (Wenger 2002) including the role of “boundary objects”, “boundary spanners” and “boundary interactions”. (Hustad 2007) Their cultivation has also been suggested to benefit from being
supported by a flexible framework rather than prescribing their establishment and leaving them
to develop independently. (Ranmuthugala et al. 2011)

Boundary objects act to connect and coordinate knowledge from multiple individuals or
communities. (Wang et al. 2011) They can be abstract or concrete structures but either way
they support interactions by “satisfying the information requirements” of different individuals or
communities that come together to share knowledge. (Star & Griesemer 1989) This is achieved
by being flexible so that different groups can interpret them as they require to harvest
knowledge, yet robust enough to maintain a common identity that all the groups can contribute
to with the awareness that others are doing so also. (Levina & Vaast 2005)

“[Boundary Objects] have different meanings in different social worlds but their structure
is common enough to more than one world to make them recognizable, a means of
translation.” (Star & Griesemer 1989)

Boundary spanning refers to the process which facilitates the interactions of different
individuals or communities. Individuals may occupy this role and may be termed Boundary
spanners. They facilitate communication and sharing of knowledge by linking these different
individuals and communities who are separate in terms of location, division or function. (Levina
& Vaast 2005; Pawlowski & Robey 2004) The concept is similar but different to “knowledge
brokers”. “Knowledge brokers” are individuals who are involved in multiple communities and
share knowledge across them. (Brown & Duguid 1991)

Boundary interactions refer to the encounters between individuals from different CoPs. These
interactions may be facilitated by a boundary object or spanner but specifically refer to the time
and space in which they meet. These could include discrete encounters such as meetings or
site visits or longer connections overtime through collaborative projects or forums. (Kislov et al.
2011)
Boundary objects, spanners and interactions align with a specific list of seven factors put forward by a leading author in the field as factors that can help to cultivate CoPs (Wenger 2002):

1. Design for evolution.
2. Open a dialogue between inside and outside perspectives.
3. Invite different levels of participation.
4. Develop both public and private community spaces.
5. Focus on value.
6. Combine familiarity and excitement.
7. Create a rhythm for the community.

In healthcare, CoPs have been considered explicitly in academic literature. They have been promoted as a means of generating and sharing knowledge and improving organisational performance. (Ranmuthugala et al. 2011) The way they are structured and operate vary considerably, however, and a greater understanding of how to establish and support CoPs to maximise their potential to improve healthcare has been called for. (Ranmuthugala et al. 2011; Kislov et al. 2011)

7.1.6. Knowledge management

As already touched upon, CoPs are “a mechanism through which knowledge is held, transferred, and created” (Kislov et al. 2011) and, as such, the concept is closely linked with the Knowledge Management academic field. In healthcare, this academic field has also seen shifting focuses.

Knowledge “management”, “transfer” and “translation” (and other associated adjoining terms) are related concepts which refer to the movement of information between entities including people, teams, systems and organisations. (Straus et al. 2009) Broadly these “knowledge” fields are considered from the perspective of storing, sharing and re-using information within
an organisations. (Papargyris & Poulymenakou 2003) From the perspective of improvement, the management and transfer of knowledge is critical for learning to occur and decisions be made in order to achieve a desired outcome.

The “knowledge” field has received much attention within healthcare and its roots are linked to the process of implementing evidence-based practices in healthcare referred to back in Chapter 1. The role of knowledge transfer/translation can be considered from the view of a linear transaction from the production of research knowledge in regards to an evidence-based practice to the use of this practice in healthcare delivery. The complex and socially and contextually dependent environment of healthcare delivery has meant that a more sophisticated view of knowledge must be developed, however. (Damschroder et al. 2009)

Recognition that knowledge management when more than one person is involved is as dependent on the social interactions between individuals as the information itself links the role of knowledge management with CoP. (Papargyris & Poulymenakou 2003) This is particularly pertinent as knowledge in these situations is unlikely to be stable or acontextual. “Knowledge interaction” has therefore been proposed as more preferred term to present the back and forth nature of knowledge in healthcare improvement. (Davies et al. 2008) This complements the consideration of knowledge used within CoPs and also the cyclical nature of PDSA cycles.

“Set against such understanding, terms such as knowledge transfer and knowledge translation misrepresent the uncertainties, complexities and contextually contingent ways in which knowledge is created and applied. While any term is likely to open itself up to fresh critique, “knowledge interaction’ might more appropriately describe the messy engagement of multiple players with diverse sources of knowledge.” (Davies et al. 2008)

Where “knowledge” is stored can be considered in three forms: as an object; embedded within individuals; and embedded in a community. (Wasko & Faraj 2000) As an example of the latter,
CoPs are a mechanism by which knowledge around a common practice is discovered and shared. This can be explicit expertise or tacit, “sticky” knowledge which is based on experience and hard to capture and share between groups. (Wenger et al. 2002) It is this knowledge which is often most useful when trying to make improvements in a complex, social dependent system: it is “useful for enhancing care, providing learning opportunities, analysing practice, problem-solving, sharing knowledge, and generating ideas”. (Kislov et al. 2011)

“Sociologists claim that the reason behind failures to leverage knowledge sits on the fact that knowledge cannot be seen as an object linked to an individual. They argue that knowledge is anchored and embedded in distributed and situated practices, and that individuals can access it by participating in CoP.” (Papargyris and Poulmenakou 2003)

The use of QI methods, whilst providing technical benefit through harnessing scientific principles to learn, can also be hypothesised to support the social interactions necessary for improvements, in particular the facilitation of different CoP and sharing of “sticky” knowledge. It is these interactions that are a focus of this study to understand how PDSA cycles are used in practice.
7.2. Method

7.2.1. Values

This study was part of the international qualitative study into the empirical reality of using PDSA cycles that was also reported in Chapter 6 and takes the same interpretivist view.

7.2.2. Sample

Two organisations, one from the U.K and one from the USA, using PDSA cycles across a number of projects formed the sample of the study. The organisations were pragmatically sampled through existing relationships of the researchers. Two organisations were studied to provide different contexts in which the method is conducted.

From within each organisation four improvement projects that conducted and documented PDSA cycles were focussed on as well as the organisational structure that supported these. These improvement projects were identified by asking a manager with an overview of improvement work to identify those currently active and using the PDSA cycle method. Individuals within these improvement teams and the organisation’s team supporting improvement work were then approached to participate in the study.

7.2.3. Data Collection

Semi-structured interviews with improvement team members and members of organisation whose roles support or influence the improvement were conducted (Appendix 6). Interviews at a team level were used to understand current and typical PDSA conduct and the context they were used within, including perceptions of PSA cycles and organisational factors. At organisational level, they explored the awareness of improvements in the organisation, perceptions of using of PDSA within the organisation and the support mechanisms in place to support improvement and PDSA work. In total, 59 interviews were conducted by 2 researchers (CM and JR) across a range of projects/ areas: the Emergency Department, Medical
Assessment unit, Stroke unit, Kidney Transplant, Psychiatry, Gynaecology and Hospital operations.

The process of testing change in practice and team meetings in which PDSA cycles were devised and discussed was also observed and informal feedback asked for conversationally. Observations in meetings captured the actual conduct of planning PDSA cycles and the subsequent discussions following a “do” stage, including both the “study” and “act” stages. Documentation of improvement team PDSA cycles and other project related items were also available and formed background material.

Interview transcriptions and researchers field notes were transferred to Nvivo 10 software for analysis.

7.2.4. Data analysis

To help draw observations in relation to reality of using PDSA cycles, the analysis sought to identify the social and knowledge interactions necessary to use the method. Specifically, it aimed to identify enablers and challenges articulated and observed in regards to these.

Inductive thematic analysis (Guest et al. 2011) based on the constant comparative method (Glaser 1965) was conducted. Initial focus was placed on reading and re-reading transcripts, highlighting relevant text and making annotations. “Open” codes were then identified to describe the social and knowledge interactions within the raw-data in regards to PDSA use. Through comparison across transcripts, these codes were then grouped into hierarchical thematic categories and subcategories to provide an initial framework for further coding and findings (Appendix 7 presents the hierarchy developed). The developed theoretical framework of PDSA cycle conduct (Taylor et al. 2014) was initially used to frame the hierarchies but was not rigidly applied. Coding that did not fit with the framework were attributed to new categories driven inductively by the data. Coding was discussed between researchers through a series of meetings and coding structure refined iteratively. The intention was not to compare the
organisations, but use as a collective research sample for the challenges and enablers of PDSA cycle use.

7.2.5. Methodological quality

Methodological quality was considered using evaluative criteria appropriate for the research questions and approaches. (Roulston 2010; Tracy 2010) Purposive sampling was used to invite the most appropriate individuals, with experience relevant to the research questions. Specifically, these individuals were part of improvement efforts, organisational or smaller team based, that were involved in the use of PDSA cycles. The participants did not necessarily need to be aware of the PDSA cycle method but able to articulate their role and experiences within the improvement effort. Methodological rigor was enhanced through conducting pilot interviews with improvement team members local to the researchers to test and adapt research questions. Researchers also presented initial findings to a group of participants at the included organisations and at local research meetings to sense check themes and act as critical friend.

7.2.6. Ethics

The study was approved by a multicentre research ethics committee (Appendix 8) (REC reference: 13/WM/0436). Relevant research governance was sought and obtained at each participating organisation. All participants were notified in writing and staff briefings of the study aims and methods in advance of participation. Written consent was obtained from interviewees (Appendix 8).
7.3. Findings

The study’s findings are split into three sections in relation to the conduct of PDSA cycles: completing a single cycle; completing multiple linked PDSA cycles; and documenting cycles. For each, PDSA cycles were observed to act as a boundary object to support knowledge interactions between different communities of practice. For completing a single cycle there was a need to share knowledge and support negotiation between multiple CoPs. Various challenges and enablers to this were observed including the role of QI specialists who could play role of boundary spanner. For completing multiple cycles, difficulties in managing knowledge over time, particularly emergent learning from conduct of PDSAs, was observed. In some instances this appeared as an “explosion” of learning that needed to be managed and navigated to support effective use of multiple PDSAs. Finally, the role of documentation of PDSAs was explored in to how it supports these negotiations and navigation by sharing and capturing knowledge between multiple CoPs. The value of this, however, was questioned by users.

These findings are presented in relation to the conduct of PDSA cycles: negotiating through a single cycle, navigating through multiple linked cycles and narrating learning by documenting.
7.3.1. Negotiating through a single cycle

PDSA cycles were carried out by teams and involved participation of a broad range of stakeholders. These teams, whilst coming together for a common goal, were often individuals from different CoPs. For example, a lead academic clinician, a business manager, a nursing manager, a junior doctor, a frontline nurse, a data analyst and a QI specialist facilitating the QI team. The PDSA cycle method provided a framework by which these individuals and communities could come together and discuss, develop and deliver change to healthcare delivery. Through this lens, the PDSA cycle was observed as a boundary object: it aimed to facilitate interactions between different individuals and communities in a structured manner. (Wenger 2000)

“You actually are doing the PDSA through your discussion, really …and that’s kind of how we’re trying to run our team meetings, as well, is... so you’re... we’ve tried something different. How was it for everybody? What would be changed? What’ll we do next month?” (Interviewee 27, Site 2)

“I mean otherwise it would just be a kind of random generic… it structured it around the test, we planned the test, we planned the specific details of the test. And without that we wouldn’t have done that” (Interviewee 35, Site 3)

Regardless of whether a cycle was being used to test the initial functionality of a change or to learn how to best implement a change in routine practice, the overarching theme of a single cycle was to facilitate knowledge interactions. These interactions can best be described as negotiations due to the two-way nature of the knowledge shared between different people or groups. They involved communicating explicit knowledge (e.g. quantitative data or evidence based data) however; most often they involved sharing tacit knowledge based on experience: “sticky knowledge”.

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“[The team] identify other things in the system that then you’re going to have to step back and say, okay, well what if [the nurse] does that. Could you do that? So you find yourself negotiating, I think, a bit, you know.” (Interviewee 38, Site 3)

“That’s actually where I think the most value [of PDSA] comes in… you have to have a conversation with people to realise most of us don’t hold it all, right? …that’s a two-hour conversation sometime… just getting to that point is what takes a long time but also where the most valuable conversation can happen” (Interviewee 53, Site 3)

Within each stage of a PDSA cycle, the method required interactions within teams to communicate, apply and create knowledge in regards to a change aimed at improving a particular outcome. Within the “plan” stage this included sharing knowledge to identify the problem and a change or adaptation to address it, as well as then sharing knowledge to contribute to a detailed action plan to test the change. Within the “Do” stage the interactions involved communications of knowledge between the team devising the plan and the individuals that would carry out the test of the change. This included engaging them to agree to test the change and then ensuring the test was carried out as planned. For the “Study” stage, knowledge was retrieved from those that tested the change and then knowledge interactions occurred to determine success and areas to address. Finally, for the “Act” stage, knowledge interactions were required to determine the next steps and communicate these to others.

Whilst the method instigated these knowledge interactions, challenges and enablers to their occurrence were observed.

**Challenges to successful knowledge interactions within a single PDSA cycle**

In general, the challenges concerned factors that related to bringing together different communities of practice. This included the ability to draw on local knowledge and views of different CoPs to develop a plan or study a test. It also included the ability to communicate the
tests of change to those required to execute them, who were often not present during planning
discussions, and maintaining engagement in doing so.

Failure to draw on local knowledge and views of different CoPs could mean that incorrect
assumptions were made about current practices, a lack of detail went into the plan or learning
did not occur effectively; all inhibiting the ability to improve. Within the plan stage, this could
occur through the lack of involvement of all CoPs relevant to the area of improvement or
relying on an individual rather than a collective view.

“I think the hardest part with the PDSAs in the group is communication. Yes, because
the front-line staff, they’re the ones that are doing it... We discuss it at our meetings. We
meet bi-weekly, and we’ll say, we’re going to test A, B and C. They’re not there, you
know what I mean. It’s your front-line folks that are doing it” (Interviewee 38, Site 3)

“the danger is that sometimes these projects are the idea of one person” (Interviewee
29, Site 2)

“there’s a tendency to say, let’s just ask an expert, the expert will tell us and we’ll do it,
and so for us in this environment I think that’s one of the challenges, to take a step back
and say no, to get our expertise to work we actually have to sit down and do the
improvement work ourselves” (Interviewee 36, Site 3)

Drawing on the local knowledge of a range of CoPs could also be inhibited if the language
used by those more experience in using QI methods was “jargon” heavy. This could distract
from focusing on the problem that was trying to be addressed or meant that some views were
not considered, particularly if there was a lack of familiarity with the method within a team. Both
prevented the sharing of “sticky” knowledge. Alternatively, some individuals from other CoPs
may be more familiar to other methods to improve care and may not engage with the method
and share knowledge immediately.
“So I think people resent more than anything, they just resent the jargon and they want to stop this kind of jargon. But if you’re in a meeting and you say okay, so what is this that we’re trying to accomplish, that’s not jargon, and that doesn’t really turn them off.” (Interviewee 35, Site 3)

“our frontline people have enough rocket science taking care of, you know, the physiology of the human body in crisis… if I add another level of complexity [PDSA cycle language], I’m just going to distract them” (Interviewee 57, Site 3)

“the ideas of those who have not been trained in the mysterious arts of improvement methodology, tend to be disregarded and projects that are not documented and presented within that methodology are not supported, not because they’re not good ideas but because they are packaged in the wrong methodology” (Interviewee 18, Site 2)

Failure to draw on local knowledge was also influenced by team’s discipline to plan a change to a sufficient level of detail or study it objectively. For example, there may be a tendency to insufficiently plan a test of change as others place pressure on “doing” or a failed test of change may have resulted in resigning to the view that an idea won’t work rather than pausing to study it objectively and learn what could be done differently. The time it took to collate knowledge also implicated team’s ability to effectively plan or study, this may be due to the physical time and space to collect knowledge, or the time it took to discuss and negotiate ideas.

“I think the issue with PDSAs is getting the discipline of people following through with them.” (Interviewee 27, Site 2)

“[the intervention] works for a week and it drifts and [the QI project team] say, oh, it didn't work, rather than, actually it did work, we showed that it works, so do it again and
ignore the fact that it drifted back or try and see why it drifted back but don’t take that as an indicator of failure” (Interviewee 18, Site 2)

“we haven’t cracked [PDSA cycles] at all yet, and I think it’s because we don’t really have a systematic approach for that… to asking for feedback from staff and patients.”

(Interviewee 27, Site 2)

As well as drawing on others’ knowledge, the negotiation and knowledge interaction challenges also related to communicating information to different CoPs required to execute a planned test. These individuals or groups were often not the ones involved in planning the tests and therefore the information in regards to tests of change needed to be conveyed, reliably. They also may be on the receiving end of a number of changes to test from other projects also so information overload needed to be managed.

“frontline types.. so, like [the people] actually making it happen. You may not be the person that, you know, dreams it up or, you know, puts it on paper, but when all these people… decide, like, oh, this is what we’re going to do, I’m the person that was doing it and seeing how that goes” (Interviewee 50, Site 3)

“(the plan) kind of gets filtered down through the managers and then down through the charge nurses. …What I have found is that the more it gets filtered down, the more diluted it gets…. You know what I mean? Like if I heard it on Monday on reports, then by Thursday it’s not the same message, because I think sometimes the message gets lost or confused after it’s been said several times.” (Interviewee 48, Site 3)

“as the safety lead I feel, like, my tests and my team initiatives should be of number one priority to everybody over there. Well, so does the flow-team and so does, you know, our turnover-team and so there’s the, every team feels like their test is the most important” (Interviewee 49, Site 3)
Overlapping communication and tests of change could disengage these staff required to execute the plans. Engagement of these individuals could also be negatively affected if the change was felt to be imposed by another CoP or if they did not have the opportunity to contribute to its development. Staff could be hostile or anxious towards the change as they perceive it to be a suggestion that they are not doing their job properly or that their job is changing.

“…the overlapping and competing priorities of the teams created a lot of confusion for the frontline staff. And so the staff just [say] forget it…I'll do what I know I need to do, which is take care of the patient.” (Interviewee 49, Site 3)

“the reason we decided to do this is [because] we were told to do it as part of [the organisation strategic initiative]. And so that’s a very important I think… It’s, like, does affect, kind of, the psyche people who’ve done the quality improvement work if they feel that’s imposed on them” (Interviewee 51, Site 3)

“the nurse, comes and joins the team kind of mid-cycle [and says]… ‘You know, like what do you mean, what does it mean? Are you changing my job? You know, like what is going on, you know?’” (Interviewee 53, Site 3)

Enablers to successful knowledge interactions within a single PDSA cycle

A number of enablers were observed to overcome these challenges and support the negotiations and knowledge interactions necessary for successful PDSA cycle conduct. Again, these included some technical abilities such as ability to access and analyse data or use other QI methods such as Driver diagrams and Failure Modes Effect Analysis to identify a change. However, they were predominantly social factors that were dependent of the QI specialist that was responsible for leading the QI project in question and the use of the PDSA cycle method. In doing so they played a boundary spanning role to facilitate knowledge interactions between different CoPs.
These social interactions to manage knowledge, facilitated by the QI specialist, were key to maintaining scientific rigour and harvesting learning from the PDSA cycle method. If these interactions between individuals and communities were not achieved positively then progression towards learning and the achievement of an improvement aim was curtailed. It was not an unwillingness to use the method with high fidelity but the ability to facilitate a team to do so that was crucial to good quality use of PDSA.

“its all about social skills – the technical are important but you won’t be successful without social skills” (Interviewee 52, Site 3)

To successfully carry out a PDSA cycle, QI specialists needed to negotiate using a number of different social interaction tactics. These came in number of forms including facilitation, communication, empathy, motivation, influencing and mediating and represented the QI specialist’s role as a boundary spanner. The interactions were enhanced by positive relationships the QI specialists had developed with and between the individuals and groups historically. The QI specialists with more experience using the method were often more cognisant of the need for addressing the social interactions and reflective in regards to adapting them based on their audience.

“So I think my role is very much a supportive one and to try and help create the space to let people who are actually delivering, arrive at the answers themselves” (Interviewee 18, Site 2)

“And they come back with the conclusion that your plan didn't work because the results are same as they were before. And, you know, you see that a lot so there is that. The bit that we have to do first is – well, persuade people is really the wrong term – is lay out the evidence in such a way as they decide for themselves that the thing that you think might be a good idea is also their good idea and then a high chance of delivery” (Interviewee 18, Site 2)
The dominant role of the QI specialist was to facilitate discussion to create dialogue and manage the knowledge of a range of individuals and groups. By following the PDSA cycle method, implicitly or explicitly, QI specialists would encourage structured dialogue within a team’s normal working environment. This included a range of interactions such as identifying a change to test, planning the test and gaining consensus, ensuring the change is executed, studying the results from a test of change and deciding on next steps. It often involved asking clarifying questions such as “what do you think will happen because of the change?” to gain a prediction or asking for the team to explicitly state the objective, something often done implicitly and not necessarily natural in normal conversation.

“you need to have a dialogue. It needs to be inclusive. It needs to be unthreatening. The process needs to be something that they can fit into what they do every day”
(Interviewee 26, Site 2)

“What’s the objective? And what’s your prediction? What do you think’s going to happen? And if you get them to think about that, then they’re much more likely to… buy into it, yes. They really do. I think once you explain it, and you had talked about facilitation skill. If you’re talking about it and they understand it and they see the value”
(Interviewee 38, Site 3)

“I wouldn’t imagine any of my staff would turn to me and say, I want to do a PDSA on this. They would come in here and say, I think… why don’t we try something like this? And I suppose then, my role was to say, well, right, we could do that, but how are we going to sort of measure…? “(Interviewee 21, Site 2)

The QI specialist also played a role in engaging different CoPs in using PDSA. This included motivation, influencing and mediating roles. When using the method, there was a risk that the overarching goal of a team was forgotten or changes were perceived to be imposed on others.
Both of which can inhibit motivation to participate. By making the patient care problem explicit as the rationale for the work, the QI specialist help motivate others to participate.

“I think most people are in healthcare for the right reasons, that they ultimately want to improve... so you kind of appeal to that more altruistic side of folks that originally got in this area to begin with.” (Interviewee 53, Site 3)

“I think it's mainly you know we talked about the champion role, it's explaining the why... it's because this then impacts this, we can get patients out faster which means there's less queuing, and your shift will go easier. That's our ultimate goal, and so trying to be able to communicate that, generally a majority of people will get on board once they understand the real why” (Interviewee 47, Site 3)

The demonstrating of empathy to understand and relieve concerns was also necessary and supported the QI specialist act as a boundary spanner. Knowledge interactions may have involved discussion in regards tensions or conflicting view which individuals in certain CoP may take personally; QI specialists were therefore required to take responsibility to mediate. These interactions were enhanced by positive relationships the QI specialists had developed with and between the individuals and groups historically. The QI specialist would benefit from positioning themselves as a supportive resource that was not there to dictate what was to be done.

“where I start is start talking with them about my experience, you know, working in hospitals way before I got into QI, you know, what it was like work on the floors in psychiatry and they recognise, oh, he's one of us, he really understands what this is like, he knows what a bad night at the hospital is like.” (Interviewee 36, Site 3)

“[the QI specialist] would go, okay, time out, I think we need to address what's the underlying current, what's going on in the room here, you know, and so that was helpful. So most… it's kind of… someone has to blow the whistle and say, all right, we can’t…
we’re not talking about PDSAs right now, we’re going to talk about what’s going on in this room right now…” (Interviewee 53, Site 3)

QI specialists reported the need to adapt their support between teams. One key social interaction consideration taken by successful QI specialists, in relation to communication but also relevant to engaging and motivating others, was the use of language depending on the previous experience of the QI team and framing conversations using the terminology of the PDSA cycle method implicitly or explicitly. For inexperienced teams, QI specialists expressed the opinion that using PDSA language was not helpful as it added a level of complexity that inhibit the problem solving and drawing on “sticky knowledge” that was important for the necessary knowledge interactions. Instead they themselves would use the PDSA cycle in their head to guide conversation and ask questions; they didn't discuss specific stages but rather framed conversation around it. Once a few tests of change had been facilitated, the QI specialist may begin to bring in the concept and language of PDSA.

“If I got my laptop out in the meeting and went through a PDSA, people wouldn’t come back. It’s a fine line between being useful and pushing people away.” (Interviewee 52, Site 3)

“I tend not to use the terminology when I’m working with a new team, so, I tend to explain it more in, maybe, layman’s terms,” (Interviewee 44, Site 3)
7.3.2. Navigating multiple cycles

To gain the real benefit of using the PDSA method, multiple cycles iteratively adapting, adopting or abandoning change(s) are required. This involves the repeated knowledge interactions and negotiations between CoPs within a single cycle but also navigation through various potential decisions and actions that are both in and out of an individual’s or team’s sphere of control or influence and related to a range of other processes and systems.

**Challenge: Multiple cycles increases complexity which needs to be navigated**

Conducting multiple linked iterative PDSA cycles is often presented as a smooth progression focussing on a single change at a time. In reality, however, an increased complexity was observed due to an “explosion” of learning. This was when a number of problems and potential actions were identified following a single PDSA cycle. This explosion could occur at any stage of using the PDSA cycle method but tended to occur when a change was transitioning from being tested in isolation to being tested in routine healthcare delivery. This transition was part of increasing the scale of testing and involved moving from more controlled conditions where learning is aimed at the individual functioning of a change to less controlled conditions where more people are involved and other processes are necessary to be initiated following the change.

The original change being tested was no longer the only issue that needed to be considered. Testing a change would often reveal other issues that needed to be addressed to make the desired improvement. It was not just a question of scaling up, adapting, adopting or abandoning a single original change, but what further changes/ actions where necessary. These were often unexpected issues, ranging from supporting the original change or separate issues completely and involving other care delivery processes or systemic cultural issues. The main challenge to address these issues often rested with the varying degree to which individuals or the QI team were able to influence them effectively.
In one sense, this learning was positive as it was offering insight into how to successfully achieve improvement. On the other hand, it was challenging as multiple tests of change and actions needed to be managed simultaneously. This increase in complexity challenged the ability to conduct PDSA cycles and in turn harmed the ability to learn further in the pursuit of improvement. It would considerably slow the process of conducting PDSA cycles and would go against the commonly held view that the quick and easy small scale tests of change would continue. The empowerment that initial PDSA cycles offer, allowing teams to (re)apply knowledge as they see fit, would also reduce.

An example based on collated experience of different teams included within the study is presented below to help outline this challenge. It is based on the experiences described by interviewees and observed by researchers. It is combination of different teams experience to help describe the challenge usefully and anonymously. It includes:

- **Example intervention** (Figure 34)
  - An example intervention, a discharge checklist, is used to frame the challenge. This checklist is known to work in other settings but needs to be adapted to the setting in question

- **Initial PDSA cycles series to test the usability of the intervention** (Figure 35)
  - Typically, an initial series of PDSA cycles would test the usability and applicability of the intervention in “controlled” situations, when the QI team was present. This would result in agreement within the QI team that the intervention was fit for purpose.

- **First PDSA testing the intervention in routine practice and resulting in “explosion” of learning** (Figure 36)
  - After being deemed fit for purpose, the intervention would be tested within routine healthcare delivery. This was in a less “controlled” situation and the intervention was require to fit with other processes and structures.
Following this test there tended to be an “explosion” of learning where multiple factors that need addressing would be identified.

- **Explosion of learning - multiple factors that need addressing across different contextual levels** (Figure 37)
  o The multiple factors that need addressing would often be across different contextual levels. The ability for the QI team to influence these different levels would vary.

- **Explosion of learning - multiple factors that need addressing are also influenced by different levels of context** (Figure 38)
  o The multiple factors that need addressing would also themselves be influenced, positively and negatively, from different levels of context. Again, the ability for the QI team to influence these different levels would vary.

### Intervention example:
- Checklist to support the discharge of a patient from a hospital to their home
  o Successfully used in other organisation
  o Checklist consists of:
    - Review of final items of care
    - Medication check
    - Patient information provision
    - GP follow-up appointment
    - Transport arrangement
  o Setting of use:
    - Acute care ward
    - Staff member to use and communication processes (to be decided)

*Figure 34. Example intervention tested using PDSA cycles*
**PDSA Series #1 - Adapting Discharge Checklist to Our Hospital**

Test 1 - 1 consultant (Dr M)
Test 2 - 1 consultant (repeat Dr M)
Test 3 - 1 consultant (repeat Dr M)
Test 4 - 3 consultants (Dr N, Dr O, Dr P)
Test 5 - 2 nurses (Nurse A and B)
Test 6 - 1 nurse, 1 physio and 1 junior doctor (Nurse A, Physio Z and Dr X)
Test 7 - 2 pharmacists
Test 8 - MDT - 1 consultant, 1 nurse, 1 junior doctor, 1 pharmacist (Dr M, Nurse A, Dr X, Pharmacist C) - 1 patient
Test 9 - MDT - 1 consultant, 1 nurse, 1 junior doctor, 1 pharmacist (Dr M, Nurse A, Dr X, Pharmacist C) - 3 patients
Test 10 - MDT 2 - 3 patients
Test 11 - MDT 1 - 1 shift
Test 12 - MDT 3 - 1 shift

End of series - checklist considered to be fit for purpose for our hospital

What types of adaptation were made:
- Language adapted to reflect terms and concepts used locally
- Lay out of Q3-6 changed to mirror another form used by nursing to minimise confusion
- A new section added to meet needs of our patient population
- Q9 and Q12 removed as considered not relevant to our patient population
- Q10 adapted to reflect hospital policies
- Box added against all items for data to be added next to initials of who had completed item on checklist

Figure 35. Initial PDSA cycles series to test the usability of the intervention
PDSA Series #2 Use of Discharge Checklist in Ward 6

Team/Project: Patient Flow Team

Test Objective: (what is being tested and what do you want to learn?) Will use of discharge checklist (v12) improve patient discharge?

Test Population: Ward 6 for 5 days (M-F) beginning Monday 13th October

Plan

How will you know change is an improvement?

- Improve efficiency of discharge: earlier in the day, consistent across week and less discharge delays.
- Reduce length of stay.

What action effect diagram factor(s) does change impact?

- From discharge checklist, through factors, to “Appropriate discharge from hospital” and overall aim.

Prediction:

- The checklist will be used and completed for all patients leaving hospital during the test period. The discharge checklist will be helpful to all members of multi-disciplinary team to discuss, coordinate and manage discharge process. Delays for discharge will be reduced and patient length of stay.

Data Collection Plan

- #discharge checklists initiated [forms are numbered and list of initiated forms with name of consultant - managed by Charge Nurse]
- #discharge checklists completed [completed and returned to Charge Nurse once patient has left]
- Feedback from staff on use of form.
- #delay discharges with reasons for delay [routine data collection]
- Length of stay [routine data collection]

Plan for test

<table>
<thead>
<tr>
<th>Task</th>
<th>Who</th>
<th>When</th>
<th>Where</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify patients who meet discharge checklist criteria</td>
<td>Charge nurse/nursing staff</td>
<td>Beginning of each morning shift 13th - 17th October</td>
<td>Ward 6</td>
</tr>
<tr>
<td>Use discharge checklist to facilitate MDT discussion and decision making during ward round</td>
<td>Lead consultant/jnr doctors/nurse plus pharmacist and physio if available</td>
<td>Morning ward round each morning 13th-17th</td>
<td>Ward 6</td>
</tr>
<tr>
<td>Use discharge checklist to guide completion of actions</td>
<td>All relevant staff</td>
<td>As necessary</td>
<td>Ward 6</td>
</tr>
</tbody>
</table>

Do

Was the cycle carried out as planned?

- No.

Deviations from the plan:

- Charge nurse was able to identify patients for checklist but it was not always possible to get MDT (minimum consultant/junior doctor/nurse) together to use checklist.

Record data and observations:

- #discharge checklists initiated = 28
- #discharge checklists completed = 2
- Feedback from staff on use of checklist.
- When used in MDT discussions forms were found to be helpful to structure conversations.
There was frustration by all staff about challenges of making time for an MDT discussion. Even once MDT had made decisions there were challenges finishing actions due to other issues.

- #delay discharges with reasons for delay
- 6 delayed discharge - waiting for senior decision making
- 4 delayed discharge - waiting for diagnostic results
- 2 delayed discharge - waiting for pharmacist
- 2 delayed discharge - waiting for community bed
- Length of stay - Average 3.3 days

**Study**

**Did the results match your prediction?**

- No. Predicted that all eligible patients would have a checklist completed. Only 2/28 were done. Checklist did facilitate conversations when MDT present but this was difficult to achieve.

**Compare the result of your test to previous performance:**

- Worse! Before we had the MDT assembled for the purpose of the test (1 shift only) so did not encounter these problems.

**What did you learn?**

- It is difficult to assemble an MDT during morning ward rounds on a routine basis
- Some consultants do their ward round early (8am) whilst the nurses are giving patient medications so nurses unable to attend
- Some consultants do not notify nurse that they are starting ward round so were not aware of which patients were eligible for discharge checklist and nurses not involved with decision making.
- There was a long wait (24-48 hours) for some diagnostic tests (bloods in particular) to be returned which meant information was not available to inform decision making and led to delayed discharge
- Only pharmacists are currently able to give inhaler technique training to patients. This led to delays in discharge due to wait for pharmacist to provide training.
- One nurse informed us that at previous hospital she worked at nurses were also able to provide inhaler training.
- All staff found the item ‘arrange follow up appointment with GP’ very hard to complete. No processes for doing this exist. Query raised whether this was possible and whether it should be on the checklist. Need to understand how this can be facilitated if it is going to remain on checklist.

**Act**

**Potential Changes for next test:**

- **Consultant behaviour:** Review consultant ward round behaviours and investigate options for increasing awareness about discharge checklist/ need to involve nurse in MDT discussions
- **Diagnostics communications:** Improve speed of diagnostics tests returns
- **Inhaler training:** Provide education for nurses on inhaler training for patients
- **GP appointment:** Improve process for arranging follow up appointment

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Figure 36. First PDSA testing in routine practice and resulting in “explosion” of learning
Figure 37. Explosion of learning - multiple factors that need addressing across different contextual levels

Figure 38. Explosion of learning - multiple factors that need addressing are also influenced by different levels of context
**Specific challenges due to increased complexity**

**Scale-up:** The added complexity and contextual influence caused confusion over how best to approach the scale up of testing. There was an assumption that perceived quick and easy nature of small scale cycles will continue or that success achieved on a smaller scale or elsewhere will occur instantly elsewhere. Teams were tempted to no longer test the changes gradually and learn but instead “implement” the intervention without reflection. This challenge was exacerbated when other CoPs, such as senior management, did not understand the increase in complexity and the time and engagement required to conduct tests of change.

“maybe it’s around actually the exec team don’t understand actually how much… what capacity you require to run a PDSA or a project. They think it’s a quick… But maybe we’re not good at articulating that and escalating [that its not].” (Interviewee 28, Site 2)

“I think that’s a challenge for the organisation. Well, personally I think it’s a challenge that we have management folk who say, roll out this now, get it in as quickly as possible, so you can’t follow proper improvement approaches. It’s just implement, educate and implement, and we’ve done it well in ward 11 so it’ll work everywhere” (Interviewee 25, Site 2)

**Using data to learn and inform actions:** If the intervention being tested required multiple changes or to change completely then the data set up to monitor impact would also have to be changed. The complexity of the multiple changes meant it was hard to study them all individually. Not having this data in place in a timely fashion could slow down the process of change. In addition, involving more people and more areas of focus increased the time and difficulty to collect qualitative feedback.

“So nobody deconstructs it to say, what aspects of what is often quite a complicated change... because even though, like, you tend... you know, certainly the way we try and
do it, we try and pick something simple to change but the ramifications of that can be quite complex.” (Interviewee 18, Site 2)

Engaging people to change: The added complexity also made it harder to engage all the relevant people. This was not only due to the quantity of people required to know and accept the change but also that the individuals testing the change earlier on were more engaged and motivated in the change than others. The change may have meant changing people’s jobs which they might not have liked or were worried by. It was difficult to sustain this engagement and understanding overtime, especially if the intervention was still in a place where it is still being iterated.

“the challenges are when you get to the point of having to convince a wider audience to do something that’s different from what they do at the moment” (Interviewee 55, Site 3)

This increased complexity often challenged further progression and caused a disappearance in the application of PDSA cycles to facilitate learning and improvement. This was observed in a two of ways:

Teams didn’t effectively execute tests: Teams implemented multiple parallel changes that crossed different time periods (Figure 39) or collated a number of different changes within a single cycle (Figure 40). For both, this often resulted in ineffective tests of change with a reduction in formality/ rigour and little learning achieved to progress consequently. There was a tendency to not treat these changes as “tests”, instead they were just implemented without reflection.

“We kind of PDSA-ed it. So somebody went away and did it for a week. And then two people tried it for a little bit of time and came back and said, yes, feels much better. And then we sat down and have a conversation about it and said, rather than carrying on PDSA-ing it, let’s just do it. Because it’s difficult to manage it on a small scale because it
actually involves everybody. Everybody needs to change. So we went – bang.

(Interviewee 28, Site 2)

“Did we do everything that we should have done? No. Why are we surprised, then, if it hasn’t been as effective as it should’ve been? I don’t think we’ve got that right.”

(Interviewee 26, Site 2)

Teams didn’t re-apply learning: Teams implemented or scaled up a change that had not been shown to be effective or agreed by others or ended a QI project without trying other options. This would involve teams not pausing sufficiently, or at all, to study a test of change and determine next steps. Instead, they jumped straight into the implementation of an original change without addressing the other issues that arose during smaller scale testing or stopping the QI effort. This was largely influenced by the prevailing view that PDSA cycles should be conducted quickly and the tendency to see failure as an indication of a lack of effort which should be addressed by persistence rather than critiquing what was observed in relation to the original predictions and altering the course of action appropriately.

“So, and what we haven’t really got right is the structure to manage how we modify this, real-time. So if all this isn’t working, this isn’t… so what we’re doing is, every six weeks getting together and going, that’s not working. When actually, what we need to be getting… we should be much more dynamic about how that works.” (Interviewee 26, Site 2)

“I mean, yes, I’m an enthusiast and it can be okay, but we have to be clear, they are reversible cycles of change that are dumped if they don’t work, or modified and then repeated, and modified and then repeated, but not imposed, because sometimes, what are called PDSA are not PDSAs” (Interviewee 29, Site 2)
Figure 39. Implementing multiple parallel changes that cross different time periods

Figure 40. Collation of a number of different changes within a single cycle
Enablers: Planning and focussing on learning

The challenges that arise with increased scale and complexity of PDSA are not often taught or communicated to those using the PDSA cycle method and can be a barrier to successful improvement. A few practical examples of managing the complexity were observed, although awareness of the challenge was limited. Those that overcame the challenges were often more experienced practitioners of QI and held practical experience to the conduct of PDSA above and beyond simply following the four stages of the method. They would take a step back from focusing on the conduct of a single cycle or an iteration to the next cycle and, instead, focus on planning a series of potential PDSA cycles over a particular timeframe or consider the type of learning that a cycle was trying to achieve to support more objective thinking.

**Long term proactive planning of tests in advance:** Proactively planning a series of PDSA cycles rather than focussing on a single PDSA at a time supported the navigation of multiple linked cycles. This can best be described as developing an intended path of how PDSA cycle testing may progress and a decision tree of directions to take if learning deviated from this path. This meant broadening a prediction from a single cycle to across a series of cycles. Whilst the increasing complexity meant that testing would not always keep to the predicted path, it meant that learning was less reactive and more prepared for in advance. Potential decisions that may be required to be made were articulated and discussed in advance and greater control was taken by engaging the necessary people earlier. Another element of this was to schedule testing of different areas in relation to a change. This would allow issues to be parked for future consideration rather than acting reactively to observed challenges.

“*So what we feel like is just as important as that PDSA is thinking about that ramp. So here’s where I am, here’s where I want to be, what is my plan for getting there? So that doing a PDSA is not just... I’m thinking about this test of change and I’ll decide what I’m going to do after I do that test. You have the larger plan in mind, so you make decisions differently I think if you have that plan in mind.*” (Interviewee 35, Site 3)
“Essentially what I drew out is a back-of-the-napkin sort of, thing, is we said for every PDSA… this is a way that we could display this to say we started here, we went down this path, and you know, they can have multiple branching points. But you know we went down this path, we did not revisit this because of this or because this was working, but we have documented that this happened, or this was a potential possibility, so we have reserved the right to go back and do that. “(Interviewee 47, Site 3)

Consider the learning stages across multiple PDSA cycles explicitly: Considering the use of PDSA cycles as explicitly about learning rather than making immediate improvement was also observed to support management of complexity. Throughout a series of PDSA cycles, the aim of learning moves through a number of stages from learning about the usability of a change to the sustainability of implementing a change (Figure 41). Early stage tests of change seek to learn specifically about the usability of a change (whether it works as intended), applicability (whether it works in different situations) or acceptability (whether it accepted by those that will be require to implement it). As scale increases, learning will be need to be directed to its scalability (can it be used at a larger scale – in more situations and by more people), “maintainability” (whether it can be implemented consistently with support of the QI team) and sustainability (whether it can be implemented consistently without the support of the QI team). In recognising these types of learning, tests or data collections can be designed, success reviewed more objectively and adaptions made accordingly.
Figure 41. Learning stages of PDSA cycle conduct
7.3.3. Narrating cycles

A final observation on the reality of conducting PDSA cycles was in relation to the documentation of the method’s use: narrating learning and improvement.

**Challenges: lack of value and time**

The storing of knowledge is an important part of the knowledge management process, however, it was widely reported and observed that each stage of PDSA was often not documented well, if at all. This was for a number of reasons but largely due to low value placed on documentation. This was influenced by the occurrence that if and when cycles were documented, the documentation was not subsequently used and any benefits not realised. This caused an immediate problem of perceived waste of resources and reduced the likelihood of documentation occurring in the future.

“we do it because they say we have to, but I’m not sure anyone ever looks at it”
(Interviewee 32, Site 2)

“documentation of PDSAs is very, very hard to make it useful” (Interviewee 42, Site 3)

Capturing the knowledge from a PDSA cycle therefore often occurred mentally and was not physically recorded with “I just do it in my head” a typical view from QI team members. Challenges to the actual process of documentation were also articulated and revolved around having somewhere to document, someone to document and the time to do it. Documentation templates, whilst used, were sometimes thought of as inhibiting as they were restrictive on what to capture (this linked with the challenge of capturing the “explosion of learning”). The process was often referred to as a time consuming task, particularly where testing was occurring frequently, and it was deprioritised against other activities as such. Taking the time to pause and document was an unnatural step in the busy and time-limited environments within which teams acted.
“I have to say, we do struggle some with getting people to do really rigorous PDSAs and writing it down” (Interviewee 44, Site 3)

“one of the complaints that my staff has around test of change... or the PDSAs is it’s very time consuming to document” (Interviewee 35, Site 3)

**Enablers: increase ease and deliver immediate value**

Some enablers to improve documentation were observed. These included drawing on the academic nature of teams to motivate them to document, the QI specialist taking responsibility to document and the adaptation of templates to recognise the different levels of detail (detailed to high-level) that PDSA cycles could be documented. This latter example also linked to the use of visual displays to present PDSA cycle diagrammatically over time. This allowed teams to clearly capture and have an overview of multiple PDSA cycles which was seen as useful to engage teams in PDSA conduct in general. This is an example of immediately deriving value from documentation. Whilst it was not commonly observed, giving value to documentation was articulated as a key mechanism to improve the extent and quality of documentation. Other values of documentation included the facilitation of conversations and clarity of dialogue and sharing learning and project examples with others.

“If there’s a barrier, we need to get in there and help them document them, then that’s what we need to do. I mean, I think our roles have to be flexible, and we do what needs to be done to move the work forward.” (Interviewee 37, Site 3)

“we can create this simple sheet, and it would require just minimal time, and that’s just what your PDSA was, the date of course when you did it, and just a brief description and some comments. Now, it doesn’t of course capture all the PDS & A that we require on the sheet, but at least you’d have a good summary” (Interviewee 55, Site 3)

“So, two things [to improve documentation], one having a place and then two creating the opportunity to get that visibility.” (Interviewee 55, Site 3)
7.4. Discussion

7.4.1. Summary

This study presents the reality of using the popular QI method; PDSA cycles, and uncovers the challenges to using with high fidelity and mechanisms to overcome these. It presents the central role of social interactions in using PDSA cycles in healthcare. It also highlights the complexity that can follow learning achieved by testing change and the implications this has. Without overcoming these challenges there is a risk that PDSA cycles will be articulated and attempted to be used but will not actually be applied as its principles prescribe.

This study also confirms the CoP and knowledge interactions involved in PDSA use and highlights the importance of a boundary spanner to facilitate the use. The study opens the black box on the often pristine view of conducting PDSA cycles and highlights this reality into three areas; negotiating a single cycle, navigating multiples cycles and narrating through documenting cycles.

7.4.2. Negotiation

An improvement effort is often needed because there is no “know-how” of what to do, or at least not universally agreed “know-how”. (Langley et al. 1996) The process of PDSA seeks to combine “know-how” and tacit knowledge to develop a change to test, learn from testing it in practice and come to a consensus on next steps. This was achieved by bringing together different communities of practice to contribute to the sharing, testing, and iterative application of knowledge and learning aimed at improvement.

“In a socially situated view of learning, individuals continuously combine and modify knowledge through their everyday operations and interactions between each other [24-26]. Apart from explicit, codifiable, ‘know-that’ knowledge, collective practice generates a great deal of tacit, ‘knowhow’ knowledge, which is embodied in the CoP members’ practical skills and expertise [27].” (Kislov et al. 2011)
The PDSA cycle method acted as a boundary object by providing structure for this group to follow. This was not enough, however, to successfully achieve the knowledge interactions necessary to use the method, it also required a QI specialist role to act as a boundary spanner. This role was benefited by an individual with experience of recognising the importance of social interactions. Those with less experience in PDSA were more focussed on the mechanics of the method rather than appreciation the importance of harnessing the community and people that were coming together in attempt to make improvements.

To utilise PDSA cycles, the role of a QI specialist involved supporting learning and influencing iterations by creating opportunity for boundary interactions and structuring these around the method’s stages. By leading the use of the method the QI specialist would take the cognitive load off of the healthcare staff and allow them to focus on sharing their “sticky” knowledge. It was often counter-cultural and difficult to learn by tests of change; to pause to reflect; to realise something went wrong and do something different. To facilitate a team to do so, within a complex organisation, with competing interests and a tendency to revert to a status quo, extrapolated these challenges. It was therefore the role of the QI specialists that was observed as crucial to successful execution of PDSA cycles and subsequent learning and improvement. They would guide a team along the journey towards improving a desired outcome by facilitating and framing dialogue. By doing so, they acted as “agents” to embed the practice of PDSA cycles in the QI projects.

“The creation and management of boundary objects is a key process in developing and maintaining coherence across intersecting social worlds. Moreover, effective boundary objects are those which are embedded in the practice of agents who use them and have a common identity across practices.” (Star & Griesemer 1989)

The role of the QI specialist was observed as one that was not just about understanding the theory of a change (Foy et al. 2011) or technical use of QI method (Taylor et al. 2014), but understanding and developing a theory of engagement. They were required to influence and
empathise with team members and staff delivering changes on the frontline. They needed to motivate others; convincing others of the need for change, telling positive stories of previous successes; and maintain momentum through failures. They also played an educational role skilling QI team members up in the use of improvement methodology. This included leading by example and providing training sessions. Publications of improvement efforts should recognise and report the implementation and success of these engagement theories in order to support the translation of successful QI interventions and use of methods elsewhere. (Davidoff et al. 2015)

This study echoes previously identified leadership traits enacted by boundary spanners. (Ernst & Yip 2009) This includes “reframing”, “nesting” and “suspending” activities. “Reframing” refers to developing and installing a common language and practices that different communities of practice can identify and engage with. “Nesting” refers to structuring and facilitating interactions within a larger common goal, such as improving patient care. “Suspending” refers to creating a “third space”; a time and place where social interactions are person- rather than profession-based. This study suggests that these boundary spanner leadership traits are vital to deploy QI methods, which require social interactions, effectively.

With these roles in mind, QI specialists had to have a technical grasp of improvement methodology but also an inherent social outlook of the world. They needed to be accepted within a project team clinical area and benefited from having some clinical knowledge understanding and an understanding of the relationships and hierarchies within healthcare delivery. Ultimately to be effective, they needed to balance an understanding of methods and ability to facilitate social situations; understanding that different individuals and groups were engaged through different means. One reason for the varied effectiveness of QI attempt may lie with the ability to facilitate the social interactions necessary to problem solving and agreeing on adaptations to an intervention; not the mechanistic view of just a QI method use to deploy
an intervention which will then influence an outcome. Research into QI attempts could benefit from being explicit about the social interactions that supported or hindered progress.

Whilst initially team members of a QI team using PDSA cycles often come from different communities of practice, the use of the method as a boundary object and role of a QI specialist as a boundary spanner help employ the seven principles of cultivating communities of practice. (Wenger 2002) As such, it can be argued that those that overcome the challenges identified become their own CoP, centred on the improvement of patient care and using the PDSA method to do so rather than an individual clinical profession or administrative role. Whilst this CoP can be developed by using PDSA cycles, it is important that team members keep their own perspective and bring different viewpoints to inform the development of a change.

7.4.3. Navigation

The purpose of PDSA is to allow ideas to be tested and adapted in light of learning what works and what doesn’t. (Berwick 1998) In the complex social systems of healthcare this flexibility is important to tweak interventions to fit with the local context and address problems. This complex social system also implicates the process by which the method is used, of which this study demonstrates.

The study reinforces past observations that the linear process of testing, adapting and increasing scale, as the method is usually depicted as, does not hold true in reality and reveals reasons why. (Tomolo et al. 2009; Reed & Card 2015) “Explosions” of learning were observed in which one PDSA cycle reveals a large amount of learning. This related to the number of different observations that further tests of change could seek to address but also different scales to these observations: some of which may be smaller issues related to processes of care others could be larger organisational issues that are harder to address.
This increase complexity caused the application of the method to disappear. This could be either through further PDSAs that collate a number of different changes in one but are not executed well, or the number of different adaptations necessary being implemented without the use of the PDSA cycles to learn. Both involve underinvestment in the planning phase due to a cultural emphasis to move quickly to “do”. This similarly influences the amount of focus on the study phase and, as such, as complexity increases teams result in getting stuck in the “do” phase.

These observations suggest that the increased complexity through explosions of learning must be met with increased sophistication to the application of the method. Early stage tests of change may be able to proceed with less detailed planning and studying, however as the scale of learning increases so does the attention to detail when using the method. Approaches to achieve this were articulated by interviewees and included proactive planning of potential tests in advance – providing a framework by which learning and application of learning can be guided – and having explicit focus on learning rather than success or failure of a test of change. Both can help teams remain more objective in learning and help better manage adaptations. Teams would also benefit from understanding the sphere of control they have over potential adaptations that are observed during initial tests of change – and what to do if they are unable to control or influence these necessary adaptations.

7.4.4. Narration

Documentation is vital for scientific rigour (Thor et al. 2007) and this includes the use of PDSA cycles. However, this study suggests that the scientific element of the method will not occur if it is not valued by the individuals using the method. Without documentation there is a risk of repetition, duplication and loss of learning. This observation hints towards a focus on “doing” and “acting” and not “studying” sufficiently to learn. The greatest opportunity to demonstrate value is by providing short term benefit, however, this was not widely perceived. Four suggested areas of value based on this study are outlined below:
• Navigate and negotiate change: to support clarity of thinking and communication in the moment of using PDSA cycles
• Capturing learning and building memory: Store individual, team and organisation that the team can draw upon throughout the project’s lifespan
• Sharing learning with others: Share learning with other current or future QI projects
• Meta-evaluation: allow access learning to conduct research on the improvement area in question or use of the method

The areas of value should be communicated to users and educators of QI in an attempt to understand the benefit of documentation and increase the scientific legitimacy of the PDSA method and QI efforts on general.

Combining the navigation and narration themes, the study also suggests (Figure 42) a build upon the typical smooth increase in scale use of PDSA cycles (Figure 19) and the “more realistically represented” use of the methods (Figure 25) by suggesting other ways of documenting the methods of use such as taking into consideration the influencing contextual factors (Figure 38) and control teams have over these or the learning stages of the PDSA cycles in question(Figure 41).
7.4.5. Limitations and future research

This study has provided an insight into the black box of PDSA cycle conduct but is still at the beginning of a research pipeline that is necessary to understand and deploy PDSA cycles more effectively in healthcare. Whilst instances of PDSA cycle application were observed, the research approach of including multiple projects and limited data collection time period did not allow for observation of the method use from start to finish. Much of the data was therefore derived from interviews with individuals engaged in PDSA conduct in a QI project. Whilst this is useful to get an understanding of some challenges and enablers, further empirical research is needed to confirm these observations in the eyes of other involved in QI. Long-term
ethnographic studies could be one mechanism to deploy to gain richer data on the reality of QI methods. This type of research is imperative to advance the science of improvement. (Perla et al. 2013)

7.5. Conclusion

Through this study, further detail pertaining to the reality of using PDSA cycles, a popular and important QI method, has been identified. Users and educators of PDSA cycles need to understand the negotiation, navigation and narration challenges and enablers to help use the method effectively. This includes recognising that the use of the method requires negotiations of different CoP and the importance of a QI specialist to do so. It also includes the need to maintain the view that PDSA is a learning method and recognise methods to navigate complexity as scale increases and provide value to documentation so that it occurs. By doing so, the method will be able to effectively support the pragmatic and scientific approach to improvement that is required in the complex, social nature of healthcare.

7.6. Contribution to overall thesis

This chapter brings the end to the research studies conducted as part of this thesis. In doing so, it presents keys challenges and enablers to actually using the method.

The chapter builds generalisable knowledge into the conduct of improvement, an idea identified in chapter 2. It suggests the challenges and enablers to using the method scientifically and suggests both technical and social factors require attention to do so.

The chapter complements the assessments of fidelity in Chapters 3, 4 and 5 by suggesting factors that may challenge high fidelity in addition to the intention and understanding to do so. It expands on the identification in Chapter 5 that the actual application of the method is a key influencer in high fidelity use. Chapter 6 presented perceived principles and benefits of the method. This study presents social factors that can help the method principles as intended. These factors are also crucial to achieve the social benefits of the method.
8. Chapter 8 - Discussion

8.1. Thesis research enquiry

This thesis set out to better understand and clarify the scientific nature of quality improvement methods, and using the PDSA method as a surrogate, their application in healthcare. In doing so, it aimed to inform the development of the emerging academic field of improvement science. Based on a historical and evidence-based account of improving quality in healthcare, the introduction to the thesis provided an overview of the theoretical considerations to explore. This began with the relationship between healthcare processes and structures that influence health outcomes of a person. (Donabedian 1988) The process of identifying and implementing evidence-based interventions to change processes and structures was then highlighted. (Naylor 2002) This included the recognition of conceptual thinking in regards to the factors that influence successful implementation: the intervention itself, the implementation process and the context. (Damschroder et al. 2009; Rycroft-Malone 2004; Pettigrew & Whipp 1993; Greenhalgh et al. 2004) These three factors influencing successful implementation relate to the use of QI methods in healthcare. The implementation theories state the importance of an intervention being able to be iterated, in light of the context it is deployed and for the implementation process to support this. This is a key role of QI methods. (Boaden et al. 2008) Like the implementation of an intervention, literature also suggested that the role of QI methods is influenced by the prevailing context. (Bate et al. 2002) Understanding this relationship had received less focus in comparison to the implementation of an evidence based intervention. (Walshe 2007; Walshe 2009) The application of QI methods and contextual factors that influence them was therefore a focus of the research undertaken for this thesis. Building on the focus on the application of QI methods, it was their role as scientific methods that was a key consideration. Whilst the original descriptions of QI methods are clearly aligned with science (Deming 1986; Box & Bisgaard 1987), questions over their scientific legitimacy
and application have arisen due to their varied effectiveness. (Vos et al. 2010; Berwick 2008a; LaRosa 2008; Bickman 2008; Durieux 2008; Berwick 2008b) This is partially a reason for the development of the improvement science field, but also an area that the field needs to address and to provide further understanding and clarity on. (Perla et al. 2013; Parry 2014) It is on this premise that the research enquiry of this thesis was further set. It aimed to help researchers within this developing academic field as well as provide valuable insight for individuals and teams using QI methods and educators and support functions that help them to do so.

Over the course of this thesis, the importance of this research enquiry has remained. Quality and financial challenges are widespread in healthcare and mechanisms such as QI methods to help tackle these problems are helpful. A number of reports have highlighted the need for greater ability to conduct QI in healthcare (Ham et al. 2016; Berwick 2013) and calls for research to support the development of improvement science have continued. (Crisp 2015; Peterson 2016; Lewis 2015; Parry & Power 2016)

The ultimate aim of this body of work was to add to the existing research base and influence future application and research into the improvement efforts in healthcare and beyond. The research structure and studies discussed were designed to address this and the collective need outlined above. As the research progressed, the focus turned to a single QI method, PDSA cycles. The thesis did not seek to link the use of PDSA cycles with reported outcomes of healthcare delivery, instead it draws on theoretical principles and empirical observations to understand how the method is reported, interpreted and applied in practice. The journey to which this focus occurred is outlined in the summary of chapters below.
8.2. Overview of chapters

8.2.1. QI methods and science review

The initial study in thesis was a systematic narrative review of the literature to identify the articulated associations between QI/ QI methods and science. The review was specifically driven by the need for greater understanding in regards to the methods of improvement science. (Perla et al. 2013)

The study presented three categories linking QI methods and the concept of science:

1. QI methods are scientific methods to facilitate change and improvement
2. QI methods are scientific methods to evaluate a change’s impact on an outcome and build a body of generalisable knowledge
3. Scientific methods should be applied to study the use of QI methods to facilitate change and improvement

The majority of articles returned in the search referred to QI methods as the practice of science to facilitate change and improvement (the first category). From this, a common QI method, the PDSA Cycle, was identified as closely analogous with the application of the scientific method. The thesis focussed on this method and aimed to understand its application, and therefore the application of the scientific method to support improvements in healthcare. By doing so, the thesis’ research approach was a reflection of the third category identified in the review.

8.2.2. PDSA cycle systematic review

The second chapter presented a systematic review into the reported application of the PDSA cycle method in peer-reviewed publications. Typical systematic reviews aim to review the evidence linking an item of interest with the outcomes it produces. This study differed by systematically reviewing how the method had reported to be applied in healthcare. To achieve this, a theoretical framework of key principles of the method was developed based on the literature. (Deming 1986; Langley et al. 1996)
The study deductively assessed the fidelity of the method against the developed theoretical framework. In doing so, it revealed low fidelity use of the method with the application and reporting of PDSA cycles not complying with the principles that underpin it. The extent of low fidelity conduct of PDSA cycles drove the subsequent chapters. Firstly, to further develop the evaluation framework to assess the fidelity of PDSA cycles and apply it to improvement teams’ documented accounts of PDSA cycle. Secondly, to conduct qualitative studies to understand the interpretations and social reality of using PDSA cycles. For both, the role of context and how it influenced PDSA cycle conduct was investigated.

8.2.3. Refining the PDSA cycle assessment framework

To support consistent and detailed assessment of PDSA cycle fidelity and help others use and teach the method, further developments were required to the theoretical evaluation framework. Chapter 4 made these updates by qualitatively assessing a range of PDSA cycles documented by improvement teams. The updated framework remained based on the six key principles of the PDSA cycle method: Learning Activity, Prediction, Iterative cycles, Incremental testing scale, Regular data over time and Documentation. Further detail was added to support consistent assessment of fidelity and to help describe conduct more generally.

The framework is intended to act as a guide for the advanced application, reporting and analysis of PDSA cycles. Specifically, it aims to support the conduct of PDSA cycles across three areas: act as guide to users of the method to conduct PDSA cycles with high fidelity; help educators and supporting programmes to assess the QI ability of an improvement team; and allow evaluations of improvement efforts to assess whether PDSA cycles are used with high fidelity and contribute this assessment to broader evaluation of improvement success, context and process by which a change to practice was made. The last aim was pursued in the remaining chapters.
8.2.4. Linking QI fidelity and context

Chapter 5 investigated the change in PDSA cycle fidelity over time and the factors that may have influenced any change in fidelity, specifically the efforts of an overarching QI collaborative support team.

The study demonstrated statistically significant improvements over time in the number of cycles conducted and the fidelity of these cycles against key principles of the method. However, across the total sample of QI projects PDSA cycle fidelity was low. Qualitative analysis identified reasons that may have influenced this low fidelity and the change over time. It demonstrated that PDSA fidelity improved as a result a QI support team targeting deliberate iterative actions taken by towards the intention, understanding and application process of teams using the method.

8.2.5. Perceived benefits of PDSA

The thesis culminated with two studies from an international qualitative investigation into the reality of using PDSA cycles in healthcare. The perceptions of improvement team members and the factors that are required to enact the method in social practice were explored. The study sought to understand how users of the method interpreted, articulated and applied the method in the reality of healthcare improvement efforts.

Chapter 6 presented the rhetoric of PDSA cycles in three international healthcare sites that had chosen to use the method. It indicated how the method’s functions and benefits are interpreted and articulated, highlighted differences between organisations and suggested key themes that can inform future QI education, support and research.

All sites expressed views of the principles of PDSAs that aligned with the theoretical framework developed in this thesis. There were varied extents to this alignment, however, which linked to QI maturity. Three themes were identified in relation to the perceived benefits of using the method: logical, ethical and social benefits. Logical and ethical benefits reflect the guidance on
the method that frame the method as a structure to support the achievement of learning (a logical benefit) and doing so efficiently (an ethical benefit). The additional social benefits that were articulated referred to the personal feelings and social interactions that are granted through the use of the method.

8.2.6. Reality of PDSA

The final study of the thesis, part of the international qualitative study, aimed to understand the social reality of using PDSA cycles. It drew on Communities of Practice (CoP) and Knowledge Management theoretical lenses to describe the enablers and challenges of using the method. The study presented the central role of negotiating through social interactions within a single PDSA cycle. It highlighted the complexity that can follow testing change and the need to navigate how to best re-apply learning that is acquired. It also demonstrated the need for teams to value documentation of the method if it is to occur. For all areas, challenges to using the method with high fidelity and mechanisms to overcome these were presented. Without overcoming the challenges identified there is a risk that PDSA cycles will be articulated and attempted to be used but will not actually be applied as its principles prescribe. The study highlighted the importance of a boundary spanner role of a QI specialist to facilitate the use of the method.

8.3. Emerging themes – contributions to the literature and key implications

8.3.1. Key contributions to the literature

As stated, this thesis set out to better understand and clarify the scientific nature and application of QI methods in healthcare. In doing so, it has demonstrated that the methods are scientific and clarified the association between science and a range of QI methods. Using the measures of fidelity as a proxy for the application as the PDSA cycle method as science, it has demonstrated that whilst the method may be aligned with the scientific method, it is not
necessarily applied as such. A range of factors have been shown to influence its use, namely the intention and understanding of the team using them and the ability to negotiate, navigate and narrate when applying the method.

Taken both individually and collectively these emerging themes from the studies in this thesis have made key additions to the improvement science literature and are described below.

View of improvement science and research designs to study improvement

This thesis develops and applies further conceptual understanding to progress the academic field of improvement science. Through a review of the scientific associations of QI methods, three lenses in which to consider improvement as a science were proposed. Two were in regards to the QI methods themselves acting scientifically, either facilitating change and improvement or evaluating improvement outcomes. The third outlined the need to investigate and study the use of the methods from scientific perspective.

The three categories identified in relation to QI methods suggest three key areas for the improvement science field to consider: facilitating change and improvement (local application of the scientific method); conducting research on the outcome of change (building generalisable knowledge); and conducting research on the process of facilitating change through the use of QI methods (building generalisable knowledge about how the scientific method is applied in improvement efforts). The identification of these suggests that if a single definition of improvement science is to be developed then it must remain broad enough to consider all three themes. What is more important is recognising the different angles in which improvement science can be viewed.

In terms of QI methods, the thesis reaffirmed that the methods are scientific in nature. The research has demonstrated that the methods are, in theory, practical tools to invoke science in a complementary deductive, hypothesis driven manner (through steps to identify and test change) and inductive manner (through reliable measurement and comparison to theory). This
application of the scientific method helps local QI teams develop learning in regards to the
development and implementation of a change aimed at improvement. QI methods can also be
used to scientifically evaluate the outcome of a change, however, they may benefit from being
used in tandem with other research methods depending on the overarching goal of their use.
The thesis proposes that for the field of improvement science to progress it should not seek to
continue to debate whether QI methods are theoretically scientific or not, but instead seek to
understand whether they are actually being used scientifically in practice.

The studies in this thesis subsequent to the review of QI methods and science sought to
represent research designs to understand whether QI methods are being used scientifically
and how and why they may or may not be. The assessments were dependent on the
development of a theoretical framework. The studies throughout the thesis have suggested
that the overarching principles of the method identified (Learning Activity, Prediction, Iterative
cycles, Incremental testing scale, Regular data over time and Documentation) are broadly
valid. The ability to assess against the principles to derive an indication of the fidelity of PDSA
cycles is necessary to drive scientific standards of the method’s conduct, support further
exploration in the reality of using the method and consider effectiveness.

*PDSA cycle is used with low fidelity*

The studies which investigated whether PDSA cycles were being used with fidelity, indicating
whether they were being used scientifically, demonstrated that they were not. This is a key
addition to the literature produced by this thesis. The observation that PDSA cycles are
conducted with low fidelity was identified in the systematic review of publications reporting
PDSA cycles use, the review of QI teams documentations and the challenges presented in the
international qualitative study. They all suggest that the method is not always applied with
scientific rigour which may minimise learning and improvement. This had been suggested by
some prior individual studies (Baxley et al. 2011; Vos et al. 2010; Walley & Gowland 2004) but the extent and overarching view of this low fidelity had not been quantified before.

Prior to this thesis there had been no systematic study of the PDSA cycle method in the improvement literature. The thesis therefore provides the first study with a mechanism to review PDSA cycle fidelity, the first study to assess publications using the method and the first study to assess improvement teams’ documentation of the method. The findings caution against viewing PDSA cycles as a “black box” intervention (Dückers et al. 2009) and only aiming to link success with a statement of whether the method has been used or not.

Social benefits

The thesis has indicated that the perceptions of users of the methods align with the theoretical framework but also that there can be distinction between views. The benefits of the method are also perceived in line with the method’s guidance, in addition however, a prominent focus is placed on the social benefits of using the method.

In regards to perceived benefits, the large value place on the social benefits offer insights into how to position and articulate the method to newcomers. It also suggests areas for further research; whether those using PDSA cycles with higher fidelity also experience the social benefits of the method to a greater extent. If QI methods can be a tool to which employees are engaged in their work then this should be recognised and promoted.

Contextual influence and reality of using PDSA

Building on the identification that fidelity is low; the thesis adds further novel research through the study of fidelity over time and contextual factors that influence it. Past empirical studies had predominantly focused on the influence of context an intervention and/ or the overall outcome. Whilst some studies (Berwick 1998; Vos et al. 2010; Kaplan et al. 2011) have suggested factors that may influence the use of PDSA cycles, no previous studies have set out to purposefully link the two. This notion links to the conceptual view of the use of improvement
methods and context set out in the introduction which describes how context can influence both an intervention and the use of a QI method.

The thesis reinforces the literature that suggests engagement and fidelity in using QI methods is challenging but provides further detail of why this may be. The intentions and understandings of the individuals and teams using the method were identified to influence fidelity. In addition to this, however, the actual application of the method provides challenges to using the method with high fidelity. With this, the thesis provides novel findings in regards to the reality of using the method. The application of the method was shown to be more complicated than often depicted and dependent upon facilitated social interactions. Combined, the studies suggest that the PDSA cycle method both enables and requires social interaction.

The development of the framework, in Chapter 4, to assess fidelity and describe general conduct of PDSA cycles, alongside the observations of the social mechanisms required to deploy the method in practice, suggests that the PDSA cycle is an adaptable method that can be used in different manners. This relates to the notion of a “hard core” and “soft periphery” which has been made in relation to the spread and required adaptation of QI interventions. (Damschroder et al. 2009; Castro et al. 2010) The “hard core” of the PDSA cycle method can be viewed as the key principles of fidelity. The “soft periphery” can be viewed as the versatility that is granted to apply, for example, different learning activities and different uses of data as well as the approach taken by individuals facilitating the use of the method. A specific type of adaption to the soft periphery of an intervention has been referred to as “cultural adaption”. This is when adoptions are made in relation to the culture of an organisation that an intervention is deployed within. In the case of the PDSA cycle, Chapter 6 and 7 demonstrate that the QI culture of an organisation is one element that informs the adaption of how the method is practically deployed.

Considered through theoretical lenses of CoP and knowledge interactions, the research into the reality of using the PDSA cycle method perhaps offers the most practical findings for those
using the method. By summarising the negotiation, navigation and narration roles in using the PDSA cycle method, the final study of the thesis uncovers challenges and enablers to applying the method. It highlights the human and team side of change and suggests that no matter how much technical expertise can be built, the social skills to negotiate interactions are vital. It is important to note that this does not diminish the PDSA cycle methods as a reflection of the scientific method; instead it highlights reasons why it may not be applied scientifically and solutions to help doing so.

In addition to the focus on the use of the PDSA cycle method, the final study also contributes to the continued development of the CoP literature. QI teams, made up of different CoPs, using the PDSA cycle method were shown to be supported by the boundary object role that the PDSA cycle plays. This was not sufficient, however, and it was the boundary spanning role that QI specialists played that was identified as crucial to facilitating boundary interactions when using the method. The prominence of the boundary object, spanning and interaction roles, key elements involved in CoP, suggest the use of QI methods are a helpful research topic to further understand the more contemporary view on purposefully cultivating a new CoP. (Wenger 2002)

Overall, it is proposed that to scientifically apply the PDSA cycle users and educators of PDSA cycles need to understand the negotiation, navigation and narration challenges and enablers in using the method. This includes recognising that the use of the method requires negotiations of different CoP and the importance of a QI specialist to do so. It also includes the need to maintain the view that PDSA is a learning method and recognise approaches to navigate complexity as scale increases.

With healthcare involving an interaction between a healthcare provider and a patient, any effort to improve it will require someone to change the way they work. This will benefit from being able to be iterated and, as such, the learning for the studies in this thesis can be generalised to
any attempts to change iteratively. Technical principles to support iterations, as well as social interactions to facilitate groups of people to do so, are both important to consider.

The contributions of this thesis can be aligned to applying to practitioners, academia and policy as follows:

- Contributions applicable to practitioners (QI teams and QI support teams)
  - Presentation of six key principles of PDSA cycle use that represent high fidelity conduct.
  - Novel identification of the social dimensions of applying the PDSA cycle method including negotiating through a single PDSA cycle and navigating the iteration and scale up of change.
  - Empirically grounded description of the complexity of scaling up tests of change and the need to plan for the learning in advance.
  - Articulated social benefits of the PDSA cycle method to help engage individuals and teams in using the method.
  - Novel association between individuals’ and teams’ understanding, intentions and process of applying the PDSA cycle method and the fidelity of the method’s use.
  - Novel description of challenges faced by QI support teams when educating and supporting QI teams use the method.

- Contributions applicable to academia
  - Empirically grounded description of the complexity of PDSA cycle application as demonstrated by mixed fidelity and multiple influences of context.
  - Developed theoretical framework to guide evaluations of PDSA cycles.
  - Demonstration of a research approach to open the “black box” of PDSA cycle use, and other QI methods. This is achieved by considering the reality of using
the method, including social dimensions of its application, in addition to fidelity of use (rather than a simple context-independent intervention evaluation).

- Contributions applicable to policy
  - Demonstration of the complexity of delivering change and the potential for the use of PDSA cycle to navigate and negotiate through the practical reality of delivering improvements.
  - Demonstration of the complexity of educating and supporting the use of QI methods which suggests the need for investment in people and organisational structures to do so.

8.4. Methodological reflections and future research

In addition to the specific limitations presented within the chapters, there are a number of methodological reflections and collated limitations which are useful to discuss. Based on these limitations and the natural next steps to explore subsequent to the studies presented, a number of areas for future research are also outlined.

8.4.1. Research focus

This thesis’ overarching research enquiry has been to investigate and understand the application of science, through PDSA cycles, in improvement efforts in healthcare. The focus on PDSA cycles was informed by the research findings in Chapter 2 and also the discovery of low fidelity use of the method. It should be noted, however, that the broader suite of QI methods exist, in addition to many other ways in which improvement in healthcare can be supported. These other methods and ways to improve healthcare should be further investigated and the study designs used within this thesis can act as approaches to do so.
8.4.2. Ontological and Epistemological approaches

The studies described in this thesis have incorporated a mix of epistemological approaches. With improvement science a developing academic discipline, little previous research has looked specifically at the application of QI methods (Perla et al. 2013) and, as such, the study designs deployed are presented as examples of how to investigate their application as well as being mechanisms to develop generalisable knowledge.

The studies in this thesis have described two different ontological and epistemological approaches when looking at PDSA cycle method application. The assessment of the fidelity of the method represents a post-positivist critical realist view of understanding its application. It aims to develop theory in regards to how the PDSA cycle is used but recognises that the real-world settings that it is carried out within will influence its use. As part of this, Chapter 5 aimed to develop theory in regards to the links between fidelity and context to understand why and how application of the method may differ. The last two chapters are predominantly focused on understanding the views of those using the method and represent an interpretivist approach. This was taken to understand participants’ subjective interpretation, articulation and application of PDSA cycles within their given context. The thesis as a whole, as well as aiming to develop theory in regards to PDSA cycle conduct through these two approaches, can also been seen to have taken a pragmatism approach with the aim that a better understanding of their use will practically help teams using the method and in turn drive improvement in their use. (Saunders 2011)

At an early stage of understating, it has been helpful to deploy these different approaches to produce knowledge on the use of the method. Continuing to balance the approaches, by combining an objective assessment of the method’s fidelity but understanding the context it is used within, including how this conduct is perceived by the people and teams using the method, can help continue to provide useful generalisable knowledge for users, educators and researchers of QI methods.
8.4.3. Data sources

The studies in the thesis have relied predominantly on the documentation or articulation of the method’s use rather than observing it in reality over time. Chapter 7 did involve participant observation data collection, however, as indicated in the due to challenges of observing the use of the method from start to finish in real-time, the study relied more on the views of interviewees to gain insight to the use of the method. Both are therefore open to bias and may not necessarily reflect reality.

Further understanding of the reality of using the PDSA cycle method, and other QI methods, is required through further observation of their conduct. Achieving this would require longitudinal, ethnographic studies that allow observations of how the method is actually deployed and interpreted over time and the context within this it occurs. A “researcher in residence” approach in which a researcher forms part of the QI team to collect data but also contribute and feedback to the team has been proposed as a specific example in the QI literature. (Marshall et al. 2014)

8.4.4. Comparison with other individual and organisation learning mechanisms

As emphasised throughout the thesis, the PDSA cycle method is an approach to support learning. As such, further research could be conducted to compare its use to other learning approaches, be that individual, team or organisation learning approaches. (Edmondson et al. 2007) Specific comparisons to make include with the Kolb cycle (Kolb 1984) which prescribes the use of experience to support an individual’s learning. In comparison to cognitive learning theories, which emphasise cognition to support learning, and behavioural learning theories, which do not follow conscious or subjective experiences in the learning process, experiential learning has been demonstrated to result in positive improvement outcomes. (Kolb et al. 1999) In addition, at a team level, learning activities that support teams identify “how” to achieve an improvement, rather than learning activities that support identify “what” intervention could be
used to achieve an improvement, have been shown to be more appreciated by users and to result in better outcomes. (Tucker et al. 2007) Comparison between these types of learning approaches in healthcare, viewing PDSA as a method for learning by experience or to identify “how” to achieve improvement, could be beneficial to progress understanding.

The use of PDSA cycles also relates to the concept of single and double loop organisational learning. (Argyris et al. 2015; Mikkelsen & Holm 2007) The concept relates to whether learning influences the immediate iteration of an action (single loop) or the mental mode that informed the selection of an action in the first place (double loop). (Argyris et al. 2015) It is possible for both to be achieved within a single or across multiple PDSA cycles and future research could seek to identify the prevalence of single or double loop learning when assessing the use of PDSA cycles. (Argyris 2002) This could also be taken further to ascertain the social interactions necessary to achieve double loop learning by using a similar research approach to that used in Chapter 7.

8.4.5. Application within other industries

With PDSA cycles used across a range of industries, the implications of this thesis could apply more broadly than just healthcare. There are examples of research efforts directed towards the learning approaches taken by organisations and teams in other industries, (Edmondson 1999) however, there is limited research into the use of PDSA cycles in industries other than healthcare. A search of the literature at the time of finalising this thesis revealed no objective assessments of PDSA cycles, including their fidelity or application, in other industries. This demonstrates the added value of the research in this thesis; it has the potential to make a significant contribution to research on the use of QI methods, and in particular PDSA cycles, in all industries. Whether the method is used with higher fidelity or how it is used in reality of improvement efforts is currently an unknown and a potential avenue for future research. The research approach taken in this thesis could be extended to help achieve this comparison.
8.4.6. Linking fidelity and outcomes

The thesis has not compared the fidelity of PDSA cycles to reported improvement outcomes and therefore does not conclude whether better application of the PDSA method results in better outcomes. Instead, it has drawn theoretical principles and empirical observations to understand the use of the method better and link fidelity with the context in which the method was used.

The decision to not investigate fidelity and improvement outcome was made due to the necessity to understand the reality of using PDSA cycles first. Also, importantly, successful use of PDSA cycles does not result in immediate improvement but is instead the achievement of learning. It is intended that better use of PDSA would equal more successful outcomes; however it is not a simple cause and effect or black box intervention. Instead, the learning achieved from using PDSA cycles must be applied and the research in this thesis has demonstrated that this is not necessarily straightforward: learning must be effectively negotiated, navigated and narrated. Any future studies that aim to compare QI method fidelity and improvement outcomes must also consider this and the translation of the learning gained through PDSA cycles into practice.

8.5. Concluding remarks

This thesis has provided novel research to support the development of improvement science. It set out to better understand the application of science to improve healthcare and, to do so, it has focused on the application of QI methods, specifically the PDSA cycle. It has demonstrated that whilst the method can theoretically be considered scientific, it is not currently always used as such. To apply the method with fidelity, both technical principles and social interactions are required to be addressed. Understanding of the method’s application is vital to understand in QI teams are to successfully and reliably pursue improvements in healthcare.
The ability to change is the crux of improvement. Without facilitating change, local healthcare teams cannot actively pursue improvements to healthcare processes and structures and, ultimately, health outcomes. Developing further understanding of how to best support frontline improvement teams is vital in the consistently challenging environment of healthcare. It can help benefit both staff and patients and this body of work has aimed to so.
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## 10. Appendix 1 – Systematic narrative review of scientific nature of QI approaches – full results for all included articles

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References


37. Audet AMJ, Doty MM, Shamasdin J, Schoenbaum SC. Measure, learn, and improve: Physicians’ involvement in quality improvement - Evidence that quality improvement still has not permeated the professional culture of medicine, although progress is evident. Health Aff. 2005;24(3):843–53.
### 10.2. Appendix 2 – PDSA Cycle Systematic Review – full results for all included articles

*a* = No detail of cycles reported, *b* = Themes of cycles provided (but no additional details), *c* = Details of individual cycles, but not of stages within cycles provided, *d* = Details of cycles including separate information regarding stages of cycles provided

*0* = Unclear, 1 = Not referred to, 2 = Further changes implemented, 3 = Changes made permanent, 4 = Further changes suggested, 5 = New PDSA scheduled

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**References**


10.3. Appendix 3 – CLAHRC NWL PDSA Cycle conduct – Examples PDSA Cycle

learning activities

Potential of change - Testing change by simulation: receiving feedback from others prior to testing in healthcare practice

<table>
<thead>
<tr>
<th>Title</th>
<th>[Medical condition] Information leaflet</th>
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</thead>
<tbody>
<tr>
<td>Plan</td>
<td>To create [Medical condition] Information Leaflet.</td>
</tr>
<tr>
<td>Do</td>
<td>To write first draft of the leaflet and circulate to the team for feedback</td>
</tr>
<tr>
<td>Study</td>
<td>Feedback from team and expert patient was that the information was too detailed and not user friendly enough. Quotes from a [Patient] to be added, and certain words need to be highlighted to make the document more personal.</td>
</tr>
<tr>
<td>Act</td>
<td>To complete abbreviated version of leaflet and circulate to team for feedback. Initial longer version to be placed on [Medical condition] hospital website for more detailed information.</td>
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Functionality - Testing a change in healthcare practice and learning about the functionality of the change

<table>
<thead>
<tr>
<th>Title</th>
<th>1. A) Pilot [Medical condition] Prevention Education Session</th>
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<tbody>
<tr>
<td>Plan</td>
<td>Objective: Deliver a pilot Education session to patients and their next of kin to trial delivery and completion of outcome measures. Questions asked: 1. Would a PowerPoint presentation be helpful or would it make the session too formal, we decided it would help? 2. Would patient and next of kin engage in the session? We made the slides to ask for responses from the patient and to generate discussion, to avoid the session becoming a lecture, which wasn't the idea as the patient and next of kin had already been given an information leaflet on how to reduce the risk of further strokes, and the idea of the session is to discuss how they are going to make changes to their lifestyle). 3. How could we ensure we have the resources to give the session? We planned for 1 member of staff to give the talk at a time that we were not short staffed, and to give the session in our stroke gym which we had control and access over as booking rooms can be very difficult sometimes. We allowed 2 hours for the whole session to allow for unforeseen problems such as next of kin arriving late or patients being unavailable due to going off the ward for investigations or for toileting as incontinence is a common problem in our stroke patients) 4. Would the patients and their next of kin find the session helpful? We devised a very simple evaluation form for the patient and next of kin to complete at the end of the session to show if they thought their knowledge of risk factors had increased and how they could go about decreasing theirs, this could then be compared to the same question which was included in the outcome measures form which was completed at the start of the session. Predictions made: 1. The Outcome Measures would take the 10 minutes to complete at the start of the session. 2. It would be an interactive session with the patient and the next of kin. 3. The patient would enjoy the session</td>
</tr>
<tr>
<td>Do</td>
<td>Education session given to one patient, his wife and daughter, in the gym with a PowerPoint, by one member of the team. Unforeseen circumstance: Only 1 in-patient available who met our criteria and no [Medical condition] Patients from out-patients. Patent needed a toilet break</td>
</tr>
<tr>
<td>Study</td>
<td>Outcome Measures took too long to do for the patient, about 30 minutes. It was essential for the family to be there and to be able to re-enforce the lifestyle changes when the session is complete.</td>
</tr>
</tbody>
</table>
the patient went home, as the patient was poorly motivated to change his lifestyle which included drinking and smoking. He also lacked concentration so found the outcome measures difficult to complete. Presentation style worked well. Resources correctly identified. Inclusion criteria too strict.

<table>
<thead>
<tr>
<th>Act</th>
</tr>
</thead>
<tbody>
<tr>
<td>We will trial the session again.</td>
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</table>

Direct impact - Testing a change in healthcare practice and learning about direct impact

<table>
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<tr>
<th>Title</th>
<th>1. B) Revised [Medical condition] Prevention Education Session</th>
</tr>
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<tbody>
<tr>
<td>Plan</td>
<td>Objective: To deliver the revised session with the shorter outcome measures and hopefully increased number of patients with their next of kin present. Questions asked: Time needed? If we had increased numbers of patients would we have enough time if a lot more discussion was needed, but the shortened outcome measures would hopefully off set this? Outcome measures? Had the measures been shortened enough so our patients didn’t struggle with them? Resources? If we had increased numbers of patients and next of kin would the gym still be big enough and would we have enough chairs.  Predictions:  The outcome measures had been simplified enough, that we wouldn’t get greatly increased numbers of patients so the gym would be big enough, and that 2 hours would be long enough even with toilet breaks.  Plan to answer our questions:  As before through feedback from our evaluation form of the session and the feedback of the presenter at our CLAHRC meeting.  Plan to collect the data:  Again very simply by the presenter at the time of the session.</td>
</tr>
<tr>
<td>Do</td>
<td>The session was run for 3 patients and 4 next of kin. One next of kin was 30 minutes late for the session, we waited for 15 minutes for them which was as long as our patients could tolerate.</td>
</tr>
<tr>
<td>Study</td>
<td>Outcome Measures took about 10 minutes to complete which was much more realistic and acceptable to the patients. Increased interaction and discussion, it felt that problems were being shared and support was being provided between the next of kin.</td>
</tr>
<tr>
<td>Act</td>
<td>To keep the shortened outcome measures and if possible to give the session to more than 1 patient if possible because of the benefits of increased interaction.</td>
</tr>
</tbody>
</table>

Indirect impact - Testing a change in healthcare practice and learning about the indirect impact

<table>
<thead>
<tr>
<th>Title</th>
<th>Visual aid and [intervention]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan</td>
<td>The [intervention] is only being completed between 55-75%. There appears to be an even divide between the medics and the surgeons not filling out the questionnaire. Would a visual prompt in the doctor’s office increase the likelihood of the medics filling in the [intervention] form?</td>
</tr>
<tr>
<td>Do</td>
<td>A poster was put up in the AAU doctor’s office explaining how to fill in the [intervention] questionnaire and how to give a brief intervention.</td>
</tr>
<tr>
<td>Study</td>
<td>10/09/10 - 85% of [intervention] questionnaires were completed. 21/09/10 - 55% were completed. The visual aid does not appear to have had a sustained result.</td>
</tr>
<tr>
<td>Act</td>
<td>A further visual aid was placed in trolley bay.</td>
</tr>
</tbody>
</table>
## 10.4. Appendix 4 – CLAHRC NWL PDSA Cycle conduct assessment – full results

This appendix presents additional results and examples regarding the principles of PDSA Cycle conduct.

### Overall

**Adherence to number of principles of PDSA cycle conduct**

<table>
<thead>
<tr>
<th>Number of principles adhered to</th>
<th>Number of Cycles (Total 421)</th>
<th>% of Total</th>
<th>% of total fully documented</th>
<th>Breakdown of features adhered to</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>122</td>
<td>29.0</td>
<td>N.A</td>
<td>Not fully documented</td>
</tr>
<tr>
<td>1</td>
<td>5</td>
<td>1.2</td>
<td>1.7</td>
<td>5 cycles - Fully documented (FD) only</td>
</tr>
<tr>
<td>2</td>
<td>120</td>
<td>28.5</td>
<td>40.1</td>
<td>120 cycles – FD &amp; describing a Learning Activity (LA)</td>
</tr>
<tr>
<td>3</td>
<td>53</td>
<td>12.6</td>
<td>17.7</td>
<td>42 cycles - FD, LA &amp; within an Iterative Cycle (IC); 11 cycles - FD, LA &amp; containing a Prediction</td>
</tr>
<tr>
<td>4</td>
<td>72</td>
<td>17.1</td>
<td>24.1</td>
<td>5 cycles - FD, LA, IC &amp; containing a Prediction 50 cycles - FD, LA, IC &amp; Use of data over time 17 cycles - FD, LA, IC &amp; Increasing testing scale</td>
</tr>
<tr>
<td>5</td>
<td>42</td>
<td>10.0</td>
<td>14.0</td>
<td>29 cycles – All features except Prediction 12 cycles - All features except Increasing testing scale 1 cycle - All features except Data over time</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
<td>1.7</td>
<td>2.3</td>
<td>7 cycles – All features adhered to</td>
</tr>
</tbody>
</table>

311
Documentation

71% (299/421) of initiated cycles documented all stages of the PDSA cycle. For incomplete cycles, there was no trend for at which stage documentation stopped or which stages were missed. Cycles that were not fully documented were excluded from further analysis as they could not be adequately assessed across all principles of the framework.

Of the fully documented cycles, 11% (34/299) captured “Do”, “Study” and “Act” stages in future tense (e.g., documentation referred to plans of what was going to be studied, rather than a reflection on actual results and implications. See example below) suggesting that cycles may have been planned but not executed or documentation was not updated. A further 4% (12/299) captured the “Do” stage in the past tense but “study” and “act” in future tense suggesting an activity was carried out but either not reflected on or, that documentation was not updated. We include the documented intentions of these future tense cycles in the remainder of the analysis however recognise the extent they were fully executed cannot be determined.

Types of documentation “completeness” of PDSA Cycles reviewed

<table>
<thead>
<tr>
<th>Stages Documented</th>
<th>Plan</th>
<th>Do</th>
<th>Study</th>
<th>Act</th>
<th>Stage(s) skipped</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDSA cycles with stage documented</td>
<td>421</td>
<td>378</td>
<td>332</td>
<td>307</td>
<td>N.A</td>
</tr>
<tr>
<td>Percentage</td>
<td>100%</td>
<td>89.8%</td>
<td>78.9%</td>
<td>72.9%</td>
<td>N.A</td>
</tr>
<tr>
<td>PDSA cycles with stage and all previous stages documented</td>
<td>421</td>
<td>378</td>
<td>329</td>
<td>299</td>
<td>8</td>
</tr>
<tr>
<td>Percentage</td>
<td>100%</td>
<td>89.8%</td>
<td>78.1%</td>
<td>71.0%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Uncompleted PDSA cycles with stage and all preceding stages documented but no subsequent stages documented</td>
<td>39</td>
<td>45</td>
<td>30</td>
<td>N.A</td>
<td>8</td>
</tr>
<tr>
<td>Percentage</td>
<td>32.0%</td>
<td>36.9%</td>
<td>24.6%</td>
<td>N.A</td>
<td>6.5%</td>
</tr>
</tbody>
</table>
Learning Activity –

Approximately two-thirds (69% (206/299)) of cycles were testing change and a third (29% (88/299)) collecting information only. A small number of cycles had no explicit intention to set out on a process of learning; instead they were used to capture a specific task without reflection.

<table>
<thead>
<tr>
<th>Learning Aim</th>
<th>Learning Activity</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Testing Change</strong></td>
<td></td>
<td><strong>206</strong></td>
<td><strong>68.9</strong></td>
</tr>
<tr>
<td>Potential of change</td>
<td>Testing change by simulation: receiving feedback from others or a data set prior to testing in healthcare practice</td>
<td>48</td>
<td>16.1</td>
</tr>
<tr>
<td>Functionality of change</td>
<td>Testing a change in healthcare practice and learning about the functionality of the change</td>
<td>28</td>
<td>9.3</td>
</tr>
<tr>
<td>Direct Impact of change</td>
<td>Testing a change in healthcare practice and learning about the direct impact of the change</td>
<td>66</td>
<td>22</td>
</tr>
<tr>
<td>Indirect Impact of change</td>
<td>Testing a change in healthcare practice by introducing an additional activity to influence uptake of the change and learning about the impact of the original change OR measuring an outcome of change only indirectly impacted</td>
<td>64</td>
<td>21.4</td>
</tr>
<tr>
<td><strong>Collecting Information (no change tested)</strong></td>
<td></td>
<td><strong>88</strong></td>
<td><strong>29.4</strong></td>
</tr>
<tr>
<td>An ongoing change</td>
<td>Collect information on a change already being tested</td>
<td>40</td>
<td>13.4</td>
</tr>
<tr>
<td>Current service</td>
<td>Collect information on the provision of a current service</td>
<td>40</td>
<td>13.4</td>
</tr>
<tr>
<td>Data collection</td>
<td>Collect information on data collection</td>
<td>8</td>
<td>2.7</td>
</tr>
<tr>
<td><strong>No learning aim or outcome</strong></td>
<td></td>
<td><strong>5</strong></td>
<td><strong>1.7</strong></td>
</tr>
</tbody>
</table>

Prediction

313
Only 12% of cycles documented an explicit prediction of the results or other consequences of a test of change or the collection of information.

*Predictions documented within PDSA Cycles*

<table>
<thead>
<tr>
<th>Prediction Type</th>
<th>Total</th>
<th>% of total</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Explicit</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive prediction of outcome of change tested</td>
<td>35</td>
<td>11.7%</td>
<td>“Prediction: Number of patients referred will start to increase”</td>
</tr>
<tr>
<td>Prediction of learning outcome</td>
<td>21</td>
<td>7.0%</td>
<td>“Feedback will be that we need stakeholder engagement”</td>
</tr>
<tr>
<td>Challenges of process of testing change predicted</td>
<td>7</td>
<td>2.3%</td>
<td>“Predictions made: it would be difficult to attract men to our stall as the leaflets have a female model in the front cover”</td>
</tr>
<tr>
<td>Positive prediction of process of testing change</td>
<td>4</td>
<td>1.3%</td>
<td>“Predictions: It would be an interactive session with the patient and next of kin. The patient would enjoy the session”</td>
</tr>
<tr>
<td>Prediction of impact of learning</td>
<td>3</td>
<td>1.0%</td>
<td>“Predictions: This will inform the GP educational package and the patient digital story”</td>
</tr>
<tr>
<td><strong>Implicit</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implicit through aim and proposing change</td>
<td>44</td>
<td>14.7%</td>
<td>“To improve the transfer of medicines for patients moved to another ward by introduction of green plastic bags”</td>
</tr>
<tr>
<td>Implicit through question</td>
<td>7</td>
<td>2.3%</td>
<td>“We want to find out whether this (direct advertising) will lead to an increase in self referrals”</td>
</tr>
<tr>
<td>Implicit through outlining current problem and proposing change</td>
<td>4</td>
<td>1.3%</td>
<td>“The issue could be top and bottom copies separated easily, so plan to staple together with a PIL to make a pack.”</td>
</tr>
<tr>
<td><strong>No prediction</strong></td>
<td>220</td>
<td>73.6%</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>299</td>
<td>100.0%</td>
<td></td>
</tr>
</tbody>
</table>
Iterative cycles

Just over half of cycles documented, 55% (163/299), were classified as iterative cycles. Across all cycles and teams, there were 64 iterative chains (sequences of PDSA cycles) with a mean number of cycles per chain of 2.5 (40 two-cycle chains; 18 three-cycle chains; 4 four-cycle chains; 1 five-cycle chain; and 1 eight-cycle chain).

36% (23/64) of chains structured testing of change in healthcare practice only (as identified in section 3.3). The remaining chains of cycles moved between types of learning activities as the chains progressed. A wide variety of transitions were present and there was no clear tendency for this progression., i.e. from collecting information to simulating change to testing change in healthcare.

Of the isolated cycles, those that were not part of an iterative chain, many of the “Act” stages reflected opportunities for further cycles but did not document these or conduct as such.

Isolated cycles last “Act” stage themes

<table>
<thead>
<tr>
<th>Last “Act” stage theme</th>
<th>Number of cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change(s) made Permanent</td>
<td>18</td>
</tr>
<tr>
<td>Continue to monitor</td>
<td>5</td>
</tr>
<tr>
<td>Future PDSA cycle outlined</td>
<td>3</td>
</tr>
<tr>
<td>Further change(s) made</td>
<td>20</td>
</tr>
<tr>
<td>Further(s) change(s) to be made</td>
<td>48</td>
</tr>
<tr>
<td>Further information to be collected</td>
<td>7</td>
</tr>
<tr>
<td>Repeat testing at future date</td>
<td>1</td>
</tr>
<tr>
<td>Learning summarised - no further action stated</td>
<td>7</td>
</tr>
<tr>
<td>N.A Study and Act Future tense</td>
<td>23</td>
</tr>
<tr>
<td>N/A – No learning activity</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total Isolated cycles</strong></td>
<td><strong>136</strong></td>
</tr>
</tbody>
</table>
Small Scale testing

86% (258/299) of cycles documented the duration of each stage using drop-down date fields and 9% (28/299) with the free text stage field (23 of the latter also documented duration in date field). Cycle size was reliant on free text stage documentation and only 35% (106/ 299) cycles documented this. Cycle size was described either as the number of times a change was tested or the number of subjects the change was tested on/ information was collected from. In addition, 8 cycles testing change referenced more than one change being tested within a cycle.

31% (20/ 64) of iterative chains displayed an increase of testing scale. Of the chains that did increase scale, only 2 increased scale of changes tested in practice: one chain increased the number of attendees at an education session from 1 to 3 and another other increased the number of education sessions delivered. 7 cycles moved from simulation testing to testing in practice and 2 from testing a single change to testing multiple changes. The remainder displayed increasing durations as documented by the date field, however, these cycles did not document that this increase in scale was an explicit intention.

Increasing scale of testing change within iterative chains

<table>
<thead>
<tr>
<th>Type of iterative chain testing chain and nature of increasing scale</th>
<th>Number of iterative chains</th>
</tr>
</thead>
<tbody>
<tr>
<td>2+ iterative cycles testing change in practice</td>
<td>29</td>
</tr>
<tr>
<td>Simulation to testing</td>
<td>2</td>
</tr>
<tr>
<td>Increase in sample size scale over cycles</td>
<td>2</td>
</tr>
<tr>
<td>Increase in time scale over cycles</td>
<td>8</td>
</tr>
<tr>
<td>Increase in number of changes tested</td>
<td>2</td>
</tr>
<tr>
<td>No increase to sample size or time scale</td>
<td>15</td>
</tr>
<tr>
<td>2+ Simulation</td>
<td>5</td>
</tr>
<tr>
<td>Increase number of people asked for feedback</td>
<td>1</td>
</tr>
<tr>
<td>No increase to feedback sample size or time scale</td>
<td>4</td>
</tr>
<tr>
<td>Simulation to testing change in practice</td>
<td>5</td>
</tr>
<tr>
<td>Testing change in practice to simulation</td>
<td>3</td>
</tr>
<tr>
<td>None or only 1 cycle testing change</td>
<td>22</td>
</tr>
<tr>
<td>Grand Total</td>
<td>64</td>
</tr>
</tbody>
</table>
Use of Data over time

13 % (38/299) of cycles reported the use of both quantitative and qualitative data, 23% (69/299) quantitative only and 62% (184/299) qualitative only. Cycles that did not use any data were documented in the future tense or were not structuring a learning activity. Of note, over half of cycles (54% (37/69)) reporting the use of quantitative data only did so prospectively (documenting the intention to use data but not the results or interpretation of this data) and did not report any qualitative observations. For those cycles that did use qualitative data (with or without quantitative) the majority used the observations of the individual documenting the PDSA. Other types of qualitative data included feedback from the improvement team, healthcare staff external to the improvement team (ranging from clinical staff to management), patients receiving care at the time of the cycle, and patient and public representatives.

Quantitative and Qualitative data use within PDSA cycles

<table>
<thead>
<tr>
<th>Type of data referred to and tense of documentation in PDSA cycle</th>
<th>Total</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Both</td>
<td>38</td>
<td>12.7</td>
</tr>
<tr>
<td>Past tense</td>
<td>38</td>
<td>12.7</td>
</tr>
<tr>
<td>Quantitative only</td>
<td>69</td>
<td>23.1</td>
</tr>
<tr>
<td>Future tense</td>
<td>37</td>
<td>12.4</td>
</tr>
<tr>
<td>Past tense</td>
<td>32</td>
<td>10.7</td>
</tr>
<tr>
<td>Qualitative only</td>
<td>184</td>
<td>61.5</td>
</tr>
<tr>
<td>Future tense</td>
<td>5</td>
<td>1.7</td>
</tr>
<tr>
<td>Past tense</td>
<td>179</td>
<td>59.9</td>
</tr>
<tr>
<td>None</td>
<td>8</td>
<td>2.7</td>
</tr>
<tr>
<td>Future tense</td>
<td>3</td>
<td>1.0</td>
</tr>
<tr>
<td>N/A - No learning activity</td>
<td>5</td>
<td>1.7</td>
</tr>
<tr>
<td>Grand Total</td>
<td>299</td>
<td></td>
</tr>
</tbody>
</table>
10.5. Appendix 5 – CLAHRC NWL Core team PDSA cycle support and training interviews

Semi-structured interview questions

Introduction:

We would like to learn more about the progression of PDSA cycle conduct over the CLAHRC programme. We will be looking at the support provided by CLAHRC and training materials from round 1 to 3. We will be investigating changes in use by teams and we would like to know if this is related to a change in teaching and/ or other factors. As a member of the team who has been there from the start/very early on, we would like to ask you a few questions. We will not be using your name or any identifiable titles to attribute statements you have made. All data will be anonymised.

Questions for participants:

Show prompts

We will first show you a list of all dates relating to Rounds, events and agendas. This may have to prompt your memory.

We will start by discussing training and then support in each round and end with overall reflections across rounds.

1. Please describe the training for PDSAs in round 1? (give relevant round slide pack)
   a. What was your experience of this?
   b. What do you think the projects’ experience was

2. What was CLAHRC support like at this time (during this round)?
   a. What was your experience of this?
   b. What do you think the projects’ experience was?

3. What were your perceptions of the team’s feelings towards the method?

4. Please describe the fidelity of use to the methodology?
5. What else was happening at this time/ anything else you’d like to add?

6. *Repeat above for each Round*

7. What are your overall reflections of PDSA conduct and CLAHRC support and training over the program?

8. Why did changes occur?

9. (If time) What would do differently/ next time/ advising another support programme?

Potential prompts:

- We have noticed that all training for PDSAs in round 1 were targeted at round 2 teams.

- We have noticed that early on the methodology was presented quite simply with very little explanation. This developed into more detailed examples of use and even further to teams themselves explaining the benefits of the method.
10.6. Appendix 6 – International study on the conduct of PDSA cycles – Interview questions

PDSA Cycle conduct in healthcare: Achieving a scientific and pragmatic approach to improvement -
Semi-structured interview questions and script

(Topic guide for informal feedback during observations will be based on these interview questions)

As you are aware from the information sheet we are interested in the notion of testing and adapting changes in healthcare improvement work, with a particular focus on a specific supporting method, PDSA cycles including the functions that facilitate it’s conduct, people’s perception of the method and other contextual factors that influence how the method is used.

The format of this interview:

I have a number of questions to ask and discuss in an informal manner, and at the end you can ask any additional questions or comments that you may have.

If I have not made the question clear or it is ambiguous to you please feel free to ask me to clarify.

There is no right answer to the questions. This is an exploratory piece of work looking to understand the activities and perceptions of healthcare improvement teams.

I’m interested in how PDSA cycle conduct has taken place within your improvement team/ your perceptions of the method/ the notion of testing and adapting changes in healthcare to make improvements (dependent on role in or out of team)

Everything you say will be treated confidentially and transcripts and interviews will be kept on a secure drive that can only be accessed by approved researchers. Any quotes used from this interview in publications will be fully anonymised, and you have the right to withdraw from the study at any time you choose.

Ask to sign Informed Consent Sheet (for Interview) if haven’t already (two copies – one for them one for us). Confirm OK to record interview and set digital recorder going.

Questions:

First I’m going to ask question on your role within your organisation and improvement team and then move on to focus on PDSA cycles. (If patient – move to section C and miss job role question)

1. Could you briefly describe your job role, the improvement team you are part of and the role you play within in?

Great. Thanks. I now want to discuss the improvement work activities you are involved in; following this I will ask you some questions on your opinions on improvement work.

You are involved in project X which is making changes to the delivery of healthcare, structured using PDSA cycles.
To what extent are you involved in the conduct of PDSA cycles? Could you describe this involvement?

(Depending on answers tailor questions to address either notion of developing, testing, adapting changes or the PDSA cycle conduct more specifically. Use guide questions as appropriate)

A. “Not a lot”

1. Application

   i. How is a change discussed and implemented in your project?

   ii. What other activities are you involved in? (e.g. collecting data)

   iii. Do you and the team use data to monitor changes?

   iv. Do you consider the scale of the changes you make?

   v. How are the observations of a change monitored and documented?

2. Perception

   i. What do you believe are the key facilitators and barriers to using the testing change/PDSA method effectively in your improvement project?

   ii. How does the approach compare to other improvement approaches you’ve experience that aim to change healthcare delivery?

   iii. What are your thoughts on the concept of “testing change” and learning through failure?

   iv. What are your thoughts on the resources and time needed to conduct and document the testing of change/PDSA cycles/other improvement methods?

3. Org. context

   i. To what extent was the service area and team in which the improvement was taking place supportive in using and documenting the testing of change/PDSA cycles?

   ii. To what extent was the rest of improvement team supportive in using and documenting testing of change/PDSA cycles? To what extent was there infrastructure in using and documenting PDSA cycles?

   iii. To what extent was the organisation supportive in using and documenting testing of change/PDSA cycles?
B. “Fully involved”

1. Application
   i. Who is usually involved with the cycle? How is dialogue achieved? Who made decisions? How does this differ between each stage of the PDSA
   
   ii. What different activities were the cycles used for? (Was a prediction made? What knowledge source did the activities come from?)
   
   iii. Do you tend to used sequential cycles linked together?
   
   iv. Did you consider the scale of the activities and, if so, what were these considerations?
   
   v. What source of information was used to determine the success of the cycles? E.g. numerical data or staff feedback. How was data collected and documented? Is this collected through a regular mechanism?
   
   vi. Who documented the cycles details and how did this occur? How did this differ between each stage of the PDSA?

2. Perception
   i. What do you believe are the key facilitators and barriers to using the PDSA method effectively in your improvement project?
   
   ii. How does the method compare to other approaches you’ve experience that aim to change healthcare delivery?
   
   iii. What are your thoughts on the concept of “testing change” and learning through failure?
   
   iv. What are your thoughts on the resources and time needed to conduct and document PDSA cycles?

3. Context
   i. To what extent was the service area and team in which the improvement was taking place supportive in using and documenting PDSA cycles?
   
   ii. To what extent was the rest of improvement team supportive in using and documenting PDSA cycles?
   
   iii. To what extent was there infrastructure in using and documenting PDSA cycles?
   
   iv. To what extent was the organisation supportive in using and documenting PDSA cycles?
   
   v. How has the complexity of the process and staff groups in the healthcare organisation influenced you use of PDSA cycles?
10.7. Appendix 7 – Coding hierarchy for Chapter 7 analysis

This appendix presents the coding hierarchy for the analysis to investigate the social reality of using PDSA cycles in project teams in Chapter 7. The hierarchy is indicated by the indentations within the table. The most indented text present the initial open codes attached to the data.

The “greyed-out” text represent the categories developed to group these codes.

<table>
<thead>
<tr>
<th>Name</th>
<th>Sources</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Navigating a single cycle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.0. Initiating PDSA cycle use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acceptability of PDSA method</td>
<td>42</td>
<td>159</td>
</tr>
<tr>
<td>Barrier to using PDSA - traditional scientific research thinking</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Challenge - newcomers may be dubious of using PDSA</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Challenge - QI terminology is another new thing for frontline staff - needs to be facilitated</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Facilitator - encourage teams that testing not forever, link to an end goal, if it doesn’t work we won’t continue with it</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Ownership required to successfully use PDSA</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Team receptiveness dependent on if they feel they are supported more generally by organisation</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Team receptiveness to PDSA dependent on team culture</td>
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<tr>
<td>Balancing patient care priority with improvement work</td>
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<tr>
<td>Balance between primary aim of patient care and focussing on QI work including PDSA</td>
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<tr>
<td>Challenge - time</td>
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<tr>
<td>Barrier - busyness</td>
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<tr>
<td>Busyness influences use of PDSA</td>
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<tr>
<td>Challenge - busyness</td>
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<tr>
<td>Choosing improvement approach</td>
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<tr>
<td>Driven by focus on patient care</td>
<td>4</td>
<td>6</td>
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<tr>
<td>Facilitator to using PDSA - don’t start with the PDSA but with the problem that is trying to be solved</td>
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<tr>
<td>Start conversation on rationale for improvement work, not the methods</td>
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</tr>
<tr>
<td>Influence of senior manager or clinician</td>
<td>2</td>
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<tr>
<td>Benefited if senior manager is skilled in improvement</td>
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<tr>
<td>Clinical lead buy in important to lead PDSA</td>
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<tr>
<td>Routine structure and language to discuss and execute PDSA</td>
<td>6</td>
<td>9</td>
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<tr>
<td>Challenge - no structure to where and what to start PDSAs</td>
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<tr>
<td>Challenge - not having facilitators across all departments - these departments can be left behind or ignored</td>
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<tr>
<td>Facilitator - align with normal work and don’t see as an extra</td>
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<tr>
<td>Facilitator - PDSA language and run charts org norm</td>
<td>1</td>
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<tr>
<td>Facilitator - PDSA is normal days working</td>
<td>1</td>
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<tr>
<td>Facilitator - PDSAs stem from regular meetings looking at data</td>
<td>1</td>
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<tr>
<td>Facilitator - principles of PDSA are just common language in meetings</td>
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<tr>
<td>Use of PDSA driven by organisational leadership</td>
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<tr>
<td>Too many improvement projects</td>
<td>4</td>
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<tr>
<td>Challenge - Improvement fatigue</td>
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<tr>
<td>Difficult in getting buy in when there is so much testing going on</td>
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<tr>
<td>Improvement collision</td>
<td>1 2</td>
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<td>-----------------------</td>
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<tr>
<td>Teams can see PDSA as just another thing they are being asked to do</td>
<td>1 1</td>
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<tr>
<td>Test fatigue</td>
<td>1 1</td>
<td></td>
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<tr>
<td>Understanding of PDSA</td>
<td>4 4</td>
<td></td>
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<tr>
<td>Challenge - can be aware of method but need to be aware of other examples to use properly</td>
<td>1 1</td>
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<tr>
<td>Challenge - peoples understanding of PDSA - term can be banded around but not understood</td>
<td>1 1</td>
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<tr>
<td>Facilitation important first few times then people get it</td>
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<tr>
<td>Teams need to experience completing a few PDSA cycles to see benefit - qi facilitator role is key in this</td>
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<tr>
<td><strong>1.1. Planning</strong></td>
<td>17 30</td>
<td></td>
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<tr>
<td>Dialogue to plan test of change</td>
<td>7 11</td>
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<tr>
<td>Caution against making assumptions</td>
<td>1 1</td>
<td></td>
</tr>
<tr>
<td>Assumptions often made or misinterpreted when planning</td>
<td>1 1</td>
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<tr>
<td>Challenge - some people’s ideas can be knocked down if not trained in improvement methodology - need a facilitator to help</td>
<td>1 2</td>
<td></td>
</tr>
<tr>
<td>Challenge of creating time and space for dialogue</td>
<td>1 2</td>
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<tr>
<td>Frontline staff often aren’t and can’t be at meetings where tests of change are discussed so additional work to them communicate to them and a potential stumbling block</td>
<td>1 1</td>
<td></td>
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<tr>
<td>Real benefit gained from engaging frontline staff in development of a change, but also a challenge to get them there</td>
<td>1 1</td>
<td></td>
</tr>
<tr>
<td>Facilitated using lay language - not about the PDSA</td>
<td>2 2</td>
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</tr>
<tr>
<td>Multidisciplinary team involved in devising a PDSA therefore lay language is helpful</td>
<td>1 1</td>
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</tr>
<tr>
<td>QI facilitator asking what peoples predictions were helped the plan and act</td>
<td>1 1</td>
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</tr>
<tr>
<td>Negotiation between QI team and frontline staff</td>
<td>1 1</td>
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<tr>
<td>Negotiation between qi team and frontline staff when developing a test of change</td>
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<tr>
<td>Supported by prompts or documentation template</td>
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<tr>
<td>Planning stages supported by prompts which ensure clarity on test of change</td>
<td>1 1</td>
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<tr>
<td>Uncertainty and lack of clarity if plan stage prompts not used</td>
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<tr>
<td>Team exercise to discuss initial test on a structure way so not your idea vs mine</td>
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<td></td>
</tr>
<tr>
<td>Getting to the detail</td>
<td>2 3</td>
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<tr>
<td>Challenge to get teams engaged to complete the prompts in the PDSA plan stage at first - they do not see the importance</td>
<td>1 1</td>
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<tr>
<td>Facilitator - QI facilitator key to get down to the detail and engage frontline staff in planning a test - discussing in project meeting can remain high level</td>
<td>1 2</td>
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<tr>
<td>Jumping into change without enough planning</td>
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<tr>
<td>Challenge - tendency to jump into testing changes without enough forethought</td>
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<tr>
<td>Reason for change</td>
<td>8 8</td>
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<tr>
<td>Develop bottom up</td>
<td>3 3</td>
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<tr>
<td>Facilitator - initiating PDSAs suggested by frontline staff - central role of qi facilitator important</td>
<td>1 1</td>
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<tr>
<td>Facilitator - ensuring teams come up with the ideas rather than being top down - facilitation key</td>
<td>1 1</td>
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<tr>
<td>Facilitator - QI facilitator supporting frontline staff ideas being used</td>
<td>1 1</td>
<td></td>
</tr>
<tr>
<td>Linked to broader patient care problem or org goals</td>
<td>2 2</td>
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<tr>
<td>PDSAs and tests of change driven by organisational agreed priorities</td>
<td>1 1</td>
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<tr>
<td>QI facilitator links change to org strategy</td>
<td>1 1</td>
<td></td>
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<tr>
<td>Top down</td>
<td>3 3</td>
<td></td>
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<tr>
<td>Challenge - if test top down driven</td>
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<tr>
<td>Challenge - starting a PDSA that was top down driven versus thought up by the project</td>
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<tr>
<td>Improvement team or higher in hierarchy enforcing a change onto frontline staff</td>
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<tr>
<td>Use data to inform planning</td>
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<tr>
<td>Use data to structure conversations</td>
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<tr>
<td>Use of other QI methods</td>
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<tr>
<td>Facilitator - use other qi method to inform planning</td>
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<tr>
<td>Using FMEA to identify tests</td>
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<td></td>
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<tr>
<td>Who is involved in planning</td>
<td>2 4</td>
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<tr>
<td>Critical that teams develop the change not the qi facilitator</td>
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<tr>
<td>Facilitator - need dialogue to understand people’s perceptions and get them to test something out</td>
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<tr>
<td>Importance of subject matter expert in developing a test of change</td>
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<tr>
<td>Real benefit gained from engaging frontline staff in development of a change, but also a challenge to get them there</td>
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<tr>
<td>1.2. Do</td>
<td>19 44</td>
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<tr>
<td>Acceptability of testing</td>
<td>9 11</td>
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<tr>
<td>Challenge - hostility from frontline staff as sometime perceive a change as they are not doing job properly</td>
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<tr>
<td>Challenge - Frustrating for frontline staff if they don’t know the reasons for the new or adapted change</td>
<td>1 1</td>
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<tr>
<td>Challenge - Testing fatigue, too many tests</td>
<td>5 5</td>
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<tr>
<td>Challenge - buy-in to test change as so many other priorities and times consuming</td>
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<tr>
<td>Challenge - PDSA fatigue - too many tests</td>
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<tr>
<td>Lots of testing going on - potentially too much</td>
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<tr>
<td>Too many other changes being tested at once</td>
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<tr>
<td>Too much testing can be challenging</td>
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<tr>
<td>Facilitator - good relationships between facilitator and frontline</td>
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<tr>
<td>Facilitator - testing seen as part of the org culture</td>
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<td>Testing can results in anxiety</td>
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<tr>
<td>Challenge of testing on rare or complex events</td>
<td>5 8</td>
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<tr>
<td>Challenge - complex system sometime hard to test on a small scale</td>
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<td>Challenge - testing on rare incidents</td>
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<tr>
<td>Difficult of testing on small scale</td>
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<td></td>
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<tr>
<td>Testing change on rare events</td>
<td>3 3</td>
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<tr>
<td>Testing on 1 patient difficult in certain situations so test on one day</td>
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<tr>
<td>Watching out for a rare event for a PDSA test of change</td>
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<tr>
<td>Choosing who to do the test</td>
<td>4 4</td>
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<tr>
<td>Challenge - if you start with early adopters then you might not learn as much</td>
<td>1 1</td>
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<tr>
<td>Challenge - who to test the change on first - early adopter or laggard</td>
<td>1 1</td>
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</tr>
<tr>
<td>Target early adopters to see what test is like under best conditions then address outliers</td>
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</tr>
<tr>
<td>Testing a change on small scale - can go with resistor or champion</td>
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<tr>
<td>Ensuring the change is actually tested</td>
<td>10 21</td>
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<tr>
<td>Challenge - adherence to the tests</td>
<td>3 5</td>
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<tr>
<td>Adherence to testing the change</td>
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<tr>
<td>Buy-in needed to execute test</td>
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<tr>
<td>Challenge - getting people to actually test the change - test fidelity</td>
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<tr>
<td>Challenge - qi facilitator presence needed to get change tested</td>
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<tr>
<td>Communicating the test</td>
<td>5 10</td>
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<tr>
<td>Communicating with frontline</td>
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<tr>
<td>Communicating a test of change - using an insider</td>
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<tr>
<td>Communicating test of change</td>
<td>1 1</td>
<td></td>
</tr>
<tr>
<td>Communicating tests of change to frontline staff doing them is challenging</td>
<td>1 1</td>
<td></td>
</tr>
<tr>
<td>Dilution of information when communication goes from one to another in regards to what the change to test is and why</td>
<td>1 1</td>
<td></td>
</tr>
</tbody>
</table>
Facilitator - having peer to peer engagement - having an insider help communicate the tests of change

Facilitator - huddles to announce any testing

Hardest part of PDSA is communicating to frontline staff what the test is

Importance of communicating test to get them to happen

Utilising multiple methods to communicate test of change

Engagement with change

Engaging others in testing a change

Facilitator - good relationship between QI facilitator and frontline important to get change tested

Facilitator - Frontline insider to do the test and get the feedback - QI team not always there so it’s necessary

Necessary to explain rationale to ensure test occurs

Presence on QI team

Presence necessary to communicate why and what about the test

QI facilitator present at early stages of testing

1.3. Study

Clinical area and improvement knowledge helpful

Facilitator - clinical expert with improvement knowledge who can overview discussion and steer from both perspectives

Data on rare incidents

Challenge - getting data on rare incidents

Dealing with failure

Challenge - Tendency to study the outcomes of a test assuming the test itself went as planned instead of recognising it was not carried out and understand why it didn’t
draft

Facilitator - State negative predictions in plan so failures noted in study stages do not catch team off guard

Facilitator - Team cohesion helpful to share and deal with failure and instigate learning rather than judgement

Feedback must be used on disengages others

Acknowledging feedback

Regular dialogue to get feedback

Facilitator - Frontline insider to do the test and give feedback - QI team not always there so it’s necessary

Regular dialogue between frontline and QI facilitator important

Truly learning rather than resigning to failure

1.4. Act

Celebrate success

Leadership ensures success is celebrated

Decision to make to move to next cycle - tweaks at small scale, change scale, do something different but supportive

Making decisions in regards to next steps

Challenge - Focussing just on whether a success or failure rather than what has been learnt and what can be done next inhibits the act stage decisions

Challenge - people PDSA in their head and do not learn rigorously and make decisions based on that learning

Facilitator - balancing learning achieved by PDSA and emotional, why, side of the change from patients perspective

Facilitator - relating learning to bigger picture and overall aim of project can help next steps

1.5. Dialogue throughout cycle

Conversations framed by a facilitator

QI facilitator frames conversation round PDSA cycle

QI facilitator framing questions e.g. asking what the objective is
<table>
<thead>
<tr>
<th>Language used to discuss PDSA</th>
<th>8</th>
<th>13</th>
</tr>
</thead>
<tbody>
<tr>
<td>At a level where stages of PDSA not referred to but all knew what was going on</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Challenge - fine line between framing with qi jargon and too much qi jargon</td>
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</tr>
<tr>
<td>Facilitator - asking questions informed by PDSA rather than qi jargon</td>
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<td>1</td>
</tr>
<tr>
<td>Facilitator - consider audience when using PDSA cycle language</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Facilitator - good level of improvement understanding and good facilitation can negate need for QI jargon</td>
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</tr>
<tr>
<td>Facilitator - introduce concept of PDSA after a few test have been done - qi facilitator frames conversation beforehand</td>
<td>2</td>
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<tr>
<td>PDSA and test of change common language</td>
<td>1</td>
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<tr>
<td>Qi facilitator translates the PDSA plan prompts</td>
<td>1</td>
<td>2</td>
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<tr>
<td>Qi facilitator uses lay language to maintain engagement of qi team</td>
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<tr>
<td>Team applies PDSA principles without using the language</td>
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<tr>
<td>PDSA stages facilitate dialogue</td>
<td>2</td>
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</tr>
<tr>
<td>Dialogue supported by asking questions which are prompted by PDSA method</td>
<td>1</td>
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<tr>
<td>Kept PDSA in back - didn’t discuss specific stages but rather framed conversation around it</td>
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<tr>
<td>PDSA done by discussion</td>
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<td>1</td>
</tr>
<tr>
<td>PDSA facilitates dialogue, qi facilitator supports using PDSA</td>
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<td>1</td>
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<tr>
<td>Structure conversation around PDSA proforma</td>
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</tr>
<tr>
<td>Regular meeting times to discuss PDSAs</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Facilitator - do PDSA through routine discussions</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Facilitator - have regular time to discuss change and people don’t have to realise it is a PDSA cycle</td>
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<tr>
<td>MDT regular meeting discussing PDSA cycles</td>
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</table>

### 2. Negotiating multiple cycles

<table>
<thead>
<tr>
<th>2.1 Assumption that perceived quick and easy nature of small scale cycles will continue</th>
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<tbody>
<tr>
<td>Assuming PDSA is quick and easy</td>
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<tr>
<td>Assuming success will work instantly elsewhere</td>
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<tr>
<td>Challenge - if senior mgmt. don’t understand the complexity of using PDSA</td>
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<tr>
<td>2.2 Awareness of testing</td>
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<tr>
<td>Don’t also broadcast that we are running early stage PDSAs</td>
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<td>1</td>
</tr>
<tr>
<td>Scale influences facilitation and communication - if small then limit communication</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2.3 Communicating iterations</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Challenge of providing rationale for all the iterations - need to be able to see overall vision of improvement</td>
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</tr>
<tr>
<td>Communication to and fro frontline and QI facilitator to make iterations</td>
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<tr>
<td>Dilution of communication of iterations</td>
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<tr>
<td>2.4 Data to inform and check iterations</td>
<td>7</td>
<td>8</td>
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<tr>
<td>Challenge - not studying properly</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Challenge - pausing to study properly and inform next decisions</td>
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<tr>
<td>Challenge - time to pause</td>
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<tr>
<td>Challenges - sometimes don’t have the data to support learning</td>
<td>1</td>
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<tr>
<td>Qualitative feedback can be used early on about usability as form quant data is developed</td>
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<tr>
<td>Using data properly to learn</td>
<td>3</td>
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</tr>
</tbody>
</table>

### 2.5 Disappearance of PDSA structure

<p>| Challenge - can be tempting to jump straight into implementation                           | 1     | 1  |
| Challenge - not sticking to PDSA methodology formally                                    | 1     | 1  |
| Challenge - not treating large scale tests as PDSAs                                       | 1     | 1  |
| Challenge - ok to conversationally follow PDSA but is the full rigour and best learning occurring | 1     | 1  |
| Challenge - PDSA cycle formalities dropped off as scaled up                               | 1     | 1  |
| Challenge - PDSAs not also formally followed                                              | 1     | 1  |</p>
<table>
<thead>
<tr>
<th>2.6 Engagement to aid scale up</th>
<th>15</th>
<th>17</th>
</tr>
</thead>
<tbody>
<tr>
<td>Challenge - actually doing PDSA is a lot different to the simple model that is often taught</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Challenge - can be hard to contain to small site</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Challenge - changing people’s jobs and they might not like that or it might worry them</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Challenge - difficult to sustain engagement and education over period of scale up</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Challenge - engaging others as scale up</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Challenge - perception and culture of senior staff - need to engage juniors</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Challenge - scaling something up whilst still tweaking it and engaging others in the process</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Challenge - takes a lot of time to engage everyone - balance between engagement and using the methodology exactly</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Challenge - takes time to engage staff, too often jump into scale up without enough engagement</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Challenge - timing engagement of others - naysayers will naysay early and alter</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Challenge - voluntold vs engaged</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Engaging others to change their routine</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Moving from small scale testing to getting larger group to engage and sustain the change</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>QI team to regularly discuss tests rather than individuals leading the improvement</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Scale up is challenging because you not just asking others to try it out but to do it routinely</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Scale up requires engaging people not within your sphere of influence</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.7 Issues with scale up</th>
<th>4</th>
<th>14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Challenge - the small scale test may not be sustainable at a larger scale - need to test out its sustainability and adapt accordingly</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Challenge of scale up</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Difference between spread and ramp</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Maintaining momentum and learning about sustainability</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Moving between testing and routine</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Scale up - difference between ramps and spread</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Scale up can be intensive and requires rapid feedback</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Scale up easy, sustaining hard - links to learning aim, not just scaling up for the sake of it</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Specific considerations about different types of scale up</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Sustainability of scale up</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Sustaining hard, ramp up easy</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.8 Long term planning of tests in advance</th>
<th>7</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrier if just think about single test of change</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Challenge - cant predict everything - learning means often are reactive</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Facilitator - QI facilitator asks where want to be in a years’ time - planning for cycles</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Facilitator if you think about scale up and string of PDSAs in advance</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Facilitator and compromise - need to hold back on testing sometime to wait for data otherwise testing can be pointless</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Focus on string of PDSAs not a single test of change is helpful</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Linking learning with pre-identified decision tree</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>PDSA cycles testing timing planned in advance - not just reactive - planned time to test certain things</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Planning for scale up important</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Proactive PDSA planning - considering learning in advance</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Scheduling tests of change</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Too many other test going on - need to be scheduled</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.9 Managing explosion of learning</th>
<th>13</th>
<th>18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can be difficult to manage and looks of complex information which can cause disengagement</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Challenge - confusion over ramp, adapt, new chain of cycles</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Challenge - lots of learning once tested in reality - challenge to manage</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Challenge</td>
<td>Description</td>
<td>Value 1</td>
</tr>
<tr>
<td>-----------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td></td>
<td>perception that one failure means the whole idea isn’t right</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>perception that things going wrong is failure rather than opportunity to learn</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>time consuming to manage</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>running multiples tests at once</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>difficult to use data to judge exploding changes</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>getting the proportionate data in effort and learning terms - if don’t have then could be learning the wrong things</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>dealing with and learning from multiple variables</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>not having data can really slow things down</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>The original data may not be helpful for the supporting changes to reliable get an original change into practice is made</td>
<td>1</td>
</tr>
<tr>
<td>Facilitator</td>
<td>having a regular meeting to discuss tests</td>
<td>1</td>
</tr>
<tr>
<td>Facilitator</td>
<td>regular meeting to report back to</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>hard to keep on top of all the learning</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>hard to keep up and manage with multiple series all iterating change</td>
<td>1</td>
</tr>
<tr>
<td>Planning</td>
<td>visual representation of iteration decisions</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>reverting to routine when difficulties arise - not carrying out test</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>testing a single change can identify multiple other changes that are needed</td>
<td>1</td>
</tr>
<tr>
<td>2.10</td>
<td>Original change often not the only thing that needs to be addressed</td>
<td>4</td>
</tr>
<tr>
<td>Challenge</td>
<td>tendency to stick to one change even if learning suggest you shouldn’t</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>lots of unexpected tweaks to implement one change - often not just straightforward scale up of the change - many supporting structure needed</td>
<td>1</td>
</tr>
<tr>
<td>Learning</td>
<td>from failure and not sticking with original change idea for the sake of it</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>lots of factors that need to be addressed just to implement one change</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>not as simple as just scaling up - often unintended consequences that need dealing with</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>some tests of change require complete reorganisation - buying harder</td>
<td>1</td>
</tr>
<tr>
<td>2.11</td>
<td>Running multiple tests at once</td>
<td>1</td>
</tr>
<tr>
<td>Logical</td>
<td>to test separate aspect of a process separately but then need to bring together</td>
<td>1</td>
</tr>
<tr>
<td>3.1</td>
<td>Challenge - what prevents documentation</td>
<td>9</td>
</tr>
<tr>
<td>Documentation</td>
<td>articulated as challenging</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>documentation challenging particularly if you are testing frequently</td>
<td>1</td>
</tr>
<tr>
<td>Documentation</td>
<td>is challenging</td>
<td>1</td>
</tr>
<tr>
<td>Documentation</td>
<td>not good</td>
<td>1</td>
</tr>
<tr>
<td>Does not fit with day to day work activities</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Challenge</td>
<td>- pausing to write up</td>
<td>1</td>
</tr>
<tr>
<td>Documentation</td>
<td>needs to be flexible to people preference and work routine</td>
<td>1</td>
</tr>
<tr>
<td>Need someone to be willing and motivated to document</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Even with web tool if requires someone to document</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Struggles to get people to do PDSA rigorously and documenting</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Need to use it otherwise pointless</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Challenge</td>
<td>- need time to review otherwise pointless</td>
<td>1</td>
</tr>
<tr>
<td>Not sure what to document</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Blank documentation template can be intimidating</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Not sure who should document</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Deliberation over who documents - team or qi facilitator</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Time consuming</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Challenge</td>
<td>documenting perfectly can detract from other important activities</td>
<td>1</td>
</tr>
<tr>
<td>Challenge</td>
<td>seems and is time consuming - often do these sorts of things in your head</td>
<td>1</td>
</tr>
<tr>
<td>Documenting tests of changes is time consuming</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Seen as time consuming</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Too many places to document</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Challenge - templates can be inhibiting if language not helpful</td>
<td>1 1</td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>-----</td>
<td></td>
</tr>
<tr>
<td>Multiple places to document</td>
<td>1 1</td>
<td></td>
</tr>
<tr>
<td>Multiple forms exist to document PDSA</td>
<td>2 2</td>
<td></td>
</tr>
<tr>
<td>Too many places to document PDSAs</td>
<td>1 1</td>
<td></td>
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</tbody>
</table>

### 3.2 Facilitator - how can documentation be helped

<table>
<thead>
<tr>
<th>Academic nature of teams</th>
<th>1 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academic teams more likely to document</td>
<td>1 1</td>
</tr>
<tr>
<td>QI facilitator can help</td>
<td>1 4</td>
</tr>
<tr>
<td>Example of practical use of documentation</td>
<td>1 1</td>
</tr>
<tr>
<td>Improvement facilitator took responsibility to document in order to maintain rigour of method use</td>
<td>1 1</td>
</tr>
<tr>
<td>Organisation decided to put responsibility to document on QI facilitators</td>
<td>1 1</td>
</tr>
<tr>
<td>Qi facilitator supports documentation</td>
<td>1 1</td>
</tr>
<tr>
<td>Reflect on different levels of documentation</td>
<td>2 3</td>
</tr>
<tr>
<td>Different degrees of documentation detail</td>
<td>1 1</td>
</tr>
<tr>
<td>Documentation - use detail documentation for current PDSAs but then summarise them briefly as they became more historical</td>
<td>1 1</td>
</tr>
<tr>
<td>Multiple different documentation types - detailed vs high level</td>
<td>1 1</td>
</tr>
</tbody>
</table>

### 3.3 Value of documentation

<table>
<thead>
<tr>
<th>Facilitates dialogue and clarity</th>
<th>6 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documentation facilitating conversations</td>
<td>1 1</td>
</tr>
<tr>
<td>Documentation supports clarity</td>
<td>1 1</td>
</tr>
<tr>
<td>Documentation template helps guide dialogue and ensures clarity</td>
<td>1 1</td>
</tr>
<tr>
<td>Frames conversation</td>
<td>1 1</td>
</tr>
<tr>
<td>Guided conversation</td>
<td>1 1</td>
</tr>
<tr>
<td>Helps frame dialogue around a test of change and make sure all information is planned</td>
<td>1 1</td>
</tr>
<tr>
<td>Used to share with others</td>
<td>1 1</td>
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</table>

### Role of Improvement facilitator - crosscutting

<table>
<thead>
<tr>
<th>Accepted within and Knowledge of project team clinical area</th>
<th>3 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facilitator - constant QI facilitator support who knows the ins and outs</td>
<td>1 1</td>
</tr>
<tr>
<td>Facilitator - QI facilitator that understands the situation is key - can be cognisant of dept. issues</td>
<td>1 1</td>
</tr>
<tr>
<td>Qi facilitator benefits for being seen one of them</td>
<td>1 1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Adaptable to project team QI experience</th>
<th>5 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>For novice teams 0 QI facilitator introduces concept of testing and then writes up an initial test as a PDSA an show structure to team</td>
<td>1 1</td>
</tr>
<tr>
<td>Qi facilitation dependent on experience</td>
<td>1 1</td>
</tr>
<tr>
<td>Qi facilitation role dependent on team experience</td>
<td>1 1</td>
</tr>
<tr>
<td>Qi facilitator changes approached depending on team experience</td>
<td>1 1</td>
</tr>
<tr>
<td>Qi facilitator role needs to be flexible to teams needs</td>
<td>1 1</td>
</tr>
<tr>
<td>Qi facilitator to lead early PDSAs in team have little experience of the approach</td>
<td>1 1</td>
</tr>
</tbody>
</table>

### Educational role

<table>
<thead>
<tr>
<th>Helpful to have top ups on qi terminology</th>
<th>2 2</th>
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</thead>
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330
<table>
<thead>
<tr>
<th>Facilitates dialogue</th>
<th>4 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engages others</td>
<td>4 5</td>
</tr>
<tr>
<td>Qi facilitator needs to empathise with team members</td>
<td>1 1</td>
</tr>
<tr>
<td>Qi facilitator role of engaging others</td>
<td>1 1</td>
</tr>
<tr>
<td>Role of convincing others of need for change</td>
<td>1 1</td>
</tr>
<tr>
<td>Story telling</td>
<td>1 1</td>
</tr>
<tr>
<td>Telling positive stories</td>
<td>1 1</td>
</tr>
<tr>
<td>Facilitates dialogue</td>
<td>4 8</td>
</tr>
<tr>
<td>PDSA - Facilitator - QI facilitator taking the role of leading conversations and documenting</td>
<td>1 1</td>
</tr>
<tr>
<td>Keep PDSA documentation and language in background</td>
<td>1 1</td>
</tr>
<tr>
<td>Language considerations</td>
<td>1 1</td>
</tr>
<tr>
<td>Qi facilitator frames meeting with PDSA but without the language</td>
<td>1 1</td>
</tr>
<tr>
<td>Qi facilitator or others trained helps as a translator</td>
<td>1 1</td>
</tr>
<tr>
<td>Qi facilitator require to prompt teams to state objective - not natural as often implicit</td>
<td>1 1</td>
</tr>
<tr>
<td>Qi facilitator role is build education in their teams and to facilitate conversations</td>
<td>1 1</td>
</tr>
<tr>
<td>Some teams don’t like qi jargon</td>
<td>1 1</td>
</tr>
<tr>
<td>Facilitators dialogue</td>
<td>3 7</td>
</tr>
<tr>
<td>Barrier - getting qi facilitators with balance between understanding methods and ability to facilitating and social situations</td>
<td>1 1</td>
</tr>
<tr>
<td>Barrier to use PDSA and using to high fidelity isn’t laziness of a qi facilitator but the ability to facilitate a team to think and work in that way</td>
<td>1 1</td>
</tr>
<tr>
<td>Doesn’t take long to build capability but does need careful facilitation</td>
<td>1 1</td>
</tr>
<tr>
<td>Expert qi facilitator is important</td>
<td>1 1</td>
</tr>
<tr>
<td>Facilitation of teams</td>
<td>1 1</td>
</tr>
<tr>
<td>Facilitator - social skills of qi facilitator</td>
<td>1 1</td>
</tr>
<tr>
<td>Qi facilitator needs to understand their role as a facilitator</td>
<td>1 1</td>
</tr>
<tr>
<td>Impact of facilitation</td>
<td>2 2</td>
</tr>
<tr>
<td>Qi facilitator supports learning and influencing iterations</td>
<td>1 1</td>
</tr>
<tr>
<td>Qi facilitator takes cognitive load off of frontline teams</td>
<td>1 1</td>
</tr>
<tr>
<td>Navigating improvement effort</td>
<td>2 3</td>
</tr>
<tr>
<td>Guiding team along journey</td>
<td>1 1</td>
</tr>
<tr>
<td>Qi facilitators lead the navigation of testing</td>
<td>1 1</td>
</tr>
<tr>
<td>Role of qi facilitator</td>
<td>1 1</td>
</tr>
<tr>
<td>Negotiation role</td>
<td>1 1</td>
</tr>
<tr>
<td>Negotiation role of qi facilitator</td>
<td>1 1</td>
</tr>
<tr>
<td>Org structure for facilitator to work in</td>
<td>1 1</td>
</tr>
<tr>
<td>Infrastructure important</td>
<td>1 1</td>
</tr>
</tbody>
</table>
10.8. Appendix 8 – International study on the conduct of PDSA cycles – Consent form

Consent Form

Plan-Do-Study-Act Cycle conduct in healthcare study

Please read and confirm your consent to participate in this study by initialling the appropriate box(es) and signing and dating this form.

1. I confirm that the purpose of the study has been explained to me, that I have been given information about it in writing and read it, and that I have had the opportunity to ask questions about the research and have had these answered satisfactorily.

2. I understand that my participation is voluntary, and that I am free to withdraw at any time without giving any reason and without any implications for my legal rights.

3. I give permission for the interview to be audio-recorded by the researcher, on the understanding that the recordings will be kept in a secure locked cabinet and/or secure password protected computer server and destroyed at the end of the study.

4. I understand that anonymised quotes may be used in publications stemming from the research but not in any way that might allow for identification of individual participants.

5. I understand that all personal and interview data will be kept confidential at all times.

6. I agree that my details, including personally identifiable details, may be kept on Imperial College London computer systems/premises.

7. I agree that my research notes/data may be accessed by responsible persons from the Sponsor, NHS Trust, or regulatory authorities, in order to check that the research has been conducted correctly.

8. I agree to take part in this study.

9. I give permission for researchers to observe me and use the observations in the study.

____________________________  ___________  ____________________
Name of respondent             Date                      Signature

____________________________  ___________  ____________________
Name of researcher taking consent  Date                      Signature

13.12.2013  PDSA evaluation Informed Consent Form v2.0