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Complexity, co-creation and social practices – re-constructing quality improvement: a case study in mental health

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Thesis submitted in accordance with the requirements for the degree of Doctor of Public Health of the

University of London

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Health Research and Care Northwest London

I, Stuart Andrew Hofer, confirm that the work presented in this thesis is my o	wn
Where information has been derived from other sources, I confirm that this has b	eer
indicated in the thesis.	
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Abstract

The use of research evidence to change clinical practice remains a significant challenge. Quality improvement (QI) offers a methodological approach to support this 'knowledge to practice' process. However, most research on QI focuses on the use of knowledge and not its creation to improve practice. This research aimed to address this gap through an exploration of the social process of co-creating knowledge within a QI project. The case study aimed to improve the physical health of people with serious mental illness through the introduction of a physical health 'pathway'. The QI project used participatory approaches to introduce new evidence-based clinical practices, initially on a single ward, and then scaled-up across five additional wards within an acute mental health unit in the National Health Service (NHS) in England.

This four-year study used ethnographically-informed qualitative participatory approaches where the researcher was part of the QI project. Data were generated through participant observations, interviews and documentary analysis. The analysis included generating a narrative of the project, and the use of Knowledge Mobilisation and Implementation Science frameworks.

This research offers a window on the social construction of a QI project. Improvement is a socio-technical process that relies on social practices to generate the work required to support the 'knowledge to practice' process. QI methods draw on the tacit knowledge and experiences of stakeholders which is codified in outputs from workshops, which in turn can be used in the co-design of interventions. This co-constitutive process of simultaneous knowledge 'use' and 'creation' contributes to the co-creation of collective understandings and meanings, which compose the social practices of QI. However, issues of responsibility and accountability pose a significant challenge, and a careful balance needs to be found between the use of the data for managing performance and supporting staff to reflect on their practice.

This thesis is dedicated to Sandra Jayacodi and Jenny Trite.

Two women who through their own commitment and passion for improvement inspire me daily.

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Table of abbreviations

Action Effect Diagram (AED)

Action Effect Method (AEM)

Body Mass Index (BMI)

Cardio-vascular Disease (CVD)

Care Quality Commission (CQC)

Chronic Obstructive Pulmonary Disease (COPD)

Collaboration for Leadership in Applied Health and Care (CLAHRC)

Clinical Team Leaders (CTLs)

Commissioning for Quality and Innovation (CQUIN)

Consolidated Framework for Implementation Research (CFIR)

Context and Implementation of Complex Interventions framework (CICI)

Doctor of Public Health (DrPH)

Electronic Health Record (EHR)

Expert Recommendations for Implementing Change (ERIC)

Evidence-Based Medicine (EBM)

Health Care Assistants (HCAs)

Higher Education Institutes (HEI)

Implementation Science (IS)

Institute of Healthcare Improvement (IHI)

Knowledge to Action cycle (K2A)

Knowledge Mobilisation (KMb)

London School of Hygiene and Tropical Medicine (LSHTM)

Making Every Contact Count (MECC)

Mental and Physical Wellbeing (MPW)

Modified Early Warning Scores (MEWS)

Model for Understanding Success in Quality (MUSIQ)

National audit of Schizophrenia (NAS)

National Institute for Health Research (NIHR)

National Institute of Health and Care Excellence (NICE)

Normalization Process Theory (NPT)

Organisational Policy Analysis (OPA)

Plan-Do-Study-Act (PDSA)

Physical Health Assessment (PHA)

Physical Health Plan (PHP)

Psychiatric Intensive Care Units (PICU)

Pulmonary Rehabilitation (PR)

Quality and Outcomes Framework (QOF)

Quality Improvement (QI)

Recovery and Wellbeing College (RWC)

Serious Mental Illness (SMI)

Service User (SU)

Shared Decision Making (SDM)

Statistical Process Control (SPC)

Successful Healthcare Improvements from Translation of Evidence into practice (SHIFT-Evidence)

United Kingdom (UK)

United States of America (USA)

Web Improvement Support for Healthcare (WISH)

Integrating statement

This preface provides an overview of the last 10 years of my career through the quality improvement (QI) projects I have worked on and their associated publications. This illustrates how my work has integrated with my studies over the course of the Doctor of Public Health (DrPH) programme. This preface demonstrates how my academic interests and practice led me to undertake a DrPH that covers the fields of QI, knowledge mobilisation (KMb) and Implementation Science (IS) to support the 'knowledge to practice' process, that is using research evidence to change clinical practice. I commenced the DrPH programme in 2013 whilst working as a Public Health Research Fellow and QI Practitioner as part of the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Northwest London. As part of my job at CLAHRC Northwest London, within the School of Public Health at Imperial College London, I have worked on numerous projects to support 'knowledge to practice' using QI methods.

In 2008, my initial role within the CLAHRC Northwest London programme focussed on supporting the involvement of patients, service users and the public in research and improvement. Following this, I was responsible for supporting QI teams to develop improvement measures to monitor the implementation and uptake of interventions within clinical settings. Through this role, I was involved in supporting a range of projects in diverse locations including improving access to primary care for people with sickle cell disease (1-5); screening harmful and hazardous alcohol use in the acute medical setting (6); implementing a care bundle for chronic obstructive pulmonary disease (COPD) in hospital (7); and screening for inpatient diabetic foot complications. In 2012, I was appointed as a Project Evaluation Manager and Public Health Research Fellow, which led to the role as a project manager for a community pulmonary rehabilitation (PR) project. The project aimed to improve access to post-hospitalisation PR for people with COPD through the development of interventions using experience based co-design (8). During this time I undertook research looking at access to community mental health services for common mental disorders, such as anxiety and depression (9–14).

At this stage, I reflected that much of the work I was engaged in was focused on QI as a set of tools or methods that could help healthcare professionals to work with patients to introduce improvements to their services. This did not account for why these methods were sometimes effective and sometimes not. I came to appreciate that QI employed a socio-technical process that required technical skills and relied on the relational aspects of the QI tools as participatory methods. It was this aspect I was keen to understand, to go beyond QI methods and models, to see how other similar fields that aim to get 'knowledge into practice' could help explain this work.

In 2013, I enrolled on the DrPH programme, taking a one-year sabbatical, during which I undertook the requisite courses at London School of Hygiene and Tropical Medicine (LSHTM): Evidence Based Public Health Policy and Understanding Leadership & Management in Organisations. Through these assessed modules, I broadened my knowledge of health systems and services and explored research methodologies and theories. For my organisational policy analysis (OPA), a ninemonth research project exploring how policies are implemented in organisations, I chose to be based within my home institution. I undertook a secondary analysis of data collected about three projects I had been involved with to implement clinical guidelines using QI in the acute medical setting. Derek Bell, Professor of Acute Medicine at Imperial College London and director of the NIHR CLAHRC Northwest London co-supervised this work. The research used the Consolidated Framework for Implementation Research (CIFR) to conduct an analysis on secondary data generated from the three case studies:

- 1. A screening tool for identifying harmful and hazardous alcohol use;
- 2. A care bundle to support the discharge of patients with COPD;
- 3. A care bundle to identify and manage diabetic foot complications.

The research identified several key practitioner and organisational barriers and facilitators to the implementation of the care bundles:

- The availability of resources for implementation;
- The sustainability of change;
- Senior leadership engagement;
- Practitioner incentives.

The OPA, titled: Implementing clinical guidelines using quality improvement methods - An organisational analysis of three case studies in the acute medical setting, was submitted in February 2015 as part of the requirements of a DrPH. From this, a peer reviewed article was published in BMC Health Services Research, drawing on analysis of the two of the three case studies that used a care bundle approach to support guideline implementation (15). I followed-up this work outside the DrPH programme by co-authoring a systematic review on the design, implementation and evaluation of care bundles with collaborators at University College London (16). In 2014, following my return to work, I supported a new QI project that aimed to improve the physical health of people with serious mental illness. The role facilitated the use of QI methods within the team and supported the involvement of service users to implement clinical guidelines within the acute mental health setting (17,18). The project was of particular interest to me: it was about implementing guidelines in an acute setting, and because its aim was to improve population outcomes and support public health objectives in a markedly under-served population.

In 2015, whilst working on this project, I undertook a 3-month health policy internship with Curatio International Foundation in Tbilisi, Georgia, in responses to an offer from LSHTM. The Non-Governmental Organisation has a long history of undertaking policy relevant research in middle-income countries, particularly in Eastern Europe and Central Asia. As part of the research unit, I explored the financial and economic barriers to implementing policy reform of mental health services. I gained valuable experience of working in an international organisation and further developed analytical skills (19). Whilst in Georgia, the QI team in the mental health unit in London made plans to apply for additional funding to 'roll out' the project to other wards within the unit. This provided a great opportunity to continue to be involved in the programme and use this as a case study for exploring the role of QI in the implementation of guidelines. I was particularly interested in remaining involved in the project as the service users, who were very committed to the project, had been involved in co-designing the interventions. The role of service users in QI, especially in co-designing interventions is of particular interest to me, as I have been involved in many projects that have engaged with this approach (20).

The combination of having time away from the project, working on mental health reform, and the potential funding for further development of the project resulted in the decision to use the project as a case for examining the challenges of 'knowledge to practice'. My interest was supported by the call to action outlined by Holmes et al. (2016), which highlighted specific challenges related to 'mode two' research: the collaboration between researchers and those that plan and deliver services to 'coproduce' and implement knowledge (21). This is distinguished from 'mode one' research, undertaken independently of its utilisation, disconnected from the delivery of services. The opportunity to undertake research close to the front line, where I was working and had already built relationships with staff and services users, offered a great opportunity, yet it presented some challenges about my identity. This changing role from supporting the team to use QI methods to 'researching' the team, did not sit easily with me. To overcome this challenge, I took an approach somewhat akin to a joint inquiry. Using some of the questions the team had asked themselves, especially the service users, about their roles and barriers to improvement, presented an opportunity to develop research that I was interested in and had the potential to be useful to the participants and the organisation.

As both a public health researcher and quality improvement practitioner, I have found the process of designing, executing, analysing and writing-up this study illuminating. I believe that this research has helped develop skills that improved my practice of QI and has ignited my curiosity about the process of co-creating knowledge the value of developing and utilising practice theories in designing, conducting and evaluating QI projects and programmes. This thesis, like so much of the work I have been involved with, highlights the important role that health services play in promoting activities that support public health and population outcomes. QI offers a vehicle through which the public health workforce can engage beyond the boundaries of primary and community services into acute care organisation. Importantly, the many skills and competencies required for successful QI are found within the public health workforce, including their ability to provide system leadership and foster collaborative working practices. I have been keen to share this with students that I have taught on MPH courses at Imperial College London, University of Liverpool and LSHTM.

1.0 Introduction

1.1 Overview

The research I present in this thesis initially seeks to describe the 'knowledge to practice' process of the case study in the form of a quality improvement (QI) project narrative. The case study is subsequently re-conceptualised using both knowledge mobilisation (KMb) and implementation science (IS) frameworks. In using these multiple approaches, I seek to open a window on the social construction of the QI project to explore improvement as both a social and technical process. This multiperspective analysis highlights several aspects of the 'knowledge to practice' process including: the role of QI methods in assisting actors to navigate the complexity of the health system, the co-creation of knowledge and the process of implementation and improvement as a social practice.

In this chapter, I provide a commentary on the current status of QI from both a practitioner and researcher perspective, drawing on international examples of QI to outline some of the current challenges that research may be able to address (§1.2). These challenges are also reflected in my own experience of working in this field within the National Health Service (NHS) in England for the last 10 years, as outlined in the preface.

In addition, I present a summary of the specific QI project that that is the case study for this research. I also describe my changing role as both a practitioner and a researcher and highlight some of the tensions and challenges these dual roles created in undertaking the research presented in this thesis (§1.3).

I provide a brief overview of the academic context and expectations of doctoral research for the award of a Doctor of Public Health (DrPH) at the London School of Hygiene and Tropical Medicine, so as to contextualise this research (§1.4).

The penultimate section offers a detailed account of the knowledge gap within this field linked to the three research questions that this thesis aims to address (§1.5).

Finally, I summarise the main issues identified in the introduction and the knowledge gap they create and outline how this gap is addressed through the case study, providing a route map for the thesis (§1.6).

1.2 Understanding the context

The use of research evidence to change clinical practice, which can be described as the 'knowledge to practice' process, remains a significant challenge. Several approaches have been proposed to support this process, one of which is QI. QI offers a methodological, albeit largely atheoretical, approach that has been adopted globally by healthcare organisations and health care systems including the National Health Service (NHS) in the United Kingdom (UK) (22). QI approaches are commonly promoted by healthcare funders, commissioners and regulators, which in the UK include organisations such as NHS England, NHS Improvement and the Care Quality Commission (CQC). There are also organisations that have been established with the primary purpose of promoting QI by monitoring healthcare processes and outcomes through national audits such as the Healthcare Quality Improvement Partnership (HQIP). Furthermore, international healthcare organisations including the World Health Organisation (WHO) and many international development programmes promote the use of QI approaches in strengthening health care systems, especially to achieve Universal Health Coverage and deliver the Sustainability Development Goals (SDGs) in low-and middle-income countries (LMICs) (23).

The rapid global interest and use of QI methods has resulted in an expansion in the dissemination of different guidelines and frameworks to support QI, and an increasing number of published reports of individual QI projects and programmes. Concomitantly, there has been an expansion in research programmes to better understand and assess the practice and processes of QI. Over the last decade the National Institute of Health Research (NIHR) in England has commissioned and funded the Collaboration in Leadership in Applied Research and Care programme to not only support the uptake of research evidence in the NHS, including through the use of QI, but also to undertake research to identify contextual factors and mechanisms that support, or hinder, the processes involved (24). However, much of the research on QI focuses on the use of knowledge in the 'knowledge to practice' process, and not the explicit creation of new knowledge as part of this process. Central to this thesis are the issues of research and practice and their interrelationship, mediated by the 'knowledge to practice' process, which in this research focuses on the empirical QI process.

However, the broader issue of research and practice is central to any doctoral thesis in the field of health, especially that pertaining to a professional doctorate such as the DrPH, which aims to bridge the gap between research and practice and address the dichotomies that this separation creates.

At this point I would like to make two points that I feel underpin this research in its wider context as it relates to 'knowledge to practice' and public health, respectively.

The first regards 'practice', specifically my own practice. In the Preface, I provided the reader with an understanding of my own mix of practice and research that led to the DrPH programme. Both my QI practice and research continued through my involvement in the case study, which I would like to reflect a little on here. It is through my experience of this practice that I conclude that for too long the idea of research (that which generates knowledge) and practice (that which uses knowledge) have been seen separately, by researchers and practitioners. This separation could, in some ways, account for some of the challenges we face in modern health systems, with distinct structures that 'create knowledge' and 'use knowledge'. The emergence and prominence of approaches to supporting the 'knowledge to practice' process attempt to challenge this separation and bridge, what is variably termed the 'implementation gap', 'second translational gap' or 'know-do gap'. What all these terms have in common is their understanding of the separation of knowledge and practice and their desire to somehow use knowledge to change practice. However, the idea that this is a linear or simple process has been long replaced by the notion of a complex system that relies on relational as well as technical aspects of the process. This is represented, to varying degrees, by three key 'knowledge to practice' approaches: QI, KMb and IS. Whilst these are almost universally seen as separate approaches, it may be through the integration of their associated constructs that it is possible to illuminate the mechanisms of the 'knowledge to practice' processes.

The second point relates to public health, as both an academic discipline and as a practice. Public health is commonly defined as: "the art and science of preventing disease, prolonging life and promoting health through the organized efforts of society" (25). Whilst academic programmes may have broad approaches to demonstrating how this might be both researched and taught it frequently excludes patients in acute care settings.

Similarly, the practice of public health, in the UK at least, was seen almost exclusively as community medicine, allied closely with primary care and with some incorporation of primary prevention into hospital care. Whilst that alliance was broken in 2013 following the reorganisation of primary care and public health in England, following the Health and Social Care Act, public health remains firmly outside personal health services, especially hospitals (26). Despite this, most QI projects I have been directly involved with, or those funded by CLAHRC Northwest London more generally, have aimed to influence public health outcomes, even if based primarily in acute care settings, e.g. a diabetic foot project that dealt with screening and managing diabetic foot complications in hospital but which also addressed wider preventative issues. This supports the notion that public health is everyone's business and covers all health services. For too long the goal of promoting public health has not been perceived as the responsibility of health care providers. Secondly, the principles and practices of public health are perfectly aligned to the principles of QI and IS (27). Whilst this has been recognised by some Master of Public Health (MPH) programmes through the introduction of QI, at Imperial College, for example, and IS elsewhere, this is not universal (28).

Bringing these two points together, I would like to highlight the issues that might be faced by those simultaneously undertaking research and contributing as a practitioner. Whilst there may be situations where these two roles are separate, I imagine that more frequently they somehow overlap, with a shifting emphasis on one role or another. Irrespective, these dual roles can often lead to tensions that need to be recognised and resolved, where possible. The research I undertook within this thesis offers an example of the type of situation where a practitioner researcher has a dynamic and changing role with the team they are working with or the participants of their research. Of course, this is not new, action research has long dealt with the challenges of practitioner-researcher tensions. However, there are increasing number of projects and programmes established to implement innovations and improve care research whereby practitioner-researchers have roles in facilitating the use of QI combined with research. In England, much of this increase has been driven by the creation of Academic Health Science Networks (AHSNs) and Collaboration's for Leaderships in Applied Research and Care (CLAHRCs).

As both a public health researcher and QI practitioner, this thesis and the research it describes has provided an opportunity for reflecting on the process of undertaking research whilst part of a QI project team, which I have attempted to capture.

1.3 A case study for exploring improvement and my role as a researcher

QI projects have become a popular organisational mechanism by which clinical and managerial staff coalesce around particular issues to initiate change (29) Since 2008, CLAHRC Northwest London has initiated over 70 such projects across different health and social care settings in Northwest London, several of which I was involved with as outlined in the Preface. In 2013, an organisational QI project to improve the physical health of people with serious mental illness within an acute mental health unit was established. CLAHRC Northwest London was invited to support the project using participatory QI methods. The initial project (SHINE1) was funded by The Health Foundation, a national healthcare charity, but following the perceived success of the project, CLAHRC Northwest London funded a follow-on project (SHINE2). SHINE1 was delivered on a single ward between July 2014 and May 2016. The project aimed to introduce evidence-based clinical practices, based on existing clinical guidelines, that would improve the assessment of physical health as part of an inpatient physical health 'pathway'. The team co-designed and implemented several key interventions. These were subsequently scaled-up across five additional wards within the unit as part of SHINE2 between September 2016 and August 2018.

My own role within the project and relationship with the project team and clinical staff changed over the 4-year period. I first joined the project team as lead QI facilitator in November 2014 as part of the support from CLAHRC NWL. During the SHINE1 project, I was responsible for facilitating the use of the QI methods and attending monthly team meetings. More specifically, I supported both the project team and clinical staff in engaging with specific QI methods at various times throughout the project, either in the team meetings or on the ward.

This included developing a measurement strategy with the team, which initially comprised undertaking an audit of physical health assessments on the ward, developing improvement measures and setting up mechanisms for data collection, including spreadsheets and audit forms. I also worked with the clinical staff to develop their skills in analysing and interpreting data, including run charts and the use of Statistical Process Control (SPC). In addition to the technical aspects of QI, I was also responsible for building and maintaining relationships with the service users to ensure they were engaged and felt able to participate fully in the project.

Throughout SHINE1 I spent a significant amount of time with the service users supporting their engagement in different aspects of the project, such as the co-design of one of the interventions, and providing pastoral care and support. Through this process I built a very close relationship with the service users and often co-presented the project with them at various events including learning events and lectures. As the SHINE1 project came to an end, we started preparations on a number of publications that I led, the first outlined the role of service users in an QI project and the second provided a description of the project framed as a mechanism for implementing guidelines on the physical health of people with serious mental illness (17,18). In writing these papers, I attempted to involve as many of the team members, including service users, to ensure that everyone had an opportunity to contribute to the formal records of the project. This activity did help, to some degree, to re-frame my relationship with the team and demonstrate my role as a 'researcher' rather than just as a QI facilitator. During this period the team were also busy preparing a competitive application for funding direct from CLAHRC NWL to scale up the implementation of the interventions developed in SHINE1. This was an unusual application for the CLAHRC as it had only previously funded projects to spread across different organisations rather than scale-up on additional wards within the same unit. Following confirmation of the funding for SHINE2, it was agreed that I would use the projects as a case study, which would allow me to follow up the work I had been doing with SHINE1 but with less commitment (and responsibility) to deliver the project. Whilst I was keen to continue to be involved in the project, I found it difficult to work out how I could take both an active role as a member of the project team and 'research' the project.

As someone with a background in the natural sciences, this presented an issue about reconciling my desire for 'objectivity' as a researcher but recognising the research I was undertaking was necessarily subjective, as it was drawn from my experience of being part of the QI project team. This tension was particularly difficult as my engagement with the team members, especially the service users, had created close relationships that could not be ignored. However, this close engagement with the team also offered an opportunity to access the team and their work in a way that might have been more challenging for an 'outsider'.

This liminal position could certainly prove to be an asset in both gaining and intimate understanding of the project and the stakeholders involved, and to some extent immersing myself within the organisation, which subsequently allowed me access to individuals who might not have not been so accessible, or even visible, to researchers without the relationships I had developed. As I began to understand that 'absenting' myself from the project team was neither desirable nor possible and instead my role within the team as 'an agent for change' at the time, was acknowledged. These concerns were also translated into challenges I felt about involving members of the QI team in the design of this research study and the uncertainty whether this should be done. The result was that whilst some of my initial thinking about the aim of the doctoral work was influenced by the desire to meets the needs of all the project stakeholders in offering them some way to understand their role in project, there was no formal process for engaging them as co-investigators. In retrospect this was a missed opportunity to do more to involve both the staff and service users in the research. However, this does also raise an issue about the positions of privilege and power held by me and other members of the QI project team and clinical staff, especially with respect to the service users. Whilst services users were included as QI project team members, to ensure ensuring their voices were heard and opinions included required work, both to support the service users but also to ensure structures were created to allow this. There was a particular role of the QI facilitator to support the service user members.

In terms of my role in each of the projects, as outlined, I joined the project team in November 2014 as the lead QI Facilitator. At this stage, an outline of the project had been agreed, through the funding application, and a team had been formed, which included a range of clinical and managerial staff as well as three service users. These were people that had experience of serious mental illness and using the services within the organisation. On joining, very few of the team had any experience with QI, which was not unusual.

Over the following 18 months, I built relationships with the core team members, both from interacting with them in the monthly team meetings and workshops, and also from meeting them either one to one or in small groups to support them in different aspects of the project, such as co-facilitating a workshop for the QI project team and the ward staff to explore the role of Plan -Do-Study-Act (PDSA) cycles and the use of data to monitor improvements.

The workshops and meetings were participatory in nature, as the intention was not only to involve the stakeholders but also develop their understanding and expertise in these methods, so they could develop and lead future projects within the organisation. This differs somewhat from a more usual approach offered by QI consultants who undertake the work for the project and simply aim to provide information (or intelligence) for the team. The approach developed by CLAHRC NWL was very much about building capacity and capability of front line clinical and managerial staff through the QI project with the support of the QI facilitator.

1.4 Academic context

LSHTM offers one of the few DrPH programmes in the UK and has a unique curriculum that is intended to develop future leaders in public health who are research literate. Whilst it is not explicit in its intentions to develop academics, the programme is intended to offer grounding in the rigours of academic research through both the taught and research components of the degree.

Specific to the expectations of the thesis, the student is anticipated and required to demonstrate the same conceptual 'depth' and intellectual rigour as a PhD, but with constraints in time and word count the thesis is necessarily shorter.

The thesis intends to provide a detailed account of the rationale, conduct, analysis and conclusions of the research. It also includes reflexive elements embedded within some of those sections that demonstrate how the research contributes to the advancement of the knowledge of the subject and my own development in the approaches I might take in future research and practice.

1.5 Knowledge gap

The terminology surrounding the 'knowledge to practice' process is confusing and inconsistent. Terms are used interchangeably or used with different meanings and assumptions in different contexts. Here I outline how I define QI within this thesis and how this understanding relates to the methods that were employed in the case study. Recognising that QI is not the only 'knowledge to practice' process, I aim to draw on other approaches, namely KMb and IS. This is not an attempt to assert QI as the most effective or useful approach in comparison to these others but to focus on the similarities of these different approaches. In focussing on the similarities as well as the differences, it is possible to highlight the complementary nature of these various approaches using multiple lenses.

In the context of the CLAHRC NWL programme, several QI methods were settled on at the beginning of the programme in 2008. Over time, some of these were developed and enhanced (30,31). These provided the fundamental participatory mechanisms for engaging with project teams to explore local clinical problems, propose a range of potential solutions, implement those solutions, assess their implementation and, where possible, their impact on outcomes or care processes. This approach relied on the use of different QI methods, principles and tools that could both support the involvement and participation of staff (and patients) and develop strategies for moving the project forward beyond ideas and into action.

Similarly, KMb and IS approaches aim to deliver improvements in care processes and/or outcomes, albeit through slightly different mechanisms. The mechanisms that underpin KMb and IS approaches to the 'knowledge to practice' process depend on different conceptualisations of the process. This is highlighted by Nilsen (2015), where the IS frameworks are differentiated by their overarching aim (32):

- Process Models describing and/or guiding the process of translating research into practice;
- Determinant frameworks, Classic theories, Implementation theories understanding and/or explaining what influences implementation outcomes;
- Evaluation frameworks evaluating implementation.

Whilst these explicitly refer to IS, there are clear overlaps with both KMb and QI, some of which were highlighted by Reed et (2018), which compared different frameworks for implementation and improvement (33). Categorising frameworks also offers an opportunity to compare those that have been drawn on in this research, which are identified and described in more detail in each relevant section of the background chapter (§2.3.4, 2.4.1 and 2.5.1).

However, at this stage it is worth acknowledging the inherent differences between QI, KMb and IS. This relates to the use of specific methods employed in QI that support project teams to achieve improvements, which differ from the approaches employed in KMb and IS. These types of comparison often presents QI as highly context specific and whilst QI tools can be used in a systematic way, as in CLAHRC NWL, there are rarely opportunities to demonstrate casual relationships from these endeavours that would allow generalisation (34,35).

Despite this challenge the QI projects provide a popular mechanism for improving care and generating learning about the local health system. None the less, there are significant challenges in extending this learning beyond experiential knowledge, which whilst important, often remains individualised and not shared with the wider organisation or communities of practice. Through this research I aim to move beyond QI as a technical process comprised of a set of tools or methods and explore the mechanisms by which healthcare professionals and service users engage in the 'knowledge to practice' process. I explore the relational aspects of the QI tools, as participatory methods, can be achieved through the synergistic use of KMb and IS as alternative approaches with which to re-conceptualise the QI project, specifically drawing on the use of practice theory.

Inevitably, some challenges remain unresolved despite this multi-perspective analysis, but it is hoped that through this investigation the strengths and weaknesses of each approach to the 'knowledge to practice' process can be illuminated.

Another challenge this thesis aims to address was set out by Holmes et al (2017), who explicitly called for the co-production of knowledge, drawing on Kitson (2013), where: "researchers and research users work together to co-create, refine, implement and evaluate the impact of new knowledge that is sensitive to the context in which it is created and used" (21).

The case study in this thesis represents the micro-level QI project highlighted in this call to action and this research endeavours to unpack the social practices and processes that have driven the project forward. In doing so this explicates the process of co-creating knowledge that is generated by the project from the work of the team. How this knowledge is co-created is fundamental to the understanding the success of this type of endeavour and potential for future use. This approach is implicit in IS to understand the process of implementation. Thus, this research aims to resolve, to some extent, the tensions of QI and IS. The case study provides an opportunity to explore a specific clinical problem, the identification of potential solutions, and subsequent design, testing, implementation and scale-up of interventions. It is expected that focussing on the roles of the actors involved in both the QI project and the clinical services supported by the use of theoretical approaches such as Normalization Process Theory can offer new insights into the practices and processes of improvement (36).

This thesis aims to address three research questions:

- What role do QI methods have in assisting actors to navigate the complexity of the health system to support the 'knowledge to practice' process?
- What is the process of the co-creation of knowledge in a QI project?
- How can the process of implementation and improvement be understood as a social practice?

1.6 Summary and outline of thesis

In this chapter, I provided an outline to the 'knowledge to practice' process and identified three different approaches: QI, KMb and IS (§1.2). Whilst these are generally thought of as distinct approaches that may often appear incommensurable, at least within the literature, in this research, I propose to seek to better understand the 'knowledge to practice' process by drawing on these different approaches to reconceptualise the QI case study using KMb and IS.

I offered an outline of the case study which provides the reader with the context for this research in which I specifically described my own role, as both researcher and QI facilitator, and highlighted some of the tensions that this dual role created (§1.3).

Describing these tensions and how they were resolved, where possible, or at least recognised has been a reflective exercise to ground this thesis in the realities of the research milieu and the challenges encountered.

In providing the academic context for this work, I contextualise the research within both the DrPH programme and my own practice as a public health researcher and QI facilitator (§1.4). Whilst this thesis aims to provide a comprehensive account of my research for my doctorate, it is also intended as a reflexive account for my practice as both a researcher and QI practitioner.

The clinical and academic context shape much of this work and it is through my own experience that I have come upon the knowledge gap that I wish to address through this doctoral work (§1.5). In collecting data over four years, I amassed a significant amount of information about the case study providing a unique opportunity to address this gap.

This thesis will provide a review of the different 'knowledge to practice' processes that have been highlighted here and present a number of conceptual frameworks, models and theories as examples of the 'work' these approaches do (§2.0). I will specifically identify frameworks, models and theories that are subsequently used as analytical tools to explore the case study, as set out in the methods (§3.0). The analyses draw on data from documents, observations and interviews. The first analysis uses narrative methods to outline and elaborate the social processes that emerged through the QI projects (§4.0).

The second analysis re-conceptualises the QI case using a KMb framework to further account for some of the key features identified in the narrative (§5.0). The final analysis extends the findings of the prior analyses using practice theory as an explanatory framework (§6.0). Finally, each research question is addressed and drawing together the accumulated insights from the three analyses the emergent theme of accountability and responsibility is explored (§7.0).

2.0 Background

2.1 Overview

This chapter extends the preceding introductory chapter (§1.0) by providing a narrative review of the existing literature on several key topics. This covers an overview of the general 'knowledge to practice' process (§2.2) and a detailed overview of each of the three separate approaches: quality improvement (§2.3), knowledge mobilisation (§2.4) and implementation science (§2.5). Each section highlights key concepts and definitions and acknowledges current limitations and gaps in the fields. Focus is given to how the fields define 'knowledge' and 'practice' and how this influences knowledge creation and knowledge use. Each section offers a specific theory, model or framework that is explicitly drawn on in the subsequent analyses (§4.0, 5.0 and 6.0). This is followed by several sections that explore specific aspects of 'knowledge to practice'. The first examines the many and varied ways in which knowledge is defined in the different literatures and the various conceptual models that have been proposed to describe the process (§2.6). This is followed by an overview of the 'knowledge to practice' process within complex systems and offers an introduction to the different lenses that may be useful in understanding the 'knowledge to practice' process (§2.7). The concepts of social practices, practice theory and communities of practice are offered as theoretical constructs that may be useful in unpacking the practices and process of implementation and improvement. This is followed by the development of a conceptual model for exploring improvement as a social practice within complex systems (§2.8). This draws on a practice theory lens to explore improvement in response to the knowledge gap and the research questions (§1.5). The chapter concludes with a summary of the different 'knowledge practice' approaches that inform the conceptual model and explicitly links this to the research questions and the proposed analysis that is further outlined in the methods chapter (§2.8).

2.2 The 'knowledge to practice' process

The concept of the 'second translational gap' emerged in the late 2000's and highlighted a: "disconnect between the development and the implementation of new interventions in clinical practice" (37). This contrasts with the 'first translational gap', described as the problem of 'translating ideas from basic and clinical research into the development of new products and approaches to treatment of disease and illness' (**Figure 1**). These gaps were underpinned by the recognition of the delays in translating research into patient benefit, measured variably to take an average 17 years (38).

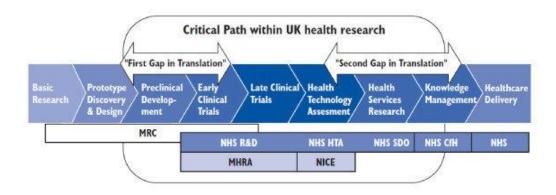


Figure 1: Pathway for translation of health research into healthcare (37)

The need for health systems to identify effective ways of introducing research evidence into the organisation and delivery of care has resulted in a growing interest in fields of inquiry and activities related to 'knowledge to practice'. 'Knowledge to practice' has itself been built upon the decades of work developing the evidence-based medicine (EBM) movement. These approaches, QI, KMb and IS, aim to link research evidence with clinical practice.

The link between EBM and QI was explained by Glasziou et al. (2011): "[EBM] has focused more on 'doing the right things' based on external research evidence whereas [QI] has focused more on 'doing things right' based on local processes" (39). This explanation helps define the link between the development of evidence-based interventions, practices, recommendations and standards of care and subsequent QI approaches that aim to support their implementation in practice (Figure 2).

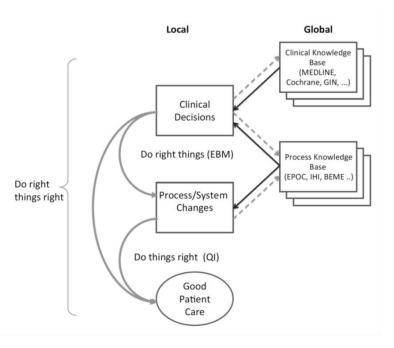


Figure 2: A conceptual model proposed by Glasziou et al. (2011) links evidence-based medicine and quality improvement to 'Do right things right' (6)

This link has prompted an increase in activity in both academia and healthcare systems to ensure better use of evidence in healthcare with the goal of improving clinical outcomes and experiences for patients (and staff). Research has offered insights into the barriers and facilitators of improvement in health services (40). Despite the growing interest in QI research the field largely remains the domain of clinical practice, through the use of QI tools to improve services for patients (§2.3) and the approach remains mostly atheoretical (22). However, some propose that research on QI is itself a new field: 'Improvement Science' (41).

2.3 Quality Improvement

QI has a long history, originating in manufacturing industries with adoption in healthcare beginning in the 1990s with the Institute of Healthcare Improvement (IHI) in the United States of America (USA) being a lead proponent (29). More recently, QI has emerged as a *tour de force* promising to revolutionise healthcare and the way healthcare professionals engage with their practice, and sometimes the promise of reducing costs.

Batalden & Davidoff (2007) defined QI as: "the combined and unceasing efforts of everyone—healthcare professionals, patients and their families, researchers, payers, planners and educators—to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development", as depicted by **Figure 3**, which highlights the necessary participatory nature of QI (29).

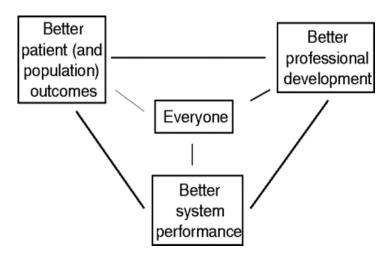


Figure 3: Aims of improvement as described by Batalden and Davidoff (2007) (29)

Batalden and Davidoff (2007) declared: "...everyone in healthcare really has two jobs when they come to work every day: to do their work and to improve it" (29). Whilst there have been long-standing approaches to QI including clinical audit and clinical guidelines, often associated with quality standards, more recent approaches have promulgated the use of QI methods and tools (42–44). Many of these methods and tools were re-packaged by the Institute for Healthcare Improvement (IHI) and promoted in the UK, initially by NHS Modernisation Agency, then the NHS Institute for Innovation and Improvement, followed by NHS Improving Quality and more recently by NHS Improvement. Batalden & Davidoff (2007) expanded the understanding of QI to characterise the types of knowledge that are both 'created' and 'used': "Although all improvement involves change, not all changes are improvement... we need to be sure that the changes we make systematically incorporate generalizable scientific knowledge... [and] to know that change is producing improvement, we need accurate and powerful measurements of what is happening... [but] we need to characterise the settings in which care is actually delivered (micro-systems, meso-systems and macro-systems)"(29).

This represents the 'knowledge to practice' process (*Figure 4*) which differentiates professional knowledge (subject matter expertise) and improvement knowledge, which form part of Deming's System of Profound Knowledge (45).



Figure 4: Formula illustrating the way in which knowledge systems combine to produce improvement (29)

- 1. Represents the knowledge that is being drawn on to inform the improvement;
- 2. Highlights the knowledge that is both simultaneously used and generated about the particular "physical, social and cultural identity of local care settings (e.g. their processes, habits and traditions)";
- 3. Identifies the need to create knowledge about the "effect of changes by using study methods that preserve time as a variable, use balanced measures (range of perspectives, dimensions), analyse for patterns";
- 4. Describes the use of knowledge to identify the variety of methods available for connecting evidence to particular contexts that inform plans for change;
- 5. Highlights the need to create knowledge that "provides insight into the strategic, operational and human resource realities of particular settings (drivers) that will make changes happen due to the execution of planned changes.

Central to the model proposed by Batalden & Davidoff (2007) is the idea that professional development, delivery of care and health outcomes are inseparable within a health system and they propose: "stimulation among these three domains invites both sustainability and unending creativity in their efforts" (29).

2.3.1 Quality improvement programmes

QI Organisations and programmes have been established. These include internationally, such as the Institute of Healthcare Improvement, nationally, such as NHS Improvement (for England) and locally, such as the Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Northwest London (NWL).

Across these organisations, there is diversity in their funding arrangements, organisational structure, programme management and delivery, and the models of QI they adopt. I focus on the CLAHRC NWL programme.

The National Institute for Health Research (NIHR) established the CLAHRC programme in England in 2008 in response to the Cooksey report, which described the second translational gap (§2.2) (37). Nine CLAHRC programmes were originally established in 2008 and increased to 13 in 2014 (*Figure 5*). CLAHRCs were tasked with closing the second translational gap by developing a programme of work within their geographical regions and working alongside NHS partner organisations and higher education institutes (HEI), to support the implementation of research to improve the quality of care patients receive and reduce variations in outcomes.



Figure 5: Geographical boundaries of CLAHRC programmes in England

2.3.2 Quality improvement methods

A range of QI methods are promoted by different organisations and programmes, aimed at engaging staff and stakeholders in using practical tools which may support the development of a complex intervention and/or its implementation.

Often the participatory methods or tools are intended to be facilitated by QI practitioners, with this becoming an important, if not essential role for QI practitioners. QI practitioners come from a range of backgrounds including healthcare professionals or managers from the organisations/services undertaking the QI project or external facilitators, as used by CLAHRC Northwest London. A common approach to QI, is based on the 'Model for improvement', composed of three simple questions (*Figure 6*) (46). The Model for Improvement is linked to the Plan-Do-Study-Act cycle. This basic mechanism is suggested as the driving force for translating ideas and intentions into action in QI (47).

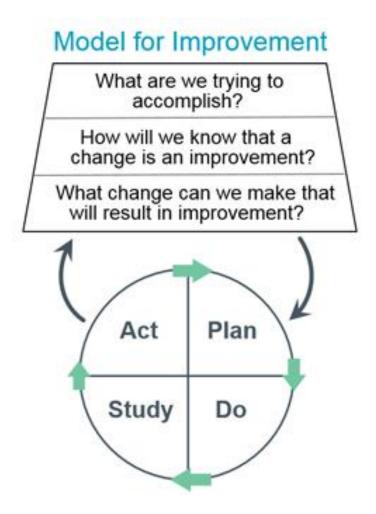


Figure 6: The model for improvement (46)

The model provides a way to approach complex problems and is the starting point from which range of other QI methods are derived based on this approach to QI. CLAHRC Northwest London uses eight explicit QI methods as part of its systematic approach to QI, summarised in *Table 1*.

Table 1: Quality improvement methods included in the NIHR CLAHRC Northwest London's systematic approach, with key references (adapted from (48))

QI Methods	Purpose of using the method	
Action Effect Method (31)	To clarify and agree the aim and scope of the work and identify the ideas for action (intervention) in the context of their anticipated effects, articulated through the production of an Action Effect Diagram (AED).	
Dissemination of learning (49)	To share and disseminate the experience and learning generated in the project internally and externally including through peer-reviewed journals	
Long Term Success Tool (30)	To identify and collectively address the factors that may affect long-term success.	
Measurement for improvement (50)	To determine operational definitions of process and outcome measures to ensure that these are consistently used and understood within the project, with routine weekly use of the data to inform implementation.	
Model for Improvement including PDSA (46)	To establish and agree what is to be accomplished, how to demonstrate that the change is an improvement and to generate ideas for what those changes might be.	
Patient and public involvement (51)	To engage with patients and the public to ensure the voice of the customer is clear in the work.	
Process mapping (52,53)	To reveal the current working practices of all those involved in the multi-disciplinary care of patients through the production of a process map.	
Stakeholder engagement (54)	To identify and engage effectively with all key stakeholders and groups.	

2.3.3 Outline of a typical CLAHRC QI project

This section outlines the stages of a QI project as delivered by CLAHRC NWL, highlighting where specific QI methods might be used (*Figure 7*). This model presented is based on a paper published on the case study presented in this thesis, SHINE 1 (17), with generalisation.

Understanding the problem	 Draw on existing data and research to understand the problem
Reviewing existing evidence	 Conduct review and synthesis of current policies, guidelines and evidence
Establishing a team	 Identify and engage potential stakeholders to build a multi- disciplinary team
Developing a shared aim	 Use Action Effect Method to draw on experience & evidence to generate programme theory
Exploring systems & processes	 Use process mapping to identify current systems and processes and opportunities for improvement
Engaging Stakeholders	 Identify stakeholders and develop strategy to influence and engage
Developing interventions	 Co-design interventions with stakeholders that will be involved in delivering/receiving interventions
Undertaking tests of change	 Use PDSA to iteratively develop interventions and identify successful strategies for implementation
Assessing improvements	 Use improvement measures to monitor implementation and feedback to staff
Reflecting and learning	 Use structured team meetings and learning events to share learning with the team
Communicating success	 Share learning through dissemination of findings
Sustainability and scaling up	 Identify key factors to sustain interventions and opportunities for scale-up and spread

Figure 7: Outline of a typical QI project in CLAHRC NWL based on SHINE 1 (17)

2.3.4 Quality Improvement Frameworks

One of the best recognised QI frameworks is that of Batalden (1993): the framework for the continual improvement of health care (*Figure 8*) (55). This framework draws on Deming's System of Profound Knowledge, which combines improvement knowledge with professional knowledge (subject matter expertise) to propose a descriptive model to achieve continual improvement in healthcare (45).

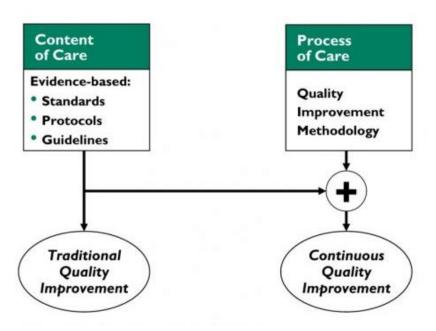


Figure 8: The components of professional knowledge and improvement knowledge, showing the linkage required to permit continual improvement (55)

More recently attempts to develop a empirically derived framework to support improvement activities are described, notably the Successful Healthcare Improvements for Translation of Evidence in complex social systems (SHIFT-Evidence), which is grounded in observations of QI projects (56). The SHIFT-Evidence framework is presented through 12 simple rules for navigating improvement in complex systems in *Table 2*. Whilst much effort has been expended in developing methods and tools for improvement and their use in practice, significant gaps exist in research on QI. The first relates to the interaction between the clinical interventions that QI projects often introduce and the specific clinical and organisational context. The role of context in mediating the effects of QI is well documented, but not well understood, and even less well characterised in a way that helps both researchers and practitioners (57).

Table 2: Principles and rules in the Successful Health Improvements From Translating Evidence (SHIFT) Evidence Framework (56)

Principle	Simple rules for complex systems
Act scientifically & pragmatically: Knowledge of existing evidence needs to be combined with knowledge of the unique initial conditions of a system. Interventions need to adapt as the complex system responds and learning emerges about unpredictable effects.	 Understand problems and opportunities Identify, test and iteratively develop potential solutions; Assess whether improvement is achieved, capture and share learning; Invest in continual improvement
Embrace complexity: Evidence-based interventions only work if related practices and processes of care within the complex system are functional. Evidence-translation efforts need to identify and address existing problems with usual care, recognising this typically includes a range of interdependent parts of the system. This emphasises the need to investigate and understand the uniqueness of each local system and respond to complexity from the micro- to macro-system	 Understand processes and practices of care; Understand the types and sources of variation; Identify systemic issues; Seek political, strategic and financial alignment
Engage and empower: Evidence translation and system navigation requires commitment and insights from staff and patients with experience of the local system. Changes need to align with their motivations and concerns. The principle reflects factors that influence engagement at an individual and team level through to supporting infrastructure and organisational level	 Actively engage those responsible for and affected by change; Facilitate dialogue; Foster a culture of willingness to learn and freedom to act; Provide headroom, resources, training and support

Exploring the role of context may offer inroads to a better understanding how QI projects can be more effective and, more importantly, how they may be scaled-up and spread. The development of the model for understanding success in quality (MUSIQ) and MUSIQ2 (**Figure 9**) frameworks propose distinctive types of context (58,59):

- Type 1 refers to the context of the setting(s) of care;
- Type 2 describes the project-specific supporting context;
- Type 3 describes the context for supporting QI in general.

All these types of context are relevant to QI and understanding the success or failure of QI projects. Whilst much effort has been made to understand the complexity of interventions and their need to be adapted to fit different settings, less effort has been made to understand the role of context. For example, frameworks such as the Consolidated Framework for Implementation Research (CFIR), acknowledges the role of the core and periphery of interventions in mediating implementation, less attention has been given to understanding the complexity of context, especially in terms of the role of context in mediating change in complex systems (60). The layers of context characterised by the MUSIQ2 framework offer an outline of the complexity of the setting in which complex interventions are to be implemented (Type 1), the complexity of QI project context (Type 2) and the wider complexity of QI support (Type 3).

QI is one approach to understanding (and undertaking) the 'knowledge to practice' process, the next section will introduce Knowledge Mobilisation as an alternative field (§2.4).

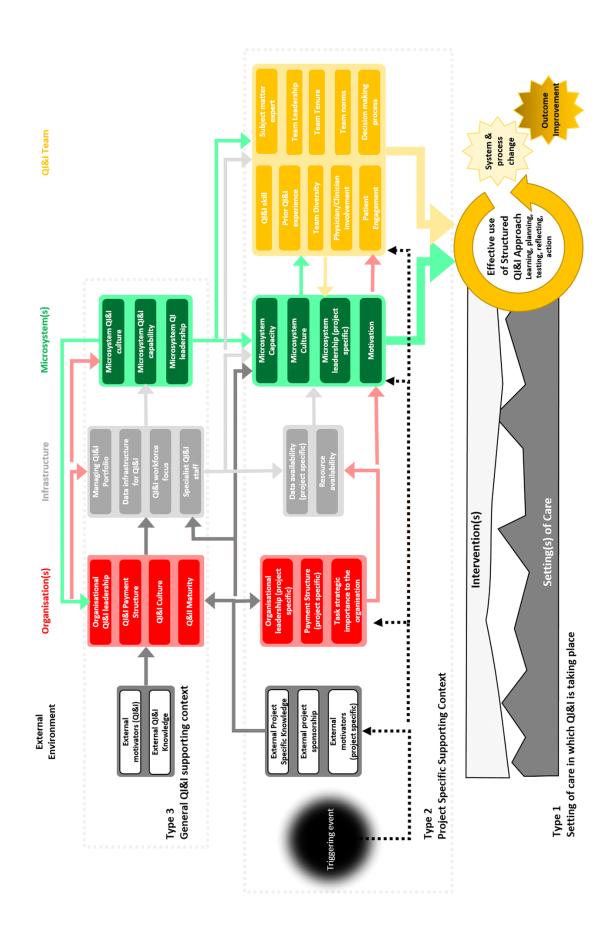


Figure 9: Model for understanding success in quality v2.0 (MUSIQ2) (59)

2.4 Knowledge mobilisation

This section offers an overview of Knowledge Mobilisation (KMb) with the specific objective of providing an understanding of the underpinning rationale for KMb and introduction to a KMb framework used for the analysis presented in a later chapter (§5.0). Whilst QI in healthcare is almost exclusively seen within the context of clinical research and the delivery of care, (KMb) is often understood in a much broader context to include the uptake of management and organisational knowledge (61). Like, QI, there has recently been recognition of the importance of seeing KMb from a complex systems perspective, which had already eschewed the linear, rational model of 'knowledge to practice', recognising the role of KMb in navigating the complexities of social and relational processes (62).

2.4.1 Knowledge Mobilisation Frameworks

Whilst there are several KMb frameworks, one of the most highly cited is the Knowledge to Action (K2A) cycle (**Figure 10**), which links knowledge creation to knowledge application (63). The framework was based on a review of 31 existing KMb frameworks. It separates out the knowledge creation and application (action cycle) phases and recognises their interaction. Whilst the transfer between the knowledge creation and the application phases represents an 'implementation gap', where knowledge often fails to result in action, less is understood about the process co-creation of knowledge at these interaction points.

The framework moves through several stages that highlight the work necessary to proceed through the cycle, illustrating the directional relationships between each stage and the need to review and re-work stages. The model emphasises the need to consider the process of implementation, which may use relevant process theories to guide the planning, organisation and influence of activities to support implementation (64). The interaction between the knowledge creation and application phases may be interpreted as an opportunity to co-create knowledge, rather than representative of knowledge translation (§2.6). Whilst the literature includes examples of the practical use of the K2A cycle, there are uncertainties about its role as an explanatory framework (65).

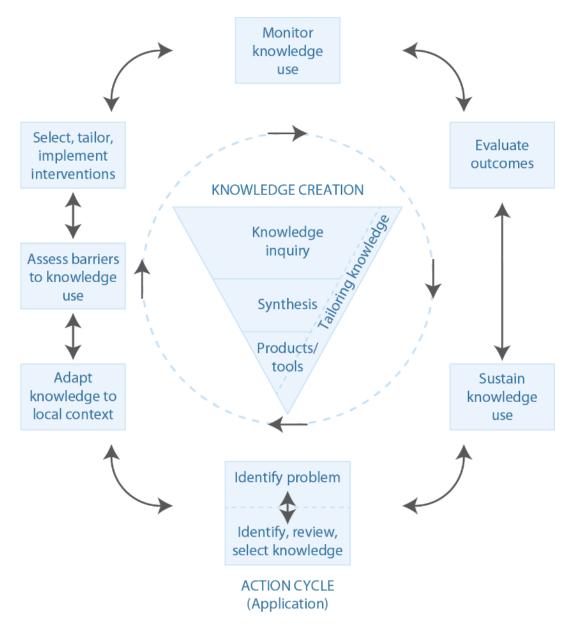


Figure 10: Knowledge to action (K2A) cycle offers a conceptual framework that describes knowledge creation and application phases and recognises the interaction between these processes (63)

Both QI and KMb are approaches to understanding (and undertaking) the 'knowledge to practice' process, the next section will discuss implementation science as an alternative field (§2.5).

2.5 Implementation Science

This section offers an overview of IS thereby providing an understanding of the underpinning rationale for IS and the introduction of a theoretical framework used for analysis, presented in a later chapter (§6.0). IS has been defined by Eccles et al. (2009) as: "...the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice, and hence to improve the quality (effectiveness, reliability, safety, appropriateness, equity, efficiency) of health care. It includes the study of influences on healthcare professional and organisational behaviour" (66). This may seem similar to the definition of QI offered by Batalden and Davidoff (2007) (29), however, IS focuses on studying and developing methods that promote the uptake of research, first and foremost, the corollary of which is that any improvement gains are secondary to the research process. Here the intervention is fixed, or subject to tight control. Researchers retain control of the process; through the protocols they design and the research tools they introduce. Whilst interventions maybe delivered by healthcare professionals, this is often under the direct or indirect control of researchers.

This contrasts with QI, which focuses on practice, rather than research, with a primary goal to improve care driven by healthcare professionals and managers, rather than researchers. So, whilst these terms are often used interchangeably there is a legitimate argument for separating how these terms are defined, based on the difference in their approach and intention. In summary, a fundamental difference between QI and IS in that IS assumes that its knowledge is generalisable whereas QI tends to assume that its knowledge is mostly or entirely contextually specific.

2.5.1 Implementation Science Frameworks

There are a growing number of IS frameworks (67). Normalization Process Theory (NPT) is a well-established theoretical framework that defines implementation as: "a deliberately initiated attempt to introduce new, or modify existing, patterns of collective action in health care"(68). NPT proposes that interventions should have a number of characteristics: "institutionally sanctioned; formally or informally defined; consciously planned; and intended to lead to a changed outcome" (68).

Unlike the K2A cycle, NPT offers an explanatory perspective of the implementation of interventions and can offer an understanding of social processes associated with implementation. NPT comprises four main constructs that represent aspects of the process of the implementation of interventions (*Figure 11*):

- Coherence is represented by work that defines and organizes the components of a complex intervention;
- Cognitive Participation is represented by work that defines and organizes the people implicated in a complex intervention;
- Collective Action is represented by work that defines and organizes the enacting of a complex intervention;
- Reflexive Monitoring is represented by work that defines and organizes assessment of the outcomes of a complex intervention;

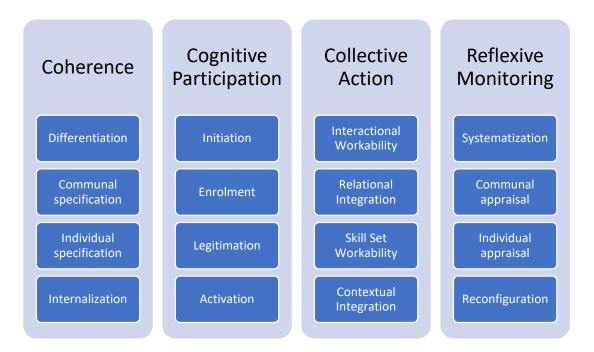


Figure 11: Four main constructs of Normalization Process Theory (NPT) (68)

The previous sections introduced QI, KMb and IS. In the next section, how knowledge is defined and conceptualised across the fields of public health and health services research is explored. Specifically highlighting the different ways in which 'knowledge to practice' may be represented (§2.6).

2.6 How knowledge is conceptualised

The understanding and meaning of 'knowledge' and how it is used continues to be contested. Whilst there are no universally agreed typologies of knowledge, a common classification divides knowledge into either tacit, derived from experience, or explicit, which is codified (69). Von Hippel (1994) argues that: "being socially situated, tacit knowledge is 'sticky' and difficult to transfer across contexts", suggesting that the social process of codifying knowledge is a pre-requisite to sharing that knowledge (70). Alternatively, Ward (2017), reminds us that Aristotle's original classification distinguishes between episteme (scientific or factual knowledge), techne (practical or experiential knowledge) and phronesis (judgement or values and beliefs) (71).

Renedo et al. (2018) highlight the tensions between knowledge from research evidence, derived from biomedical studies, and knowledge from experience, but suggests that: "understanding knowledge as relational and hybrid helps us move beyond assumptions about a dichotomy between 'objective science' and 'subjective experience'" (72). The authors conclude: "creating enabling environments is important if we are to allow new forms of knowledge – and improvements in patient care that might result – to emerge from the burgeoning patient participation initiatives within healthcare services". These tensions are seen between different healthcare professionals, as many professionalised fields, as highlighted by Nicolini et al. (2008), acknowledge the: "fragmented and distributed nature of medical knowledge" within healthcare. This fragmentation is somewhat resolved through collaborations across professional and organisational boundaries, reflecting the delivery of healthcare as a collaborative process that draws on both explicit and tacit knowledge (73).

Davies et al. (2008) contests a single definition of 'evidence' and propose that evidence or knowledge can be generated from a range of actors within a system and take many forms, where diversity of knowledge can support understanding (74). Furthermore, knowledge can be seen in a more subtle way, not just used instrumentally to create interventions that are implemented, as maybe the focus of IS, and in ways that influence beliefs and attitudes and thus the nature of the decisions that are made (74). This latter approach is much more aligned with the conceptualisation of knowledge within this research.

Different models have been proposed to help researchers and practitioners conceptualise alternative relationships between knowledge and practice. Van de Ven & Johnson (2006) propose three ways to frame the gap between knowledge and practice (*Figure 12*) underpinned by different understandings of knowledge (75). The first model (A) presents knowledge for practice as derived from research knowledge and thus the gap between knowledge and practice is understood as a 'knowledge translation/transfer' problem. The second model (B) views knowledge from practice and research as epistemologically distinct and used for answering different, but complementary, questions. The third model (C) views knowledge as co-produced, or co-created, through collaborations between researchers and practitioners to solve problems and thus identifies the gap as a 'knowledge production' problem, representing the idea of engaged scholarship.

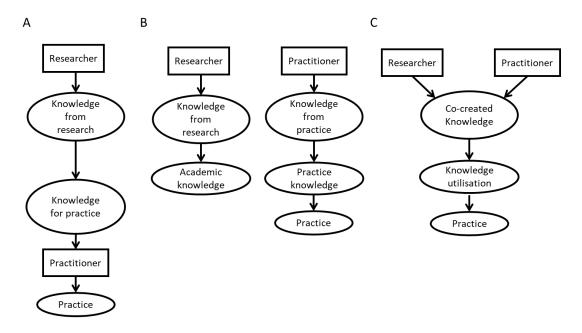


Figure 12: Three alternative ways to frame the gap between research knowledge and practice: A - Knowledge transfer problem; B - Problem of distinct epistemologies; C - knowledge production problem (56).

Whilst these models address an epistemological question about the nature of the relationship between knowledge and practice, they do not address the mechanisms of action between knowledge and practice. The acquisition of knowledge is insufficient to change behaviour, or practice, simply offering people information is ineffectual and requires activities that can somehow bring about changes in behaviour or practices (76).

The value placed on QI by policy makers, clinicians and QI practitioners, has been its focus on the enactment of change through QI projects that should, one hopes, result in improvement(s) in some or all the measures used to assess uptake and implementation. The knowledge created by the QI team is often seen exclusively as quantitative data used to assess the: "effect of changes by using study methods that preserve time as a variable" which is subsequently reported (#3 in Figure 4). However, as Batalden and Davidoff (2007) have identified, other types of knowledge are created by a QI project, namely knowledge about the particular "physical, social and cultural identity of local care settings (e.g. their processes, habits and traditions)" (#2 in Figure 4) and knowledge that "provides insight into the strategic, operational and human resource realities of particular settings (drivers) that will make changes happen due to the execution of planned changes" (#5 in Figure 4) (29), both of which are of specific interest to this research.

As Greenhalgh and Wieringa (2011) discuss, there has been support from some academics for the 'social practice view of knowledge' in recognition of the challenges of getting different types of knowledge into practice that have been: "generated by the diverse communities of practice which exist within and across organizations" (77). Based on their research in management and organisation studies, Brown and Duguid (2001) propose that the use and creation of knowledge cannot be isolated from the socio-cultural context in which it occurs, where individual and social identities are intricately linked (78). Drawing on Bruner (1996), Brown and Duguid (2001) highlight: "people do not simply learn about; they also learn to be. Learning... doesn't just involve the acquisition of facts about the world, it also involves acquiring the ability to act in the world in socially recognized ways" (79). The connection between social practices and the 'situatedness' of knowledge is explored by Smith (1990), as discussed by Stoetzler and Yuval-Davis (2002), who proposes that 'situated' knowledge can be generated from shared experiences (80,81).

So far, this chapter presents a summary of the different conceptualisations of the 'knowledge to practice' process and various ways in which knowledge might be defined. However, 'knowledge to practice' does not occur in isolation and is situated within the complex social system that constitute the health system. The associated socially mediated practices are explored in the next section (§2.7).

2.7 'Knowledge to practice' in complex systems through a social practice lens

2.7.1 Complex systems

Gilson (2012) proposes the system in which the 'knowledge to practice' process is conducted can be understood as composed of three levels and the relationships between actors and processes at all levels should be considered (82). Actors within the system operate at all levels, the macro (policy), meso (organisational) and micro (clinical), and in doing so create complex social systems, where relationships and culture form an extremely important part of the system (**Figure 13**). This is distinguished from the three types of context presented earlier (§2.2), which included the context of the setting of care (Type 1), the project-specific supporting context (Type 2) and the context for supporting QI in general (Type 3). These are mostly understood at the micro and meso-levels of the system, although are undoubtedly influenced by the macro-level.

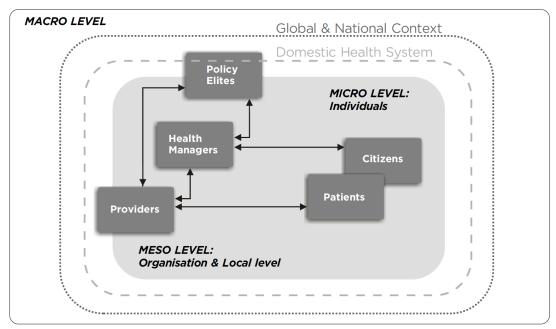


Figure 13: The different levels of health systems (82)

Deming described a system as: "a network of interdependent components that work together to try to accomplish the aim of the system" (45). However, a complex system is much more than this and associated with three key features: agency, interconnectedness and dynamism. Agency relates to the autonomy of the actors within a system who are responsible for modifying and changing their actions.

Interconnectedness highlights the role of behaviours, actions and processes within a system that influence and constrain other parts of the system. Dynamism alludes to the continually evolving nature of systems and the fact that future actions may be determined by historical actions. These features often work in concert to inhibit or amplify deliberate attempts to change one part of the system, often producing unexpected and unintended consequences in other parts (83).

The key challenge is to understand and characterise a system and its aims as a precursor to attempting to change it. This has been further elaborated within the context of KMb by Best and Holmes (2010) who identified a number of key components integral to the KMb process using a systems model (**Figure 14**): evidence and knowledge; networks; leadership; and communication (62).

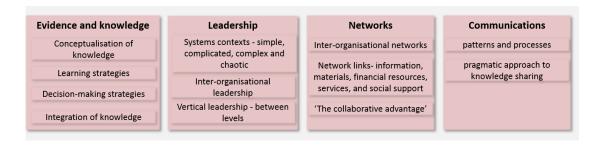


Figure 14: Key concepts of a systems model for 'knowledge to practice' (62)

The evidence and knowledge component builds directly on the K2A cycle (63). The framework emphasises that the successful uptake of knowledge is actively facilitated through the development of networks and 'communities of practice', especially those that foster relationships between researchers and decision-makers/practitioners (62). This type of relational model recognises the dynamic relationships between actors that shape the processes linked to knowledge use. However, Best and Holmes (2010) assert that to enact change this relational model needs to be extended to a systems model that places the interactions and relationships of the actors within the context of the wider system (62). The need for such an approach towards KMb in complex systems was been confirmed by Holmes et al. (2016) (21).

2.7.2 Social Practices

Social practices occur across society, becoming embedded into daily life and routines, examples include eating dinner, commuting, watching TV or smoking (84). Whilst these activities may be related to behaviours, it is not the behavioural aspects that are important rather it is how these practices become routinized and performed.

Reckwitz (2002) defines a social practice as: "... a routinized type of behaviour which consists of several elements, interconnected to one other: forms of bodily activities, forms of mental activities, 'things' and their use, a background knowledge in the form of understanding, know-how, states of emotion and motivational knowledge. A practice — a way of cooking, of consuming, of working, of investigating, of taking care of oneself or of others, etc. forms so to speak, a 'block' whose existence necessarily depends on the existence and specific interconnectedness of these elements, and which cannot be reduced to any one of these single elements." (85)

This highlights components that need to be integrated to construct social practices, elaborated further by Shove et al. (2012) (86):

- materials (objects, consumer goods and infrastructures);
- competence (including understandings of the situation; practical know-how);
- meanings (including embodied understandings of the social significance of the practice and past experiences of participation)

Reckwitz (2002), emphasised the embodiment of practices and how they are performed, such as hands (for holding instruments or writing) and mouths (for speaking). Embodiment is seen as central in performance of the task and engaging others, as a fundamental aspect of the 'social' in social practice.

Although physical in their manifestation, they are simultaneously cognitive activities, such as the ability to regulate one's emotions, and linked with a certain knowledge, especially related to predicting how others may act. Reckwitz (2002) uses the example of playing football, where the mental and physical activities are aligned to create the practice of 'playing football'. The activity consists of a set of bodily performances that become routinized and are connected to the intellectual capacity to interpret particular actions, such as the behaviour of other players, with the intention of winning the game (85).

Reconceptualising activities as practices rather than behaviours offers an opportunity for understanding the interdependent and unpredictable properties of these activities. This argument has been made in re-orientating our understanding of health behaviours to one of health practices, with the potential of challenging current efforts to modify risk factors through interventions at the practice level rather than behaviour change (87). This concept is less well described in relation to actors involved in OI.

The performance of activities is the basic unit of a practice. Activities need to be performed and re-performed to ensure continuation of social practices, which in turn, support social processes and can be studied through practice theory and communities of practice.

2.7.3 Practice Theories

The development of practice theories can be plotted, to some extent, through the various theoretical propositions of the works of Bourdieu and the empirical work of Latour, to name but a few, however, later Schatzki proposed the concept of practices and their study, as outlined by Nicolini (88). Practice theory offers a range of ways of understanding social practices as a starting point of understanding complex social systems. In healthcare, practice theories have been used to better understand and interpret findings from implementation studies that examine the process of implementing interventions, especially through the use of NPT as a practice theory (89). However, this has been less fully applied in the study of improvement practices. Nicolini (2012) offers insight into the growing interest in the use of practice theories to understand social and organisational phenomena: "the appeal of what has been variably described as practice idiom, practice standpoint, practice lens, and a practice-based approach lies in its capacity to describe important features of the world we inhabit as something that is routinely made and re-made in practice using tools, discourse and our bodies. From this perspective, the social world appears as a vast array or assemblage of performances made durable by being inscribed in human bodies and minds objects and texts, and knotted together in such a way that the results of one performance become the resource for another" (88).

2.7.4 Communities of practice

The original development of community of practice (COP) theory was in the field of education by Wenger (1998) (90). Since then COP has been applied to understanding the role of 'communities' in both the production and transfer of knowledge in healthcare (91). Central to COP theory is the idea is that learning is a social process and requires interactions and relationships between learners to enhance and facilitate the learning experience. A COP was defined as a: "groups of people who share a concern, a set of problems, or a passion about a topic, and who deepen their knowledge and expertise by interacting on an ongoing basis" (90). Wenger (1998) proposed four components of framework for a social theory of learning (90):

- Meaning our ability to experience the world as meaningful;
- Practice shared historical and social resources, frameworks and perspectives that sustain mutual engagement in action;
- Community the social configurations in which our enterprise is defined and our participation is recognisable as competence;
- Identity how learning changes who we are.

The QI literature has many examples of how COP has aided the understanding and application of implementation (92,93). Although, Ranmuthugala et al. (2011) noted in their systematic review a shift away from COPs focusing on the learning and exchanging information and knowledge towards a COP seen specifically as: "a tool to improve clinical practice and to facilitate the implementation of evidence-based practice" (94).

QI projects offer opportunities to begin to unpack the social processes of improvement and interpret them through a practice theory/community of practice lens, as explored in the final section (§2.8).

2.8 Developing a conceptual model for exploring improvement as a social practice through a practice theory lens

Greenhalgh and Swinglehurst (2011) describe studying the use of technology through a social practice lens as akin to studying drumming, where previously the focus has been on the drum or drummer, the focus is now on the interaction between the drum and the drummer (95). This metaphor illustrates that whilst studies that focus on individuals (drummers) or technologies/objects (drums) are helpful, a focus on their interaction (the practice of drumming) opens up a more expansive field for exploration. Similarly, whilst some studies examine the structures of QI (and their resultant outcome), or the QI methods themselves, it is the study of how individuals use the QI methods to achieve a successful QI project that offers new perspectives.

This research aims to build the analysis in a stepwise fashion using all three 'knowledge to practice' approaches. This multi-perspective analysis will be used to draw on the strengths of each approach to 'fill in the gaps' of the preceding analysis (**Figure 15**). The multiple re-conceptualisations of the case study and subsequent analysis will draw on all three approaches, rather than rely on a single dominant approach of QI, KMb or IS. This also offers an opportunity to explore the intersections between the approaches, as it is often within these 'fuzzy' boundaries that interesting and surprising results can be found.

The QI approach relies on the different QI methods to structure and deliver an organisational QI project. This has been described by Reed et al (2018) as a process for enabling improvements in complex social systems, such as healthcare (56). However, whilst exploring the case study through a QI approach may highlight how QI methods are used to navigate this complexity, this is insufficient to extend our understanding of the actions of the actors involved. This is offered by the use of a KMb framework, such as the Knowledge to Action cycle (63). The structure of this framework allows the role of actors at each stage of the process to be explored. Holmes et al (2017) also linked the KMb approach to the process of the co-creation of knowledge (21). Whilst KMb focusses on the empirical actions of actors, it is through the use of practice theory that a theoretical lens can be applied to unpack the practices and processes of improvement. NPT, an IS framework, is one such practice theory that can be used to re-conceptualise the case study to understand improvement as a social practice, as opposed to a solely technical process (68).

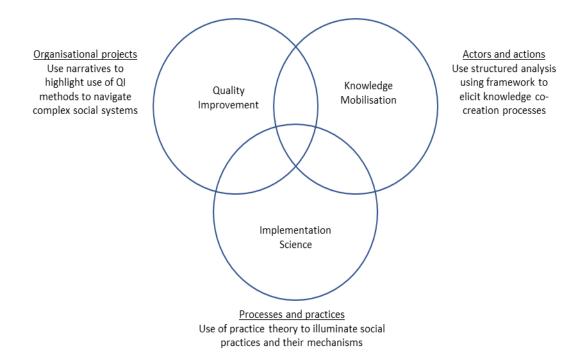


Figure 15: This conceptual model outlines the inter-relationship between the three different 'knowledge to practice' approaches: quality improvement, knowledge mobilisation and implementation science. This recognises that whilst the approaches differ there are also similarities and overlaps between each other.

Fundamentally, a major challenge in understanding improvement as a social practice is the intricate inter-relationship between the QI practices and the clinical practices that QI aims to influence. Whether it is helpful to disentangle and separate out these practices or understand them as irrevocably entwined to contextualise the sensemaking and motivation for change of those carrying out the practices? This challenge reflects a reductionist versus holistic argument which this thesis seeks to address. As highlighted by Allwood et al. (2018), developing both technical and relational QI skills is key to improving the future delivery of healthcare (96). Gabbay et al. (2017) extend the relational role required for successful improvement to include: "complex organisational and personal skills, as well as the ability to learn collectively" (97). How these manifest to support QI practices how these practices link to the process of the co-creation of knowledge, a central theme of a systems model for KMb and QI, is little explored (29,62).

2.9 Summary

This chapter introduced the concept of the 'second translational gap' as a "disconnect between the development and the implementation of new interventions in clinical practice" (§2.2). This established the problem within health systems of how we can effectively introduce research evidence in the organisation and delivery of care. Several fields have been established to support this 'knowledge to practice' process, extending the EBM movement, which has mainly focused on generating evidence of the most efficacious treatments or 'doing the right things'. These emerging fields, especially QI, have been described as 'doing things right'. Together these concepts link the development of evidence-based interventions and recommendations for care to approaches that aim to support their implementation in practice which has the potential to transform care.

QI has long been an established method for improving healthcare processes and outcomes (§2.3). Despite its popularity, the approach remains mostly atheoretical, although there has been increasing research interest in QI methods, with some even proposing a new field of research: 'Improvement Science'. Whilst QI is replete with empirical examples of the use of these methods, the lack of theoretical underpinning is of particular interest in this thesis. Drawing on the more theoretically informed fields of KMb and IS, the research shines a light on the QI processes and establishes a better understanding of QI as a social practice, drawing on existing frameworks from the KMb and IS fields.

QI has been defined as a process of improving three interlinked elements: professional development, system performance and patient/population outcomes. This simple definition belies the complexity of health care systems and the challenges faced in improving any one of these elements. QI methods provide a set of tools and principles by which this can be tackled. The focus of QI is to support the implementation of generalisable knowledge within a specific context to achieve improvements in 'performance'. However, Batalden's model of continuous quality improvement acknowledges both the use of tacit knowledge in supporting the 'knowledge to practice' process and the creation of situated knowledge that provides insight into the process.

Whilst methods and tools vary across QI programmes and organisations the case study presented is situated within a particular QI context with a standardised set of methods that have been applied to more than 70 QI projects over the last decade.

The programme is underpinned by SHIFT-Evidence, a framework developed from the empirical study of the QI projects. The framework offers 12 'simple rules' for guiding improvement within complex systems. Complementary to this, the MUSIQ framework offers insight into the contextual factors that play an important role in mediating improvement at different levels of the health system. Together these frameworks play a role in both understanding how the case study was delivered and as an analytical tool for identifying the supporting contextual factors and processes that facilitated the delivery of the project.

KMb is presented as an alternative approach to the 'knowledge to practice' process with a greater emphasis on the use of non-clinical research evidence in supporting the organisation and delivery of care (§2.4). KMb begins to offer a more explicit social perspective on the process, often under-emphasised in QI methods. KMb frameworks can guide the 'knowledge to practice' process, for example, the K2A cycle separates out different knowledge creation and knowledge application stages.

IS offers a final approach and is based on the study of the methods that support the 'knowledge to practice' process. However, it is sometimes seen as a practice in itself (§2.5). NPT, a well-established explanatory IS framework, provides a practice theory that begins to unpack the processes and practices of interaction between the intervention and the context mediated through implementation. Whilst NPT identifies many of the factors that are important for implementation (and improvement), these are not operationalised in a way that directly lends itself to changing practice, unlike the QI methods which are specifically developed as participatory tools.

Appreciating the strengths and weakness of the individual approaches outlined highlights the potential advantages of is drawing on all three, rather than relying on a single approach. Whilst this thesis does not intend to present a unified approach to the 'knowledge to practice' process, it does present the use of frameworks across these different approaches and highlighting some of their gaps or limitations.

Through the use of multiple approaches, it is also possible to highlight where these approaches might be complementary and how these gaps might be filled to generate new insights.

The concept of 'knowledge' and how knowledge is generated is contested with a range of different models and definitions, which offer different interpretations of the 'knowledge to practice' process (§2.6). Whilst it is possible to envisage the 'knowledge to practice' process as a knowledge transfer problem, in this thesis it is proposed as a knowledge production problem. This explicitly values the knowledge co-created between researchers and practitioners that may be both generated and utilised during the 'knowledge to practice' process. This highlights the importance of socially situated knowledge that is by its nature context-specific and linked to the identities of the individuals involved and their experiences.

This research also recognises that the 'knowledge to practice' process in healthcare takes place in a complex social system (§2.7). This is comprised of complexity of the interventions, the context and the process itself. An appreciation of the characteristics of complex systems, especially agency, interconnectedness and dynamism, is necessary to understand the impact these have in both supporting the change needed for improvement and the system's resistance to change. Characterising systems and understanding them, remains a challenge but a necessary step in effectively changing the system. Systems models help identify areas for appreciation, such as the nature of evidence and knowledge, and the roles of leadership, networks and communications. These factors are also represented within existing theoretical conceptualisations that are helpful for both understanding and exploring the 'knowledge to practice' process. One such helpful concept is that of 'social practices', which is associated with practice theories and communities of practice. Social practices are routinised activities that are composed of three fundamental elements: materials, competence and meanings. It is the performance and re-performance of these activities that form the basic unit of a practice, which in turn supports social processes. Practice theories offer a way of understanding social practices in complex social systems. One such example of a practice theory is NPT, which has been typically applied to IS activities, but less so in the context of improvement. Similarly, the concept of communities of practice has been applied to both the production and transfer of knowledge in healthcare.

This places an emphasis on the relational and interactional activities of learning as a social process and is composed of four elements: meaning, practice, community and identity. Unlike practice theory, COP has been used in the QI field as well as IS.

QI projects offer opportunities to begin to unpack the social processes of improvement and interpret them through a practice theory lens (§2.8). Using different 'units' or focus of analysis offers an increasingly refined understanding and conceptualisation of the 'knowledge to practice' process allowing one to zoom in (and out) to connect a set of methods and tools within an organisation (QI) to the resultant actions of actors (KMb) and underlying practices and processes (IS). Furthermore, using the multiple conceptualisations enables exploration of the intersections and boundaries between these different approaches.

3.0 Methods

3.1 Overview

The conceptual model (**Figure** 15) is comprised of several elements including the different 'knowledge to practice' approaches: Quality Improvement (QI), Knowledge Mobilisation (KMb) and Implementation Science (IS) and the three phenomena: complexity, the co-creation of knowledge and social practice. This chapter intends to highlights the connection between the elements and the three separate research questions and three different focus of analysis and the related analytical frameworks, which together comprise the study design (§3.2). A brief outline of the epistemology underpinning the research and outline of the assumptions are offered (§3.3). Ethical considerations (§3.4) and data management processes (§3.5) are described. An overview of the methods used for data collection (§3.6) and the analytical approaches taken (§3.7) are provided. The penultimate section justifies the need for reflexivity within this research and the importance of recognising how the researcher interacts with the participants and influences the subsequent data collection (§3.8). The final section offers a summary of the research methods employed in this study (§3.9).

3.2 Study design

This study explores the social processes of the development and delivery of a QI project to implement evidence-based practices, drawing on constructs and concepts from the fields of QI, KMb and IS. It aims to address three research questions:

- What role do QI methods have in assisting actors to navigate the complexity of the health system to support the 'knowledge to practice' process?
- What knowledge is co-created within a QI project?
- How can implementation and improvement be understood as a social practice?

This study uses an ethnographically-informed qualitative participatory approach to explore the case study, grounded in a critical realist epistemology. Subsequent sections provide a justification and detail of that approach (§3.3).

The case study, as outlined (§1.3) is comprised of two linked QI projects, which can be understood as complex social interventions in their own right. This contrasts with the complex (clinical) interventions they often try to introduce into practice. Whilst much resource has been mobilised to undertake research to generate evidence of the effectiveness of clinical interventions this is not reflected in the resources used to better understand how evidence-based intervention can be delivered in practice. Or put differently, it is all about 'doing the right thing', with little attention paid to 'doing the thing right' (§2.2). Whilst there are studies of QI, these are usually confined to descriptive reports or process evaluations. This multi-layered analysis reconstructs the case study using theories, models or frameworks from the three different 'knowledge to practice' approaches, thereby offering multiple perspectives. The focus of analysis associated within each approach are: QI - organisational project, KMb – actions of actors and IS – practices and processes. These are described further in the data analysis section (§3.7) The methodology employed in this study draws on ethnographically-informed methods, which aim to offer a much more exploratory account of QI.

Dixon-Woods (2003) stated that ethnography is characterised as: "the process of querying understandings and practices that are taken for granted: it renders the everyday world problematic by making the 'ordinary' 'extraordinary'..." (98). Soukup et al. (2017) identified that ethnographic methods, can be useful in helping researchers: "understand and define complex systems and... identify the roles of participants in a system, explore factors associated with problems" (99). Moreover: "an ethnographic approach [offers] the freedom from constrictions or assumptions built into the original hypothesis, which can allow researchers to focus solely on the discovery of the nature of the phenomenon of interest" (99). Thus, ethnographic approaches are a methodology that offer a structured guide to the collection and analysis of data but allows one to explore particular phenomena.

However, the use of ethnographic methods is often associated with an 'immersive' experience, necessary to identify various perspectives of different stakeholders, which may be over a longer or shorter timeframe (100). As Jowsey (2015) argues, the term 'ethnography' can be misapplied to research that does not really engage with the principles of ethnography but simply employ observational methods (101).

Jowsey asserts Malinowski's description: "Ethnographic methods... involve a single researcher documenting people's lived worlds, their meaning-making, their productions and categorisations of knowledge and their interactions with one another". Whilst this goes beyond the use of observation as a tool for generating data it encourages the judicious use of the claim to 'an ethnography'.

So, whilst the research methodology used in this study is not an ethnography, it does have some basis in this field, using an ethnographically-informed qualitative participatory methods. Fundamental to these methods is the appreciation and awareness of how knowledge about the subject is constructed and understood as a meaningful representation of 'truth(s)'.

3.3 Epistemology

Epistemology can be divided into the positivist or constructivist camps. Positivists assert that truth and knowledge can be established through a process of deduction, reasoning and logic, and that absolute truths can be established, especially through the use of the scientific methods (102). Conversely, constructivists assert that knowledge and truth are socially constructed by individuals and communities, and that whilst the world exists independently of the observer, our understanding of it does not (102). Between these extremes lies realism, which recognises that whilst humans do construct their own understanding and interpretation of the world, these relate to a reality external to the individual, recognising that versions of 'truth' lie on a spectrum between the extremes of positivist and constructivist paradigms (103). Realism aims to reconcile our understanding of the world and the knowledge generated from our study of it, which are often interpreted between these opposing perspectives. Realism recognises the existence of multiple realities which coexist.

Critical realism is a philosophical framework offered by Bhaskar which attempts to integrate the natural sciences and social sciences and extend them with specific reference to the different domains of reality (104). This is based on the *empirical* level, in which our everyday experiences are grounded, which is connected to the *actual*, which represents the events that underpin our experiences, and the *real*, in which the generative mechanisms are causal in their power the create the events, independent of one's ability to sense or prove their presence.

Whilst this research could be seen exclusively through a constructivist paradigm, the case study engages specifically with what may be exclusively positivist studies in the form of guideline recommendations. This gives pause for thought and consideration of the role of a paradigm, like realism that allows one to integrate aspects of constructivism and positivism. Thus, this research is based on a critical realist approach and aims to understand QI through a realist paradigm. This recognises the intrinsic tensions and contradictions of a study of the implementation of knowledge that is overwhelmingly perceived as positivist, whilst exploring social practices that use an approach influenced by a constructivist philosophy of knowledge.

3.4 Ethics

The DrPH proposal was reviewed and accepted in August 2016. Approval to conduct data collection for this research was granted by the Research Ethics Committee of LSHTM in March 2017 (Ref: 11965). All participants who were observed were provided with a participant information Leaflet (PIL) (§9.1) and asked to sign an informed consent form (ICF) prior to the start of the workshop or meeting (§9.3). Likewise, key informants who were interviewed were provided with a PIL (§9.2) and ICF (§9.3) prior to the interview via email. Both were reviewed on the day of the interview and signed. The case study was well known within the Trust and many of the key informants and participants of observations were known to each other. To preserve anonymity, I have omitted further details about the roles of individuals and their identity obscured using initials, with quotes used minimally in this thesis to avoid attribution.

3.5 Data Management

Qualitative data collected observations and interviews with informants, including audio and verbatim transcripts of interviews (The Transcription Agency, UK) were stored on an allocated password-protected network drive at the LSHTM to maintain confidentiality. Interview and observational data were only handled and accessed by the researcher (SH). Key informants were anonymised during analysis and discussion with my supervisors and organisational identifiers, such as names of wards have been changed.

3.6 Data collection

Data were collected using:

- Observations of QI project management meetings and Ward Champions' workshops;
- Semi-structured interviews of key informants from the QI project team, clinical staff and organisational stakeholders;
- Identification of key documents from the projects, organisational sources and national policy documents.

3.6.1 Participant Observations

Participant observation refers to the nature of 'being there' with the participants, first-hand experience of the context rather than relying exclusively on accounts of others (105). Throughout both SHINE1 and SHINE2, I attended the monthly team meetings from October 2014 until January 2019, although the formal observations included in the analysis were restricted to the 12 months between May 2017 and April 2018. Whilst a number of observational frameworks exist, Spradley's (*Table* 3) remains the most comprehensive generally applicable framework and was used to guide data collection (106).

Table 3: Operationalisation of Spradley's observational framework (106)

Dimension	Definition	
Space	layout of the physical setting; rooms, outdoor spaces, etc.	
Actors	the names and relevant details of the people involved	
Activities	the various activities of the actors	
Objects	physical elements: furniture etc.	
Acts	specific individual actions	
Events	particular occasions, e.g. meetings	
Time	the sequence of events	
Goals	what actors are attempting to accomplish	
Feelings	emotions in particular contexts	

Observations were undertaken in nine monthly QI project team meetings (13.5 hours) and seven monthly Ward Champions' workshops (11.5 hours). A summary table of observations (*Table 4*) highlights the number of meetings and workshops that were attended during the data collection period.

Table 4: Summary of observations of QI project team meetings and Ward Champions' workshops attended

Meeting type	Date	Record of proceedings	Observations
Team meeting	07/04/17	Yes	Yes
Team meeting	12/05/17	Yes	Yes
Team meeting	21/07/17	Yes	Yes
Workshop	24/08/17	Yes	Yes
Workshop	05/10/17	Yes	Yes
Team meeting	06/10/17	No	Yes
Workshop	26/10/17	Yes	Yes
Team meeting	03/11/17	Yes	Yes
Workshop	23/11/17	Yes	Yes
Team meeting	01/12/17	Yes	Yes
Workshop	18/01/18	Yes	Yes
Workshop	22/02/18	Yes	Yes
Team meeting	16/03/18	Yes	No
Workshop	22/03/18	Yes	Yes
Team meeting	13/04/18	Yes	Yes
Team meeting	06/05/18	Yes	Yes

3.6.2 Interviews

Data were collected through 19 semi-structured interviews with key informants from QI project teams, clinical staff and organisational stakeholders (*Table 5*). Interviews were directed by a topic guide to ensure key themes were covered but flexible enough to allow views and topics of interest to come through (§9.4). The interviews were used to elaborate on some topics/issues identified through the observations as they were undertaken in parallel (107). The interviews deliberately attempted to draw on participants' individual narratives and their sense-making of the QI experience relating to the case study (108).

Table 5: Summary of key informants interviewed

Initials	Job role	Group
P1	Project Manager/Assistant Psychologist	SHINE1
P2	Psychiatric Registrar	SHINE1
P3	Pharmacist	SHINE1/2
P4	QI Manager/Staff Nurse	SHINE1/2
P5	Service User	SHINE1/2
P6	Service User	SHINE1/2
P7	Project Manager/Assistant Psychologist	SHINE2
P8	HCA/Research Assistant	SHINE2
P9	Project Manager/Assistant Psychologist	SHINE2
P10	Recovery practitioner	SHINE 2
<i>C1</i>	CT1 Doctor	MHU
C2	FY2 Doctor	MHU
<i>C</i> 3	Bed Manager	MHU
C4	Ward Champion	MHU
C5	Staff nurse	MHU
01	QI Lead	Trust
02	Occupational Therapist	Trust
03	QI programme manager	Trust
04	Physical Health Education Lead	Trust

3.6.3 Documents

The collection and analysis of documents was important for this this study, providing an invaluable resource to capture the historical development of the projects, the events surrounding the projects and as outputs from the QI workshops. Collectively, the documents provided a range of positions, from official policy (e.g. guidelines), through organisational assessments (e.g. audit reports), plus capturing the practices on the ward through process maps. Document collection was an ongoing process that collated and captured materials from the project team, some of which I co-authored. Thirty key documents were collated and analysed (**Table 6**). Links to documents, where available are provided in the Appendix (§9.5).

 Table 6: Key documents collated and analysed

Project	Date	Document name	Summary	
	14/12/11	NICE CG 136	Policy document	
SHINE1	25/10/13	Project Application	Project document	
	12/02/14	NICE CG 178	Policy document	
	01/06/14	Lester Tool 2014	Policy document	
SHINE1	01/09/14	Action Effect Diagram	QI Workshop output	
	24/09/14	NICE CG 185	Policy document	
SHINE1	01/10/14	Ward process map	QI Workshop output	
	08/10/14	National Audit of Schizophrenia	Policy document	
SHINE1	05/11/14	Stakeholder analysis	QI Workshop output	
	12/02/15	NICE QS 80	Policy document	
SHINE1	01/06/15	CLAHRC poster	Project output	
SHINE1	01/09/15	Final project review report	Project document	
SHINE1	01/02/16	Lancet Psychiatry article	Project output	
SHINE1	17/02/16	NIHR presentation	Project output	
SHINE1	01/04/16	HQIP PPI in QI Guide	Project output	
SHINE2	21/04/16	Application	Project document	
SHINE1	18/06/16	JMHTEP paper	Project output	
SHINE2	28/10/16	Action Effect Diagram	QI Workshop output	
SHINE1	26/01/17	NICE Shared learning	Project output	
SHINE2	06/02/17	AHSN presentation	Project output	
SHINE2	12/02/17	CMHT presentation	Project output	
SHINE1	19/04/17	Pharmacy presentation	Project output	
SHINE2	25/04/17	CLAHRC presentation	Project output	
	18/08/17	CQC Acute wards Report	Organisational report	
	18/08/17	CQC Quality Report	Organisational report	
SHINE1	04/10/17	Conference Poster	Project output	
SHINE2	06/11/17	AHSN presentation	Project output	
SHINE1	02/01/18	IJMHS paper	Project output	
	31/01/18	National Clinical Audit of Psychosis	Policy document	
SHINE2	25/01/18	CLAHRC presentation	Project output	

3.7 Data analysis

The data from the key informant interviews, observations and documents were organised, managed and analysed using Nvivo 12 (QSR International). The analysis integrated the different data sources to construct three separate accounts of the case study using different focus of analysis. The first account was the 'organisational project' – constructed using narrative methods to highlight the use of QI methods to navigate complex social systems (§3.6.1). The second account used a KMb framework to structure the analysis describing the actions of actors to elicit the process of the co-creation of knowledge (§3.6.2). The third account used an IS practice theory to illuminate the practices and processes of improvement, especially the social practices and their mechanisms (§3.6.3). Each analysis explicitly builds upon the previous analysis, outlined in the overview and summary of each chapter. The analysis is then extended in the discussion chapter with each separate analysis answering the research questions related to specific phenomena: complexity (§7.2), the co-creation of knowledge (§7.3), social practices (§7.4) and the emergent themes of accountability and responsibility (§7.5). The supporting data for the analyses are presented at a very high-level, necessary due to the restrictive word count and breadth of the analysis offered.

3.7.1 Constructing narratives of quality improvement

To construct a logical and detailed account of the two projects within the case study, a narrative approach was used, a common methodology in QI (§4.0). Greenhalgh et al. (2005) provide four types of narratives which are able to capture to the complexity of context and processes of implementation (108):

- Narrative interview Researcher collects the stories of service users and/or the people involved in the QI initiative
- Naturalistic story gathering Researcher becomes a field worker immersed in the organisation to collect "real" stories in informal space and interpret them in context
- Organisational case study- Researcher presents an account of the QI initiative in the form of a detailed story

 Collective sense-making - Researcher joins QI project team and works with them to develop a shared perspective on the problem and its causes, and to plan and implement action

Whilst the analysis aims to offer a clear narrative, it is also a simultaneous account of collective sense-making. The analysis presents a narrative for SHINE1 which is drawn from my personal recollection, supported by documentation from the project (*Table 6*) and informal conversations with the QI project team members as well as a published account of the work (17). This project was undertaken prior to the formal data collection process for the thesis research, which only includes data from SHINE2 which more formally draws on observations, interviews, and documents., made possible through my role as an embedded researcher. The narrative focuses on the biographical (who?), historical (what led to this?) and the situational (context) aspects of the case study.

3.7.2 Identifying key aspects of knowledge mobilisation practice

The knowledge to action (K2A) cycle (*Figure 10*) was developed to provide a conceptual understanding of the process of KMb and consists of two interlinked phases of knowledge creation and application, with eight stages (63):

- Identify problem
- Identify, review, select knowledge
- Adapt knowledge to local context
- Assess barriers to knowledge use
- Select tailor and implement intervention
- Monitor knowledge use
- Evaluate outcomes
- Sustain knowledge use

The K2A cycle aims to extend understanding of the QI projects beyond the 'simple' descriptive narrative and begins to categorise actions according to the stages of the framework (§5.0). The K2A cycle was developed into an analytical framework and a deductive analysis undertaken through its systematic application to the data. The resultant nodes of coded data were used to construct a narrative around the KMb processes related to the case study.

3.7.3 Using practice theory to characterise improvement practice

The third analysis was based on an explicit re-construction of the case study using Normalization Process Theory (NPT) to generate an explanatory understanding of practices and processes from the case study (*Figure 11*). Data were coded using the main concepts of NPT: Coherence, Cognitive Participation, Collective Action and Reflexive Monitoring. The resultant nodes of coded data were used to develop a *post hoc* theorising of the case study focusing on the relational and interactional aspects of social practices (§6.0).

3.7.4 Links between the research questions, analytical approaches and organisation of the thesis

This thesis presents three separate re-constructions of the case study according to each 'knowledge to practice' approach (*Table 7*). These are followed by the discussion chapter which addresses each of the research questions and draws together accumulated insights from the three analyses, including the emergent theme of accountability and responsibility.

Chapter 4 (§4.0) presents a narrative re-construction of the case study focused on the use of QI methods in organisational QI project. The discussion chapter explores the complexity of the health system and answers the first research question: What role do QI methods have in assisting actors to navigate the complexity of the health system to support the 'knowledge to practice' process? (§7.2).

Chapter 5 (§5.0) presents a re-construction of the case study using a KMb framework and presents an analysis focusing on the actions of actors. The discussion chapter explores the co-creation of knowledge to addresses the second research question: What is the process of the co-creation of knowledge in a QI project? (§7.3).

Chapter 6 (§6.0) presents a re-construction of the case study using an IS practice theory and presents an analysis focussing on practices and processes. The discussion chapter explores implementation and improvement as a social practice and addresses the third research question: How can the process of implementation and improvement be understood as a social practice? (§7.4).

Table 7: Outline of the organisation of the thesis related to the fields of study, analytical approach, theoretical lens and research questions. Sections are indicated in parentheses.

Chapter	4	5	6
'Knowledge to practice' approach	Quality Improvement (§4.0)	Knowledge Mobilisation (§5.0)	Implementation Science (§6.0)
Focus of Analysis	Organisational QI project	Actions of actors	Practices and processes
Analytical framework or approach	Narrative (§3.6.1)	Knowledge to Action cycle (§3.6.2)	Normalization Process Theory (§3.6.3)
Phenomena investigated	Complexity	Co-creation of knowledge	Social practices
Main research question addressed	What role do QI methods have in assisting actors to navigate the complexity of the health system to support the 'knowledge to practice' process? (§7.2)	What is the process of the co-creation of knowledge in a QI project? (§7.3)	How can the process of implementation and improvement be understood as a social practice? (§7.4)

3.8 Researcher stance and reflexivity - drawing on personal experience

As a researcher and QI Practitioner, I provided technical support to the case study during the initial project between 2014 and 2016 with my role naturally changing when I started collecting data for my doctoral research. When undertaking qualitative participatory research, the researcher has to be aware of the perspectives they bring to their work (109). Articulating these perspectives and not ignoring them is key to reflexivity. Objectivity is not the desired outcome, rather clarity in setting out the relationship between the researcher and the 'researched' phenomena. This section will focus on explaining the perspectives with which I came to this work and how I positioned myself throughout the research by discussing the 'researcher stance' and my approach to this work as a reflexive researcher.

3.8.1 Researcher Stance

One of the first steps in undertaking ethnographically-informed qualitative participatory research is to be clear about the researcher stance in terms of 1) expertlearner, 2) insider-outsider and 3) whether the research is on, with, or for, the participants (102). The expert-learner refers to the perspective that the researcher brings to the observations and interviews and whether they draw on existing theories and frameworks to guide the data collection (expert) or develop a more organic and inductive approach (learner). Similarly, the insider-outside stance relates to the position of the researcher as 'part of the community' which they are researching (insider), or strictly as an observer standing back from the activity (outsider). Relatedly, understanding the level of involvement of the participants in the research process is useful, whereby 'research on' infers the participants are simply seen as subjects in the study, 'research with'- as co-inquirers, and 'research for'- as commissioners of the research or other beneficiaries such as patients. These factors, are captured in Gold's (1958) types of research role: complete observer, observer as participant, participant as observer and complete participant (110). The three dimensions: level of expertise of the researcher, researcher involvement in the improvement and the participant involvement in the research can be represented along different axes to assess the stance of the researcher in relation to a case study and how this might change over time (*Figure 16*).

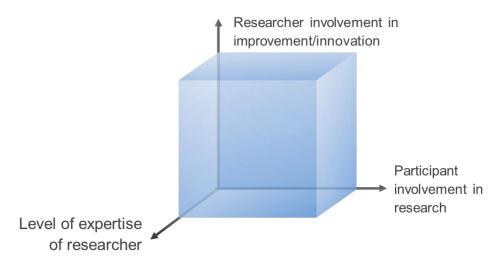


Figure 16: Researcher stance as viewed through three dimensions, level of expertise of researcher, researcher involvement in the improvement i.e. position within the community and the participant involvement in the research

During the period of my involvement with the case study, my position according to the three axes was dynamic. From the researcher perspective, the team saw me as the 'expert' in SHINE1 as I was the only one with any research experience. The team was busy learning about QI and consequently were unable to focus on learning about research. However, during this period and in the discussions about using SHINE2 as a case study for my research, the team developed a greater interest in the research being undertaken and, in the research, they could undertake about the project and QI practice.

As for the insider-outsider stance, this was dynamic and complicated. In SHINE1 I was an outsider, as I was from a different organisation. However, through the development of personal relationships with the team members I very much felt like an insider. Yet this caused some conflicts in terms of being given access to information from the Trust that was not always appropriate or the permissions I had to access people and places within the Trust, not typically seen in those 'outside' the organisation. As evidence of my insider status, I was invited to join the team when they won an organisational award for SHINE1. The inter-personal relationships I built up with the QI project team members, especially the service users may have supported my status as an insider.

The stance on whether the research is conducted on, with, or for, the participants is complicated and not fully resolved. I originally started this process by discussing with the team some of the issues they felt my research had the potential to address.

Overwhelmingly, I felt that the QI project team members wanted some perspective on their work, to understand what they had been involved with and to use their involvement in the research as an opportunity for reflection. Of course, a particular challenge was that the doctoral work should be my own and therefore precluded potential opportunities to work more closely with the team to conduct research that they could actively participate in. However, as the research was for my doctorate many of the staff specifically made themselves available to support my education and professional development. It should be disclosed that I continued to have a role within the project team, supporting the team to collect monthly improvement data.

3.8.2 Reflexivity

Etherington (2004) describes reflexivity as a process by which the roles of practitioner and researcher can be reconciled through the explicit acknowledgement of the researcher's own experiences and realities as a practitioner, and how these inform the research process and the subsequent reality that is constructed (111). The notion of reflexivity may be well established in the academic disciplines that use approaches such as auto-ethnography, or traditions of reflective practice such as those of counselling and therapy, but the potential in health services research for this approach to research is underused. Health services research is mainly drawn from a positivist tradition, where 'objective' knowledge or truth is sought by policy-makers and practitioners to inform the organisation and delivery of health services (112). Whilst there have been suggestions about the integration of different paradigms and perspectives, including in the field of economic evaluations in health care, reflexive research is certainly not a standard approach (113). This research offers an opportunity to bring to bear my own experience that has led to this research and provide an opportunity to reflect on the practice of introducing improvements in healthcare.

3.9 Summary

This chapter introduced the study design (§3.2) that was selected to respond to the challenges set out in the knowledge gap and the proposed research questions (§1.5). This, in turn, led to the development of the conceptual model (§2.8) which proposes a multi-perspective analysis to explore the intersection of the three different 'knowledge to practice' approaches. In addition, the conceptual model proposes the exploration of three phenomena that are key to understanding the 'knowledge to practice' process: complexity, the co-creation of knowledge and social practice. The ethnographically-informed participatory qualitative research methods provide a framework for both generating data and the subsequent analysis. This is underpinned by a critical realist epistemology §3.3). The process for ethical review and informed consent of all participants was also outlined (§3.4) as well as the secure management and storage of confidential and sensitive data (§3.5). The use of participatory qualitative research methods used to generate and collect data were outlined (§3.6) and the analytical approaches taken (§3.7) provided. The important role of reflexivity within this research and relationship between the 'researcher and researched' were discussed (§3.8). The preceding three chapters prepare the reader for the analytical chapters and discussion which are offered in the final four chapters.

4.0 Navigating complexity within an organisational project using QI methods

4.1 Overview

This chapter re-constructs the case study as an 'organisational project' using QI methods to structure a narrative. This acts as both an account of the collective sense-making of the team and the researcher (§3.6.1) and as a description of the use of the QI methods to navigate the complexity of the health system. This describes how a team set about transforming a range of strategic intentions into everyday practices through the use of a 'form' to organise both 'knowledge' and 'work', as an example of the 'knowledge to practice' process. The narrative highlights the complexity of the context (§4.2) and the role of actors (§4.3) in creating the organisational project using QI methods (§4.4). The context is categorised using the MUSIQ2 framework, which describes three types of context: the local clinical setting (§4.2.1), the project context (§4.2.2) and the organisational context (§4.2.3). The context introduces a number of actors involved in the organisational project, which include the QI project team (§4.3.1) and their clinical roles (§4.3.2).

The use of QI methods is extensively detailed over the course of the four-year case study. Each stage of SHINE1 is described, specifically: how the problem was understood (§4.4.1), the evidence reviewed (§4.4.2), a team created (§4.4.3), a shared aim agreed (§4.4.4), systems and processes explored (§4.4.5), actors engaged, (§4.4.6), interventions developed (§4.4.7) and tested (§4.4.8) and improvements assessed (§4.4.9), along with opportunities for reflection, learning (§4.4.10) and dissemination (§4.4.11). This led to SHINE2, which is described in more detail drawing on contemporaneous data, and highlights the opportunity to ensure sustainability of the interventions through scale-up (§4.4.12) The QI project team went through several discrete stages and processes including developing a shared aim (§4.4.13), updating the interventions (§4.4.14) to ensure sustainability on the SHINE1 ward (§4.4.15), scaling up to other wards in the unit (§4.4.16) and recognising challenges to spreading the interventions to a community setting (§4.4.17). The final section (§4.5) summarises the analysis, highlighting the main findings but also the gaps in the analysis and how these are addressed by the subsequent analysis presented in Chapter 5.

Whilst this chapter is necessarily largely descriptive it provides a basis for addressing the research question: what role do QI methods have in assisting actors to navigate the complexity of the health system to support the 'knowledge to practice' process? using the SHIFT-Evidence framework (*Table 2*) in the discussion (§7.2).

4.2 Context

Context is categorised according to the MUSIQ2 framework **Figure 1**) as local clinical setting (Type 1), the specific project context (Type 2) and the organisational context (Type 3).

4.2.1 Local clinical setting

Type 1 context refers to the clinical setting in which the interventions and improvements are introduced. The acute MHU in which SHINE1 and SHINE2 took place serves the population of inner northwest London and is located within a community that represents one of the most socially, culturally and economically diverse areas in England. The 93-bedded unit was one of five in the region operated by the Trust, with a total capacity of over 360 beds. During SHINE1, the unit comprised four mixed-gender wards - one triage (*Ward-1*) and three treatment wards (Ward-2, Ward-3 and Ward-4), plus two single sex psychiatric intensive care unit (PICU) wards (Ward-5, Ward-6). The unit was overseen by a unit manager, three matrons, six ward managers (Band 7) supported by three clinical team leaders (CTLs) per ward (Band 6). Nursing staff were allocated to each ward and often rotated between wards and to community mental health teams. The composition of staff and skill-mix on wards was dependent on workload and allocated by the management team. On Ward-1, in addition to the ward manager and CTLs there were 12 staff nurses, six healthcare assistants and support workers (Band 2 or 3), and several allied health professionals (e.g. pharmacists and occupational therapists), and an activity co-ordinator. At the start of the project, in 2014, the medical team for the unit was two consultant psychiatrists, four specialist registrars (trainee psychiatrists), and three junior doctors.

In 2017, as part of reorganisation of the unit, the triage ward model was discontinued. All wards became direct admission and treatment wards, although the PICUs remained. Through this period there was a restructuring of ward staff, resulting in a reduction of matrons from three to two, and an increase of CTLs per ward from three to four. Changes to the medical staffing were seen at this time: the consultant cover was reduced to one, and the specialist registrar post and two whole time equivalent (WTE) junior doctor posts were lost.

4.2.2 Project context (Type 2 context)

The Type 2 context describes the project-specific supporting context related to a specific project. SHINE1 was conceived in October 2013 by *P13*, a consultant clinical psychologist, and P19, Chief Psychologist at the Trust. A proposal was submitted in response to The Health Foundation call for its 'SHINE' programme, which looked to identify innovations in the NHS that could lead to improvements in healthcare. The application was supported by the Chief Executive of the Trust. Following the successful outcome of the bid, CLAHRC NWL was invited to support the delivery of the project by *P19*, the academic Mental and Physical Wellbeing lead at CLAHRC NWL. At this stage, the clinical leads and executive sponsors looked to develop a QI project team and engage with a range of stakeholders that could have an interest in the project and influence its progress. The team development is described in a subsequent section in more detail (§4.3). In summary, stakeholders were identified before the launch of SHINE1 in September 2014, including frontline staff and service users. Whilst there was turnover of project team staff through this period, many continued to be involved in SHINE2.

In May 2016, an application for a second QI project, SHINE2, was made to CLAHRC NWL, in response to the CLAHRC NWL call for round seven of its research and improvement projects. SHINE2 aimed to sustain the interventions developed in SHINE1 on *Ward-1* and scale-up across five other wards of the MHU and 'spread' to a community setting. The project was delivered between September 2016 and December 2018. The application was again led by *P19*, Chief psychologist, supported by the Medical Director.

4.2.3 Organisational context (Type 3 context)

IT infrastructure within the Trust

The Electronic Health Record (EHR) system used by the Trust since 2007 was Jade Community Care (EMIS Health, UK). This was supplemented in late 2016 by Tableau (Tableau Software, US) a programme that draws data from the EHR directly and enables bespoke reports to be created from clinical datasets. During the projects, there was continual discussion and of the Trust's plan to implement SystmOne (TPP, UK) across its acute and community services, which eventually happened in January 2019. The QI project team assumed that implementation of SystmOne within the Trust would allow greater inter-operability and allow direct sharing of information with primary care services in the area, which also used SystmOne. The uncertainty of the future of Jade resulted in some hesitation about transferring the SHINE1 intervention on to the system, yet this did happen in March 2018. At the start of the SHINE1, the Trust did not have access to a QI platform to create and manage projects, including the uploading and analysis of data. CLAHRC NWL provided access for all the QI project team members to use the bespoke QI software Web Improvement Support in Healthcare (114). In 2017, the Trust purchased another QI software package: LifeQI (SeeData, UK). Although this was not used for the SHINE projects it demonstrated the Trusts committed to growing the number of QI projects within the Trust.

Physical health within the Trust

At the start of SHINE1, there was little overt interest in the physical health of people with SMI within the Trust. Throughout SHINE1, various policy documents and programmes began to highlight the importance and priority that should be placed on physical health. In September 2016, as SHINE2 was launched, the physical health implementation group (PHIG) was established by the Trust in response to the introduction of a new national Commissioning for Quality and Innovation (CQUIN) indicator by NHS England that. The indicator aimed to improve physical healthcare to reduce premature mortality in people with serious mental illness. The target, which is linked to provider incentives, requires that >90% of inpatients and >65% of service users should have demonstrable cardio metabolic assessment and treatment (115).

P16, the co-lead for SHINE1, was also appointed as clinical lead for PHIG, which was overseen by the director of nursing. In addition, the Trust appointed O4 as Education Lead for Physical Health, the initial role of PHIG was to undertake a gap analysis to identify immediate areas that needed to be dealt with such as training and the provision of equipment for assessing physical health. In addition, P16 led the design of physical health standards, which were intended as a local organisational policy to ensure clinicians and managers were clear about their responsibility in taking care of both the physical and mental health of patients using acute services and service users using community services. Following this work P16 and O3, a project manager, visited over 200 frontline staff across the Trust to discuss how they could support them to improve the physical health of their patients and service users. This led to the development of a strategy for implementing the physical health assessment (PHA) form, one of the interventions developed in SHINE1 across more than 40 different clinical teams and sites.

Quality improvement within the Trust

At the start of SHINE1, there was little experience in the QI project team, except for P19, who had led numerous QI projects supported by CLAHRC NWL or within the wider organisational context. As outlined in the background (§2.2), there had been a rise in the popularity and expectation that Trusts undertake QI, especially from regulators such as NHS Improvement and Care Quality Commission in England (116). The form of support offered by CLAHRC NWL in SHINE1 was a departure from the usual process of selecting projects based on an open competitive call, as the project team was already funded by the Health Foundation. CLAHRC NWL provided the QI support to the project, although the Health Foundation also provided support through an external service improvement consultancy (based at a different mental health provider Trust). However, SHINE2, was a more usual approach to supporting a project as the QI project team submitted and application as part of an open competitive call in 2016. In 2017, during SHINE2, the Trust signed an agreement with the Institute of Healthcare Improvement (IHI) in the US to provide training and support for the Trust's new QI programme.

4.3 Actors

4.3.1 Quality Improvement Team

After securing funding for SHINE1, *P13* and *P16*, the clinical leads, and *P19*, the executive sponsor, worked with *P21*, from CLAHRC NWL to establish a multiprofessional improvement team (*Table 8*). The team initially comprised of nursing, pharmacy and therapies staff as well as managers, there was a desire to involve service users (51).

At this point it is worth noting the use of specific terminology to differentiate patients using inpatient services and service users accessing community mental health services. This project specifically aims to address the physical health of inpatients through the involvement of service users, which was guided through the use of the 4Pi framework. The framework was developed by the National Survivor User Network and outlines five components of patient involvement: Principles, Purpose, Presence, Process and Impact (117). The service user role description for their involvement in the project was developed by *P21* and was circulated to the service user form, from which three service users were invited to become part of the team (18). Monthly meetings were established for the improvement team to plan and monitor work streams and ensure there was communication between team members. In addition, several bespoke training workshops were facilitated by staff from CLAHRC NWL to support the team to use QI methods.

Many of the remaining SHINE1 team members continued to be involved in SHINE2. One problematic role to fill was the project manager. Following *P1*'s departure prior to the end of SHINE1, a number of temporary appointments were made to fill in the role, with the new project manager *P11* joining in December 2016.

During the project *P11* became pregnant and took maternity leave, her role was covered by a project manager from another CLAHRC project. As this was a temporary role they moved on after five months and the project management was taken on by *P9*, psychology assistant from December 2017 until July 2018. *P15*, Improvement Manager at CLAHRC NWL, took over my role to facilitate the use of QI methods. She also became pregnant and her role was covered a project officer from CLAHRC NWL, until her return in September 2017.

Table 8: The multi-professional improvement team for SHINE1 (October 2014) and SHINE2 (September 2016)

Initials	Job title	QI Project role	Project
P1	Psychology Assistant	Project Manager	SHINE1
P2	Psychiatric Registrar	Team member	SHINE1
P3	Consultant Pharmacist	Team member	SHINE1/2
P4	Staff Nurse	Ward Champion	SHINE1/2
P5	Service User	SU Representative	SHINE1/2
P6	Service User	SU Representative	SHINE1/2
P7	Psychology Assistant	Project Manager	SHINE2
P 8	Health Care Assistant	QI Support	SHINE2
P9	Psychology Assistant	Project Manager	SHINE2
P10	Recovery practitioner	Team member	SHINE2
P11	Psychology Assistant	Project Manager	SHINE2
P12	Health Trainer Manager	Team member	SHINE1
P13	Consultant Psychologist	Co-clinical lead	SHINE1/2
P14	QI Manager	Team member	SHINE1
P15	Improvement Manager	QI Practitioner	SHINE2
P16	Consultant Psychiatrist	Co-clinical lead	SHINE1/2
P17	Activities coordinator	Team member	SHINE1
P18	Matron	Team member	SHINE1/2
P19	Chief Psychologist	Executive sponsor	SHINE1/2
P20	Ward Manager	Team member	SHINE1/2
P21	CLAHRC Lead	Lead QI Practitioner	SHINE1/2
P22	Fitness Instructor	Team member	SHINE2
P23	Staff Nurse	Ward Champion	SHINE1
P24	Service User	SU Representative	SHINE1/2
P25	Improvement Manager	QI Practitioner	SHINE2
P26	Manager	Project Manager	SHINE2

4.3.2 Clinical roles

In SHINE1, *P16* was both the co-lead of the project and the consultant psychiatrist on *Ward-1*. This offered both a leadership role for the project and a clinical and role on the ward, especially relating to the work of the junior doctors. Additionally, *P2*, a psychiatric registrar, was heavily involved in the project and co-designed the interventions with nursing staff and service users in SHINE1. The role of *P23* as *Ward-1* Champion was crucial in ensuring nurse engagement and the development of process for data collection. Following *P23*'s departure during SHINE1, due to a promotion within the Trust, *P4* was recruited as *Ward-1* Champion. This was *P4*'s first clinical role following qualification as a nurse and remained with the team through SHINE2, taking on a broader nurse leadership role and was eventually appointed interim QI manager for the MHU in August 2017. Whilst continued engagement with *Ward-1* staff, through *P4* and *P16*, worked well in SHINE2, engagement with other wards was challenging.

4.4 The use of QI methods to support the 'knowledge to practice' process

This section describes SHINE1 and SHINE2 using the structure presented for a QI project (*Figure 7*) drawing on the individual QI methods used at each stage.

4.4.1 Understanding the problem

Several important high-level policies and reports were central to the inception of the SHINE1 (118–120). However, it was the benchmarking undertaken by the National Audit of Schizophrenia (NAS) that demonstrated the scale of the problem at both a national and organisational level. In October 2014, NAS presented a nationwide assessment of services, including the provision of physical health care (121). Six key indicators were used to assess physical health monitoring and assessment of patients:

- 1. Family history of diabetes [and Cardiovascular disease (CVD)]
- 2. Smoking status
- 3. Elevated body mass index (BMI)
- 4. Blood glucose control (blood glucose and/or HbA1c)
- 5. Blood lipids (total cholesterol and HDL)
- 6. Blood pressure

The report ranked Trusts by each indicator individually and by the recording of all five cardio-metabolic risk factors (excluding family history). The Trust achieved all five recordings for only 16% of service users, placing the Trust fifth from the bottom in England and Wales. In November 2014 following discussion of the NAS report in the team meeting, *P13* and *P16* proposed that it would be useful to have a baseline assessment of physical health monitoring for *Ward-1*.

Working with *P13* and the Trust information team a 10-month audit of physical health assessments was undertaken in April 2015. The audit included 247 consecutive adult admissions to *Ward-1* and highlighted deficits in the physical assessment process. Whilst the percentage of patients receiving a physical health assessment was relatively high at 81% (201/247), the recording of BMI at 22% (53/247) and systolic blood pressure at 22% (55/247) were much lower than the national average identified by NAS, 52% and 61%, respectively. Although the recording of smoking status was better at 80% (198/247), this was still lower than the national average, 89%. The audit provided an indication of the local need for improvement and informed the development of improvement measures, forming a baseline for these measures. How this data from national reports and local audit data were combined with tacit knowledge of services to construct and re-construct the problem is further explored in the next chapter (§5.2).

4.4.2 Reviewing existing evidence

Several key clinical guidelines were published by the National Institute of Health and Care Excellence (NICE) on physical health monitoring of people with SMI prior to the project. The guidelines recommended that patients have their physical health monitored through robust assessment which should be documented in the patients' healthcare records (122,123). Much of this evidence was synthesised and collated in the form of the Lester Tool (*Figure 17*), which outlines the range of cardiometabolic indicators that should be measured in a physical health assessment, the thresholds for each indicator and the subsequent evidence-based interventions that should be offered to patients, as appropriate (124). The NICE guidelines also included recommendations for improving the service user experience in mental health through involving people using mental health services in the planning and delivery of training and services (125).

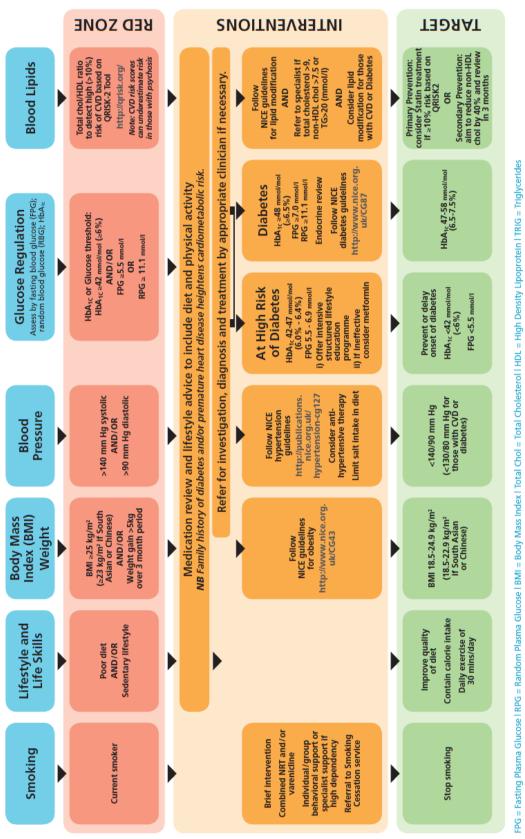


Figure 17: The Lester Tool: An intervention framework for people experiencing psychosis and schizophrenia (124)

4.4.3 Establishing a team

The development of the QI project team in SHINE1 is outlined above (§4.3.1).

4.4.4 Developing a shared aim

The initial QI workshop in October 2014 was facilitated by *P21* to develop a shared aim and support the team to begin to articulate the programme theory for the project through the use of the Action Effect Method (AEM) workshop (31). The programme theory links interventions or activities directly to intended outcomes or aim of a QI project, and should be based on evidence (126). The AEM has been developed and used with more than 50 projects supported by CLAHRC NWL. In 2018, an appraisal tool was developed to assess the quality of Action Effect Diagram (AED), which are visual representations of the outputs of the AEM workshop (127).

The workshop was an opportunity for stakeholders, including those directly involved in providing care on *Ward-1*, to contribute to developing the aim of the project and provide their own perspectives on the physical health of their patients. The workshop began with 'emotional mapping' where attendees were asked to characterise their emotions if they were a patient coming on to the ward - the results of which were mostly anxious/frightened, which set the tone for the subsequent discussion. The participants, including the improvement team and doctors and nurses from the ward, worked towards developing shared aim for the project during the workshop. The agreed aim was decided: to improve the physical wellbeing of people using the ward and community services. This was captured in the output from the workshop, the Action Effect Diagram (*Figure 18*).

Through the discussions, several potential solutions were suggested:

- 1. Patient physical health education & awareness training and information;
- 2. Map, understand and create new systems and processes for physical health on *Ward-1* and link to the Trust IT system;
- 3. Set up *Ward-1* physical health Ward Champions;
- 4. Staff physical health education & training;
- 5. Create a physical health care bundle including assessments, and appropriate interventions and referrals.

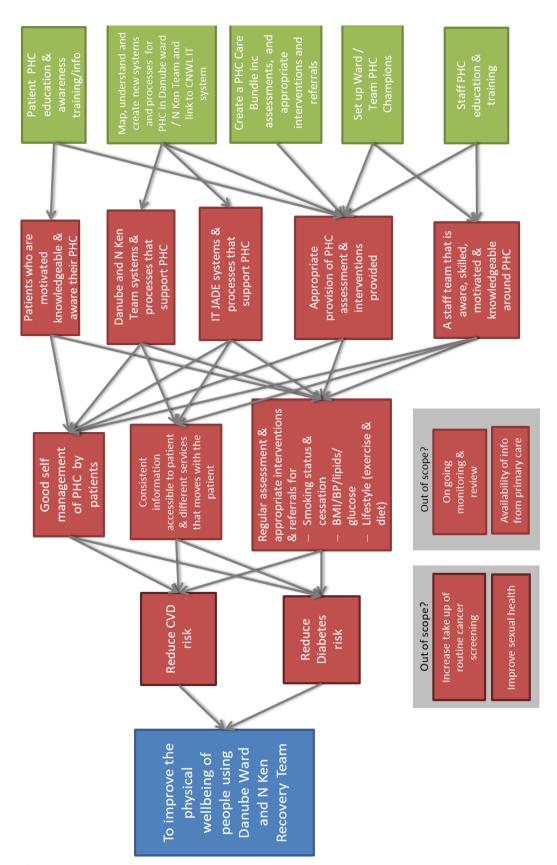


Figure 18 SHINE1 Action Effect Diagram (October 2014)

4.4.5 Exploring systems and processes

The second QI workshop followed in November 2014, facilitated by *P21*, in which process mapping was undertaken with the QI project team to 'map current systems and processes within the ward', an action identified in the AEM workshop (52,128).

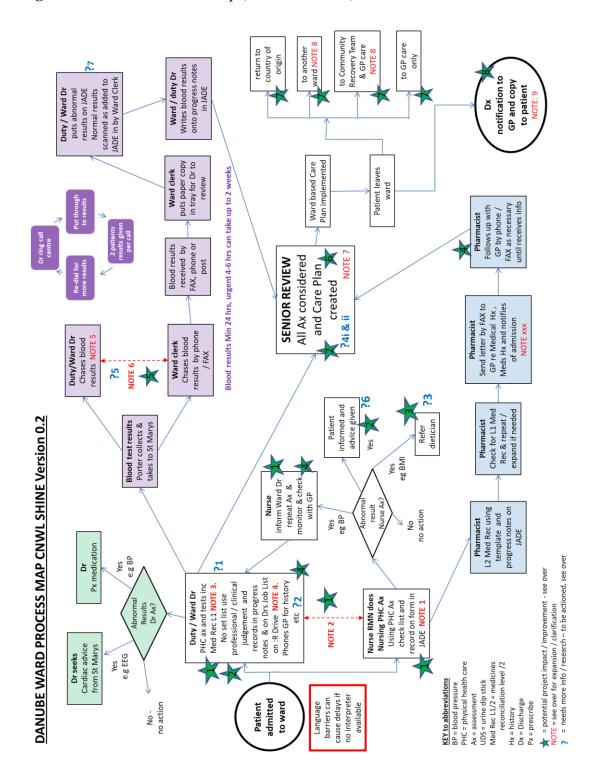
This session provided an opportunity for actors to describe current systems and processes for assessing physical health on *Ward-1*. The process mapping revealed several key problems (*Figure 19*):

- Lack of coordination between physical health assessment by doctors and nursing staff
- No information provided to patients about their physical health following assessment
- No interventions provided to patients with identified risk factors for CVD or diabetes
- Lack of coordination in engaging with GP for additional information e.g. history/medications
- Lack of coordination between clinical staff in obtaining blood results
- Poor communication with other services about patients' physical health
- No opportunity for wider multi-disciplinary input e.g. involvement of pharmacists or therapists.

4.4.6 Engaging stakeholders

Following the AEM workshop, I joined the team as QI Practitioner, taking over from *P21*. In November, I facilitated a stakeholder mapping session, where *P1*, *P5*, *P13* and *P24*, from the team identified potential stakeholders that could impact the project. The stakeholder mapping involved placing these actors within a matrix according to their potential interest in the project and potential influence in its success (54). The resultant stakeholder map (*Figure 20*) identified that patients were the most interested and had the greatest influence on the success of the project, although the problems identified in the process mapping and AEM sessions were exclusively related to the role of healthcare professionals and organisational systems. At this stage the role of patients and service users in the project was unclear. Although from the recruitment process there was a high-level of desire to involve service users, their role was emergent and responsive to the unfolding project.

Figure 19: SHINE1 Process Map (November 2014)



Psychologists were identified with the least interest and lowest influence in the project, which was surprising considering both the co-lead and executive sponsors were psychologists and the project manager was a psychology assistant.

Ward staff, which predominantly included the doctors and nurses on *Ward-1*, were seen by the QI project team as having a high level of influence but low interest in the project. This re-emphasised the need to ensure effective engagement with the clinical staff. As such, the *Ward-1* Champion, *P23*, and ward manager, *P20*, had key roles in engaging with the wider clinical nursing team. *P16* identified that there was a greater need to engage the medical team with *P2*, psychiatric registrar.

4.4.7 Developing interventions

In December 2014, I co-delivered a half day workshop with *P21* for the QI project team and clinical staff from *Ward-1*. Whilst this was open to all staff from the ward only nurses attended as doctors were unable to organise cover for their shifts. The workshop provided an overview of the CLAHRC programme and QI methodology, focusing specifically on the Model for Improvement including Plan-Do-Study Act (PDSA) cycles and measurement for improvement (46,50).

A fundamental aspect of the use of PDSA cycles are the planning of small tests of change, whereby one can learn about the use of an intervention and generate feedback to modify its design to better meet the needs of the users. *P21* led an exercise for the team to illustrate this concept, whereby staff were tasked with creating paper aeroplanes and recording the distance the planes travelled in small groups. The aeroplanes could then be modified and the modifications recorded before flying the planes again and recording the distance travelled (129). The aim of the exercise was to identify key features that result in an increase in travel distance. Following the exercise, I gave a presentation of a previous project I had worked on to develop a diabetic foot 'care bundle' and described the iterative development of the bundle and how data about its implementation were collected and used to modify the design of the bundle.

The workshop provided some space away from the clinical setting for clinical staff and QI project team to spend time together to discuss the project. The session mostly focussed on QI methods, as very few staff, from either the QI project team or clinical staff, had prior experience of QI.

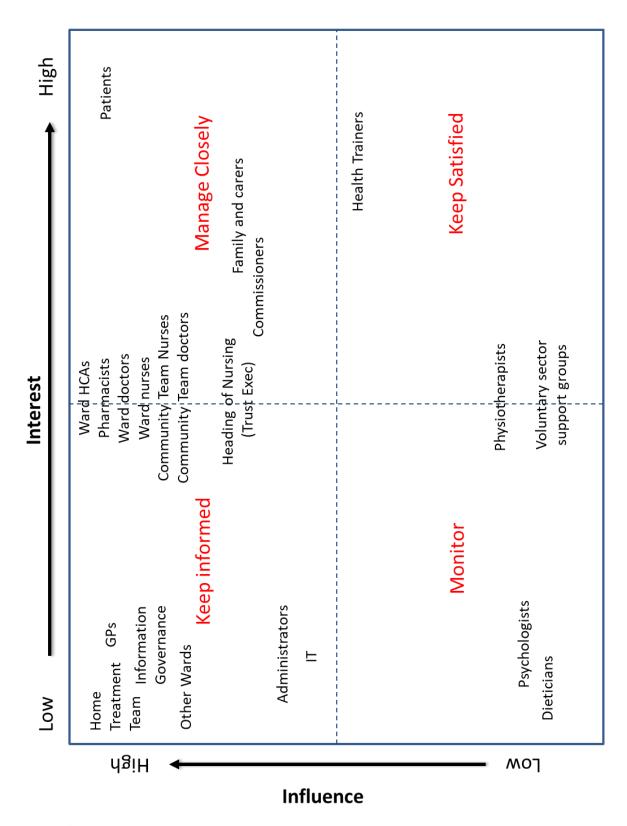


Figure 20: SHINE1 Stakeholder Map (November 2014)

Following the workshop, the QI project team began to discuss plans for designing interventions that fulfilled the activities that were captured by the AED (**Figure 18**) and the gaps in processes identified by the PM (*Figure 19*). The initial plans outlined in the application were to develop a physical health care bundle. Care bundles are defined as: "a small set of evidence-based interventions for a defined patient segment/population and care setting that, when implemented together, will result in significantly better outcomes than when implemented individually" (130).

Whilst it was clear that multiple interventions would be required to achieve the aim of the project, the focus was on developing a clinical intervention that could support the completion of the physical health assessment and provide guidance for staff and patients about potential interventions where risks were identified. However, there was recognition that without some intervention to support signposting and the delivery of interventions for patients identified with a physical health risk that the project would be ineffective to achieve its aim of improving the physical health of patients on the ward. During this discussion, *P24*, one of the service user members, asked whether patients were given information about their physical health. It was agreed by the clinical staff that there was no process for providing formal information to patients about their physical health, or mental health for that matter. In response, it was agreed that three interventions should be developed that could be used sequentially, creating a physical health pathway. It was determined that these should all be co-designed, as collaborations between healthcare professionals and service users/patients to develop clinical and educational interventions (131):

- 1. An intervention to for the routine assessment and recording of physical health;
- 2. An intervention to support the communication of the results of the physical health assessments to the patient;
- 3. An intervention to support the delivery of clinical interventions for patients (or service users) with a risk of developing a physical health issue.

The development of each intervention is described separately below, but there was overlap in their development as they were not sequential, which allowed their design to encompass feedback from the other interventions (*Figure 21*).

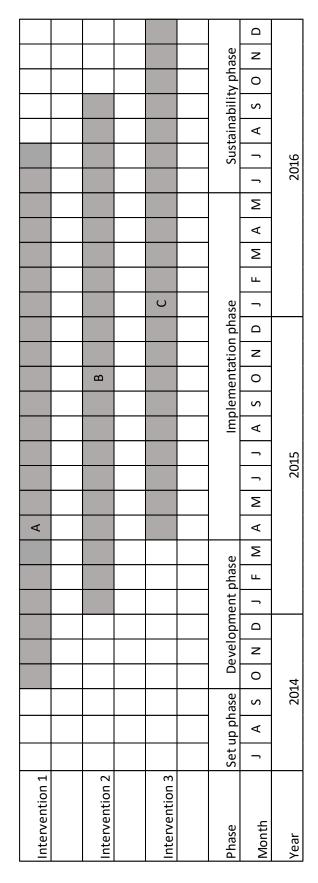


Figure 21: SHINE1 timeline - highlighting the development of Interventions, where A, B and C indicate the implementation of Interventions 1, 2 and 3, respectively

The multi-professional physical health assessment (Intervention 1)

The content of the multi-professional physical health assessment (PHA) was developed to align to existing tools and guidelines, including the Lester Tool and NICE guidelines (122–124). *P16* developed an initial version in October 2014 that was comprised of a list of assessments and recording of cardio-metabolic indicators including a CVD risk score calculated using the QRisk.

Assessments:

- Smoking status (yes, no, what, how much)
- Weight, height, BMI, Waist Circumference
- Fasting glucose/HbA1c
- Exercise (What I like, how often)
- Cholesterol
- Blood Pressure
- Family History of Cardiac Disease
- Calculation of QRisk
- Assess alcohol intake
- Assess diet

A patient-held physical health plan (Intervention 2)

The co-design of the patient-held physical health plan (PHP) was led by three service user representatives from the QI project team, *P5*, *P6* and *P24* from January 2015. They were supported by the project manager, *P1*, and an undergraduate psychology student on placement with P19, chief psychologist and executive sponsor, who oversaw the development of the intervention. Initially, the group identified existing information sources developed by healthcare or voluntary organizations and charities on physical health, none of which was tailored for people with SMI or offered the option to enter individual physical health data. However, some of the information from these materials were used to inform the content, structure and design of the first draft of the patient-held PHP. This concept was explicitly borrowed from 'My Medication Passport', a tool for patients to share information about their medications with healthcare professionals, also developed with support from CLAHRC NWL (132).

The PHP provided personalised information about the patient's physical health and was intended to support shared decision making about access to appropriate support services (e.g. health trainers, smoking cessation etc.). The content was selected by the service user representatives and created on Microsoft publisher by *P1*. The first draft included several key sections:

- My Physical Healthcare Plan- what is it and how to use it?
- What is the QRisk? (CVD)
- What is the Diabetes Risk?
- What is BMI?
- What is blood pressure?
- Smoking/Alcohol

The PHP also included information about the estimate of a 10-year risk of developing CVD and diabetes, using the JBS-3 score (rather than QRisk- explained in §4.4.8) and QDiabetes score, respectively. The CVD and diabetes risk score tools were seen as key in identifying patients with a high risk of developing these diseases in the future. The PHP included space to record the results of the PHA to personalise the information and offered information about general risk reduction strategies e.g. smoking cessation.

Educational resources to support service users and staff (Intervention 3)

Initially, this intervention was intended to provide the clinical interventions for patients identified as smokers with high blood pressure, high cholesterol and at risk of diabetes whilst in hospital. This intervention was key in ensuring patients received evidence-based treatments and strategies, according to NICE guidelines, to reduce their risk of future respiratory disease, CVD, diabetes. The rationale for this was that assessing physical health and providing information alone were unlikely to influence the overall health of the patients. However, it was recognised by the QI project team that effort should be made first to ensure that an effective physical health assessment was put in place (Intervention 1), by which time the challenge of asking staff to deliver these interventions on the ward was clearer. As such, an alternative strategy of delivering this following discharge was adopted from April 2015 (§4.4.8).

4.4.8 Undertaking tests of change

The multi-professional physical health assessment (Intervention 1)

Following the creation of the initial list of assessments, a PHA form was developed for use during admission, common for acute admissions in general hospitals (133). The subsequent structure and content were iteratively developed using the PDSA cycles to guide testing on *Ward-1* using staff feedback to co-design the form. A final version of the form was agreed by the QI project team in July 2016, representing nearly two years of development and 17 different versions, although only eight of these are presented in *Table 9* and *Table 10*.

One challenge was the selection and implementation of the CVD and diabetes risk scores. The use of these scores, whilst not included in the NICE guidelines or Lester Tool, was deemed important by the QI project team as a mechanism for identifying modifiable risk factors that could inform shared decision making (SDM) between clinicians and patients about appropriate and acceptable risk-reduction strategies. However, the challenges associated with implementing SDM within mental healthcare are well known, although less is known about the challenges of SDM in this population when discussing CVD and diabetes risk (134). However, even in primary care, where much of the work to reduce CVD and diabetes risk in the general population occurs, the delivery of services for those with SMI remains a challenge (135). Initially the QRisk score were used but later changed to the JBS3 score in May 2015, following *P13*'s attendance at a national conference where this was proposed to be the most appropriate risk score for assessing CVD risk in this patient group (136). Later this reverted back to the QRisk in SHINE2.

In the final stage of development, the PHA form was separated into two documents, one for mental health and one for physical health, although there was no change to the content. The reason behind this was that in order to integrate the Word document into Jade (§4.2.3) the size of the document had to be reduced. This splitting of the PHA form into separate mental and physical health forms somewhat echoes the division of the separation of mental and physical health. However, this pragmatic division of the forms was to facilitate its integration into the EHR, although despite this the workability of this approach was challenged by the resistance of staff to use the electronic version of the PHA form across the wider organisation.

Table 9: Summary of modification to the physical (and mental) health assessment form between September 2014 and May 2015 and a commentary on changes.

Date	Content and modifications	Explanations/Implications	
10/14	Initial form comprised of a list of cardio-metabolic factors and physical health issues for assessment and recording including QRisk score, fasting glucose (HbA1c) and alcohol use.	This initial comprehensive list was comprised of items taken from the clinical guidelines and/or Lester Tool.	
02/15	Initial list incorporated into a PHA form including all mental and physical health assessments to be completed during admission. PHA form included some pre-determined choices and sections of free text for past medical history, physical examination and observations and blood test and urine dipstick results. QDiabetes score added to form, in addition to QRisk, to assess patients' 10-year risk of diabetes, respectively, which requires the user to access a website via the form to calculate the score.	The introduction of a PHA form was new. Although this was a Word document it was on the computer so would need to be completed away from the patient, therefore requiring information captured in hard copy with patient and transposed to electronic version. The QRisk/ QDiabetes scores required staff to calculate these scores, interpret them and make a decision about the need to communicate this to the patient	
03/15	Changes of reporting of ethnicity and gender as predetermined options to free text. Structured reporting of Full Blood Count.	Feedback indicated concerns that the PHA form was too restrictive about ethnicity and gender and test results should be included.	
05/15	Colour coding of document to identify sections that should be completed by doctors (medical history, physical examination and blood results) or nurses (demographics, basic physical health questionnaire, physical observations e.g. weight/height etc., and urine) and those for both (CVD and diabetes risk scores). The QRisk was replaced by the JBS-3 score, which provides a figure of the age the patient can expect to live to without a heart attack or stroke. The diabetes risk score remained the same.	Feedback from nursing staff suggested that without clarity about who should complete sections it would be assumed to be the nurse's role. The colour coding offered clarity about responsibility. Using this information, the nurses set up a weekly 'spot check' audit to assess the completion of the nursing sections. The decision to change from QRisk to JBS-3 was based on suggestion from <i>P16</i> after attending a conference about physical health and SMI	

Table 10: Summary of modification to the physical (and mental) health assessment form between September 2014 and May 2015 and a commentary on changes.

Date	Content and modifications	Explanations/Implications
11/15	Tables added to PHA form to allow ongoing monitoring and recording of physical observations, blood tests and urine dipstick results.	As the project progressed patients were readmitted, so it was suggested that the form should allow multiple entries of results rather than one form per admission.
11/15	The PHA form was updated to include a new section to record the initial impression of the patient and their care plan on admission, including any acute physical health issues that required treatment. In addition, a discharge summary was added that provides a summary of the patients care during their admission and includes issues about the patient's physical health that can be followed up by the GP. Both new sections required signatures.	The initial impression and care plan were identified by doctors as important information needed in the PHA form often updated following a review by the senior doctor (consultant or registrar). The discharge summary was added as the discharging doctor had to create this anyway, embedding into the form gave some leverage to encourage doctors to use it. The requirement of a signature emphasised accountability.
04/16	The form included the option of identifying which assessments/tests were refused by the patient.	This was as a result of staff suggesting that the assessments were not completed due to refusal from patients.
07/16	At this stage the PHA form was split into two separate documents, one for mental health and one for physical health. All the information from the previous version was maintained but this generated two discharge summaries for the GP, one about the patient's physical health and the other about their mental health. However, the physical health summary did include information about whether the patient was given a physical health plan (Intervention 2) at discharge.	In one way the project could be understood as an opportunity to integrate the fragmented mental and physical health of patients, in which case this de-integration could be seen as symbolic of a failure to do that. This could be representative of the division of skills, knowledge and resources for delivering mental and physical health and allows staff to reprioritise one over the other.

A patient-held physical health plan (Intervention 2)

Following the development of the initial outline of the booklet by the service users and discussions in QI project team meetings, more information about lifestyle changes to support CVD/diabetes risk reduction was included plus a list of local services and organisations that support risk reduction strategies (e.g. Recovery College and NHS Smoke Free). Drafts were circulated amongst the team and suggestions taken on board. P19 redrafted the text to align to behaviour change principles. The final version was developed by the communications team with corporate branding. This was seen by a visiting mental health researcher from Australia at one of the collaborative learning events and was replicated in Queensland as part of its metabolic monitoring programme, which was a state-level project to improve physical health monitoring in people with SMI (137).

Educational resources to support service users and staff (Intervention 3)

This intervention was initially developed with the Trust's Recovery and Wellbeing College (RWC) through collaboration between *P5* and *P24*, service user representatives, and *P2*, psychiatric registrar. The RWC model, which is widely used in the UK, supports self-management of mental health through service user education (138). Two new courses aimed to integrate physical health issues into the curriculum and raise awareness of the importance of good physical health, how to maintain it and where to get additional support. The first half-day workshop was called 'Healthy Lifestyle: Introductory Workshop', which introduced the range of available short courses that support a physically healthy lifestyle and demonstrated how the individual courses on physical health are linked together. The courses included topics such as healthy eating, keeping active etc. The second half-day workshop was 'Type 2 Diabetes: What's my risk?', which introduced attendees to the basics of diabetes, specific risk factors, the importance of early diagnosis and strategies to reduce the risk of developing diabetes.

4.4.9 Assessing improvements

Several strategies were developed to support the implementation of the multi-professional PHA on *Ward-1* from March 2015. These included establishing a *Ward-1* Champion for physical health; educational sessions for staff and programme of audit and feedback, as part of the wider CLAHRC QI methodology of 'measurement for improvement' as recommended by the Institute for Healthcare Improvement (IHI) (139).

The role of the Ward Champion was taken on by *P23*, staff nurse on *Ward-1*, and included the day-to-day promotion of SHINE1 to clinical staff, with the support of *P20*, the ward manager. *P23* was allocated protected time to work on the project, delivering support to other ward staff and collecting the weekly data for the audit and feedback.

Educational sessions were delivered to different stakeholder groups including nurses, doctors and more general sessions for the MHU, which outlined the early mortality of people with SMI, and reflected on the Trust's own performance in this area and outlined the aims of the project and the responsibilities of staff. This opportunity was also taken to strongly emphasise the use of data to support staff to improve rather than 'performance management'.

Five measures were identified to monitor implementation and improvement, four were aligned to the indicators used in the baseline audit, which allowed continuous analysis across the baseline and intervention periods, the fifth assessed the provision of an individualised CVD risk score:

- 1. Percentage of patients that received a physical health assessment (PHA)
- 2. Percentage of patients where the smoking status was documented in the PHA
- 3. Percentage of patients where the BMI was documented in the PHA
- 4. Percentage of patients where systolic blood pressure was documented in the PHA
- 5. Percentage of patients where a CVD risk-score was documented in the PHA

Data were collected by *P23* and uploaded to the Web Improvement Support for Healthcare (WISH) tool between March 2015 and May 2016. Using WISH, I subsequently generated visualisations of the weekly data through the use of Statistical Process Control (SPC) to generate control charts to identify changes in processes (140). However, it was later identified in discussion with other members of the CLAHRC team that there were some issues with the small denominator that meant that there were likely to be issues of accuracy with the use of control charts and run charts would have been more appropriate. The visualisation were presented in the format of a poster, which I talked through with the QI project team each month and was sometimes displayed on a notice board on *Ward-1* for staff and patients to see (*Figure 22*). The data collected included qualitative free text comments from staff, where the PHA was incomplete, as a mechanism for understanding challenges in implementing the assessment that could be used to inform changes to the process.

Comparison of the average recording for each indicator from the baseline period (April 2014 to February 2015) with the implementation period (March 2015 to May 2016) showed comparative improvements in three of the indicators, but not smoking status (*Table 11*).

Table 11: Comparison of the recording of key physical health indicators during the baseline and implementation periods

Indicator	Baseline period n/N (%)	Implementation period n/N (%)
Percentage of patients that received a physical health assessment (PHA)	201/247 (81.3%)	308/318 (96.9%)
Percentage of patients where the smoking status was documented in the PHA	198/247 (80.1%)	225/318 (70.9%)
Percentage of patients where the BMI was documented in the PHA	53/247 (21.6%)	204/318 (58.6%)
Percentage of patients where systolic blood pressure was documented in the PHA	55/247 (22.4%)	239/318 (75.9%)
Percentage of patients where a CVD risk-score was documented in the PHA	N/A	118/318 (31.7%)

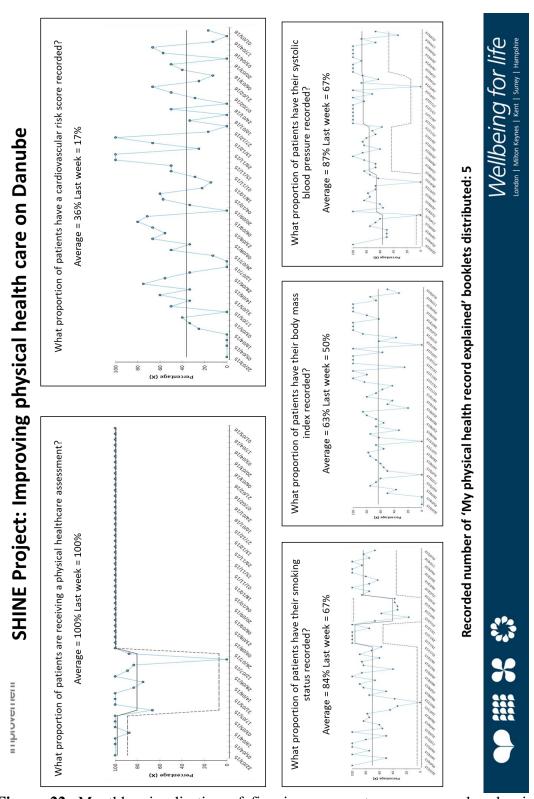


Figure 22: Monthly visualisation of five improvement measures analysed using Statistical Process Control to generate control charts

However, in QI, it is usual to use time series data to identify improvements rather than use two-point comparisons between a baseline period and implementation period (141) (*Figures 23-27*).

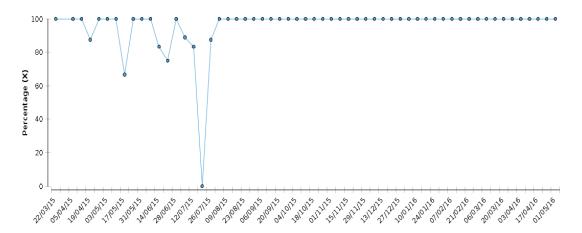


Figure 23: Weekly percentage of patients discharged from *Ward-1* with a physical health assessment

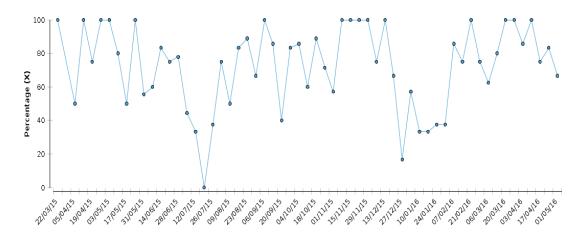


Figure 24: Weekly percentage of patients discharged from *Ward-1* with a documented smoking status in their physical health assessment

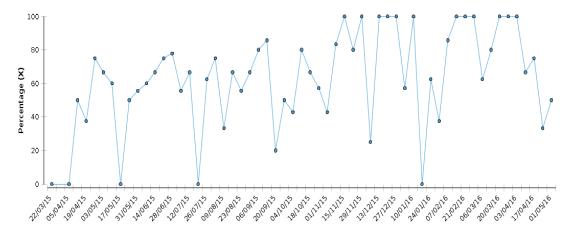


Figure 25: Weekly percentage of patients discharged from *Ward-1* with a documented body mass index (BMI) in their physical health assessment

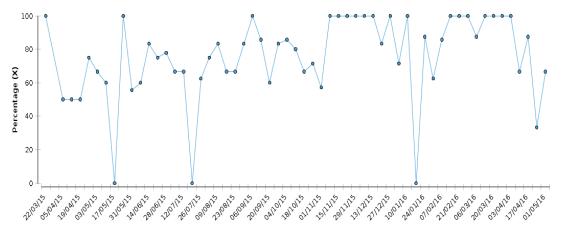


Figure 26: Weekly percentage of patients discharged from *Ward-1* with a documented systolic blood pressure in their physical health assessment

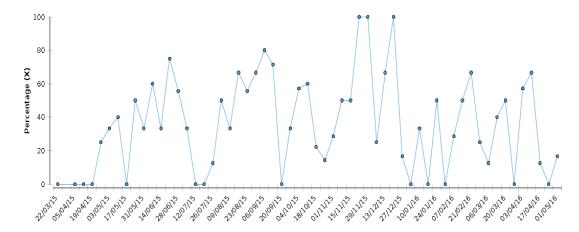


Figure 27: Weekly percentage of patients discharged from *Ward-1* with a documented cardio-vascular risk score in their physical health assessment

The implementation of the interventions and the broader context of their potential for sustainability and scale-up is explored in the next chapter (§5.4) drawing on a range of implementation strategies.

4.4.10 Reflecting and Learning

As part of the CLAHRC NWL's systematic approach to QI, the QI project teams were invited to attend a collaborative learning event every three months during their QI project. At these events, QI project teams had an opportunity to present their work to other QI project teams supported by CLAHRC NWL and get feedback from the wider community including patients, service users and the public (142). These events focussed on learning about QI methods, sharing examples of the use of QI methods and the development of QI communities of practice across northwest London.

4.4.11 Communicating success

A key aspect of CLAHRC NWL's systematic approach to QI was the dissemination of learning as a mechanism to spread key messages about the success of specific QI projects and approaches, and the general use of QI (49). SHINE1 was very keen to promote and share its learning within the QI project team and across the MHU, as well as within the Trust and more widely at national events. Different members of the team, or combinations of members of the team presented with service a service user, several external events included the researcher and other members of the QI project team. These included with *P16*, Consultant Psychiatrist, at 'Grand Rounds' to an audience of consultants and trainees in psychiatry about the project, with a focus on the evidence-base for interventions. Additionally, with *P3*, a pharmacist, with a presentation at the Royal College of Psychiatrists Prescribing Observatory for Mental Health symposium, focusing on the use of audit data to stimulate improvements. Also, at a National Institute of Health Research (NIHR) meeting about the project, with was co-presented with *P24*, a service user, and focussed on the role of PPI and QI methods.

4.4.12 Sustainability and scale-up

Between May and September 2016, there was a transition period between SHINE1 and SHINE2. During this period, several issues arose, mostly linked to planned organisational rollout of the physical heath form (§4.2.3). However, SHINE2 aimed to extend the implementations of the interventions developed in SHINE1 by scaling up in a similar setting; i.e. five additional inpatient wards and spreading to a different setting; i.e. community mental health services. As outlined in the SHINE2 application, this project explicitly aimed to: "convert information into action ensuring that information that is collected about a patient's physical health was used to connect them to interventions that can modify their health risks". The team that led SHINE2 included a number of those involved in SHINE1. This was specifically designed to draw on the experiences of key staff from Ward-1 and support them to lead on the work with their peers from the other five wards in the MHU (§4.3.1).

4.4.13 Developing a shared aim

In October 2016, as part of the QI approach, an AEM workshop was facilitated by *P21* to gather views and opinions from a wide range of stakeholders, including eight improvement team members and six clinical staff. This was very similar to the workshop that had been held for SHINE1 in October 2014, with the exception that all the stakeholders were already familiar with the interventions that had been developed for SHINE1. As attendees arrived at the meeting, they were asked to identify the emotions associated with different 'touch points' where patients and service users have contact with the services. The results showed that the most common emotions were 'anxious' and 'hopeful'. It was explained that many chose 'hopeful' as a way of encapsulating the confidence that patients might feel about accessing these services. Participants reflected on their aims for the project and the main factors that could achieve the aims and the activities required. The aim was identified as improving the quality of life, physical health and life expectancy of people with long term mental health needs who received care in the Trust through delivering a holistic approach to service users' care (*Figure 28*).

The aim of the project was to improve the quality of life, physical health and life expectancy of people with long term mental health needs who received care from the Trust. This was a much broader aim than that of SHINE1, which was to improve the wellbeing of the patients from Ward-1 and the community team. The new aim extended the levels at which improvement should be seen - i.e. process (through the assessment), outcomes (quality of life) and impact (life expectancy) - and the reach, which now included all people with long term mental health needs within the Trust. The stakeholders identified several key actions that would deliver this aim. The first was the continued assessment of the patient's physical health using the PHA developed in SHINE1, which required a review of the assessment form and support for its delivery through Ward Champions. This was linked to the provision of training for staff around the link between mental and physical health and the assessment of physical health. Secondly, the AED identified the need to provide information to the patients and communicate their own physical health risk, using the physical health booklet from SHINE1 (Intervention 2). The stakeholders also identified the need to provide information to the patients about interventions or services to address physical health risks, including the RWC courses.

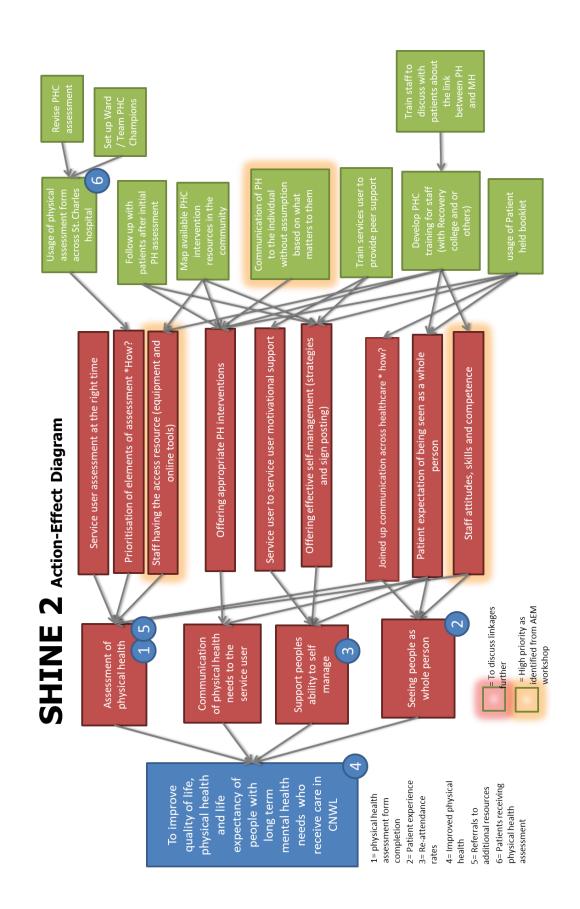


Figure 28: SHINE2 Action Effect Diagram October 2016

4.4.14 Updating interventions

The interventions developed and implemented in SHINE1 continued to be delivered on **Ward-1** during the transition period, although the improvement data were not collected during this period. There were some significant changes to the PHA form in SHINE2.

The multi-professional physical health assessment (Intervention 1)

Although the content of the multi-professional PHA form was finalised in July 2016, between this date and January 2017, the original Word document (§Error! R eference source not found.) was integrated into Jade, the electronic health record (EHR) system. This was part of the Trust-wide implementation of the assessment form in response to the introduction of the physical health CQUIN, which it was expected would support the achievement of the target across more than 40 different units, departments and teams. However, much criticism was made across the Trust of the form by doctors, reported through a staff survey. Most of the criticism was related to its length, which had expanded from the original seven-page Word document to over 25 pages. This related to the amount of work required to complete the form for each patient, and as some suggested: "it is the GPs' job to deal with physical health":

"We have had some challenges with the form. I think mainly so, as I said, it was five pages on Word and when we put it onto Jade, which is our clinical system, I think it became 25, I can't quite remember, it was roughly round about that number, but it became a much bigger form." (O3, Organisational lead)

The selection of Intervention 1 for the organisational roll-out was based on the availability of 'proven' interventions within the Trust that were amenable to being rolled out:

"...It worked on one ward, let's roll it out Trust wide. There were two reasons why we did that, partly because we knew it had worked somewhere, but also because we had nothing else, and so it felt like, why start from scratch when we've got something that seems to be working... So, we had lots of different forms, we had nothing that was as well researched, rounded, thought out as...

...the SHINE form. So, people were making notes prior to that, some teams had developed their own physical health assessment forms, some teams were writing it in progress notes, some teams were using theirs as a results recording section within Jade, which only one team seemed to know about. So, one team was using that, so there were these variety of forms, so we were, we had a choice of start from scratch or use something that we know, and the SHINE team were looking at putting it on to the clinical system as their next step anyway" (O3, Organisational lead)

The new version of the multi-professional PHA on Jade was introduced across the Trust, including all six wards of the MHU, in March 2017. However, there were those that saw benefits for maintaining the more flexible Word version:

"The best thing about [the physical health form] was obviously that because it was a Word document, you could edit it as you liked, and you had all the room in the world to put all the details. So I think that was the main benefit that we found but then proved to be a little bit of a challenge when we moved into Jade... in the Jade now, you don't have a specific place to have to write the forensic history if you need to so this is a very important part of the history that you end up putting in the, social/accommodation because you have nowhere else to put it." (C2, Healthcare professional)

Although there were also perceived benefits from including the PHA in Jade:

"...We've got the template sorted out on Jade which... but the doing of that has caused chaos, attention, and political, and issues but has really, really raised the profile of what are we doing." (P3, Healthcare professional)

However, there was a general sense that Jade, as an EHR, obstructed rather than supported staff to fulfil their clinical roles:

"...Jade is just a ridiculous system to use and it doesn't help, and it doesn't support, and we can't argue against that ..." (P3, Healthcare professional)

On the other hand, this was not consistent. Some reported that the form was more manageable on Jade:

"The form before was a Word document... now that there's a SHINE [form] for mental health and physical health, that's the Jade version and that divides the two. What we were having before was one document with everything on it, so it was quite long... because it compiled everything. It had all of your background information, it had your mental state exam and then it had the physical health stuff and if I remember rightly, I'm not sure the blood results were being updated on there? We would have had to type everything. So it was, yeah, I think that was perhaps a bit, yeah quite tiresome, quite long. With them being on Jade it's very, very easy. There's minimal typing required, for the mental health one you obviously do expect quite a lengthy examination but with the physical health stuff the majority is tick boxes to be honest and entering just the blood pressure score or the height or something and there's minimal typing involved. So, I think having it all in such an easy format is really user friendly. *Yeah it's good.*" (C3, Healthcare professional)

A patient-held physical health plan (Intervention 2)

The patient-held physical health plan (PHP) was also updated in December 2017 by **P5, P9** and **P19**. These were minor changes resulting from the change in recommended allowances for alcohol consumption in 2016 and the addition of a directory of borough-specific support services (143).

Educational resources to support service users and staff (Intervention 3)

The educational resources to support service users and staff were expanded to include two-day physical health training for all staff, following the appointment of a head of physical health training for the trust (P19) in October 2017.

The training provided basic clinical skills for undertaking the PHA and communications skills/motivational interviewing to discuss physical health with patients and service users, as part of the Making Every Contact Count (MECC) agenda, which aims to: "support the idea of making every contact with patients and [service users] count to help change behaviour" (144).

4.4.15 Sustainability on Ward-1

Although the implementation of the interventions developed within SHINE1 continued through the transition period and SHINE2 set-up (June 2016 to January 2017), no data were collected to assess this. In February 2017, the Jade version of the multi-professional PHA form was introduced to Ward-1, a month before the other wards. P4 was appointed as the Ward-1 Champion during SHINE1 and continued the role until September 2017, when they were promoted to QI Manager for the MHU. Working alongside them was a Health Care Assistant, P8, who was tasked with supporting **P4**, especially with the data collection for **Ward-1**, which included weekly spot checks and improvement measures. The spot checks were developed for SHINE2 as a way of proactively identifying patients that had missing elements of their physical health assessment, so these could be completed prior to discharge, when the improvement data were collected. P4 and P8 worked with the Ward-1 manager and ward staff, including doctors, nurses and allied health professionals, with P13 and P16, to create a culture where norms and values are shared and that responsive to the physical health needs of the patients (145). Whilst **P4**'s time was offered as part of their role, P8's time was paid for by the project budget as a research assistant. P8 was key in collecting the spot check data and following up with the named staff (responsible for the physical health of their patient) to encourage them to complete all physical health assessments and provide information to the patients, in the form of the patient-held PHP, and refer/signpost/intervene as appropriate. P8 collected Ward-1's discharge data directly from the EHR from February 2017, which was entered on to WISH. The data were then visualised, and I generated a report for each of the wards. A new indicator was introduced to monitor the distribution of the patient-held PHP. The monthly implementation data for Ward-1 are shown in Figures 29-34, which demonstrate a stable process with similar values to those achieved in SHINE1.

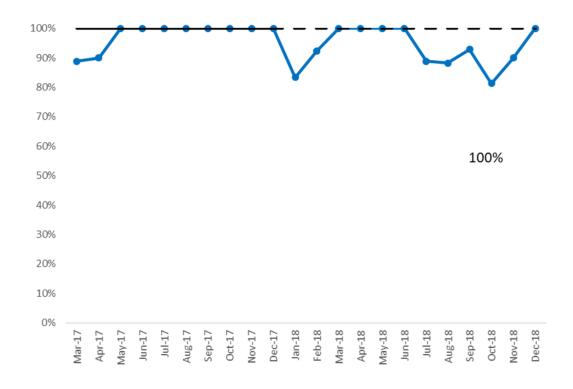


Figure 29: Monthly percentage of patients discharged from *Ward-1* with a physical health assessment. Median of 100%

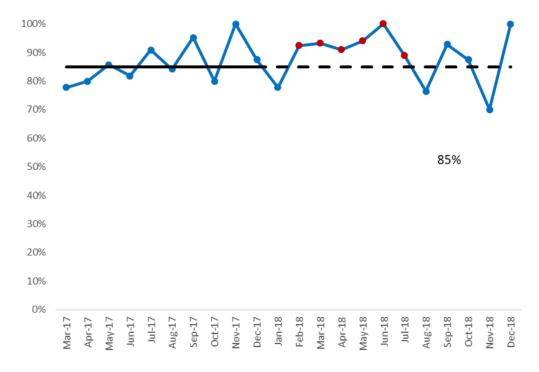


Figure 30: Monthly percentage of patients discharged from *Ward-1* with a documented smoking status in their physical health assessment. Transient increase noted from 02/2018 to 07/2018, so median not revised. Median of 85%

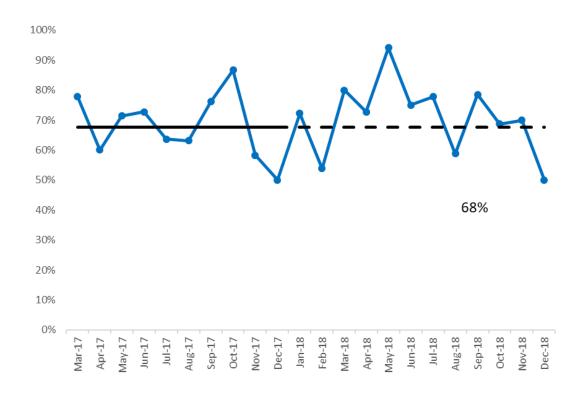


Figure 31: Monthly percentage of patients discharged from *Ward-1* with a documented body mass index (BMI) in their physical health assessment. Median of 68%

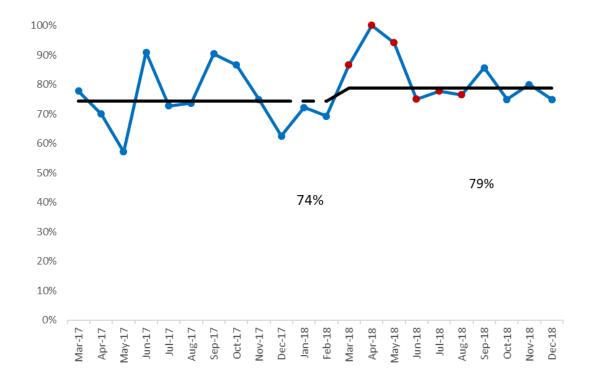


Figure 32: Monthly percentage of patients discharged from *Ward-1* with a documented systolic blood pressure in their physical health assessment. Increase from a median of 74% (03/2017 to 12/2017) to 79% (03/2017 to 12/2018)

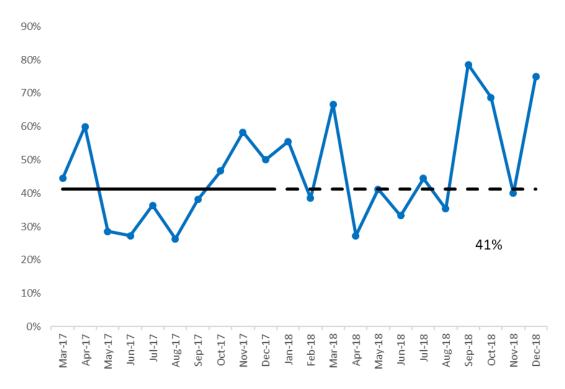


Figure 33: Monthly percentage of patients discharged from *Ward-1* with a documented cardio-vascular risk score in their physical health assessment. Median of 41%

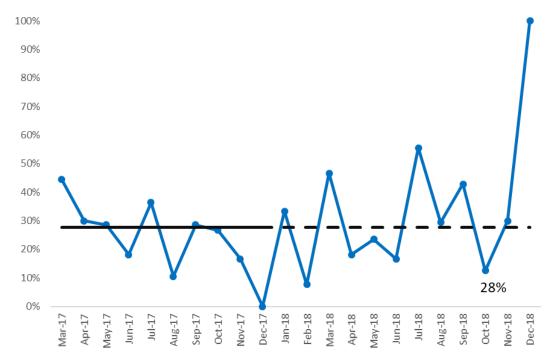


Figure 34: Monthly percentage of patients discharged from *Ward-1* with physical health plan. Median of 28%

In comparing the average values during the baseline (April 2014 to February 2015), the implementation period (March 2015 to May 2016) and the sustainability period (March 2017 to December 18), it is clear all measures demonstrated sustainability during the final 22 months (*Table 12*).

Table 12: Comparison of the recording of key physical health indicators during the baseline (B), implementation (I) and sustainability (S) periods *- there was an improvement during the sustainability period from 74% to 79%

Ward-1 Indicator	В	I	S
Percentage of patients that received a physical health assessment (PHA)	81%	97%	100%
Percentage of patients where the smoking status was documented in the PHA	80%	71%	85%
Percentage of patients where the BMI was documented in the PHA	22%	59%	68%
Percentage of patients where systolic blood pressure was documented in the PHA	22%	76%	79%*
Percentage of patients where a CVD risk-score was documented in the PHA	N/A	32%	41%
Percentage of patients with a physical health plan on discharge	N/A	N/A	28%

The collection, inputting, analysis and sharing of data required significant time from the *Ward-1* Champion, *P4*, Health Care Assistant, *P8* and myself. In an attempt to streamline this process, multiple attempts were made to work with the information team in the Trust to integrate the analysis into Tableau, the reporting system, but these were unsuccessful (§4.2.3). The first attempt involved the team working directly with the information team to establish the measures for Tableau. This failed as there was a conflict between the reports that would be generated for the QI project and the reports that would be required for the CQUIN, due to differences in the definition of the denominator. The CQUIN only considered patients that had been admitted for more than seven days as eligible for a physical health assessment, whilst the improvement measures identified all patients, regardless of their length of stay, as eligible for a physical health assessment.

4.4.16 Scaling up across the Mental Health Unit

In addition to sustaining the interventions on Ward-1, the aim of SHINE2 was to introduce the interventions onto the five other wards within the MHU, three treatment wards: Ward-2, Ward-3 and Ward-4; and two psychiatric intensive care units (PICU): Ward-5 and Ward-6. The implementation strategy involved creating Ward Champions for each ward, as was done on Ward-1. Staff were also encouraged to participate from the beginning, with a nurse and matron from Ward-2 and nurse from Ward-3 attending the AEM workshop in September 2016 (§4.4.12). In August 2017, an additional strategy was developed by creating a monthly workshop for the Ward Champions setup by P21. These were intended to create a unique space for Ward Champions from all six wards to come together and plan, test and reflect on changes they could make on their own wards to encourage use of the interventions. The Ward Champions workshops were initially setup by **P21** but taken over by **P15** in October 2017 with the explicit use of PDSA cycles as ways to identify potential solutions to increase use of interventions and to test on wards, with the opportunity to feedback and share findings in subsequent workshops. The recording of the PDSA cycles was supported by P5, a service user representative, who inputted the PDSA cycles onto WISH, the online QI system used to also record the improvement data. The Ward Champions were provided with the monthly reports on the improvement measures:

- 1. Percentage of patients that received a physical health assessment (PHA)
- 2. Percentage of patients where the smoking status was documented in the PHA
- 3. Percentage of patients where the BMI was documented in the PHA
- 4. Percentage of patients where systolic blood pressure was documented in the PHA
- 5. Percentage of patients where a QRisk-score was documented in the PHA
- 6. Percentage of patients that received a Physical Health Booklet.

Data were collected directly from Jade, the EHR, from March 2017 to December 2018 and entered on to WISH by *P8*, the Health Care Assistant, as outlined above (§4.4.14). The data were then visualised as time series run charts for each ward (*Figure 35*) and I reported on these at the QI meeting and they were used in the Ward Champions' workshop.

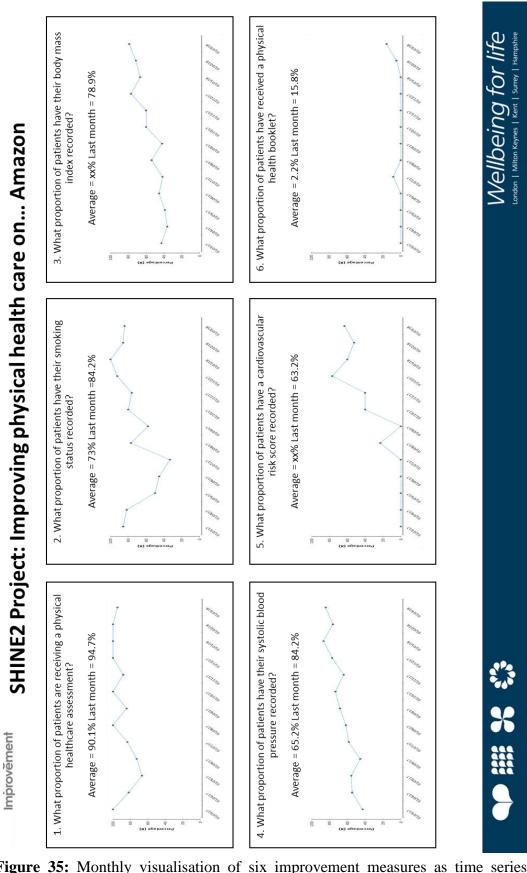


Figure 35: Monthly visualisation of six improvement measures as time series charts

Attendance at the Ward Champions' workshop was variable (*Table 13*).

Table 13: Attendance of wards at Ward Champions' workshops (August 2017 to July 2018)

Date	Ward-1	Ward-2	Ward-3	Ward-4	Ward-5	Ward-6
Aug 17	X	X	X	X		X
Oct 17	X	X	X	X	X	
Oct 17	X	X	X	X		
Nov 17	X	X	X	X		
Dec 17	X	X	X	X		
Jan 18	X		X		X	
Feb 18	X		X	X	X	X
Mar 18	X	X	X	X	X	X
Jun 18	X		X	X		
Jul 18	X		X			X
Aug 18	X		X	X		X

The final analysis presented here (*Figures 36-41*) shows the monthly aggregated implementation data for the whole of the MHU, including *Ward-1*, analysed using statistical process control to generate p-charts (131). This demonstrates improvements in five of the six improvement measures including an increase in the percentage of patients that received a PHA from 83% to 94%; a documented BMI from 48% to 68%; a document ted systolic blood pressure from 59% to 79%; a documented QRisk-score from 11% to 40% and the percentage given a Physical Health Booklet from 7.3% to 23%. The charts were generated by Yewande Adeleke, Information Officer, CLAHRC Northwest London.

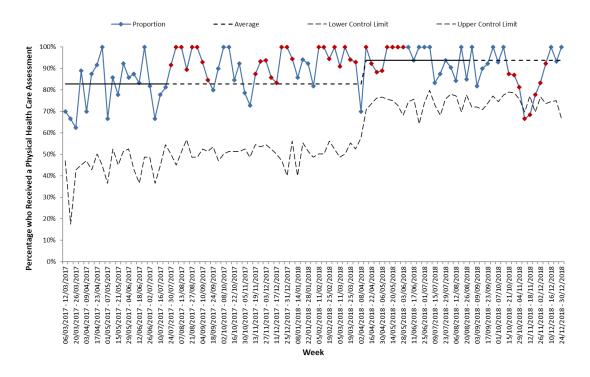


Figure 36: Percentage of patients that received a physical health assessment (PHA). Mean increased from 83% to 94%

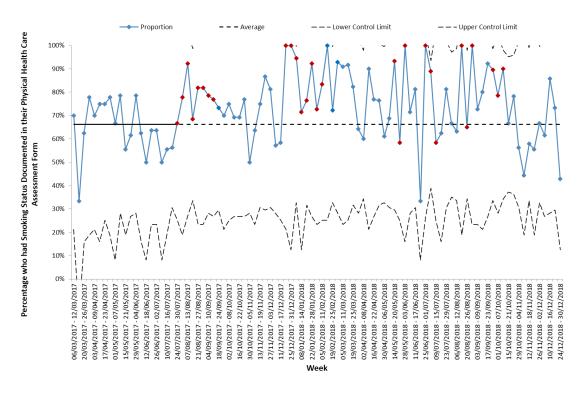


Figure 37: Percentage of patients where the smoking status was documented in the PHA. Mean is 66% with some transient changes indicated by the red data points.

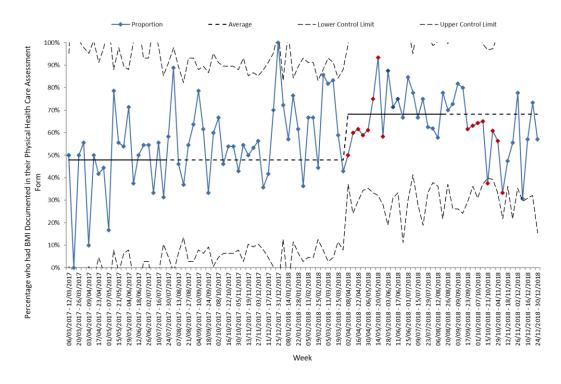


Figure 38: Percentage of patients where the BMI was documented in the PHA. Mean increased from 48% to 68%

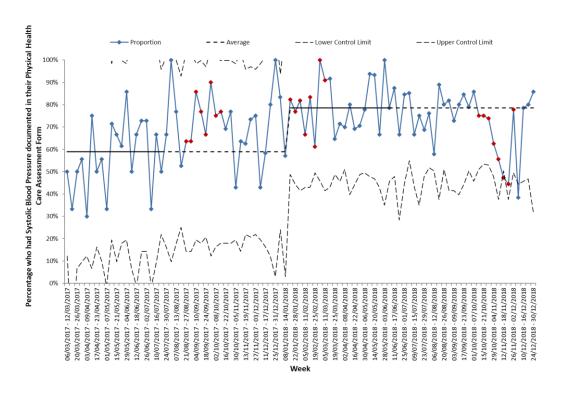


Figure 39: Percentage of patients where systolic blood pressure was documented in the PHA. Mean increased from 59% to 79%

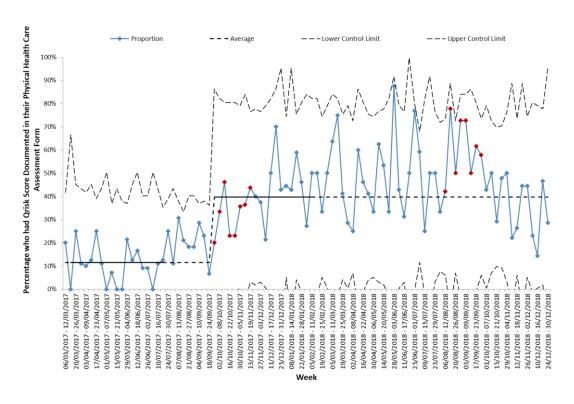


Figure 40: Percentage of patients where a QRisk-score was documented in the PHA. Mean increased from 11% to 40%

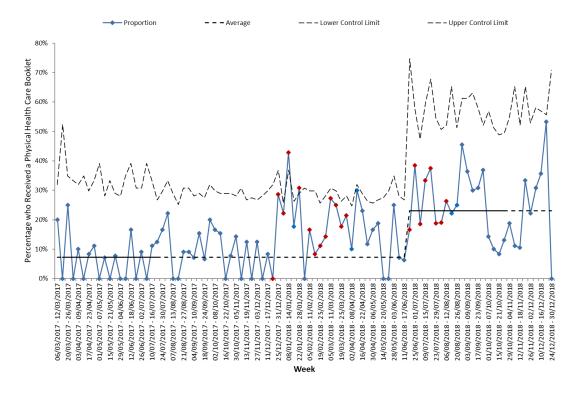


Figure 41: Percentage of patients that received a Physical Health Booklet. The mean increased from 7.3% to 23%

4.4.17 Spreading to the community

A recurring issue in both SHINE1 and SHINE2 was the spread of the physical health pathway to the community health services. In SHINE1, two potential sites had been identified, one in the North of the borough and the other in the South. These were soon discounted as sites for spread due to the lack of initial engagement in the development of the interventions, which mostly focused on the inpatient setting, and the sites' almost continuous re-organisation.

In late 2016, during the set-up of SHINE2, it seemed difficult to get a community site on board. By early 2017, several potential sites were identified that were interested. This sudden interest was attributed to the plans for the organisational rollout, as SHINE2 offered an opportunity for a community site to gain some additional support. The potential sites included a Clozapine clinic and Wellbeing clinic and an Early Intervention Team, Community Mental Health Team and Older Adults services. It was only in October 2017, over a year after SHINE2 had started that the Early Intervention Team developed its own QI project to spread SHINE2. However, this slow progress meant that the current research could not focus on the implementation in this setting.

4.5 Summary

Through re-constructing and describing the case study as an 'organisational project', the use QI methods in navigating complexity can be observed. This highlights the need to integrate perspectives from the local setting, the project and the organisation to understand the health system in which the improvements are being introduced. Identifying the strategic intentions, which can be transformed into everyday practices, required several key stages that were inter-related and non-linear. These included the sense-making processes that situated a problem within a clinical and organisational context; the development and testing of interventions that responded to the problem; the creation of a system to monitor and assess implementation and clinical and organisational processes; and changes to cultural and relational aspects of the clinical and organisational milieu.

These were mediated via a range of QI methods that worked in concert to achieve this change, and none of which alone would likely have been enough to create the observed organisational change.

4.5.1 The sense-making processes

Situating the problem within the clinical setting and broader organisational context created a set of strategic intentions. This was achieved through several associated activities that required the QI project team to make sense of the problem at different levels of the system by drawing on existing policies and reports, as well as local data collection and analysis. Involvement of the QI project team and wider stakeholders in the participatory methods offered an opportunity for early engagement in setting the priorities for the project and mobilising support. This process also, maybe unintentionally, created a 'community of practice'. However, the narrative of the case study fails to explicate the detail of this process, especially related to the roles of actors and the actions they took. This is further elaborated in Chapter 5 (§5.2).

4.5.2 Developing and testing interventions

Through planned workshops outside the regular team meetings, a wider group of local stakeholders, including service users and front-line staff, were engaged in the project. This process supported the identification of potential interventions including a PHA. This intervention was iteratively co-designed with doctors and nurses from the ward. Similarly, a patient-held physical health plan was co-designed by service users and staff. In addition, an intervention, as part of the Recovery and Wellbeing College was co-produced with service users and staff. Collectively, these three interventions represented a comprehensive physical health pathway that offered an assessment of physical health, communication of risk, and signposting to services to support risk reduction. The pathway recognised the complexity of the needs of the patients and the different points on the pathway at which different interventions were appropriate to create a systemic response to physical health needs. Whilst the codesign of interventions with different professional groups and service users resulted in the development of interventions that were locally acceptable, barriers to their implementation remained.

The developing of the interventions remains a key aspect of the case study and warrants further investigation using a more refined analytical lens in Chapter 5 (§5.3).

4.5.3 A system to monitor and assess implementation

A key feature of many, if not all, QI projects, is the development of improvement measures to assess implementation. In this case study, an effective system was created to assess the implementation of the interventions through monthly data collection. In conjunction with implementation strategies, such as the development of Ward Champions, the effectiveness of the strategies could be assessed and modified. Generally, the QI project team were interested to see how well the project was progressing but where the data demonstrated a reduction in the completion of assessments, these were often 'excused' using explanations such as 'that was Christmas'...or 'we were short-staffed'. Similarly, where SPC rule breaks were identified, indicating an improvement in the process, these were celebrated as success with little real understanding of how the improvements had been achieved. Often, it was explained that the staff were simply 'trying harder' which resulted in the improvement. So, whilst data were available, the response to the data was often inaction. One possible exception was the use of the data by service users to question the team about its responsibility to ensure that every inpatient received a physical health assessment. However, in general, despite the presence of what may have seemed an effective measurement system, this rarely resulted in 'data-driven change'. This finding suggests the need for further investigation of the effectiveness of different activities in supporting the implementation process, which is included in Chapter 5 (§5.4).

4.5.4 Changes in culture and relationships

It was generally agreed amongst the team that feedback was important in creating a culture of openness and honesty about 'performance' and recognising room for improvement. Following the perceived success of the project, the scale-up and spread of the interventions to other wards on the MHU was initiated.

This provided an opportunity for the team to explore new strategies for engaging with the wider clinical staff across the wards which resulted in the establishment of the Ward Champions' workshops. This mechanism was engaged with variably across the wards, with greatest involvement from *Ward-1*, *Ward-3* and *Ward-4*, and little initial engagement from *Ward-5* and *Ward-6*, the PICU wards. This was often ascribed to several 'cultural' differences between the staff of the PICUs and the general wards and to managerial staffing issues on those wards.

In the Ward Champions' workshops, clinical staff were encouraged to share the challenges they faced in engaging with colleagues on their wards and ideas for overcoming these barriers. Through the workshops new relationships were created between key staff on different wards where they could support each other and share experiences. This an example of the relational work of actors that was required for the development, implementation and scale-up of the QI project and if further explored in Chapter 6 (§5.0).

5.0 The actions of actors in the process of the co-creation of knowledge

5.1 Overview

This chapter re-constructs the case study to focus on the 'actions of actors' using a familiar KMb framework. The analysis is structured using the eight stages of the knowledge to action (K2A) cycle (§3.7.2). This is intended to respond to the gaps identified in the previous analysis related to the sense-making processes (§4.5.1), the development and testing of interventions (§4.5.2) and the creation of a system to monitor and assess implementation (§4.5.3). Furthermore, the analysis aims to unpack the process of the co-creation of knowledge within the case study.

The initial section (§5.2) deals with the construction and reconstruction of the problem that the case study set out to address. Using two of the K2A cycle constructs - identify problem and identify, review, select knowledge - the analysis presents how the initial definition of the problem and proposed solutions were described at the macro-level (§5.2.1). However, over time this was re-framed from the macro-level to a meso (organisational) (§5.2.2) and micro (practice) (§5.2.3) perspective. These different perspectives are combined with evidence-based guidelines to create a framework for action (§5.2.4).

The second section (§5.3) describes the social processes that resulted in the codesign of the interventions. This draws on two of the K2A cycle constructs - adapt knowledge to local context and assess barriers to knowledge. A detailed analysis of the process of designing each of the interventions is offered: the physical health assessment form (§5.3.1), patient-held physical health plan (§5.3.2), and educational resources to support service users and staff (§5.3.3). Together, the interventions were intended to create a comprehensive physical health pathway (§5.3.4).

The third section (§5.4) explores the implementation, sustainability and scaling-up of the interventions which formed the physical health pathway. The analysis is based on four of the K2A cycle constructs: select, tailor and implement interventions; monitor knowledge use; evaluate outcomes; and sustain knowledge use.

The analysis is presented using five of the implementation strategies outlined by the Expert Recommendations for Implementing Change (ERIC) taxonomy (146–148). These include develop stakeholder inter-relationships (§5.4.1), train and educate stakeholders (§5.4.2), use evaluative and iterative strategies (§5.4.3), provide interactive assistance (§5.4.4) and engage consumers (§5.4.5). Following this analysis, several organisational challenges to the implementation, sustainability and scale-up of the interventions are offered (§5.4.6). The final section (§5.5) summarises a number of themes from the analysis: the problem definition, the codesign of interventions, the implementation, sustainability and scaling-up of interventions and an the emergent theme of accountability and responsibility for delivering interventions. Whilst this chapter does not directly address the research question: what is the process of the co-creation of knowledge in a QI project? it provides the basis for outlining the actions of actors in the case study using a KMb framework. It is through this analysis that the results can be interpreted using an existing conceptual model of the co-creation knowledge from the KMb in the discussion (§7.3).

5.2 The construction and reconstruction of the problem

This section analyses how the initial problem, constructed by drawing on specific evidence and policies (outlined in the original application), became defined as a set of nested problems reconstructed through a progressively more refined understanding of the different system levels. The reconstruction of the problem led to a more nuanced understanding of system complexity. The use of reports and policy documents, as well as local data collection and analysis, supported the shifting understanding of the problem. The reconstruction of the problem drew on the experiential knowledge of healthcare staff to bridge the divide between the reports and analysis in the original application and the professional experience of the local actors involved in the health system. As the problem definition became more detailed through the use of situated knowledge (knowledge generated through sociotechnical process and practices), this led to emerging solutions located within an evidence-based framework, namely The Lester Tool (124).

The Lester Tool (*Figure 17*) draws on multiple sources of evidence and guidelines to provide: "an intervention framework for people experiencing psychosis and schizophrenia" focused on the assessment, monitoring and treatment of physical health in people with SMI based on the relevant NICE guidelines. The analysis of how 'the problem' was constructed and re-constructed suggests there are several levels at which the problem was conceptualised by the improvement team. These changed over time. Initially, the conceptualisation was focused on an appreciation of systemic problems drawing on high-level reports, policies and guidelines (§5.2.1). This was followed by an organisational understanding and quantification of the problem (§5.2.2). Ultimately the conceptualisation became an exploration of care processes to develop a practice-based understanding of the problem (§5.2.3), where solutions were more readily available, or could be more readily envisaged and implemented (*Figure 42*). The Lester Tool offered a flexible framework which combined the evidence and guidelines but allowed local actors to situate this knowledge within their own experiences and local practices (§5.2.4).



Figure 42: Construction and reconstruction of the problem at a macro (system/policy), meso (organisational) and micro (departmental/clinical) level

5.2.1 Initial definition of the problem and proposed solutions

The initial problem outlined in the SHINE1 application by P19, Chief Psychologist and *P13*, Consultant Psychologist, related to the poorer physical health experienced by people with severe mental illness (SMI), compared to the general population, that resulted in a reduced life expectancy of up to 20 years.

This problem drew on the explicit link between SMI and an increased prevalence of three main physical health problems/long-term conditions: respiratory conditions, diabetes and cardiovascular disease, caused by smoking, physical inactivity and weight gain. Physical inactivity and weight gain can be side effects of antipsychotic medications. These side effects can include lethargy, increased appetite, and impaired metabolism. The iatrogenic role of antipsychotic medication was framed as a patient safety issue and rarely acknowledged by professionals working with this population. At a system level, the application highlighted the impact of the division of mental and physical health services within the UK, resulting in fragmentation and poor inter-agency communication. In addition, the lack of clarity about responsibility for meeting the physical health needs of people with SMI, including routine monitoring of physical health and ensuring access to appropriate risk-reduction interventions was acknowledged (119):

"The physical and mental health care of the same individual [are] being separated in a way which treats them as almost completely unrelated. The physical care of the patient is the responsibility of the hospital while they are inpatients, but of the GP when they are outpatients and both mental and physical healthcare are dealt with by the GP if the patient is stable." (SHINE1 application, 2013).

The initial solution proposed in the application was to deliver the routine monitoring and management of physical health, the delivery of or referral to appropriate interventions and the monitoring of medication related risks through the use of 'care bundles' (§4.4.7). The clinical leads noted the relative success of care bundles in the acute physical healthcare setting as a way of: "translating evidence into practice and improving patient safety and outcomes", although acknowledged that this approach was rarely used in the mental health context. It was not clear from the application whether the routine monitoring of physical health would be integrated in the care bundle, or a screening tool used to identify individuals at risk and the care bundles used to deliver interventions. However, it was clear from the application that the care bundle should be co-designed by front line staff and service users, and the care bundle(s) delivered at specific points along the care pathway.

In particular, this included transitions or interfaces of care such as admission to ward, transfer between wards, discharge from ward to community mental health team, and any subsequent readmission. The engagement of front-line staff and service users was pivotal to designing solutions, and in prioritising problems, rather than having them both predetermined by the QI project team. The application was clear that the involvement of front-line staff in both exploring the problem and identifying potential solutions was central, and that they should be represented in, and be part of, the core improvement team. The application elaborated that the approach would include the use of the principles of Plan-Do-Study-Act cycles 'to capture data and drive improvement', with an emphasis on ensuring that any solution would be effective and both sustainable and scalable at a local level, with the potential to be spread nationally.

5.2.2 Organisational understanding of the problem

In 2014, the National Audit of Schizophrenia reported a nationwide assessment of mental health services, including the provision of physical health services for people with SMI (121). The audit was undertaken and reported by the Royal College of Psychiatrists (RCPsych), commissioned by the Healthcare Quality Improvement Partnership (HQIP), key stakeholders in QI in mental health services. The report used six key physical health monitoring and assessment indicators:

- Family history [of Diabetes and cardiovascular disease (CVD)]
- Smoking status
- Elevated body mass index (BMI)
- Blood glucose control (blood glucose and/or HbA1c)
- Blood lipids (total cholesterol and HDL)
- Blood pressure

These indicators were explicitly linked to the NICE clinical guidelines for Schizophrenia (CG82, replaced by CG178 in 2014 (122)). Therefore, in assessing compliance with these indicators, the audit represented an opportunity to identify how well the organisations included were delivering 'evidence-based healthcare'. However, the audit reported on samples of service users drawn from the community, not from the inpatient setting.

Thus, whilst this data was helpful to understand the organisational benchmark the team required further data to understand the gap in their services. Results from the audit were compared to the previous NAS in 2012 to provide an assessment of change over time for all the Trusts included. This presented a mixed picture, where some Trusts improved on some metrics and others deteriorated. The report described the proportions of patients that had had five cardio-metabolic indicators assessed in both 2012 and 2014, and provided an assessment of the provision of necessary physical health interventions (*Table 14*).

Table 14: Comparison between physical health monitoring of cardio-metabolic indicators and intervention in 2012, 2014, 218 for all Trusts, and 2014 and 2018 for 'The Trust' (121,149).

	All Trusts			The Trust			
	2012	2014	2018	2014	2018		
Standard 4 – monitoring of physical health risk factors							
Monitoring of all five risk factors	27%	34%	42%	16%	59%		
Monitoring of smoking	87%	89%	86%	86%	93%		
Monitoring of BMI	48%	52%	65%	43%	79%		
Monitoring of glucose control	50%	57%	59%	42%	65%		
Monitoring of lipids	48%	58%	57%	34%	72%		
Monitoring of blood pressure	57%	62%	66%	46%	82%		
Standard 5 – intervention offered for identified physical health risks							
Intervention for smoking	57%	59%	79%	N/A	84%		
Intervention for BMI > or = 25kg/m2	76%	71%	78%	82%	74%		
Intervention for abnormal glucose control	53%	36%	75%	N/A	68%		
Intervention for elevated blood pressure	25%	25%	58%	N/A	68%		

The report identified the need for improvement in the routine monitoring of physical health and in access to appropriate interventions. The report quantified the problem nationally and offered a set of indicators that could be used to measure improvement. There was variation temporally, as demonstrated by the comparison between 2012 and 2014, and between Trusts resulting in geographic variation.

Whilst the benchmarking and ranking of Trusts in terms of indicators demonstrated variation, CNWL performed particularly poorly on the monitoring of blood lipids, which at 34% was third from bottom in the ranking. Overall, only 16% service users were shown to have five of the six cardio-metabolic risk factors (excluding family history) recorded, placing the Trust fifth from the bottom nationally. This poor performance was emphasised in a feature article contributed by *P16*, one of the clinical leads (150):

"Like many other trusts in London and elsewhere, we know that physical health monitoring is an area we need to improve on—as shown in last year's National Audit of Schizophrenia." (Lancet Psychiatry, 2016).

The NAS report made a specific recommendation, that there needed to be a: "change [in] culture which often regards physical healthcare and mental healthcare as separate". The report concluded that a number of barriers existed to the monitoring of physical health (121):

"(i) restricted availability of staff time, appropriate facilities and equipment; (ii) lack of formal systems to review physical health data and interventions required on at least an annual basis; and (iii) lack of formal arrangements regarding collaboration between primary and secondary care in relation to physical health. Trust Boards should take responsibility for monitoring their own arrangements" (NAS, 2014)

The analysis in the NAS report provided an indication of how well the Trust was performing against the standards and compared with other Trusts. However, there was little insight into the situation for inpatients within the specific acute mental health unit (MHU). I explored the availability of existing organisational data from the electronic health record (EHR) with *P13*. After which, we worked with analysts from the Directorate of Information and Business Intelligence to undertake an audit.

The audit included 247 patients that had been discharged from *Ward-1* during the preceding 10-months. It was designed to include the same indicators as presented by the NAS report, except for glucose control and blood lipids, as were not readily extractable from the clinical system. The audit provided a baseline assessment for the QI project and helped the team understand how well they were currently delivering physical health assessments on *Ward-1*:

"The analysis has demonstrated that whilst there has been good coverage of patients with regards to receiving a nursing physical health assessment, the individual components of the assessment have been less well recorded... of the 247 patients... 201 (81.3%) had a physical health assessment but only 53 (21.55%) had a documented body mass index (BMI), 55 (22.35%) had a systolic [pressure] recorded but 198 (80.1%) had their smoking status documented... the analysis demonstrated the feasibility of reporting weekly parameters, but required further work to assess the ability to generate this in real-time, which would provide an opportunity to investigate when rates are low and identify local barriers to completion and pro-actively support staff to suggest potential solutions to overcoming these challenges" (SHINE1 Final Report, 2015).

The figures for *Ward-1* for the assessment and recording of both BMI (23%) and systolic pressure (22%) were much lower than those presented in the NAS report for the Trust, which were 43% and 46%, respectively. Whilst having data to confirm that there was scope for improving the assessment of physical health, QI promotes engagement with a wide range of stakeholders, including front-line staff and service users, to understand their perspectives of the problem.

5.2.3 A practice-based understanding of the problem

The preceding chapter (§4.0) highlighted the range of QI methods employed by CLAHRC NWL to support project teams to engage with various stakeholders, outlined in the stakeholder map (*Figure 20*).

At the beginning of the project, Action Effect Method (AEM) and process mapping (PM) workshops were held (§4.4.4 & 4.4.5). The Action Effect Diagram (AED) was developed by the CLAHRC NWL team to provide a structured approach to engaging with a diverse range of stakeholders (38). This was based on an enhancement of the Driver Diagram which is commonly used in QI (139). The facilitated workshops offered opportunities for stakeholders to explore their own perceptions of a problem and generate consensus with other participants on the aim of a QI project and activities that could be undertaken to achieve that aim.

In the workshops, stakeholders were able to voice their opinions drawing on their own experience and knowledge to suggest ideas for the project and to ensure that the project fitted into the local context and to highlight some potential barriers to implementation. Importantly, this workshop offered an opportunity for people to raise issues that might have been out of scope of the project but were clearly important to the individual. In addition, the workshop focussed on ensuring those that were involved were able to articulate what they wanted to gain from being involved in the project, both personally and for others. The main output from the workshop, which was the AED (*Figure 28*), attempted to capture many of the ideas and suggestions from the stakeholders that attended. Although this included some issues that were clearly beyond the influence of the project, such as the organisational processes for reporting blood test results, but which could have had a negative impact on the project.

"... To facilitate discussion about identifying a shared aim for the initiative and ensure the aim was within the spheres of influence and control within the team... [which became] to improve the physical wellbeing of people using [Ward-1] and [community] Team" (SHINE1 Final Report, 2015).

Due to the wider range of stakeholders involved across the wards in SHINE2, the AEM workshop was repeated in October 2016, although the aim was similar to SHINE1. There were 14 participants, with representatives from different professional groups including pharmacists, nurses, medics, psychologists, and service users and staff from three of the six wards.

At the start of the meeting, *P16* introduced the problem that the project aimed to address. This problem usually framed in terms of the reduced life expectancy of people with SMI and the need for improvements in their physical health. However, *P16* attempted to frame this problem as one that healthcare professionals, like those attending, were perpetuating through their inaction about the physical health problems of the patients that they cared for:

"A number of causes [of reduced life expectancy] were discussed and the role of healthcare professionals in perpetuating the role highlighted. P16 reflected on the patients they see in the unit and the problems that they face due to the unequal access to healthcare. This acted as a call to action for those in the room by highlighting the implementation gap- 'even if we have the information and know the risk, doing something about it remains a challenge...' P16 also described [the] situation as a 'perfect storm'- where those most at risk have poorer access to interventions and subsequent poorer outcomes and increased mortality." AEM Workshop, October 2016

In the workshop, healthcare professionals re-iterated the lack of clarity in the systems and health policies about their professional responsibility for the physical health of their patients. Whilst SHINE1 had focussed on developing interventions and their implementation on a single ward (*Ward-1*), *P13* highlighted a new problem for SHINE2 related to the challenges of spreading their implementation to other wards. This added an extra dimension to the problem, as despite having a solution that worked in one setting, as demonstrated by SHINE2, moving to another setting, albeit a similar ward in the same unit, threw up new challenges. *P13* highlighted some challenges that may have affected the uptake and implementation on different wards to different degrees. The first was a challenge seen across London: high staff turnover. The second was the range of acuity of the patients admitted to different wards within the unit.

As well as testimonials from staff about their experience of the challenges of addressing physical health, service users were prompted to contribute. *P24*, a service user, highlighted how being involved in the project had raised their awareness of their own physical health. *P24* reported that she had been encouraging service users and their carers to get involved in projects to raise awareness of the physical health of people with SMI and to consider how they could motivate people to take care of their physical health and make changes to their lifestyle. *P16* recognised that behaviour change remained a significant challenge. *P13* confirmed that simply assessing patients' physical health was clearly insufficient in initiating changes that would lead to improvements in physical health.

These discussions allowed participants to provide their own perspectives of the problem, drawing on their experience of the system and proposed potential solutions. During the meeting, the opinions and viewpoints captured by the facilitator and the supporting team were re-presented to the stakeholders, who were invited to vote on ideas and prioritise them accordingly.

The process mapping (PM) workshop (§4.4.5) in November 2014 brought together healthcare professionals from the wards, including doctors, nurses and pharmacists along with service users and encouraged participants to discuss their own practices and experiences. Collectively, the stakeholders created a typical process where different professionals were involved in the admission of a new patient and they identified where elements of physical health were or were not assessed, which was represented visually (*Figure 19*). This uncovered processes and practices that duplicated efforts in the assessment of physical health of patients on *Ward-1*:

"... [The process mapping was used] to identify current processes and systems involved in the assessment of a patient's physical health. [Which uncovered] two existing parallel systems for collecting information about the physical health of the patients, one by doctors, the other by nurses, each not aware of the other, that were recorded in two separate places." (SHINE1 Final Report, 2015).

Whilst service users formed part of the improvement team, and participated in the PM and AEM workshops, their input was limited at the early stage of the project. However, service users identified how information was communicated to patients about their physical health as a particular issue:

"Although assessments were taking place, there was no clear way of feeding these back to service users. Interventions were rarely happening, and when they were, service users themselves were not kept well informed. There was little or no consistent input about lifestyle choices or resources to help make lifestyle changes." ('My Physical Health Explained' poster, 2015).

This issue was highlighted by the Care Quality Commission (CQC) in its inspection report, which identified the need to do more on the wards to involve patients in their own care:

On the acute wards for adults of working and age and PICU, some patients said they did not always feel involved in their care planning" (CQC Quality Report, 2017)

5.2.4 An evidence-based framework for action

As different aspects of the project were developed, including ideas and activities to improve physical health, these resources offered some legitimacy for them. This was especially the case for the AED, where activities were linked to an evidence-base, either directly to specific National Institute for Health and Care Excellence (NICE) guidelines or through the Lester Tool. A report co-authored by *P16* and the researcher in 2017, was submitted to NICE to share an example of how NICE guidelines were implemented. The report made the link between the guidelines and the interventions more explicit, specifically identifying the recommendations that were aligned to the project from CG178 and CG185 (122,123). These recommendations outlined the need to address the physical health of people with psychosis/schizophrenia and bipolar disorder, especially those taking antipsychotics. These recommendations themselves were also linked to other NICE clinical guidelines on obesity (CG43), lipid modification (CG67) - since updated and replaced by CG181 - and Type 2 diabetes (public health guidance 38) (151–153).

The Lester Tool, and the NICE guidelines it incorporates, represented the biomedical knowledge derived from clinical research that underpinned the recommendations. Whilst the project did not set out to implement the tool, it nonetheless did so.

This provided a guiding framework for the content of the interventions and the formation of the physical health pathway. Although the Lester Tool simply offers a summary of the evidence that should underpin evidence-based care it does not offer any solutions to implementation nor the wide-ranging knowledge required to support the 'knowledge to practice' process. However, it does offer a framework within which interventions can be co-designed by local healthcare professionals and service users that can simultaneously meet the needs of the local system, including healthcare professionals and patients, whilst offering some assurance that the interventions were 'evidence-based' and thus if implemented would achieve the necessary improvements in outcomes (quality of life, physical health and life expectancy).

5.3 The co-design of a physical health pathway

This section analyses the co-design of the inpatient physical health pathway, comprised of three interventions that were developed largely sequentially, but with some overlap (*Figure 21*). This development process offered the opportunity to align the interventions to be delivered successively at different points in the patient pathway; i.e. on admission, at discharge and in the community. The analysis focuses mostly on the activities related to the development of the multi-professional PHA (§5.3.1) and a patient-held physical health plan (PHP) (§5.3.2), both of which were explicitly developed for the inpatient setting. The third intervention, educational resources to support service users and staff (§5.3.3) is touched on in relation to these interventions, as it was intended to complement and support the earlier interventions. It is explored in as much detail as possible given the limited documentation of its development, as it was rarely discussed or reported at the monthly QI project team meetings.

It is important to recognise the value of intervention 3 in ensuring that service users with a risk of developing physical health conditions were provided with appropriate interventions and care following their discharge from hospital to address both their mental and physical health. All three interventions contributed to the physical health pathway (§5.3.4). During SHINE1, interventions were designed to support the assessment, recording and communication of inpatients' physical health. These were reviewed and re-designed during SHINE2, especially related to their content and the supporting organisational processes, such as training, to support implementation.

5.3.1 The multi-professional physical health assessment form

The PM highlighted a system that duplicated the work of doctors and nurses through two separate recording systems. In order to integrate the two forms and streamline the process, a working group was convened. *P16* led the working group, supported by *P1*, the project manager. It included input from the nurses, junior doctors and managers from *Ward-1*. A major challenge in this process was ensuring consensus about the structure and content of the assessment, but at the same time maintaining utility. Plan-Do-Study-Act (PDSA) cycles were used as a framework to initiate and guide changes to the form.

Ward staff undertook trials of changes to develop the content and structure of the assessment iteratively. As highlighted above (§5.2.4), the interventions drew heavily on the Lester Tool, adapted to the local system. The initial form developed by *P16* comprised both the physical health assessments (PHA) and the clinical interventions; however, the final form focussed just on the assessment of cardio-metabolic indicators as part of physical health assessment of the patient. This was partly in response to shifting the discussion of the results of the assessment into intervention-2 when the patient was provided with the personalised patient-held PHP including their results and highlighting any current or future risks to their physical health... Whilst front line healthcare professionals were involved in the co-design of the PHA form, there was little involvement of service users in this process as they felt it was not within their remit to design the assessment form.

"...some of the times we were sitting there and saying [the physical health form has] got nothing to do with us. It was frustrating actually. But there wasn't, was nothing we could do about it. I mean, so no" (P5, Service User)

In this case, the 'co-design' referred to the involvement of different professionals; i.e. nurses and doctors working with the QI project team. The lack of service user involvement in the design of the PHA form is partly explained by the fact that the design of the patient held booklet started a few months later, which was specifically led by the service users. This was also related to work to design and test the PHA form on the ward with clinical staff.

The engagement and involvement of the staff in co-designing the PHA form provided them with a sense of ownership with the intervention and with the project. The different professionals who were involved in the iterative development of the PHA form had an opportunity to provide feedback and changes were made to the form based on this feedback, which was overseen by *P16*. The single largest modification to the PHA form, which combined the mental and physical health assessments, was when these were separated. This happened during the transition period between SHINE1 and SHINE2 when senior organisational leaders, outside the SHINE2 project, planned an organisation-wide roll-out of the PHA form (§4.2.3).

As part of this, the Trust wanted to convert the existing PHA form from a Word document, which had been developed on *Ward-1* as part of SHINE1, into an electronic form on Jade, the electronic health record (EHR) system, as highlighted in the previous chapter (*Table 10*). In doing so, the PHA form lost a key feature, namely the discharge summary, which had been specifically developed in response to feedback from medical staff as a mechanism to leverage their support. The new Jade form had omitted this section. The rationale for this decision was that including the discharge summary would exceed the permitted word limit on the EHR system that allowed documents to be printed. If the discharge summary could not be printed and sent to the GP/patient, then it would be of no use. Consequently, the discharge summary was removed.

On reflection, *P13* suggested that the removal of this section might have been a significant error and an alternative solution should have been sought, which the team agreed with. Other sections of the form related to the CQUIN or Tableau had been included as they were aligned with wider organisational work, but could, in theory, have been removed instead.

Reflecting on the role of the evidence in guiding the design of the intervention suggests that using evidence was not so straightforward in this case. Whilst the evidence offered the assurance that the interventions would achieve the desired outcome of improved physical health, this had to be balanced with developing an intervention that was acceptable, both to those that delivered the interventions and those who received them, a key aspect to ensuring successful implementation. Having the evidence base, especially aligned to NICE guidelines and the Lester Tool, also conferred legitimacy that the project did not need to demonstrate better outcomes

However, it was clear the project would never be able to demonstrate the necessary outcomes in the time available, although this was seen as unnecessary as the evidence indicated that as long as the project delivered demonstrable improvements in the processes of care, the outcomes would follow. Although the team was able measure the implementation of the assessment, they were cognizant that having BMI calculated or blood pressures measured would not improve anyone's physical health. The evidence provided the conceptual link between the process and eventual outcome, a guarantee of sorts that improving the process would improve health.

5.3.2 A patient-held physical health plan

Concurrent with the development of the PHA form, a patient-held PHP was codesigned. This was in response to the suggestion by *P24*, a service user that patients should have their physical health assessed and be given information about their physical health status and how to improve it. A sub-group of the improvement team led by service users developed of the patient-held PHP. Initially, the patient-held PHP was based on several existing tools/booklets developed within the NHS or by voluntary organizations and charities but modified to provide organisation/patient-specific advice.

Whilst the service user group was researching existing material, P2, a psychiatric registrar, undertook a short literature review to assess the evidence for the use of patient-held records. His review identified several studies that reported positive changes in health as a result of individuals having more information about their health and health status. However, there was little evidence on communicating physical health risks specifically to people with SMI. Yet P2 did identify some evidence that patient-held records and training could support better care coordination, especially between primary and secondary care, to reduce cardiovascular disease in people with SMI.

Whilst the short evidence review did not result in any changes in strategic decision-making, it did give those involved in the project the confidence that the intervention was likely to be effective and that the project was generally moving in the right direction. The involvement of service users in this aspect of the work led to a range of activities where service users and team members presented at events including workshops, conferences and posters about 'co-production' between staff and service users.

Describing the process of working together, using the co-design of the booklet and having copies of the booklet to show what could be co-produced, was extremely helpful in providing a tangible example to people about the benefits of co-design. Following the design and publication of the patient-held PHP, the first run of 500 were distributed the wards and through networking events. The patient-held plans were listed on the Trust's procurement system to ensure they were available to all staff across the MHU and the wider Trust.

After the initial distribution of the booklets in SHINE1, plans were made to update the booklet during SHINE2. This was organised by *P5* and *P9* with oversight from *P19*, executive sponsor. The plan for the new booklets included an additional a guide to services for each of the localities covered by the Trust. In compiling this information, *P9* noted that there were discrepancies in the provision of services across localities with some more affluent areas having a higher number of services compared with less affluent areas. *P13*, clinical director of one of the less affluent areas, concurred, reflecting on the differences in access to services across different localities and the inherent inequality.

P9 and P19 identified updates of NICE guidelines for alcohol and pre-hypertension that would need to be reflected in the booklet. Also, P5 identified the need for some cross-referencing with organisational policies around guidelines for smoking including e-cigarettes, vaping and the use of shisha. Following the update of the booklet, what at first seemed a simple distribution process to get the books to the wards became very convoluted. The process required co-ordination between the Trust communication team, procurement, budget holders, etc. There was little ownership within the QI project team for co-ordinating this process as it was during a transition period between project managers, resulting in complaints from staff when they did not have booklets to give patients.

In these situations, their monthly figures for the distribution of booklets, introduced for SHINE2, appeared to reflect poor uptake, until the issue was finally resolved by P9 in May 2018. However, P5, service user, expressed their frustration that she had regularly offered to co-ordinate the delivery of the booklets for the wards and prepare them but was told it was in hand. There were requests to provide booklets for the RWC training courses to ensure they could be referenced in any training provided about physical health, but again this had been delayed.

5.3.3 Educational resources to support service users and staff

In SHINE1, several educational courses on physical health were co-produced with healthcare professionals (P2) and service users (P5/P24) for the Recovery and Wellbeing College (RWC). However, it was only during SHINE2 that these became embedded within the RWC following the recruitment of P10 a Recovery practitioner. P10 was responsible for designing, administering and delivering the physical health courses, alongside a peer trainer, someone with lived experience of the issue under focus in the course. Although the courses were intended for both staff and service users there did seem to be a problem with staff training about physical health. Nursing staff had expressed concerns about their lack of confidence and competence to engage with patients about physical health issues, especially patients that did not want to discuss their physical health. Whilst this was met with offers of helpful from P8 and P24, service users, who had been keen to support staff, a more systematic approach was required as ensuring the courses met the needs of staff and service users was critical.

An example of a smoking cessation course for staff and service users at the MHU, which had had a poor uptake, was given by *P10*. The poor uptake was attributed to the focus on: "risk-reduction perspectives rather than facilitating broader discussions between staff and patients", suggesting a greater focus on the biomedical processes and not enough focus on the social and relational content. *P13* specifically drew on his own experience of quitting smoking and the importance of meeting the needs of the staff and patients to support effective discussions about smoking.

In addition to the RWC courses, *P10* reported that the physical health implementation group (PHIG) had commissioned a two-day course, developed by *O4*, the education lead for physical health in mental health within the Trust. The course provided training on the basics of physical health assessment and communication of risk and risk-reduction interventions and strategies.

5.3.4 The physical health pathway

As this section summarises, the physical health pathway was comprised of three separate but linked interventions that were co-design or co-produced with a range of stakeholders between October 2014 and December 2015.

The overlap in their design and extensive periods of testing and iterative re-design created an opportunity to ensure 'fit' between the interventions. Despite this, in SHINE1 the focus was almost exclusively on the implementation of intervention-1, whilst in SHINE2 this moved more towards the implementation of intervention-2. However, intervention-3, which in many ways represented a more complex intervention consisting of training and education for staff and service users was the least well developed and its implementation least well characterised, as explored in the next section.

5.4 Implementing, sustaining and scaling-up the physical health pathway

This section analyses how the implementation and scale-up was supported or constrained. Implementation strategies, as categorised by ERIC (147), are used to structure the analysis of the implementation of the physical health pathway, where observations and interviews are used to illustrates their use.

These strategies may have been part of CLAHRC NWL's systematic approach to QI (promoted for all CLAHRC QI projects) or strategies uniquely developed for SHINE1 and SHINE2. In the latter case, these could have been specified during the setup in the application(s) and early stages of the project or having emerged in response to challenges. In addition, some of the organisational challenges to implementation, sustainability and scale-up are outlined.

5.4.1 Develop stakeholder inter-relationships

This category encompasses a wide range of strategies that aim to develop and nurture relationships between different stakeholders, making use of strategies promoted by CLAHRC NWL. These included the development of an implementation team (§4.4.3), obtaining formal commitments (in the application stage of a project (§4.2.2), conducting local consensus discussions (§4.4.4), capturing and sharing knowledge (through PDSA cycles and improvement measures (§4.4.8 & 4.4.9) and dissemination (§4.4.11). The project team also engaged implementation experts and developed academic partnerships through their collaboration with CLAHRC NWL.

The QI project teams established in SHINE1 and SHINE2 deliberately included a wide range of stakeholders, including service users. Service user recruitment and involvement was guided through the use of the 4Pi (18). The process itself appears to have a lasting legacy and impact in creating new relationships and ways of working, as this reflection from a member of the team suggests:

"Involving service users in our project has been critical... their presence has had a real personal impact. Meeting with people who have used our services not as patients, but as colleagues has been genuinely thought provoking, helping to focus our thinking on end benefits to people using our services... it has helped to bring a more 'human' feel to the project overall' (Service user engagement in quality improvement: applying the national involvement standards, 2016)

Beyond the involvement of service users, resources were put into mapping and engaging a range of stakeholders within the Trust, as opposed to community groups (§4.4.6). The exception to this was engagement with the local CVD prevention service, which was commissioned by the local public health team, although this was simply for sharing information about the project. There was involvement from the clinical staff on Ward-1 in SHINE1, especially following the development of Ward Champion role, which became a key bridge between the QI project team and clinical staff, especially in engaging with the nursing workforce more generally. As this role developed through SHINE1, it was clear there was a need to establish similar roles on the other five wards in SHINE2. However, recruitment and retention to the role was problematic. There was a systemic issue of staff continuity and turnover of clinical staff and QI project team members. The turnover and rotation of clinical staff had caused particular challenges in ensuring staff received training and support and in attending meetings. There were issues about sickness of senior staff on some wards leading to a lack of engagement in the project (Ward-2) or staff feeling that their ward was different and should be exempt from the process (Ward-5). These concerns were symptomatic of a greater issue of who had responsibility for delivering and monitoring SHINE work in the MHU (further addressed in §5.4.2).

Similarly, staffing of the improvement team in SHINE2 presented several challenges. There were three separate project managers (P11/P26/P9) over the 18 months of the project with periods of no project manager. In addition, changes in the support provided by CLAHRC NWL led to three different members of staff covering this key role. There were also changes in organisational roles for both P19, who became clinical director of a service in response to an emergency situation and P13, who became clinical director of another region. All these changes affected those individuals' abilities to continue to attend meetings and contribute to work for the project. The absence of P16, due to sickness, had an impact on the junior doctors in July 2017. The doctors had unilaterally decided not to follow the physical health assessment on the Jade form to create their alternative ways of working. However, in September 2017, P4 reported that on Ward-1, following the new intake of doctors in August, they were working more closely together with the nurses to complete the PHA form.

There were with some instances of doctors proactively seeking out the form. Compared with the situation in July, *P4* saw this as a positive shift in the junior doctors' attitude to physical health assessment.

Whilst the regular team meetings established in SHINE1 provided protected time for the QI project team to meet and discuss the project and the implementation of interventions, little time was created beyond to protect the time of clinical staff on *Ward-1*. In SHINE2, this was resolved with the introduction of monthly Ward Champions workshops where staff from all the wards were able to share their learning through facilitated discussions and activities based on PDSA cycles. Inevitably, the issues identified above with regard to turnover of staff had a significant impact on the attendance but, more importantly, continuity of attendance (§4.3). Unfortunately, whilst protected time was identified for some staff, in this case, the Ward Champions, others raised concerns that they did not have protected time to commit to attending training/workshops or deliver elements of the physical health pathway. This highlighted a significant tension, which contradicted assertions from organisational leaders, that there was commitment from managers to support the project.

In April 2017, emboldened by the evidence from the improvement data that there was little improvement on the wards *P24*, service user, decided, as she put it, 'to say things that other won't'. *P24* questioned the commitment of the MHU managers and the Trust more widely to delivering SHINE2. She reflected on the poor uptake of assessments as shown by the improvement data, especially relating to the use of the physical health booklet. Whilst this was acknowledged to some extent by some members of the QI project team, it was challenged, with responses about 'pressures' and the wards being 'challenging places'. However, *P13*, clinical lead, did suggest that more should be made of leveraging support from *P20*, the previous manager from *Ward-1* and QI project team member, who had recently been promoted to Matron. Whilst *P13* recognised the value of *P24*, a service user, challenging the commitment of the Trust, they suggested that the criticism should be phrased in a more sensitive way.

Irrespective, *P24* conceded that she was keen to understand the challenges the wards faced and wanted to support the staff, personally, where possible. *P13*, the clinical lead, felt that maybe the data were not being shared effectively with the teams to ensure they had oversight of progress, or areas for improvement.

5.4.2 Train and educate stakeholders

This category of implementation strategies included a wide range of approaches to train and educate staff, patients and service users. Much of the educational component of the staff training in the clinical skills required to deliver physical health assessments and interventions effectively was incorporated in intervention-3. However, the learning related to QI, which was fundamental to the project, was delivered during the project through facilitated workshops (AEM and PM (§4.4.4 & 4.4.5)) and regular attendance at collaborative learning events where the team presented and attended presentations from other QI project teams supported by CLAHRC (§4.4.10).

Following attendance at the RWC course, C4, the Ward-4 Champion provided positive feedback, highlighting that the course provided an overview and introduction on how to motivate patients to initiate behaviour change and aimed to support staff to facilitate discussions with patients about their physical health. P16 was clear that the course was essential to ensure staffed were upskilled to deliver the interventions within the physical health pathway and enabled to take responsibility to co-deliver future sessions with peer trainers. The Ward-2 Champion attended the PHIG two-day training and reported that is covered similar areas as RWC but was more clearly aligned to organisational initiatives and new assessments.

In response to this, *P10*, lead for RWC courses, planned to contact PHIG to ensure that future RWC courses were strategically aligned to the wider organisational physical health training. *P10* wanted to ensure there was clarity related to what training was available for whom and for what purpose, as the provision of multiple courses from different sources had let to some confusion. *P10* was responsible for encouraging and supporting staff from the wards in the MHU to attend the RWC courses, especially Ward Champions, as there had historically been poor uptake of courses from the MHU.

Unfortunately, there had been some ongoing issues with online booking system for courses. Another issue was that most if not all training was based off site, at either the RWC site or the Trust's headquarters, both a significant distance from the MHU.

Despite the best efforts of *P10*, there was a lack of co-ordination and communication about the RWC courses, especially how they supported staff and service users. In addition, despite the general increase in interest in physical health courses across the Trust, attendance from staff in the MHU seemed somewhat behind other departments within the division. Whilst protected time for training on a Thursday afternoon had been identified to deliver courses locally at the MHU, this had yet to happen. There were issues about the ability to monitor attendance on RWC courses, although locally it was suggested that in the MHU they use sign-in sheets. *P10* had been delivering courses on physical health in the community at a GP practice, and the funding by the CCG had stopped, requiring GP practices to apply directly for their own funding for these courses.

5.4.3 Use evaluative and iterative strategies

The use of evaluative and iterative strategies encompasses several implementation strategies that are inherent to CLAHRC NWL's systematic approach to QI. Many of these strategies are included within the Model for Improvement linked to the Plan-Do-Study-Act framework: conducting cyclical small tests of change (§4.4.8) and measuring for improvement: use of audit and feedback (§4.4.9). The collection, analysis and feedback of data were used to monitor the implementation of the physical health pathway. Several challenges arose from the design and execution of the data collection system and the subsequent use of the data.

Despite the existence of a long-standing system for collecting, analysing and distributing improvement measures developed in SHINE1, this was a central issue throughout much of SHINE2. The team spent a lot of time exploring how these data collection and analysis processes could be integrated into the existing EHR. The system developed in SHINE1 required the manual monthly collection of discharge data by a Ward Champion.

These data were entered onto WISH (§4.4.9) to generate five specific measures related to the undertaking of a physical health assessment, namely, recording of smoking status, BMI, blood pressure and QRisk, with the addition of the provision of the physical health booklet in SHINE2. The researcher was responsible for analysing these data and reporting the run charts to the improvement team at the monthly team meeting and to the Ward Champion(s) via email.

Following the introduction of Tableau to the Trust in 2015, a data analytics and business intelligence tool, much effort was expended attempting to integrate the prospective weekly audits (spot checks) into this system. In November 2016, *P16* initiated discussions with the Trust's Directorate of Information and Business Intelligence, with support from members of the CLAHRC NWL team. Unfortunately, no progress was made in attempting to automate the spot check data collection process using Tableau. The explanation was that Tableau had been set up to collate data for the CQUIN, which used different denominators to the improvement measures; i.e. the improvement measures counted all patients that were admitted to the MHU, whilst the CQUIN only included those that were admitted for longer than seven days. This was indicative of some of the challenges of establishing improvement measures (154).

In December 2017, further meetings with the Directorate of Information and Business Intelligence were organised in new attempt to integrate the data collection process. Whilst initial meetings seemed promising, this again resulted in no changes to Tableau. Despite this issue, the improvement team continued to support clinical staff to conduct their weekly prospective audits. Each week, a clinical team leader (CTL) or Ward Champion updated the list, which identified which physical health assessments had not been completed for which patients still on the ward. This contrasts with the monthly improvement reports, which included the percentage of patients discharged that had had a specific physical health assessment recorded.

The issue of data collection raised two other issues - whether data should be used to assess performance of individual wards and whether targets should be set for completing each physical health indicator. Whilst there were some team members that thought these were both appropriate uses and interpretations of the data, the researcher specifically disagreed.

The ethos of improvement data collection is predicated on providing those that collect data an opportunity reflects on their own practices (and implementation), either collectively or individually. Using these data for also assessing performance, or managing performance, seemed to undermine the principles of QI, where data is not used for judgement or performance but for reflection and improvement.

The corollary of this stance was that where data were not used for performance monitoring and showed poor completion of physical health assessments, managers could not use them as leverage to improve completion. Concerns from the QI project team about a lack of senior organisational responsibility for delivering and monitoring SHINE2 work, outside the improvement team, further illustrated this issue.

Despite several activities that had been undertaken on the wards, such as one-to-one training by *P8* and visits to the wards by *P24* to discuss their own experience of physical health problems, these had failed to result in demonstrable improvements in the physical health assessment. This further strengthened the improvement team's concerns that too little effort was being made by ward staff to undertake the physical health assessments. Whilst there had been no immediate or noticeable improvement in the data, *P8* reported that *P24*'s visit did have a positive impact on staff and especially their awareness of the project.

The second issue related to the introduction of targets, with which the researcher disagreed. *P24* also disagreed and stated that all patients should be entitled to a physical health assessment and setting targets, of say 90%, risked suggesting that it was acceptable for some patients not to receive this assessment. *P24* conveyed a genuine concern about the use of targets. The team capitulated and agreed that targets were not appropriate. Another issue specifically related to the collection of data about the completion of care processes was associated with the perceived accuracy of the health records in reflecting the actual numbers of physical health assessments completed. *C4*, *Ward-4* Champion, suggested that some assessments had been completed but not documented, although this could not be quantified or corroborated.

The Jade form could only be finalised, that is 'saved' on the system, when both the nursing and medial sections were completed by a nurse and doctor, respectively. However, nurses asserted that often the medical section was left incomplete by doctors, preventing the form from being finalised. This had two consequences, firstly, the nurse that completed their section was not identified on the form as this could only be done when finalised. Secondly, any physical health assessments that were completed were reported as incomplete on the EHR, as these were only registered when the form was finalised.

There had been a long running discussion about the time frame within which the assessments should be completed. Originally, it had been planned that they should be finished within the first 48 hours, later this was changed to be when it was the most appropriate for the patient during their admission. These arguments raised the wider issue of the extent to which staff were individually or collectively accountable for delivering a complete and comprehensive physical health assessment, providing patients with their results and giving appropriate interventions or information. However, in time, a greater interest developed in SHINE2, with some ward managers attending the monthly Ward Champions workshops that were set up from August 2017 and the reporting of SHINE2 data at the Care Quality Meeting, chaired by the manager of the MHU.

5.4.4 Provide interactive assistance

The category 'provide interactive assistance' is comprised of four main strategies: facilitation, the clinical supervision and the provision of both local and central technical assistance. This was almost exclusively provided by CLAHRC NWL for this project, although no clinical supervision was provided and some technical assistance was offered by the Trust to integrate the PHA form on Jade and some attempts as developing reportable formats of the improvement measures on Tableau (§4.4.14). Facilitation has been defined by Kitson et al. (1998) as: "a technique by which one person makes things easier for others. [and] describes the type of support required to help people change their attitudes, habits, skills, ways of thinking, and working" (155). This was very much my remit whilst working with *P21* in SHINE1 and later the role of *P15*, Improvement Manager, in SHINE2.

The facilitation roles were standard in all CLAHRC NWL QI projects and were the key mechanisms for supporting the learning of QI methods and practices. The technical assistance provided by CLAHRC was predominantly focused on activities related to QI, such as the local audit that I conducted and establishing a system for monitoring implementation and supporting data collection analysis.

5.4.5 Engage consumers

The category 'engage consumers' includes a number of strategies including the involvements of patient and family members, intervening with patients such as offering patient reminders and incentives and preparing patients to be active participants in their care through empowering them. To a greater or lesser extent all these strategies were included in the project, the most notable being the active involvement of service users as part of the QI project team. The impact of which is reflected here by *P16*, clinical lead:

"The integration of people with lived experience as equal members of the project team from the outset was incredibly important for the success of this project, as it incorporated the experience and perspective of the 'end-user' of the intervention in a way that would not be possible otherwise. The fact that these team members led on the patient-held booklet means that it is unique and innovative. I feel that we have a much higher chance of enabling our patients with SMI to self-manage their long-term physical conditions in the light of this work. This feels like far more effective service user involvement than the addition of a 'representative' to a meeting or project group, which risks feeling tokenistic". (Service user engagement in quality improvement: applying the national involvement standards, 2016)

The role of the patient-held PHP, intervention-2, was specifically to engage and empower patients and service users about their own physical health and provide them with a mechanism to actively participate in their healthcare. This ethos was further developed with the educational resources to support service users (and staff), intervention-3, which was a community-based programme of courses to inform and educate service users about their physical health.

5.4.6 Organisational challenges

There were several organisational challenges to sustaining and scaling-up the three interventions that comprised the physical health pathway. The physical health assessment was rolled out across the whole Trust from March/April 2017, with all staff asked to complete the PHA forms for their patients and service users in inpatients and community services, respectively. This was followed by a survey, conducted in July 2017, to gather feedback on the form. *P13* argued that whilst most nurses had engaged with the form, this was not the case with doctors, where harsh criticism had been levelled at the form, particularly from community teams in relation to the huge amount of information that was required to complete the form, which staff felt was not always appropriate, especially entering the blood results on the Jade form, which they felt were tedious.

The antiquated system of receiving blood test results from the laboratory, where results were faxed through to either the community clinic or MHU, resulted in a problem of transposing these individual patients' results from the fax onto the EHR. However, this problem was beyond the scope of the project, as highlighted earlier (§4.4.5). As *P13*, clinical lead, reflected, there will always be complaints when more work needs to be done, and the challenge is to dissect real problems that need to be resolved from the general resistance to change. Hearing this 'push-back' from the doctors, *P5*, service user, was surprised that they could choose not to complete the form. This raised questions about the perception of the autonomy of healthcare professionals and laid bare some of the challenges in the project, where major issues of agency/autonomy were challenged by the need (or lack of) accountability and responsibility.

The PHIG, had been setup to oversee the roll out of the PHA form as part of an organisational strategy was originally chaired by the Associate Director of Programme Management. Following the completion of the organisational roll-out project leadership was transferred to the Director of Nursing and Quality, which in doing so also transferred accountability for the ongoing implementation of the PHA form. This may have been considered symbolic of the nurses' role in delivering the PHA form.

It was also only at this point, in September 2017, six months after the implementation of the Jade form that the extent of the changes that had been made to transition the SHINE1 form to Jade became apparent, namely, the increase in length of the form and the information required to populate it, which attracted so much criticism. However, there was also recognition from PHIG that attempting to use a form developed specifically for an acute ward as the basis for roll-out across the whole Trust, including community services would have inevitably led to problems. Nonetheless, *P13* reported that PHIG continued to support the Trust wide roll-out.

5.5 Summary

This chapter has presented the re-construction of the case study using the K2A cycle which focussed on the 'actions of actors', analysed through a Knowledge Mobilisation (KMb) framework. The areas selected for focus were in part determined by the narrative of the main QI processes presented in the previous chapter. The current analysis presented a more refined understanding of four key areas: the problem definition (§5.5.1); the co-design of interventions (§5.5.2); implementation, sustainability and scaling-up (§5.5.3) and the emergent issue of accountability and responsibility (§5.5.4). All four themes of the analysis highlight the relational nature of the 'knowledge to practice' process, which may have been less visible within the narrative in Chapter 4 (§4.0) and is explored further in Chapter 6 (§6.0).

5.5.1 Problem definition

The analysis in this chapter demonstrates how the problem was initially constructed and later re-constructed through the use and creation of different types of knowledge, offering a progressively more granular understanding of the system and its complexity. Evidence from research contributed to a general understanding of the problem in combination with existing policies and guidelines. This was augmented by numerical data on local organisational processes, and the situated knowledge of staff and service users.

The use of the participatory QI methods facilitated the codification and sharing of this knowledge and offered a step towards the development of interventions to address the problems based on modification of existing practices and processes.

The Lester Tool provided a framework around which much of the work was structured. The framework directly linked evidence to the interventions and subsequent changes in practices and processes offering some reassurances that interventions would achieve the desired outcomes. Conceptually this links biomedical knowledge and situated knowledge.

5.5.2 Co-designing interventions

The development of the interventions which comprised the physical health pathway emerged from the process of defining the problem, although not necessarily in a planned and staged manner.

The Lester Tool was used as an evidence-based framework to guide the content but allowing the evidence to be adapted to fit the local context. The use of QI methods led to the co-design of three separate interventions, albeit with different stakeholder groups. Each intervention required healthcare professionals to adopt new ways of working which included new clinical practices or clinical practices that required reorientation i.e. they had been previously used to assess the acute physical health of patients but were now being used to identify risks for the long-term physical health of patients. The development of the multi-professional PHA was explicitly linked to the identification of inadequate/ineffective processes. The co-design of the PHA included involvement from nurses, junior doctors and managers from the ward to iteratively test and develop the intervention, using PDSA cycle. However, the fidelity with which the PDSAs were both undertaken and recorded was generally poor. Whilst the initial PHA form developed in SHINE1 using Word, this was subsequently transferred to the EHR in SHINE2 resulting in significant changes to the intervention. Following the PHA, all patients were expected to receive a patientheld PHP, which would outline the results from their assessment, highlight any abnormalities and provide them with a personalised risk for both diabetes and CVD. The intervention was co-designed by service users and staff as a booklet to provide information and personalised results.

It was intended to be used to facilitate a discussion between the patient and healthcare professional about long-term physical health and facilitate shared decision making about appropriate lifestyle interventions and strategies to reduce risks, where appropriate. The final community-based intervention was the delivery of educational resources to support service users and staff.

Primarily the intervention was aimed at raising awareness of CVD and diabetes risk factors and interventions to reduce risk and was delivered as part of the RWC curriculum. These interventions created a physical health pathway extending from admission to post-discharge. The provision of the first two interventions alone was considered unlikely to have impacts on the physical health of patients: the third intervention was intended to address both their mental and physical health.

5.5.3 Implementation, sustainability and scaling-up

The ERIC categorisation of implementation strategies offers a range of approaches to implementation. Many of those used in the case study were facilitated and augmented by the QI methods. It is not possible to judge the relative importance of each approach to the success of the case study. Each was critical in the delivery of the projects. The strategies prominent in the case study were: developing stakeholder inter-relationships; training and educating stakeholders; the use of evaluative and iterative strategies; and the provision of interactive assistance and engagement of consumers. How these strategies were deployed in the case study is summarised, along with several of the challenges encountered.

The development of stakeholder inter-relationships was clear from the outset of the case study, with the formalisation of organisational commitments through the application process, development of the QI project team, including service users, and through the use of the AEM workshop to generate consensus amongst the team and wider clinical stakeholders. This was further developed by capturing and sharing knowledge, achieved using PDSA cycles, improvement measures and dissemination activities. The Ward champion role was developed as an interface between the QI project team and clinical staff. During the scale-up phase, more Ward Champions were required for each of the six wards. The recruitment and retention of this role proved difficult across all wards, with staff often reluctantly taking up the post.

Despite this, a number of those that did take up the post were successful in leading their wards and staff to achieve improvements in all/many of the measures. So, whilst the importance of clinical engagement was recognised, it was not without its challenges. Some effort was made to engage doctors through educational sessions, although attendance was variable and unsustainable due the frequent rotations of junior doctors.

The lack of attendance and engagement by doctors led to some perceiving the initiative as nurse-led and simply something the nurses should be responsible for. Staffing was also an issue for the QI project team more generally which posed continuity challenges. The systemic issue of staff continuity/turnover was problematic and is a common feature of clinical training where staff often rotate through different specialities and clinical areas/settings. However, continuity of service user engagement was maintained throughout the case study, with at least two of the three service users regularly attending all workshops and meetings.

The case study included two parallel processes for training and education. The use of QI methods for the project team, and the development of clinical skills and knowledge for delivering the physical health assessments and interventions. CLAHRC NWL took responsibility for the former, through facilitated workshops, meetings and learning events. Whilst the QI project team initially took responsibility for the latter, this was later taken up by the Trust through the two-day staff physical health training. The QI training for the project team was provided through the initial AEM, PM and PDSA facilitated workshops that included both training about the QI methods and then a workshop to facilitate the method and develop a specific output product. This approach relied heavily on both the expertise of the facilitator in communicating and teaching about the method and working with a broad range of stakeholders to develop the output, which the team could use to develop their project. The products and the processes linked to their use were often the focus of the learning event where members of the QI project team would present to other QI project teams supported by CLAHRC NWL. The presentation would usually cover how a particular method supported the QI project and the challenges of its use. This approach aimed to create a community of QI practice and learners.

The physical health training covered both the clinical aspects of assessing physical health and the underlying biological processes, but also the administrative component about how to complete the PHA form and booklet. However, the coordination of training was challenging as this was off-site and required time away from the clinical area to undertake, with no follow-up.

The use of evaluative and iterative strategies was encompassed in several of CLAHRC NWL's systematic approaches to QI and included the Model for Improvement, linked to the Plan-Do-Study-Act framework and Measuring for Improvement.

Several challenges were encountered in the use of the data collection system in supporting both the PDSA cycles and the monitoring of the implementation of the interventions. Even though significant effort was expended in developing an initial data collection system, automating or reducing the resources required to collect the data presented insurmountable problems, despite the integration of the PHA form into the EHR. The lack of inter-operability posed a significant challenge to the sustainability of collecting data to assess ongoing implementation on the wards. Furthermore, despite access to a web-based reporting tool, the analysis was conducted manually as there were some ongoing issues with the analysis generated by the tool. Whilst the audit and feedback were perceived as useful by the QI project team, this was haphazardly distributed to clinical staff.

So, whilst the intention of the data was to support staff in improvements, this was still interpreted as an assessment of performance and productivity despite the decision not to introduce targets. This also related to the perceived accuracy of the data and the lack of corroboration between the data and the clinical care offered. This itself became an issue of accountability and clinical governance in ensuring that appropriate care was being both delivered and recorded in the clinical notes.

The provision of interactive assistance covered facilitation as well as technical assistance, much of which was provided exclusively by CLAHRC NWL, with little engagement and support from the Trust.

Whilst this enabled CLAHRC NWL to offer strategic support, this was done, to some extent, in isolation from the organisation, although the clinical leads did report to various boards and high-level meeting, despite this, there was little organisational oversight. Whilst there was significant overlap between the technical assistance provided for the project and the facilitation, the facilitation aimed to extend beyond simply delivering the projects.

Through the facilitation, QI project team members were coached to lead or be actively involved in future QI projects as well as developing their own skills and competencies in improvement. This differs somewhat from a more traditional consultancy, where resources are brought in to deliver a project, as the facilitation process aimed to bring about changes in the organisational and clinical culture, with some emphasis on moving away from performance management and instead creating a supportive framework to empower staff to tackle the problems they encountered.

The final strategy involved engaging consumers as active participants in their own care but also as representatives in this type of project. The development of the patient-held PHP (intervention 2) and education sessions (intervention 3) were intended as mechanisms to empower patients to both understand and change their risks of developing long-term physical health problems. The involvement of service users in their development was a key aspect of the case study. However, the broader involvement of service users in the project had a greater impact than just the development of the interventions. Many of the QI project team reflected on the positive contributions from the service users and the difference they had made as members part of the project team, which for many staff was the first time they had worked alongside service users in this way.

In practical terms, one of the key roles occupied by the service users, observed in meetings, was their role in scrutinising the delivery of the project and holding the team to account. This remained an important, but sometimes contentious, aspect of their involvement.

5.5.4 Accountability and responsibility - emergent issues in the case study

Despite the relative success of the implementation strategies, there were challenges to implementing, sustaining and scaling up the physical health pathway. These almost all related, to a greater or lesser degree, to the contested accountability and responsibility of staff for delivering the interventions, especially related to the completion of the PHA form. This was in large part related to the changes to the PHA form during transition to the EHR, which were perceived by staff as an increase in its length but with less functionality. Following the Trust-wide implementation of the PHA, a survey was undertaken to ascertain the views of staff. The survey demonstrated some engagement with completing the PHA form, this was widely rejected by medical staff as being too onerous. Staff reporting that the amount of information to collect was unnecessary and rejected the assertion from organisational leaders that this was necessarily their responsibility. This was exacerbated by frustrations of staff with existing systems for example, with the collection and reporting of blood test results from the laboratory, which were sent by fax and then needed to be manually entered on the EHR.

However, some service users questioned these criticisms given by staff and challenged the autonomy afforded to healthcare professionals and their perceived freedom to complete the physical health assessment or not. To the service users, this appeared to represent a lack of accountability and responsibility for delivering physical healthcare for patients. Beyond clinical accountability, there were also challenges in the organisational accountability for delivering both the QI projects that make up the case study and the Trust-wide roll-out of the PHA form on the EHR.

This analysis demonstrates that many of the actions of actors are related in some way to the accountability and responsibility for delivering changes to clinical practices and processes. This relationship is further explored in Chapter 6 (§6.0). Whilst this analysis hasn't attempted to explicate the process of the co-creation of knowledge, this is examined in the discussion (§7.3).

6.0 Implementation and improvement through a practice theory lens

6.1 Overview

This chapter re-constructs the case study to focus on the 'practices and processes' of improvement using a practice theory lens. This lens is offered by Normalization Process Theory (NPT), an Implementation Science theory introduced in Chapter 2 (§2.5). The analysis is structured using the four main constructs of NPT: Coherence, Cognitive Participation, Collective Action and Reflexive Monitoring (*Figure 11*). Activities undertaken within the case study that relate to improvement and implementation are categorised according to the NPT taxonomy. The analysis responds to the need to go beyond the descriptive account of the case study that is offered in chapter 4 (§4.0) and extend the basic explanatory offerings of Chapter 5 (§5.0). This chapter attempts to elaborate the findings of the previous analytical chapters and integrate the main themes into the conceptual framework (**Figure 15**).

The analysis highlights the sense-making activities (Coherence) that the QI project team members, clinical staff and organisational leaders undertook in the QI projects (§6.1). This sense-making process allowed stakeholders to come together and situate the proposed activities within their own understanding of the clinical and organisational problems and the proposed evidence-based solutions.

The analysis then focuses on the investment and work in building and maintaining relationships (Cognitive Participation) between individuals and different professional and organisational groups involved (§6.3). The aim of relationship building was to ensure ongoing use of interventions and subsequent changes in clinical practice to ensure sustainable improvements in the delivery and organisation of care.

The study also identifies the operational activities and tasks (Collective Action) undertaken to support changes in clinical practice (§6.4). These could be understood as the main socio-technical activities of QI and implementation of the interventions that result in changes in practice.

The last analytical section offers a multi-layered reflexive account (Reflexive Monitoring). This initially focuses on the reflexive activities undertaken by the QI project team and clinical staff involved in the QI projects but is then extended to the research activities (§6.5). These include the collection and analysis of the data, and the inherent reflexivity of the researcher involved in both the delivery of the QI project and the research for this thesis.

Finally, the findings of the analysis are summarised which highlights key concepts developed through the analysis which focus on the relational and interactional aspects of improvement (§6.6). Whilst this chapter does not respond directly to the research question: How can implementation and improvement be understood as a social process? It does analyse the case study by focusing on the practice of implementation and improvement, which provides a basis for the discussion that draws on an existing conceptual model of social practices that is applied to the IS field (§7.4).

Prior to introducing the analysis, *Table 15* summarises the three interventions (§4.0), the supporting processes (§5.3) and implementation strategies (§5.4), highlighted from previous chapters.

Table 15: Summary of three interventions, supporting processes and implementation strategies

Interventions	Supporting processes	Implementation strategies
 The multiprofessional physical health assessment form The patient-held physical health plan Educational resources to support service users and staff 	 Access to equipment Knowledge about physical health Skills for assessment Collection and analysis of data on implementation Access to training Recognition and support from managers 	 Develop stakeholder interrelationships Train and educate stakeholders Use evaluative and iterative strategies Provide interactive assistance Engage consumers

6.2 Coherence

This section focuses on the sense-making process that members of the QI project team and clinical staff undertook to situate the proposed activities within existing clinical problems and practices. It explores how actors compared their current work with the proposed new practices (Differentiation) and how collective (Communal Specification) and personal (Individual Specification) sense-making was facilitated through team-wide and role-specific participatory workshops, respectively. Lastly, the section outlines the development of a 'community of practice' that coalesced around the issue of physical health for people with SMI and the use of QI methods (Internalization).

6.2.1 Differentiation

The concept of Differentiation compares how the 'work' that people do would change following the introduction of new practices. This was mostly focussed on the introduction of physical health assessment (PHA), rather than the physical health plan (PHP). The analysis identified key issues in differentiating between the assessment of acute physical health, also known as 'vital signs' or 'observations', and those for identifying the risk of long-term physical health problems, as required for the PHA.

How these were differentiated and/or linked was unclear, with clinical staff indicating that regular physical health assessments (vital signs) were undertaken to identify acute changes in physical health and recorded in the modified early warning scores (MEWS) charts, separate to the process of completing the PHA form. The multiple recording and transposition of data were not apparent in discussions with staff or the team during workshops and meetings and added an additional layer of complexity and bureaucracy to the PHA process. This was reinforced by scepticism about how well existing data captured the practices related to physical health, specifically whether assessments were being completed but not recorded. A range of individuals and professionals including nurses, health care assistants (HCAs), apprentices and medical staff carried out the actual practices required to complete the PHA.

This suggests that the sense-making process for implementing new practices might be different for different professionals, dependent on their engagement in the PHA process. Healthcare professionals from the wards overwhelmingly framed the physical health of patients using the acute medical model, rather than considering their long-term physical health. The focus on acute physical health problem was highlighted by the different response some staff gave when questioned about their responsibility for the acute and long-term physical health of patients:

"R: Whenever we see something that is acute, then we have to deal with it fast. We had someone that had... hyperlactatemia and then we had to request an MRI scan, we have to call endocrine to request a fuller blood test and all these things... if it's urgent, we're the ones to see in the middle of this process if it's urgent or not, I was clerking someone and I saw that he had an AF but it was a long term AF, then like, all right, let's leave for the day team...

I: How easy [is it to] potentially to differentiate [acute] physical health versus this longer-term physical health.

Yeah, I think [nurses] try really hard but for some of them, especially those nurses that are only trained in mental health nursing and not physical health nursing, it's just very difficult....

I: So just in terms of the, not the acute physical health of the patients but the longer-term physical health of the patients, do you think that's your job?

No. I think while they are there, I try to do my best, we're trying to not give biscuits on the ward for, as snacks but give fruit and stuff, but long term things, they do have a GP and we're in an inpatient setting, I can try to do my best but there's a limit, I can't help the whole world." (C2, Healthcare professional)

Furthermore, examples of the interaction between mental and physical health actors provided in their interviews covered a wide range. These included the interface between common mental disorders and long-term conditions, serious mental illness and acute physical health problems, or neurological problems and physical health issues such as mobility. However, none of these examples demonstrated the specific interaction that the projects aimed to address: the impact of serious mental illness on long term physical health.

Other challenges to delivering the physical healthcare of patients in a mental health setting, as opposed to a general hospital, were identified. These included physical obstacles, such as availability of equipment and access to the patients' rooms. Also, the need to monitor certain physiological signs and symptoms or biochemical markers related to medication or side-effects of medication e.g. elevated prolactin levels due to antipsychotics.

6.2.2 Communal specification

The participatory workshops provided spaces for collective sense-making for both the QI project team and the clinical staff. In SHINE2, clinical staff from each of the wards were invited to participate in the AEM workshop to develop a shared understanding of the aim of the project and identify the anticipated benefits that could be realised. However, the presence of clinical staff was limited, as only two matrons and a ward manager attended the workshop. Additionally, a shared understanding of existing practices and processes of care was articulated and codified through the use of PM. The team meetings were also opportunities for individuals to share their thoughts and ideas, as well as contribute and inform decision-making processes.

6.2.3 Individual specification

Whilst collective sense-making was achieved through the use of the participatory methods, as the focus of the project shifted from the co-design and testing of the interventions on a single ward (SHINE1) to their implementation across five additional wards (SHINE2), a more personalised approach to sense-making was required. This was especially true for the Ward Champions who acted as a bridge between the QI project team and the clinical staff on each ward.

As a result of this specific need, monthly Ward Champions' workshops were introduced from August 2017. These workshops provided a space where Ward Champions were able to share their experiences in implementing the interventions on their own wards. During the workshop each Ward Champion was provided with a detailed breakdown of the monthly data on the improvement measures (*Figure 35*) to aid their understanding of the impact of changes and support shared learning.

6.2.4 Internalization

The primary purpose of the Ward Champions' workshops was to provide nurses with an opportunity to develop implementation strategies for their wards and raise the profile of physical health for their patients. However, to be effective this process expected a commitment of resources, including scheduled time for the involvement of ward staff. This required engagement and agreement of ward managers, which was not always the case. The Internalisation of the project included the recognition of the emerging issue of the physical health of people with SMI but also the QI methods that where being used to change practices. There was a sense, especially from the service users, that a community had formed around this issue of physical health, and staff and service users together would try to enact social change, focusing initially on the QI project, but seeing this as part of longer-term piece of work. The powerful and emotive expressions from service users about the impact of the project on them personally and the broader issue of the disadvantage experience by those with SMI became a clarion-call for the wider Trust.

In addition, the 'outsider' perspective was useful to the QI project teams, many of whom were either non-clinical or had limited roles on the ward; i.e. they were not permanently based on the wards and could questions existing processes.

6.3 Cognitive Participation

This section describes the rationale for the involvement of multiple stakeholders (Initiation) and presents examples of how individuals invested in building and maintaining relationships across professional groups, settings and organisational levels (Enrolment). This relational work was intended to ensure those involved were engaged and fully supported to participate (Legitimation).

The relational work facilitated the development of approved supporting processes that would ensure the implementation and long-term sustainability of interventions (Activation).

6.3.1 Initiation

The project required the involvement and engagement of a range of stakeholders, including different professional groups and service users. Some of these were based on existing working relationships, and others, like the service users, were new to the team. The commitment to involve service users as part of the QI methods was facilitated by the use of the 4Pi framework (§4.3.1). As the team matured, the relationships between the individuals also developed. Whilst there was commitment from those involved, there was rarely, if ever, any accountability for those involved in the project. The CLAHRC NWL team attempted to engender a sense of community around the project to facilitate the collaborative working. Also, the desire of the CLAHRC NWL team to deliver a successful project resulted in them frequently taking on aspects of the QI work, such as the audit or chairing meetings, rather than just facilitating the process. This 'hand-on' approach also provided a platform for building relations with the team. At times the relationships between the OI project team and clinical staff were strained; as clinical staff left and moved on to new roles, new staff needed to be recruited which usually meant they were cajoled or pressured to participate.

6.3.2 Enrolment

Those involved in delivering the interventions needed to establish new ways of working, including how they engaged with their colleagues, patients and/or objects (such as equipment and patient records). Recognising that engaging staff might be challenging, QI project team members were flexible in their approach and attempted to meet with clinical staff face-to-face to maximise engagement. Even within the QI project team, there were challenges related to workload and prioritisation, especially as individuals' clinical workloads or roles changed, although these were often not visible to the rest of the QI project team. Delivering the project relied heavily on developing effective relationships with different professional groups and individuals across different parts of the Trust.

The absence of the clinical lead left much of the negotiating and leadership responsibilities to *P4*, *Ward-1* Champion, who was a peer to the staff on other wards rather than a senior leadership figure. The challenge of engaging other wards was recognised early, as the staff on the other wards had not been involved in the development of the interventions as part of SHINE1, so lacked any sense of ownership that was observed on *Ward-1*.

6.3.3 Legitimation

In this study, several members of the QI project team expressed concerns about not being part of the 'system' or being 'non-clinical'. Whilst this caused them some anxiety it did however prove beneficial, as their naivety allowed them to ask questions to probe the current system and way of doing things, challenging the *status quo*. Although, this may only have been possible through the supportive environment that was created by the team. This was demonstrated in various meetings where *P9* asked pertinent and insightful questions that encouraged staff to clarify and explain their comments.

The role of both internal and external recognition in encouraging involvement in the project was an important motivator for legitimising the new practices. Internal recognition was achieved through organisational awards and feedback from senior staff. External recognition included acknowledgement of the project in CQC inspection reports following site visits and the presentation and publication of project materials at conferences and in peer-reviewed journals, respectively.

Despite the general support from the organisation, one view expressed by a senior leader downplayed the merits of the project itself and instead emphasised the development of the QI skills for those involved which could be used elsewhere in the Trust, building capacity for the organisation. On one hand, it might seem that this undermines the legitimacy of the whole project and the practices that were introduced, on the other hand, it could simply be recognition that projects can be helpful ways of learning about QI whereas the more important work needs to be achieved at a system level. None the less, team members and clinical staff also expressed the value of the experience they gained from their involvement, with some directly linking this experience to promotions or new job opportunities.

Partnership working with service users was highly valued by the QI members and clinical staff involved. This was often cited as genuine involvement, in comparison with tokenistic types of involvement wherein the presence of patients and service users is de-legitimised.

6.3.4 Activation

Initially, actors were recruited to the QI project team to shape new practices through the co-design of the interventions. However, following this it was necessary to 'activate' new clinical staff to support sustained implementation on Ward-1 and scale-up across the new wards. The main mechanism for this was through the recruitment of the Ward Champions. These clinical staff played a crucial role as ambassadors for the project but also as a key link between the QI project team and clinical staff on the wards. There were however challenges to their recruitment and retention. With little formal recognition of the role, those that agreed to take on this additional work were influenced through existing relationships between the QI project team, particularly **P4** and **P8**, to take up the role. Even once the role was appointed for the ward there were additional challenges in supporting the staff to carry out their role, as due to shift patterns it was not always possible for Ward Champions to attend the monthly meetings consistently. Also a number of staff were promoted or rotated into different roles and settings or moved to new jobs in different organisations, this often rapid turnover posed a challenge in not only recruiting a replacement but also ensuring consistency of developing strategies on each ward, despite the fact that attempts were made to record these in the form of Plan-Do-Study-Act cycles.

6.4 Collective Action

This section provides examples of the operational activities and tasks that were undertaken to support changes in the administrative and clinical practices at different stages of the patient journey through the MHU. These practices align to the SHINE interventions or the supporting process to deliver the physical health pathway (**Table 16**).

Table 16: Summary of administrative and clinical practices at different stages of a patient journey through the acute mental health unit

Stage	Administrative and clinical practices	SHINE Intervention
Admission processes	 Allocation of key nurse Orientation of patient on ward Physical examination Medication history Past medical and family history Assessment of social situation/family/employment Entry of data into EHR 	The multi-professional physical health assessment form
Diagnosis/ treatment	Prescribing medicationAdministration of interventions	Educational resources to support service users and staff
Discharge	 Referral to interventions Follow up appointments for outpatients Communication of information to service users and GP 	The patient-held physical health plan
Community care	Access, attendance and completion of intervention programmes	Educational resources to support service users and staff

The analysis describes how actors interact with each other and/or objects to enact the practices required to deliver the improvements in care (Interactional Workability) and the activities that build the accountability of staff responsible for delivering these new practices (Relational Integration). It also outlines the allocation of work (Skill Set Workability) and other resources (Contextual Integration) to support the implementation of new practices.

6.4.1 Interactional Workability

The interaction of actors within and between the QI project team and clinical staff functioned as a mechanism by which to change practices. New interventions were co-designed by members of the QI project team, with some engagement of frontline staff, either as members of the QI project team or through testing out the interventions and providing feedback.

The interventions prescribed a vast array of new practices or required staff to reorientate existing practices to ensure the interventions were delivered. The
knowledge and skills required to deliver the interventions were taught through
several face-to-face sessions, including organisational training, developed by *O4*, the
Education Lead for Physical Health, as well as through the delivery of training
sessions on the wards by members of the QI project team and by Ward Champions.
The latter were especially important in building up relationships between the QI
project team and Ward Champions with the clinical staff on each of the wards. The
Ward Champions' workshops also provided opportunities for the Ward Champions
to share learning with colleagues from other wards.

The specific inclusion of clinical staff as members of the QI project team was a route to ensuring the acceptability of any changes brought about by the development of the interventions. However, whilst in SHINE1 there was involvement with medical staff, through P2 and P16 as members of the QI project team, there was little formal engagement of doctors, especially junior doctors, beyond this. This may explain the resistance of some doctors to engage with the physical health pathway, even though several fields of information required in the PHA form were specified as to be entered by these doctors. Assigning responsibility for the practices associated with specific fields on the PHA form to different professional groups was the main mechanisms of accountability and is explored further in the next section.

6.4.2 Relational Integration

There is a need for both staff and patients to have confidence in new practices which are introduced and delineate accountability for different aspects of the intervention(s). In SHINE1, the interventions, and associated practices and supporting processes, were co-designed by the QI project team, with input from ward staff. This resulted in the development of sets of practices that were acceptable and agreed by most of the ward staff, except for junior doctors who were not directly involved in the development of the interventions, especially the PHA form. A colour coding system was used on the PHA form as a mechanism for establishing responsibility for different sections of the form, with most of the observations coded for nurses, and the examinations and history coded for doctors.

However, a number of sections were coded so any staff could enter the data, whilst this was initially left ambiguous to allow some freedom for staff to decide who was most appropriate in completing the entry, this had the undesirable consequence of resulting in frequent omissions of the data, attributed to the lack of accountability for any one person or profession to complete. There was also some criticism of this system and non-nursing/medical professionals also expressed a wish to input on the physical health of patients but were left with little scope for doing so. In addition to the challenge of assigning professional accountability, there were challenges in engaging staff in collective accountability for ensuring the completion of the PHA form and PHP. Following the success of the PHA form on Ward-1 in SHINE1, the interventions were scaled-up across five additional wards. This demonstrated a spectrum of engagement from the outset with some wards (Ward-5 and Ward-6) clearly dis-engaged and other (Ward-4) quickly adopting the intervention, corroborated by the improvement data provided to the clinical staff on wards (Figure 35). The difference in engagement was attributed to several factors by key informants, from challenges in staffing and management, through to differences in culture and the needs of the patients served by psychiatric intensive care units like Ward-5 and Ward-6. However, some of these were challenged by other key informants as simply excuses, and that the patients on these wards may in fact be those in the greatest need with regards to their physical health.

6.4.3 Skill Set Workability

There was clearly a link between assigning responsibility for certain practices and allocating the work to deliver the interventions. The QI project team took considerable control of the process of not only developing the new practices but also the decision about who would undertake such practices and their associated clinical and professional accountability to do so. Whilst this might have appeared to the team to be relatively straightforward, this was contested by key informants who expressed a spectrum of responses. There were those that fully acknowledged their responsibility for caring for the long-term physical health of patients; and those that rejected the imposition of this new responsibility, outlining their duty of care was for the acute mental and physical health of the patients only.

This professional accountability was somewhat disrupted by one ward team who engaged apprentices to undertake both the physical health assessments and develop information boards for both staff and patients about physical health, although these were directly supervised by nursing staff. In addition to the allocation of responsibilities to professional groups there was of course the allocation of work to the individual. Following admission patients were usually assessed by the on-call doctor and available nurse. At this point much of the initial physical health assessment would be undertaken and recorded in the admission notes. As already acknowledged, this process was primarily to identify any immediate concerns about the patients' acute physical health such as elevated blood pressure or problems breathing. However, much of this data would have been applicable to the PHA form, some of which may have been recorded in the form, some of which was recorded in hard copy elsewhere. In these situations where the physical health assessment data were missing this was left to nurses to manage the identification of the missing data and then allocate these tasks either to a named nurse for the patient or to a member of the ward team to undertaken at the weekend, when the wards are quieter.

6.4.4 Contextual Integration

Effective allocation of the resources required to ensure implementation of the interventions was necessary. The process of delineating the practices that are required to ensure the interventions were delivered and the array of supporting processes was complex. This was highly dependent on the specific context in which the intervention was delivered, which even in a single setting such as the acute mental health unit was continuously changing. Whilst the PHA form did not require any supplementary staff *per se*, there was clearly a need for staff to undertake additional work, or at least re-orientate some of the work they were doing. There was also a need for some equipment to ensure the assessments could be conducted, which included height measurers, weighing scales and automated sphygmomanometers. In addition, the results of routine blood tests were required to ensure accurate estimates of CVD and diabetes risks could be calculated. These calculations required access to an online calculator through a website. In addition to the clinical practices themselves, the improvement practices required a significant investment of resources of staff time and management of the project.

These resources were mostly funded through the HF grant allocated in SHINE1 and the CLAHRC NWL grant allocated in SHINE2, but also included matched funding in the form of commitments from the Trust and support from the CLAHRC NWL team. Much of this was agreed and organised outside of the organisation, which meant there was little oversight or investment from the organisation, in financial terms at least.

6.5 Reflexive Monitoring

This section describes the work to appraise the impact of new practices on those that are affected by them. This includes processes for collating a range of information from different actors within the system about the effect of the new practices and processes (Systematization). As part of this evaluative work actors develop their own experiences of interacting with new practices (Individual Appraisal).

The analysis presented for this section differs somewhat from the previous sections as it attempts to layer the analysis and demonstrate the 'meta' nature of the reflexivity. By this it is meant the mechanisms through which reflexivity is achieved within the project, predominantly through different QI methods, but also the reflexive space that is created by the research process that informs this thesis. Through the different data collection methods (and subsequent analysis) members of the project team and clinical staff were given opportunities to discuss and reflect in the project and their role within it.

6.5.1 Systematization

Throughout the case study several formal and informal mechanisms were developed to facilitate reflexive monitoring within the projects. These included the creation of processes for facilitating the assessment (and reflection) of collective practices at the ward level. This complemented the assessment that was already carried out at a unit or organisational level through the CQC inspections and NAS reports, which offered a mix of qualitative and quantitative assessments of physical healthcare. In SHINE2, these were joined by the addition of the CQUIN indicators that measured the delivery of physical health assessments and appropriate interventions, according to the definitions and data collection specified by those administering the CQUIN.

In addition, as part of the QI methods, improvement measures were established to assess the delivery of the physical health pathway at the ward level that was not primarily for assessing performance but intended to support staff to reflect on their practice related to physical healthcare and make decisions based on this information. The measurement system, whilst conceptually simple - just five/six indicators, presented numerous challenges in the data collection, analysis and how actors did (or did not) respond to the data. In addition to the collection of quantitative data, the QI methods facilitated the articulation and codification of individual actors' experiences of the system, although this predominantly, if not exclusively, focused on the system prior to the development and implementations of the interventions. However, this concept continued in the Ward Champions' workshops, which offered a space in which clinical staff were able to present the views on the project from the ward perspective and also reflect on their role in the project and the role of their colleagues on the ward in delivering physical healthcare.

In addition to the project level mechanisms for reflexivity already outlined, the research process offered additional opportunities for QI project team members and clinical staff to engage in reflexive practice. This was predominantly through the interview process. Furthermore, the dual role of QI facilitator and researcher created a unique opportunity to both support the delivery of the project and explore the case study.

6.5.2 Individual Appraisal

Beyond the quantitative measurements and judgements made by QI project team members and healthcare professionals delivering the interventions, there were other opportunities for the team to reflect. Many of the participatory QI methods promoted a reflective approach to practice, such as in the AEM and PM workshops, although there were fewer structured opportunities to do this in the later stages of the project. Whilst many people were involved in the projects over the many years, a small number were involved for significant periods of time. This included the service users, such as *P5* and *P24*, reflected that through their involvement had developed new skills and new approaches to solving problems. In addition, the felt they had been a significant transformation in their identities and wanted others to appreciate their QI skills as well as their experience as service users.

6.6 Summary

The analysis using NPT offers a new lens with which to unpack practices and processes of improvement in the case study. The analysis using the four main NPT constructs, summarised below, offer insights into the sense-making process (§6.6.1); the building and maintaining of relationships (§6.2.2); the operational tasks and activities of the projects (§6.6.3); and the creation of opportunities for reflexivity (§6.6.4).

6.6.1 The sense-making process

NPT presents four different processes for sense-making: Differentiation, Communal Specification, Individual Specification and Internalization. The analysis delineates these different processes undertaken by QI project team members and clinical staff as part of sense-making within the case study.

In comparing new with existing practices (differentiation) healthcare professionals in both the QI project and clinical staff attempted to understand the project through their own professional experiences of caring for people the physical health of people with mental illness through their training or clinical practice (§6.2.1). Whilst many actors recognised their role in collecting information and responding to issues around the acute physical health of patients, this was less clear in terms of the long-term physical health of patients. So, whilst the PM session had focussed on capturing existing processes of physical health assessment it appears that this failed to capture the assessment of acute physical health. This was despite the existence of already well-developed forms and processes for observations of vital signs, as such missed the opportunity to build on existing practices and re-orient them to the assessment of long-term physical health assessment. This was further complicated by the array of different professionals that were involved in collecting this information, which included doctors, nurses, healthcare assistants and apprentices. This resulted in uncertainty for many about where responsibility for the long-term physical healthcare of patients in the MHU lies. This was further exacerbated by the general lack of awareness either through training or clinical experience of the interplay between serious mental illness and long-term physical health.

The collective sense-making was mostly undertaken in the participatory workshops (Communal Specification) and created a space for actors to share their own experiences and participate in the co-design of the QI project through contributions to the problem definition and suggestions for potential solutions (§6.2.2). However, ensuring that there were representatives of all wards and professions proved challenging, although opportunities were taken to engage those missing from the workshops at other formal and informal meetings. Similarly, outside the workshops, regular meetings with the QI project team members, with occasional attendance from clinical staff, provided a forum for discussion and decision-making.

The Ward Champions' workshop also provided a space for personal sense-making (Individual Specification) and opportunities to develop strategies for implementing changes on the wards and share their success and failures with their peers (§6.2.3). The workshops also provided opportunities for professional development of nursing staff with coaching on the collection and interpretation of data and demonstration of their leadership skills.

Across the QI project team, and to some extent the clinical staff, there was a realisation of the value and benefits of acknowledging the broader issues the project was trying to address (Internalization). This was achieved through the creation of a community of practice, which coalesced around both a particular issue - the physical health of people with SMI - and a methodological approach – QI- and was sustained over a four-year period (§6.2.4). The role of the service users in creating and maintaining this community was crucial as they were often called on to speak at both internal and external teaching and training events.

6.6.2 Building and maintaining relationships

NPT present four different components that represent the work in building and maintaining relationships between individuals and different professional and organisational groups: Initiation, Enrolment, Legitimation and Activation. The analysis highlights how this relational work was undertaken between QI project team members and clinical staff within the case study to ensure ongoing use of interventions to sustain improvements in the delivery and organisation of care.

A wide range of stakeholders were involvement throughout the QI projects (Initiation), some of which were based on existing working relationships and others were new (§6.3.1). Involvement of stakeholders, especially service users, was facilitated using the 4Pi framework. Despite the wide-ranging commitment from healthcare professionals to be involved in the QI project there was little discussion about accountability for delivering the aims of the project, although there was a vague sense of shared responsibility, facilitated using the consensus building QI workshops. Whilst the operational work of the project taken on by the CLAHRC NWL team facilitated the delivery of the project and filled skill/resource gaps, it may unintentionally have created some uncertainty about the expectations about the responsibility of the organisation in delivering the project.

New ways of interacting between healthcare professionals and objects or each other (Enrolment) were central to the new practices introduced by the interventions (§6.3.2). There were however challenges in prioritising activities undertaken by the QI project team, especially with the absence of senior members of the team. This was particularly of note in SHINE2, where clinical staff had not been involved in SHINE1 and required more 'work' to engage them and involve them in the project. This challenge of moving from implementing interventions with the innovators that created the interventions, to adopters is well recognised and presents a major challenge in implementation and improvement work.

There is a need for individuals to feel they have a role (Legitimation) in helping to address a particular problem, although predicated on their perception of the presence of the problem in the first place (§6.3.3). However, even with a commitment to help solve the problem, a crisis in an individual's sense of legitimacy may stem from more internalised issues such as their perceived inability to contribute or lack of skills or knowledge. Although, through the creation of a supportive environment in the project, some attributed to the use of the 4Pi framework, actors felt able to ask questions and contribute to the project team, including the service users.

Recognition through both internal and external mechanisms also contributed to the supportive environment as the QI project team members perceived this as validation of their activities.

However, there were some organisational views that the project itself was only a mechanism for capacity building and developing staff and therefore mitigating the need for any organisation accountability. However, the experience staff gained in being involved was valuable by the staff themselves and the activities were positively highlighted in several external and internal reports.

The 'activation' of new clinical staff (Activation) was necessary to support the sustainability and scale-up, which was achieved through the recruitment of the Ward Champions, who not only acted as ambassadors for the project but also as a conduit between clinical staff and the QI project team (§6.3.4). Although, with no formal recognition of the role or agreed support for staff to undertake the role it was often challenging to recruit and retain staff. Even with Ward Champions it was difficult to organise for staff to attend all workshops due to shift patterns and staffing related issues. All these factors negatively affected the consistency of developing and executing implementation strategies but also left in doubt the accountability of the delivery on each ward.

Ultimately the functionality of many of the relationships outlined above may be highly dependent on the pre-existing culture, which often appeared to be different between the different wards or professional groups. Where these relationships did not already exist, the success or failure of the project may have been dependent on creating them.

6.6.3 Operational tasks and activities

NPT presents four different components that represent the work to enact the new sets of practices: Interactional Workability, Relational Integration, Skill set Workability and Contextual Integration. The analysis highlights the operational activities and tasks that were undertaken to implement the SHINE interventions and the supporting process to deliver the physical health pathway

The interaction between actors in the QI project team and clinical staff (Interactional Workability) was one of the main mechanisms in introducing an array of new practices prescribed by the interventions (§6.4.1). Knowledge and skills to enact new practices were acquired through training sessions at an organisational and ward level.

Those delivered at the ward level were useful for creating relationships between staff to support the completion of the PHA form and ensure its acceptability to staff. However, this wasn't necessarily the case during SHINE2 where there was resistance from some medical staff. This was despite the QI project team assigning this professional group responsibility for completing specific fields on the PHA form, the main mechanism by which accountability was conferred. The response to the PHA form was not completely unsurprising, the form was a complex intervention that required a host of new practices to be implemented with assumptions made about the existing knowledge, skills and willingness of staff to complete it. In addition, it relied heavily on the professional expectations of staff to fulfil a role that many weren't confident they could deliver and some even suggested was not their responsibility. The apparent simplicity of the 'form' belies the complex relational work required for its implementation.

The work to create lines of accountability (Relational Integration) posed a significant challenge to the project (§6.4.2). There was little internal i.e. organisational or external i.e. funder oversight of the project with the exception of a mid and end point review. Although the main function of this review was to identify learning from the project, however, it did provide an opportunity to review the teams progress. As mentioned, the main mechanism by which individual accountability for practices was encoded in the PHA form was the colour coding system, although much of the form was left for those completing it to decide if it was their responsibility. A further challenge was experienced by the variable engagement of clinical staff from wards, with some keen to engage and participate and others less so, which was also mirrored in the data collection on improvement measures. The underlying reasons for this lack of engagement from some wards was attributed to staffing and managerial issues, although this was challenged by some.

The allocation of work to deliver the QI project and clinical interventions (Skill Set Workability) is linked to how responsibility for practices were assigned (§6.4.3). The QI project team took control of the allocation of a major proportion of practice by colour coding the PHA form. However, from the outset of the project assumptions of professional accountability for the delivery of long-term physical health care in the MHU were made.

Whilst these assumptions may have aligned to organisational or professional expectations, this was by no means universally accepted by clinical staff. Furthermore, the additional workload the new practices created for staff also went unacknowledged with no additional resources offered.

In addition to the allocation of work, the QI project team allocated resources (Contextual Integration) to ensure not just the delivery of the interventions but also the array of supporting processes (§6.4.4). In addition to the human resources to carry out the work, additional equipment was required, some of which were missing or unavailable on the wards. Although, it was access and use of the QRISK online calculators that proved to be a particular challenge. Many of the training resources and support were provided directly by CLAHRC NWL, which also included financial resources in SHINE2, as these were provided the HF, the funders of SHINE1. Whilst there were governance mechanisms for reporting the expenditure of these resources it was not always clear to the QI project team how they were allocated.

6.6.4 The creation of opportunities for reflexivity

The NPT construct Reflexive Monitoring is composed of four components: Systematization, Individual Appraisal, Collective Appraisal and Reconfiguration. The analysis outlines the different opportunities that allowed QI project team members and clinical staff to reflect on the care received by patients within the health system and how this could be improved and the formal processes to assess these improvements. This is complemented by a reflexivity linked to the research activities, such as the collection and analysis of the data, and the role of the researcher in both the QI projects and the research for the thesis.

The assessment of the impact of new practices (Systematization) on those that were affected harnessed existing processes for measuring the work of the system (§6.5.1). This was supplemented with the addition of specific processes for collecting and analysing 'improvement' data which assessed the delivery of physical healthcare at the organisational, unit and ward-level, but did not include evaluation of the practices of individuals.

Whilst the data presented through external channels, namely: NAS, CQC and CQUIN was presented to assess performance, the data collected, analysed and presented to clinical staff was intended for staff to reflect on their practice and assess whether improvements were being achieved.

Whilst the intention was to create a system to support staff and not to monitor performance, paradoxically this lack of accountability to the data prevented actions from being taken to improve the delivery of the interventions. The issues of poor delivery of intervention, as assessed by the improvement measures, were specifically addressed in the Ward Champions' workshops, which were also intended as supportive infrastructure, but again the turnover of staff and lack of accountability may have undermined these efforts.

As a researcher there was unique access to a QI project for a significant amount of time (over four years) and a significant amount of data and insight from the QI project team and to some extent the clinical staff. As a QI facilitator there was a unique opportunity to influence the delivery of the project and support the QI project team in engaging with the QI methods but also directly improve the care of patients through the use of research evidence.

The assessment of the delivery of practices to implement the intervention did not only include these formal assessments but also from feedback of views and opinions of colleagues and patients (Individual Appraisal). This experiential feedback was recognised to have an important role in the sustainability of the interventions (§6.5.2). Opportunities were created for sharing experiences and feedback from staff both in the design and implementation of interventions.

Conclusion

Whilst the analysis using NPT suggests that no single factor could be identified as a 'facilitator or barrier' to implementation and improvement, several interacting and dependent practices were recognised. Through interactions between improvement practices and clinical practices, changes to the system were introduced. However, the conceptualisation of these practices and their inter-relationships are not simple or static but complex and dynamic.

The relationships between the NPT constructs could be presented as linear and sequential, however the analysis of the case study suggests otherwise. The analysis demonstrates that practices that relate to the NPT constructs are recurrent, suggesting a cyclical relationship between coherence (sense-making), cognitive participation (relationship building), collective action (operational activities) and reflexive monitoring (reflection and evaluation).

Initially in SHINE1, sense-making was required to understand and outline the problem, this was followed by the relationship building to initiate the QI project team, which led to work to develop the interventions and establish a measurement system. As the case study progressed the new experiences, knowledge and information generated during the previous cycle was used by QI project team to reframe the problem, build new relationships, iteratively develop the interventions and use data use to assess and inform implementation. As the case study moved to scale up and sustain improvements in SHINE2, learning from on these cycles informed the plans for the scale-up of the interventions across the additional wards and new clinical staff had to make sense of the project and establish new relationships and new ways of working (*Figure 43*).

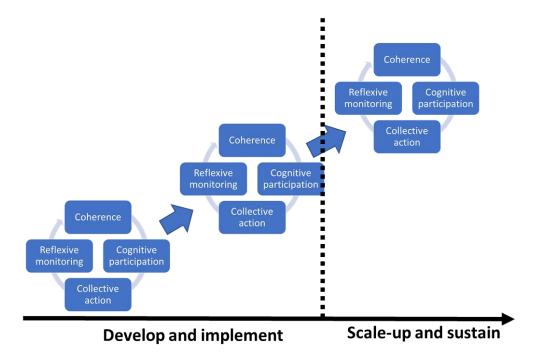


Figure 43: Cycles of sense-making (coherence), relationship building (cognitive participation), operational activities (collective action) and reflection and evaluation (reflexive monitoring) occurred throughout the case study

In addition to this general schematic representation of the main NPT constructs, there were some events/activities associated with clusters of sub-constructs, for example, the Ward Champions' workshops created a space for *individual specification* allowing staff to share experiences about the physical health and make sense of the problem they were addressing through the project. Also, it was through these workshops that *activation* to recruit and motivate clinical staff to support implementation occurred. In the workshops clinical staff were able to share strategies for improvement and implementation and discuss challenges they faced in motivating staff and introducing changes that contributed to *interactional workability*. Finally, the Ward Champions' workshop also created a space in which staff were able to review data to allow them to reflect on clinical practices, collected as part of *systemization*.

The use of NPT has enabled the analysis to move beyond the QI methods and stages of the QI project and unpack the practices and process which have illuminated some of the mechanisms by which the social process of improvement has occurred.

7.0 Discussion

This chapter offers an initial summary of the high-level results from the analytical chapters (§7.2), proceeded by three sections that each address one of the three research questions that explore a specific phenomenon: complexity (§7.3), co-creation of knowledge (§7.4) and social practices (§7.5). These are followed by a section that focuses on how accountability and responsibility mediate or modulate improvement throughout the system, a theme which emerged from all three separate analyses in respect of the three 'knowledge to practice' approaches (§7.5). Finally sections outlining the strengths and limitations of the study (§7.6) and a conclusion (§7.7) are offered.

7.1 Summary of findings

The preceding three chapters have each dealt with a different phenomenon within the case study, drawing on three different 'knowledge to practice' approaches.

Chapter 4 outlined how the case study was constructed as an 'organisational project', demonstrating how QI methods were used to navigate complexity of the healthcare system. Through several key steps, a set of strategic intentions were transformed into everyday practices, mediated by a range of QI methods. These steps included:

- the sense-making processes that situated a problem within a clinical and organisational context (§4.5.1);
- the development and testing of interventions that responded to the problem (§4.5.2);
- the creation of a system to monitor and assess implementation and clinical and organisational processes (§4.5.3);
- changes to cultural and relational aspects of the clinical and organisational environment (§4.5.4).

However, whilst the analysis demonstrated the role different QI methods played in the case study, there was a need to go beyond this descriptive account and attempt to understand the actions of those involved in the case study and the underlying mechanisms of action.

This was explored in Chapter 5, where the case study was re-constructed using the K2A cycle, which highlighted the actions of the various actors involved. The analysis identified three key stages that in the successful delivery of the case study:

- the problem definition (§5.5.1);
- the co-design of interventions (§5.5.2);
- implementation, sustainability and scaling-up (§5.5.3).

The analysis also identified the emergent issue of the accountability and responsibility for delivering improvements (§5.5.4). The results all highlighted the relational nature of the 'knowledge to practice' process, which prompting further investigation.

This became a main feature of the analysis in Chapter 6 which re-constructed the case study using NPT to unpack the practices and processes of improvement, which included an emphasis on the relational work. The analysis highlighted improvement processes linked to the four main NPT constructs:

- Coherence the sense-making process (§6.6.1);
- Cognitive participation the building and maintaining of relationships (§6.6.2);
- Collective action the operational tasks and activities of the projects (§6.6.3);
- Reflexive monitoring the creation of opportunities for reflexivity (§6.6.4).

The results of all three of these analyses are further explored in the context of the different phenomena under investigation in the next three sections.

7.2 What role do QI methods have in assisting actors to navigate the complexity of the health system to support the 'knowledge to practice' process?

Several themes emerged from the analysis based on the narrative of the QI projects (§4.0) that represent the use of specific QI methods in navigating the complexity of the system. In this section, these themes have been aligned to 12 'simple rules' for making change in complex systems as proposed by the SHIFT-Evidence framework (56). SHIFT-Evidence (*Table 2*) was selected as it is an empirically derived framework generated from precisely the type of QI projects represented in the case study (although not specifically from them) that proposes activities that should be undertaken to achieve successful use of knowledge in complex systems. The emergent themes are grouped by three main principles: Acting Scientifically and Pragmatically (§7.2.1-*Table 17*), Embracing Complexity (§7.2.2-*Table 18*) and Engaging and Empowering (§7.2.3-*Table 19*). These themes identify how some of the challenges presented by SHIFT-Evidence were both encountered and, where appropriate, overcome. These sections are followed by examples QI methods that specifically supported the 'knowledge to practice' process (§7.2.4).

7.2.1 SHIFT-Evidence: Acting scientifically and pragmatically

Table 17: Emergent themes outlined using concepts from SHIFT-Evidence (Act scientifically and pragmatically) (56)

Concept	Themes
Understand problems and opportunities	The team worked through the problem at different levels of the system to link to current practice, which illuminated potential opportunities for intervening within the system. However, the team's understanding of the problem and the co-design of the interventions were contingent. Opportunities to change practice had to be generated through the enrolment of Ward Champions, as asking already over-stretched staff to add more to their workload was a challenge.
Identify, test and iteratively develop potential solutions	Whilst the interventions in SHINE1 were iteratively developed, especially the PHA form, the use of Plan-Do-Study-Act cycles as a framework for structuring this was less formally adhered to. In SHINE2, the delivery of the formalised workshops and the use of the PDSA cycle to identify changes and plan strategies to increase uptake and this implementation of the PHA was more pronounced. Although some aspects of the recording of PDSA cycles improved in SHINE2, this was still generally poor.
Assess whether improvement is achieved, and capture and share learning	Measurement for improvement was probably the single most important method used by the team over the longest period of the project. Data were routinely collected, inputted into the online tool (WISH), reports generated and reviewed by the team and disseminated to the ward. However, how these data were used to inform actions, especially through the Ward Champions' workshops in SHINE2 is unclear, at best inconsistent, at worst ignored, with different approaches seen by different clinical staff/wards.
Invest in continual improvement	Dissemination activities were embraced and were a major driver in moving the project forward. However, these activities required resources and time that may have distracted from the main aim of the projects. Whilst the team were committed to a planned and controlled scale-up of the interventions across the MHU, this was somewhat at odds with the Trust's plan of a complete roll out across the whole organisation.

7.2.2 SHIFT-Evidence: Embracing complexity

Table 18: Emergent themes outlined using concepts from SHIFT-Evidence (Embrace complexity) (56)

Concept	Themes
Understand processes and practices of care	Process mapping was used to identify existing processes drawing on the stakeholders' experiences of care practices. Duplicated processes of care were identified and targeted for improvement that led to design of the PHA form, the main intervention.
Understand the types and sources of variation	Audit of existing services demonstrated variation in care. A concern was that staff would see the audit as performance management, but instead they perceived this as evidence for need for improvement. The challenges with the use of Measurement for Improvement as a QI approach were not related to the data collection and analysis, but the lack of 'action' initiated due to signals in the data.
Identify systemic issues	Interventions were developed and implemented by staff at different places in the physical health pathway, reflecting the complexity of the system in which they were being introduced.
Seek political, strategic and financial alignment	Whilst the interventions were not developed specifically to meet the CQUIN target directly, they were based on the Lester Tool, which itself was designed to support teams to deliver the CQUIN. As the PHA form was co-opted to be rolled-out across the whole Trust despite only being developed and tested on one ward, this created significant push back from staff across the Trust, who expressed concern that the form was onerous. The Trust failed to meet its CQUIN target, for which the PHA form somewhat took the blame.

7.2.3 SHIFT-Evidence: Engaging and empowering

Table 19: Emergent themes outlined using concepts from SHIFT-Evidence (Engage and empower) (56)

Concept	Themes
Actively engage those responsible for and affected by change	The 4Pi framework supported the involvement of service users and created a project team where contributions were given equal value from all team members. Whilst the stakeholder mapping identified those with influence within the Trust and provided scope for developing opportunities to engage them, very little stakeholder management was explicitly employed. This was mostly done by the clinical leads outside the QI project team. Interventions were co-designed with both staff and service users to develop a pathway of care from screening of PHA and communication of risk, to support in risk-reduction strategies.
Facilitate dialogue	The AED facilitated dialogue between different stakeholders, especially those outside the immediate project team. This ensured consensus on the aim of the project was achieved and gave a voice to stakeholders, especially in identifying and prioritising potential solutions. Engaging the right people at the right time was a key challenge as some of those involved early in the project lost interest.
Foster a culture of willingness to learn and freedom to act	The external funding for discretionary activities, including research or QI, which absorb resources and attention, could create a system where these are recognised as external activities and not for managerial attention within the Trust. This could lead to an emergent process for both separating out the activities, giving space and freedom to try new things, and could create a barrier to them being internalised and becoming organisationally sanctioned initiatives, leading to fully embedded innovative practices.
Provide headroom, resources, training and support	The provision of financial support, and patient and public involvement activities ensured the team included and engaged those delivering improvements and affected by them, including patients, service users (from the community) and frontline staff. The team included those with the skills and competencies to deliver improvements and endeavoured to skill-up the QI project team through various learning events and activities.

7.2.4 The role of QI methods in navigating complexity

Action Effect Method (AEM) and process mapping (PM)

These resource intensive workshops required highly skilled facilitation and organisation to ensure smooth running with the production of outputs (*Figure* 18). This approach was integral to the project in setting the direction of the project as a whole and in delineating the problems and potential solutions collectively. The AED and PM workshops provide a 'space' in which all stakeholders could participate and have a voice in deciding the aims and activities of the QI project. These workshops explicitly used participatory methods to engage with the range of stakeholders to draw on their tacit knowledge and professional and patient experience of the issue of interest which could be codified in the 'outputs' of the QI methods workshops e.g. Action Effect Diagrams.

The participatory methods were used early in the projects, which were challenging for some junior staff and service users who are unfamiliar with QI and/or other stakeholders. Whilst the participatory nature of the workshops may enhance relationship building, it could present a real barrier to the full engagement of all the stakeholders as participation requires effort and, more importantly, confidence to speak up in front of a room of people. As the participatory workshops are key activities in developing the aim and future work of the project there is a risk of excluding the voices of certain stakeholders, especially patients and service users, whose involvement are crucial component of patient and public involvement, an essential QI method.

Antonacci et al. (2018) identified benefits of PM including their ability to break down complexity and provide a shared understanding of the system; identify gaps and improvement opportunities adopting a system perspective; engage stakeholders in the project; identify and align the project's objectives; fit the intervention to the context; and increase empathy across stakeholders (156).

These are complementary to the objectives of the AEM, as outlined by Reed et al. (2014), and provide a mechanism for 'articulating the programme theory of a QI initiative through a clear visual representation of cause/effect relationships between an improvement aim and potential interventions, with annotation of related evidence' (31). Whilst the AEM workshop was effective in drawing out opinions and views from a range of stakeholders, including service users, this rarely resulted in disagreement or dissent, resulting in an 'easy' consensus. This apparent lack of conflict might be helpful in the smooth running of the workshop but leaves little room for uncertainly or dissenting viewpoints later in the project.

Plan-Do-Study-Act Cycles and tests of change

The co-design of one of the interventions was explicitly based on the use of PDSA cycles and a deliberate attempt to generate an intervention that would be locally acceptable and complement existing contextual factors. The feedback from front-line staff responsible for delivering care was used to modify the intervention. The collection and analysis of improvement data allowed quantitative data to inform the implementation process, although this mostly resulted in the engagement of additional implementation strategies, such as training, rather than direct changes to the intervention.

However, the fidelity of the PDSA cycles was poor, with few complete recording of cycles, in common with the findings of a systematic review of the use of PDSA cycles in QI studies (157). Despite the challenges of recording the PDSA cycles, the iterative development was viewed as a key mechanism to ensure fit between the intervention, the Trust and its wider systems and processes, as well as the clinical practice of the healthcare professionals. Whilst the initial versions of the Physical Health Assessment (PHA) form in SHINE1 combined both mental health and physical health assessments in one admission form, in the end these were separated due to the technical requirements of the transfer of the form to the EHR prior to SHINE2.

Measurement for improvement

Whilst audits offer a form of reflective monitoring through the assessment of the implementation of standards and guidelines, measurement is not a passive process and can become a tool for enforcing standardization and reducing variation (158). This poses a major challenge to changing clinician behaviour, for a whole of host of reasons (76). Audits as a measure of the ability of organisations to deliver evidence-based care, specifically linked to financial incentives, are associated with heavily contested evidence of their effectiveness (159). Irrespective of this, they are commonly employed by regulators and payers as mechanisms for 'improving care' at a health system level (160). Whilst in this project there was no attempt to align the project to incentives, the organisational changes that were brought about due to these incentives had a significant impact on the project, which raises the question about whether more should have been done to align the project to these incentives.

Measuring is not the same as improving. Audit methodology alone does not offer mechanisms for improvement, and additional mechanisms are needed, QI being one approach (158). The national audit was useful to benchmark the organisation and create a need for improvement, but there were limitations in applying the aggregate analysis of the whole organisation to a single ward/unit. To respond to this, a local audit to capture existing practices was conducted. Whilst the audit indicators had a crucial role in the development of the 'improvement measures' used by the team to monitor implementation; the audit alone was insufficient in promoting change. Even after the indicators or improvement measures were defined in the QI projects, which was a complex process involving key stakeholders to generate, collect, analyse and interpret the data, the measurement system itself needed to be agreed (161). In this project, despite the use of significant resources in terms of QI project team and organisational staff time, the process of agreeing a measurement system still presented problems. Once a system had been established in one setting (SHINE1), the development in a further setting (SHINE2) was still resource-intensive due to the changes in the EHR as well as the conflict between the design of 'improvement measures' and 'key performance indicators' for attracting financial rewards, although the responsibility for achieving these targets were contentious.

7.3 What is the process of the co-creation of knowledge in a QI project?

The second analysis (§5.0) re-constructs the case study through a knowledge mobilisation lens using the stages of the K2A cycle to highlight the key aspects of the projects. The focus on the actions of actors is further explored in this section with respect to the process of the co-creation of knowledge through three main features outlined by Greenhalgh (2016) (162):

- A systems perspective assuming emergence, local adaptation, and nonlinearity (§7.3.1);
- An emphasis on process the framing of the programme, the nature of relationships, and governance and facilitation arrangements, especially the style of leadership and how conflict is managed (§7.3.2).
- The framing of research as a creative enterprise with human experience at its core (§7.3.3).

These sub-sections are followed by a more discursive exploration of the process of the co-creation of knowledge within a QI project (§7.3.4)

7.3.1 Systems perspectives

The analysis presents the construction and reconstruction of what might have been perceived as a 'straightforward' problem. The initial problem outlined by the clinical leads focussed on generalizable knowledge to demonstrate the gap in life expectancy of people with serious mental illness compared with the general population. As the views and experiences of different actors came into play and different types of knowledge were identified, there was a perceptible shift in the problem conceptualisation. This moved from a high-level problem (macro) to one that drew on local data, tacit knowledge and professional experiences at the clinical level (micro). This understanding of the problem across levels of the system enabled it to be framed within the wider context of policy and evidence whilst retaining a focus on the practice-based problems that could be addressed. Improving the physical health of people with serious mental illness is a complex process and benefits may take years to materialise. Improving health outcomes cannot be addressed by relatively 'simple' changes to a system such as the introduction of a physical health assessment. However, clearly there was something that could be done.

The projects provided an opportunity to engage a large group of individuals, mostly healthcare professionals, with the problem and raise awareness and potentially 'sow the seeds' for future endeavours to change the situation. Nonetheless, as the improvement measures demonstrate, the projects were successful in developing and implementing interventions that could be both sustained (on one ward over four years) and scaled-up (across five additional wards within the same unit). Whilst SHINE1 was initially located on a single ward within a single service, the knowledge mobilisation process was inherently system focussed. This was recognised in the case study through attempts to draw on experience and evidence from different points on the patient journey, from admission to discharge and beyond. Process mapping provided an opportunity to delineate and draw out current service-centred practices and still situate this process within a 'global' or systems perspective by reimagining the practices that could ensure that patients' physical health was appropriately assessed and recorded.

7.3.2 Process-driven

There is a growing recognition of the need to involve those responsible for delivering or indeed receiving interventions in their design (131). A rational, linear approach to the practice of evidence-based care might prescribe an intervention or set of interventions based on those deemed effective from research. However, there is a need to develop locally relevant interventions that both draw on existing evidence and knowledge but are context specific. Participatory QI approaches offered multiple opportunities for a range of improvement team members and other stakeholders to express their opinions about the problem as perceived and experienced at the individual or practice level. Simultaneously, the QI approaches created a 'space' and opportunity for participants, including staff and service users, to suggest potential solutions or areas for further inquiry.

The need for governance arrangements within co-creation ensures that those involved are accountable for their actions or inactions. However, how these governance arrangements manifest is not always clear. There is a need for accountability of those that are expected to deliver the products of the co-creation process, such as new practices.

The projects show that unclear lines of accountability create a challenging environment in which conflict may be present, in this case between service users and clinical staff, as discussed later. (§7.5). Furthermore, the nature of relationships between actors in the co-creation process is a critical factor, which is in part facilitated by clear roles and responsibilities to manage expectations. However, this was not always clear, to the extent that beyond the clinical lead and project manager no other roles were explicitly defined within the projects. Even those with leadership roles did not have clearly defined responsibilities. Encouragingly, even with rare occasions of conflict between the service users and staff, the service users were treated with respect and were financially rewarded for their participation. The service users were asked to contribute more and more throughout the projects, especially copresenting with other members of the QI project team at both internal and external events. This again demonstrated the value of their roles within the projects.

7.3.3 Creative enterprise

Whilst the QI projects demonstrated the explicit creation of interventions through codesign, they also demonstrate the co-creation of knowledge, values, relationships, identities and communities. This includes different types of knowledge about clinical practice, experiences of illness, aspects of context and implementation processes; values about equality and involvement, democratic processes and accountability; and relationships between professionals and patients. This echoes the findings of Felipe et al. (2017), who state 'co-production can lead to the creation of knowledge, values and social relations' (163). Black (2018) highlights the need to involve both staff and patients through a creative process as a potential mechanism for overcoming challenges placed on the system (164). Involving patients and services users can also have consequences for their identities, as recognised by the work of Renedo et al. (2015) who previously framed these changing identities, as 'ruptures' (142). Renedo also highlighted the need for patients to: "re-organize their patient identity and master their 'participant' role to increase their influence and simultaneously contribute to the creation of cultural conditions conducive to collaboration" (142). Renedo and Marston (2011) acknowledge the identity of patients is often: "plural and contradictory, reflecting the tensions and ambiguity of the context where these representations are produced and enacted" (165).

However, the changing identities within this particular case study could be described as a 'recovery journey' for one service user. Whilst for another service user, they were able to develop expert knowledge and skills through their involvement in the projects. This latter case may reflect the relationship between learning and changing identity, highlighted by Bruner (1996) and presented in an earlier chapter (§2.6) (79).

7.3.4 The process the co-creation of knowledge within a QI project?

The knowledge created within a QI project is often perceived to be solely the improvement measures that determine the success or failure of the project. However, this instrumental notion of knowledge was challenged by Batalden and Davidoff (2007) who proposed that other types of knowledge are created by a QI project, in particular, knowledge about the particular "physical, social and cultural identity of local care settings (e.g. their processes, habits and traditions) and knowledge that "provides insight into the strategic, operational and human resource realities of particular settings (drivers) that will make change happen due to the execution of planned changes" (29). Framed within the KMb field, Langley et al (2018) propose a model for the co-creation of knowledge, understood as 'collective making', building on the principles of co-creation outlined by Greenhalgh (2016), that were used to frame this discussion (166). However, within a QI setting, as the research presented in this thesis highlights, participatory nature of the process of the co-creation of knowledge was embedded throughout the QI projects presented in the case study, as demonstrated by this empirical study. There are a plethora of examples from this thesis of how objects, meanings and knowledge were co-created (§4.4.4). Whilst the outputs and products of this knowledge were captured by the narrative offered (§4.0), it was through the analysis using the knowledge to action cycle (§5.0) that that the 'work' of co-creation could be understood better. The co-creation of objects in the form of outputs from the participatory QI method workshops exemplifies the co-constitutive process by which knowledge is simultaneously 'used' and 'created'.

The process map, for example, was created through a participatory QI methods workshop, whereby tacit and experiential knowledge is captured and codified. This was a shared process by which collective understandings and meanings were created of a care process.

This represents a form of 'situated knowledge': i.e. knowledge that is deeply contextualised. As a process, this allows participants to share experiences and knowledge and build relationships and provides a tangible output that can be used to explain to others why the work is necessary, thus offering a rationale as well as a record of the process that can be interrogated through research methods. As acknowledged by Ramaswamy and Ozcan (2014), the co-creation process can be troublesome in terms of accountability, as these complex forms of co-creation are rarely supported effectively through standard governance mechanisms (167). The challenge that accountability and responsibility present to achieving improvement through QI are explored in (§7.5).

7.4 How can the process of implementation and improvement be understood as a social practice?

The third analysis of the QI projects used Normalization Process Theory, as a practice theory lens, to characterise the work of improvement (§6.0). This section explores this work through three elements that require 'ongoing integration' to enact social practices, as described by Shove et al. (2012) (86):

- Materials objects, consumer goods and infrastructures (§7.4.1);
- Competences including understandings of the situation, practical know-how (§7.4.2);
- Meanings including embodied understandings of the social significance of the practice and past experiences of participation (§7.4.3).

Blue et al. (2016) offers smoking as an example of the integration of these three elements that result in the performance of a social practice (84): "materials: not only, cigarettes, matches and lighters; but also tobacco crops, factories, transport systems, retail infrastructures, an economy and so on; competence: to know where, when and how to smoke, for example, not only how to light a cigarette and inhale, but how to smoke in the 'correct' fashion for a given social situation (e.g. smoking in a beer garden is clearly different to smoking during a break at work) and meaning: understanding smoking as a normal and socially acceptable thing to do, variously associated with relaxation, sociability, masculinity, glamour and toughness".

As this published example demonstrates, practices draw on materials, not just those immediately required for a practice, but those necessary to create the material. Similarly, competence or 'know how' is not just a technical skill but situated within a social context. Meaning is influenced by social norms but also about the effect and resultant outcomes of the practice. Practices are often situated within a particular 'space'. Some insight will be offered about the spaces in which improvement practices took place within the projects (§7.4.4).

7.4.1 Materials

A social practice lens emphasises the 'objects' required for improvement, rather than focussing solely on relationships and actions (168). In the QI projects, material representations, specifically the physical health assessment form, played a substantial role in the social processes, and were central to the delivery of the project and its impact. The co-design of the form by members of the QI project team with clinical front-line staff symbolised the enactment of 'improving physical health' and gave meaning to what could have been perceived as abstract evidence and guidelines (explored further in §7.4.3). In this way, the physical health assessment form became a focus for the interaction between the work of improving the system (QI) and the work of improving the physical health of patients (clinical), the confluence of two types of practices with different intentions. Of course, the material representation of the clinical practices is linked, but distinct from the improvement practices, that relate to access and availability of equipment to enable the physical health assessments.

These materials included weighing scales and height measurers (for BMI), electronic sphygmomanometers (for blood pressure) and blood collection tubes (for cholesterol). The outputs from the QI methods workshops constituted a significant element of materiality, both in themselves as objects and the actors and objects that were represented, especially the process maps. The role of these objects was in facilitating technical functions relating to QI, such as identifying potential problems and solutions, and in creating dialogues and relationships (31).

7.4.2 Competences

The competences described relate to both QI technical skills, such as how to create a process map or Action Effect Diagram, and 'soft skills' related to QI, which include: "assertiveness, communication, negotiation, time management, stress management and leadership" (169). Together these skills might be necessary to facilitate the creation of an Action Effect Diagram, for example, rather than just the technical skills to know how one is created.

This distinction is important, as the technical skills may be taught and learnt in a classroom, but the soft skills are related to experiential learning. This requires the learner to be involved and actively carrying out these activities to gain the skills. This may extend into more general management skills such as how to chair a meeting, or set an agenda, or take minutes, or organise and lead a project team. In the QI projects, these types of activities often fell to the clinical leads and project managers, who were necessary to ensure continuity of the projects.

A perceived lack of QI experience/skills generated anxiety amongst members of the QI project team, especially those who were non-clinical, and relied on them building relationships and demonstrating their ability 'to help' to validate their presence on the team. This was coupled by an often less than enthusiastic approach from some clinical staff to their own involvement. Whilst the project team was resourced with some back-fill/over-time payments for their involvement, this was not the case for the clinical staff. Ward staff were expected to deliver the physical health assessments and communicate the results to patients as part of their day-to-day role and to take time out to attend project meetings and/or workshops.

This became difficult to sustain, especially as both doctors and nurses rotated out of the wards or their role as Ward Champion, often leaving gaps before the appointment of new Ward Champions. Providing training for both clinical staff, through the Ward Champions workshops, and the QI project team, through quarterly learning events and facilitated workshops, helped equip staff with the skills and knowledge required to be involved in the projects and also so that they might be involved in future organisational projects.

The development of QI skills was an important motivator for organisational leaders, with several staff moving onto new positions after the project, either within the Trust, or in other Trusts. They identified their involvement as important to their move to new roles.

The recognition of the project and the individuals involved was at both an organisational level, through an award by the Trust for the project, and in recognition of the impact of the project through external inspection by the Care Quality Commission (CQC). The CQC inspection (2017), which involved interviewing several staff across the wards, identified the projects as delivering 'best practice' by improving the assessment of physical health on the wards. This gave staff a sense of accomplishment. This was followed by the results of the National Clinical Audit of Psychosis (2018), which demonstrated quantitative improvements across the Trust in physical health assessments, an important driver of organisational strategy.

7.4.3 Meanings

The meanings that individuals or groups ascribe to their work (or practices) can be achieved through the sense-making process. In these projects, it was necessary for the healthcare professionals to understand how the work related to the newly introduced assessments (for long-term physical health) was expected to fit within the context of the existing assessments (for acute physical health). This aspect of sense-making related to the shift in clinical practices, rather than understanding the underlying principles and processes of QI. However, it was also important for the QI project team to understand and make sense of the QI process, which was achieved through basic education and training in QI methods supported by the QI practitioners.

The link between these distinct sense-making processes was crucial in giving meaning to the work, as the value of QI can be best understood through the context of the improvements. In the projects, effort was expended to understand existing physical health assessment practices and processes, using participatory methods, e.g. process mapping, thus linking the QI and clinical practices.

Engagement of the QI project team members in SHINE1, using the 4Pi framework, was effective in creating opportunities for their input. QI project team members contributed to the co-design of various interventions and their implementation.

In SHINE2, involvement was less well-structured and created challenges related to the roles and contributions of all QI project team members, with many expressing uncertainties about the 'work' they should be doing, particularly the services users.

In SHINE 1 the service users led the co-design of the patient-held physical health plan (PHP), which had clear lines of involvement and mechanisms for feedback to make meaning of their involvement. During the implementation of the interventions in SHINE2, the service users felt they had less influence over this process. However, they did question and challenge staff about the reported low uptake of some care processes, especially in relation to the accountability of staff who did not give out the patient-held physical health plans.

The role of service users was both legitimising of the project itself and represented authentic involvement, as compared with examples of tokenistic involvement. As a result, service users felt their contributions were valid. For most staff this was the first time they had been involved in a project that involved service users in this way.

These staff expressed the desire to ensure that any future projects there were involved with should also include service users, but recognised the need for support in involving service users, which was not always available within the Trust, although, two of the three service users have taken on new involvement roles within the Trust and continue to act as ambassadors for the project and for the role of QI in mental health service more generally.

7.4.4 Spaces for developing improvement practices

The monthly Ward Champions' workshops created a space for shared learning, where Ward Champions could reflect on their ideas and plan for changes specific to their wards and report the impact of using the PDSA cycle. These workshops offered opportunities to share the challenges and facilitators of implementation, as well as creating new relationships and even a community of practice (COPs).

The QI project team were much more cohesive as a group, compared with Ward Champions that attended the workshops. Partly this may have been due to familiarity and the time that the QI project team had had to mature as a group and the work most of them had been involved in in SHINE1. This resulted in a commitment spanning up to four years and the attendance at the monthly team meetings.

Creating a cohesive group was quite challenging within the Ward Champions' workshop sessions: many of the staff were from different wards and had not worked together before. There was quite a significant turnover of staff with few people attending more than two sessions.

7.4.5 Implementation and improvement as a social process

Analysing QI projects offer opportunities to unpack the social processes of implementation and improvement, constituted by the performance and reperformance of social practices, which themselves are composed of activities that integrate objects, competences and meanings. Social processes and practices can be understood through both a practice theory and communities of practice lens. The narrative (§4.0) offers an account of the high level social processes of improvement, with a particular emphasis on the relational work that supported the 'knowledge to practice' process. This shows how a form was created to organise both knowledge and 'work' to transform a set of strategic intentions into everyday clinical practices.

Codifying knowledge, especially drawn from experience, is an important and necessary part of the co-creation of knowledge, which has been argued by Von Hippel to be itself a social process (170). Additionally, as proposed by communities of practice theory, learning is a social process requiring learners to interact and build relationships.

Whether improvement practices should be disentangled from clinical practices is not clear, the intimate connection between these different types of practices presents a challenge in understanding improvement as social practices that would decontextualize them if the clinical practices are stripped away. Improvement practices depend on the underlying coherence and motivation for them to be enacted.

This in turn comes from the clinical problem at hand that requires changes in clinical practices. However, bringing into focus the materials, competences and meanings offers an alternative and context-specific understanding of improvement practices.

This is further supported by the model outlined in **Figure 43**, which proposes a new understanding of inter-relationships between each of the four constructs of NPT within a QI project. This suggests there is a cyclical relationship between sensemaking (coherence), relationship building (cognitive participation), operational activities (collective action) and reflection and evaluation (reflexive monitoring), which may be repeated over several cycles. This model differs somewhat from others proposed in the literature but may fit well for this type of QI activity, which is similar with the ubiquitous PDSA cycles, so often seen in QI (171).

7.5 How is accountability and responsibility distributed within the system?

Whilst a systems approach has advocated a no blame culture, Wachter (2013) outlines the need to balance this with individual or collective accountability for those who are responsible for delivering care (172). The tensions between improvement and accountability in healthcare have been debated since the mid-1990's (173). Whilst clinical audits are a well-known mechanism for promoting organisational accountability, the measurement and assessment of practices alone is insufficient in enacting change and improving quality (158). As such, whilst the QI methods presented in the case study, and the participatory approach they engender, have demonstrably improved the delivery of key clinical practices this thesis has also highlighted the continued tensions between improvement and accountability.

In particular, there were challenges in balancing the opportunity and freedom to develop new interventions that respond to the needs of patients (and clinical staff) with the limited time and resources available to those that deliver care.

Also, whilst the measurement of clinical practices could identify gaps in their delivery converting this into actions in response to the data remained a challenge.

Following the scale-up of the clinical interventions to other wards, there were concerns about the extent to which staff were individually or collectively accountable for assessing patients' physical health, providing patients with their results and giving appropriate interventions or information. Involvement of the ward managers and sharing of the improvement data with the unit's governance team seemed to change the perception of accountability. Whereas previously the data were only being used for staff to reflect on the delivery of the interventions on their own ward, this was now being shared at a high level within the Trust. Concerns were expressed about the use of these data for assessing or managing performance, which contradicts the principles of QI, where data are not used for judgement or performance but for reflection and improvement. However, as demonstrated using the national clinical audit data (NAS/NCAP), these data are frequently used to rank organisations and comment on their 'performance'. Service users used the data to hold the clinical staff to account for what they perceived as not 'doing their job'. This presented moments of conflict between the need to support the clinical staff to undertake the physical health assessments and holding them accountable when they did not do them. This was identified across all three analyses, in both the problem definition and delivery of the improvements, and was aligned to the relational integration construct (§6.4.2) of NPT. This is further explained by the account offered by May et al (2007): "accountability is concerned with the knowledge and practices of those enacting the complex intervention, what is the knowledge required by the work, who has this knowledge, are there disagreements about where (and with whom) the necessary knowledge lies, what contributions are required of participants, and what are the formal and informal rules that govern the distribution of knowledge and practice within relational networks" (68). Whilst this aspect recognises the role of specific knowledge related to accountability, in these projects it more closely relates to the governance structures that determine individual and collective accountability of clinical staff in ensuring patients receive a physical health assessment. The participatory methods used in SHINE1 were intended to "actively engage those responsible for and affected by change", as outlined in the SHIFT-Evidence principle and build a community of practice.

The logic was that in doing so, this would create a sense of responsibility within this community to deliver necessary care for patients. However, as the interventions were scaled-up the opportunity to actively and creatively engage staff and service users in designing the interventions was absent, as these had already been 'formalised' within the EHR. Furthermore, a cynical perspective of this shift in accountability, may interpret the projects as an attempt to re-frame responsibility for the physical health (and subsequent health and life expectancy) of people with serious mental illness as the duty of the patients themselves rather than the healthcare professionals, or the healthcare provider organisation.

Through the multi-perspective analysis of this research it appears that the need to consider accountability and responsibility is a key element that intersects the different 'knowledge to practice' approaches. As outlined, the collection of the improvement data as part of the QI approach exemplifies the tensions between improvement and performance/accountability and offer differing interpretations of the data. However, this is within the context of engagement with representative stakeholders and the collective responsibility that it was intended to create. This is further exemplified by the analysis of the problem definition, where different sources of data are drawn on and problems constructed at different levels of the system. Organisational level data provided by the national audits are interpreted as a clinical practice level problem, which had to be reconciled with the experiences of staff (and patients) at this level. Whilst this may have been recognised within SHINE1 this was much harder to demonstrate in SHINE2 as the focus was much more about implementing the interventions that drawing on their professional experiences to construct both the problems and solutions. From a practice perspective, the perceived absence of the delivery of particular clinical practices was evidence by the improvement measures, but this apparent objective measure of practices did not account for the challenges perceived by staff in delivering those 'simple' practices.

Examples of the tensions created by the assumptions or rejections of responsibility across the different analysis are suggestive of this issue providing a conceptual link between QI, KMb and IS, occupying 'fuzzy' boundaries that intersect these approaches, as outlined in the conceptual model (**Figure 15**).

7.6 Strengths and limitations

There are several limitations to this study. An inherent methodological issue of all organisational research is that we are limited by what we can observe and who we can interview resulting in an incomplete picture of any large organisation. Whilst this is an important limitation to acknowledge, it can rarely be resolved without significant resources. So, what is offered here is a case study that is re-constructed from fragments of information generated from multiple observations, interviews and documentary analysis. As such, it may not represent a complete account of the projects rather a mosaic that contains gaps. In common with many studies using ethnographically-informed approaches, this research was conducted by a single observer, hence the findings presented are provisional. I have however attempted to draw on multiple accounts and documentary sources to triangulate findings. Furthermore, this account is not neutral or value-free. One might say, as Pols suggests, that I have offered a 're-scription' rather than 'description' of the case study, acknowledging the imposition of the researcher's perspective in this account (174). The findings are contingent on these perspectives, but this study is an attempt to describe what 'is' and not intended to derive an 'ought' from those findings (175). Although, some reflections are offered.

The strengths of the study lie in the methodological approach and multi-perspective analysis. The study of implementation in healthcare could be described as the place where the worlds of the natural sciences and social sciences collide, and where their limitations and contradictions are brought to the fore, offering a new locus for the battlefield of ideas and ideology. This study describes that battlefield. Whilst the use of participatory methods to study implementation and improvement is increasing, there are challenges to move beyond the purely descriptive accounts and to position the work theoretically.

This poses a challenge to those from outside a social science tradition that want to engage with this methodology to explore the boundaries of implementation and improvement, but as this study has demonstrated, efforts can been made to engage with a range of theoretical positions to move beyond a descriptive account to illuminate the implementation process.

7.7 Conclusion

Quality improvement, knowledge mobilisation and implementation science all aim to support the 'knowledge to practice' process, ensuring research findings can be better used to deliver effective and efficient care. The simple linear mechanistic model of this process has long been abandoned with a greater recognition of the importance of understanding the role of complexity, the co-creation of knowledge and social practices (176–178). However, this study provided an opportunity to examine all three phenomena within the same case study with the intention of building up a detailed account of the two projects through different lenses to respond to three research questions, explored below.

Through the use of SHIFT-Evidence, the analysis has attempted to identify QI methods that assist actors in navigating system complexity. These included QI methods explicitly based on participatory process, such as the Action Effect Method and process mapping. These methods engaged with a wide range of stakeholders and provided a mechanism through which to draw on their tacit knowledge and experiences that could be codified in outputs from the workshops. Furthermore, the use of measurement for improvement facilitated the linkage between the macro, meso and micro level understandings of the clinical problem and demonstrate improvements.

The outputs from workshops featured as important artefacts in exploring the process of the co-creation of knowledge with the projects. They represented products from a co-constitutive process by which knowledge was simultaneously 'used' and 'created'. Through these participatory approaches, tacit and experiential knowledge was captured and codified as a process of co-creating collective understandings and meanings.

This relational work was brought in to focus when exploring implementation and improvement as social practices, moving away from the technical aspect to focus on the social, a main feature of the conceptual model (§2.8). This focus also raised the issue whether the practices of implementation and improvement could be characterised as separate from their context.

Through a social practice lens, it was quite apparent that the interaction between materials, competences and meanings suggested that the context of the practices was necessary in understanding them. In fact, the practices were embedded within a wider set of implementation and improvement processes, namely: a sense-making process, the building and maintaining relationships, operational tasks and activities, and opportunities for reflexivity.

An emergent finding from the study was the role of accountability and responsibility and the significant challenge these concepts created within projects. A careful balance needed to be found between the use of the data for managing performance and supporting staff to reflect on their own practice. Through the use of participatory methods, it was assumed that responsibilities of staff would be "built-in" to the interventions on the initial ward, which to some extent occurred. However, this did not translate into practice during the scale-up on additional wards with actors that hadn't previously been involved in the design of the interventions.

The projects aimed to address what might be described as a particularly challenging and complex problem: improving the life expectancy of people with serious mental illness. These represent some of the most vulnerable people in society, whose life is often cut-short by the very treatment that aims to makes them 'well'. Solutions to this problem fundamentally challenge the current separation of mental and physical health, evident at all levels of the health system including clinical training and the organisation and delivery of services (179). This separation has been reinforced by rounds of reorganisation of health services, which may have aimed to strengthen mental health services with the provision of specialist training, but inadvertently created a fragmented system composed of silos of knowledge and practice separating physical and mental health services and staff (180).

At a time of unprecedented pressures and cuts in health services with staff being asked to do more with less; there is an expectation that staff will be involved in QI projects. As in these projects and many like it, staff do get involved and so do service users, and together they can, as demonstrated here, make a difference. Collectively the QI project team and the clinical staff 'worked' to introduce new clinical practices to identify and begin to address some of the fundamental physical health needs of their patients.

As outlined in this thesis, QI methods can offer opportunities to engage with complexity in healthcare systems through the co-creation of knowledge and through social practices. These aim, to some extent, to address issues of accountability and responsibility within the system and, in so doing, bring about service improvements. The use of QI methods to achieve change is multifaceted and requires significant technical, cognitive and social skills. When used to its full potential, QI can generate meaningful and lasting improvements. There are encouraging signs of the increasing interest and uptake of QI methods, including in public health (181). However, there may be a temptation to encourage short-term projects and expect rapid service improvements, but as this research demonstrates, QI is resource intensive, requires extensive expert facilitation of QI methods, and its effectiveness is reliant on existing clinical practices and processes as well as the ability of staff and patients to work together to change clinical processes within a culture that values QI processes.

In the specific context of the physical health of people with serious mental illness, whilst policies, such as the Five Year Forward View for Mental Health, are now attempting to bridge this gap, the challenge of implementing change within a system where the infrastructure and processes inherently separate physical and mental health remains significant (182). Yet, as this thesis demonstrates, there may well be opportunities to integrate physical health into mental health services at a local level using QI methods. Although, this study did not intend to evaluate or validate this work but instead explore the social processes of the development and delivery of the QI projects to implement evidence-based practices.

Through this study it also became evident that the way research and practice are separated and the dichotomy that this creates continues to promote assumptions about the 'knowledge to action' process, specifically that research creates knowledges that is sequentially implemented in practice. Whilst this assumption has somewhat been challenged by the 'engaged scholarship' model proposed by Van de Ven & Johnson (2006) this has yet to be perceived as mainstream within QI. Despite this, Batalden & Davidoff (2007) recognised the role of different types of knowledge and its creation in QI, although the value ascribed to this knowledge, and more importantly the processes through which it is generated, remains unclear (75).

This study has explicitly drawn on specific frameworks to structure the analytical lens through which to unpack the case study based on different 'knowledge to practice' approaches. Whilst this use of different frameworks has been helpful in exploring different aspects of the case study in also highlights some of the deficits within each approach. As such, the somewhat "technical" or process driven approach offered by QI, the staged problem-driven approach of KMb, and practice-oriented approach of IS may individually offer useful frameworks for both action and understanding, it is their combined use or alignment that may offer more robust approaches to 'knowledge to practice'. As the number of frameworks across the QI, KMb and IS fields grow it may be necessary to integrate components to better meet the needs of practitioners and researchers and improve inter-operability between them, with some progress already reported in this area (183).

As discussed, despite the growing number of frameworks, and the attempts at categorising them, there are few attempts at situating these frameworks with the existing QI, KMb and IS landscape to explicate similarities and differences between existing and novel frameworks, and importantly the epistemological underpinnings of the empirical work, if any, that is drawn on (32). This research offers some key findings and features based on empirical work and whilst this isn't intended to theoretically extend or develop the frameworks that have been drawn on, it is through these multiple 'knowledge to practice' approaches that suggestions are made that could be further refined through future empirical work.

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9.0 Appendices

9.1 Participant Information Leaflet (Observations)

Information for Participants: Observations

Study title: Improving the quality of care for people with mental health disorders and dementia: Co-creating knowledge within health innovation and improvement networks in England- Phase 2

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and to talk to others about the study, if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

1. What is the purpose of the study?

The implementation of research evidence into clinical practice remains a significant challenge. The Collaborations for Leadership in Applied Health Research and Care (CLAHRC) Northwest London is working with Central Northwest London NHS Foundation Trust to develop an initiative (SHINE 2) that aims to bridge the gap between research and practice and improve the physical health of people with serious mental illness. The aims of this study are to examine how that initiative has been developed and to how research knowledge, combined with experience, can be used to improve health care services.

2. Why have I been chosen?

You have been asked to participate as either a member staff or affiliate of CLAHRC Northwest London or Central and North West London NHS Foundation Trust or you have been identified a someone involved in the delivery and/or improvement of mental health services

3. Do I have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason.

4. What will happen to me if I take part?

If you agree to participate your contributions to meetings held as part of the initiative will be observed. You may subsequently be invited to participate in a one-to-one interview with the researcher, but this will involve a separate consent process.

5. What do I have to do?

As a participant in the initiative you will contribute normally to discussions at project meetings. The researcher will observe you and your colleagues discussing and planning the 'SHINE 2' initiative.

6. What are the possible benefits of taking part?

Through participation in the study it is hoped that research can shed light on the process of how knowledge from research and experience can be used in the area of mental health. It is hoped that those that participate in the interviews may find the opportunity to reflect on their involvement in the initiative an enlightening process.

7. Will my taking part in the study be kept confidential?

Yes. All information collected about you and your organisation will be kept strictly confidential. No organisations or individuals will be identified in reports or publications generated from the analysis.

8. What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through Professor Nicholas Mays (nicholas.mays@lshtm.ac.uk) or Professor Derek Bell (d.bell@imperial.ac.uk)

9. What will happen to the results of the research study?

The data collected during the interview will be analysed and used to inform the overall conclusions from the work. It is hoped that a peer-reviewed publication will be subsequently be generated from the work.

10. Who is organising and funding the research?

The NIHR CLAHRC for Northwest London has commissioned this research as part of the researchers Doctorate in Public Health, which will be examined by the London School of Hygiene and Tropical Medicine, which is also acting as sponsor of the research.

11. Who has reviewed the study?

This study was given a favourable ethical opinion by the London School of Hygiene and Tropical Medicine Research Ethics Committee but does not require specific NHS REC approval as participants are staff not patients.

12. Contact Details

If you wish to discuss this study with the researcher, please contact:

Stuart Green, DrPH Student, London School of Hygiene and Tropical Medicine on 07894473482 or (stuart.green@lshtm.ac.uk).

You will be given a copy of the information sheet and a signed consent form to keep.

Thank you for considering taking the time to read this sheet.

9.2 Participant Information Leaflet (Interviews)

Information for Participants: Interviews

Study title: Improving the quality of care for people with mental health disorders and dementia: Co-creating knowledge within health innovation and improvement networks in England- Phase 2

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and to talk to others about the study, if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

1. What is the purpose of the study?

The implementation of research evidence into clinical practice remains a significant challenge. The Collaborations for Leadership in Applied Health Research and Care (CLAHRC) Northwest London is working with Central Northwest London NHS Foundation Trust to develop an initiative (SHINE 2) that aims to bridge the gap between research and practice and improve the physical health of people with serious mental illness. The aims of this study are to examine how that initiative has been developed and to how research knowledge, combined with experience, can be used to improve health care services.

2. Why have I been chosen?

You have been asked to participate as either a member staff or affiliate of CLAHRC Northwest London or Central and North West London NHS Foundation Trust or you have been identified as a key stakeholder in the delivery and/or improvement of mental health services

3. Do I have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason.

4. What will happen to me if I take part?

If you agree to participate the interview will take place between one participant and a researcher and will explore your experience of participating in the 'SHINE 2' initiative or any other relevant experience, which could take 30-90 minutes to complete.

5. What are the possible benefits of taking part?

Through participation in the study it is hoped that research can shed light on the process of how knowledge from research and experience can be used in the area of mental health. It is hoped that those that participate in the interviews may find the opportunity to reflect on their involvement in the initiative an enlightening process.

6. Will my taking part in the study be kept confidential?

Yes. All information collected about you and your organisation will be kept strictly confidential. No organisations or individuals will be identified in reports or publications generated from the analysis.

7. What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through Professor Nicholas Mays (nicholas.mays@lshtm.ac.uk) or Professor Derek Bell (d.bell@imperial.ac.uk)

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Stuart Green, DrPH Student, London School of Hygiene and Tropical Medicine on 07894473482 or (stuart.green@lshtm.ac.uk).

You will be given a copy of the information sheet and a signed consent form to keep.

9.3 Informed Consent Form (Observations and Interviews)

INFORMED CONSENT FORM

Full Title of Project: Improving the quality of care for people with mental health disorders and dementia: Co-creating knowledge within health innovation and improvement networks in England- Phase 2

Name of researcher: Stuart Green							
			Please initial box				
1. I confirm that I have read and understand the participant information sheet for <i>observations/ interviews</i> (delete as appropriate) dated 16/02/17 (version 1.1) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered fully.							
2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.							
3. I agree to take part in the a	bove study.						
Name of Participant Signature Da (printed)							
Researcher Signature Da							

1 copy for participant; 1 copy for researcher

9.4 Interview Topic Guide

Healthcare Professionals and Organisational leaders

- Could you tell me about your professional background related to your education and experience that led to your current role?
- What experience do you have of the physical health of people with mental illness? Can you provide an example(s)
- Can you tell me more about your clinical/organisational role?
- Does your role have a focus on supporting the physical health of people with serious mental illness? How?
- What experience do you have of being involved with any aspect of quality improvement?
- What was your role in the SHINE project?
- How did you get involved in the project?
- What QI methods have you used?
- Can you tell me about a typical patient journey?
- What role did you have in caring for/assessing the physical health of people with serious mental illness before the SHINE project? How has that changed?
- Who is responsible for the physical health of these patients?
- What do you feel, if anything, you have gained from being involved in the SHINE project?

Service users

- Can you tell me about yourself, your education and professional experience?
- Can you tell me how you got involved in the SHINE project?
- How much did you know about the physical health of people with mental illness before the project?
- Why did you want to be involved in the project?
- How have you been involved in the project?
- What do you think you have contributed?
- What do you think you have gained from being involved?
- What impact do you think the project has had?

9.5 Documents for analysis

Date	Document name	Source File
14/12/11	NICE CG 136	https://www.nice.org.uk/guidance/cg136
25/10/13	Project Application	N/A
12/02/14	NICE CG 178	https://www.nice.org.uk/guidance/cg178
01/06/14	Lester Tool 2014	Figure 17
01/09/14	Action Effect Diagram	Figure 18
24/09/14	NICE CG 185	https://www.nice.org.uk/guidance/cg185
01/10/14	Ward process map	Figure 19
08/10/14	National Audit of Schizophrenia	https://www.repsych.ac.uk/docs/default-source/improving-care/ccqi/national-clinical-audits/ncap-library/national-audit-of-schizophrenia-document-library/nas_round-2-report.pdf?sfvrsn=6356a4b0_2
05/11/14	Stakeholder analysis	Figure 20
12/02/15	NICE QS 80	https://www.nice.org.uk/guidance/qs80
01/06/15	CLAHRC poster	N/A
01/09/15	Final project review report	http://health.org.uk/sites/default/files/CN WL%20(7305)%20Shine%202014%20Fi nal%20Report%20for%20website.docx
01/02/16	Lancet Psychiatry article	https://www.thelancet.com/journals/lanps y/article/PIIS2215-0366(16)00010- 9/fulltext
17/02/16	NIHR presentation	N/A
01/04/16	HQIP PPI in QI Guide	https://www.hqip.org.uk/resource/a-guide-to-patient-and-public-involvement-in-quality-improvement/#.XKsWwJhKiUk
21/04/16	Application	N/A
18/06/16	JMHTEP paper	https://www.cnwl.nhs.uk/wp- content/uploads/2Green-3.pdf
28/10/16	Action Effect Diagram	Figure 28
26/01/17	NICE Shared learning	https://www.nice.org.uk/sharedlearning/improving-the-physical-health-of-peoplewith-serious-mental-illness-a-quality-

		improvement-approach
06/02/17	AHSN presentation	N/A
12/02/17	CMHT presentation	N/A
19/04/17	Pharmacy presentation	N/A
25/04/17	CLAHRC presentation	N/A
18/08/17	CQC Acute wards Report	https://www.cqc.org.uk/provider/RV3/reports
18/08/17	CQC Quality Report	https://www.cqc.org.uk/provider/RV3/reports
04/10/17	Conference Poster	N/A
06/11/17	AHSN presentation	N/A
00/11/1/	THIST (presentation	· ·
02/01/18	IJMHS paper	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5763531/

9.6 Physical Health Assessment Form (Word version)

BLUE: mandatory for Doctors; **RED:** mandatory for nurses; BLACK: Shared responsibility Dr/nurse

Patient Name:

Past Medical History:

Current Medication:

Allergies:

Family History (Medical):

Family History of: Please delete as appropriate

Diabetes YES/NO

Angina or Heart Attack < 60 years YES/NO

Stroke < 60 years YES/NO

Smoking Status:

(Please state if: Never / Ex-Smoker / Current: <10 a day / 10-19 a day / >20 a day)

Other:

Is the patient **immobile**? YES/NO Please delete as appropriate

If YES, Waterlow Score:

Has the patient had any problems with their eyes recently? YES/NO

Please detail here:

Does the patient require any aids for **hearing**, **sight**, **mobility**, **eating or other**? *YES/NO*

please detail here:

Has the patient had any problems with their **teeth** recently? YES/NO

Please detail here:

Does the patient have any problems **passing urine** or with their **bowel movements**? *YES/NO* Please detail here:

Does the patient have any Sexual Health problems or concerns? YES/NO

Please detail here:

IF FEMALE AGED 25-54: Cervical screening in past 3 years: YES/NO

If YES - result:

If NO – leaflet given YES/NO

BASELINE OBSERVATIONS

If refused, please enter "R"

Date					
Weight					
Height					
ВМІ					
Waist circumference					
ВР					
Heart rate					
O2 Sat					
Temperature					
Resp freq					
вм					

Notes:

If BMI <18.5 Malnutrition Screen Tool MST, If BMI >24.9 medication and lifestyle reviews

If Waist Circumference>79cm medication and lifestyle reviews

<u>Physical Examination</u> (if any element refused, please write "refused" for that element)

General (e.g. Cyanosis/pallor/icterus, dentition, oedema, thyroid, lymph nodes, tremor):

Nervous System (e.g. Gait, power, tone, reflexes, sensation, peripheral neuropathy, cerebellar signs, pupils, cranial nerves):

Skin (e.g. Skin lesions, rashes, injuries, pressure sores, ulcers):

Respiratory:

Abdomen:

Cardiovascular:

ECG (Please highlight when an ECG has been done):

Abnormal Findings/Impression:	
Action & Proposed Investigations:	
BLOOD TESTS:	
BLOODS SENT:	YES/NO
if no, reasons for not:	
BLOOD RESULTS	
Bloods taken: YES/NO (reason e.g. refusal)	

Date					
FBC					
U&Es					
LFTs					
Bone profile					
TFTs					
CRP					
HbA1c					
Glucose					
Cholesterol					
Prolactin					
Other					
Other					
Other					

Comments on abnormalities:

URINE TESTS:

Urine Multistick Results

Date					
Leuco					
Nitrates					
Protein					
рН					
Blood					
Spec Grav					
Ketones					
Glucose					

Cardiovascular Risk:

http://www.jbs3risk.com/JBS3Risk.swf

(you'll find the info to the below in the output sections indicated)

(Healthy Years) Risk of having a heart attack or stroke within the next 10 years: ...%

(Heart age) Their heart age is about compared to a person of the same age, gender and ethnicity with Optimal Risk factors.

(more – Outcomes) In a crowd of 100 people with the same risk factors are likely to have a heart attack or stroke within the next 10 years.

(Healthy Years) On average they can expect to survive to age......without a heart attack or stroke.

Diabetes Risk:

http://www.qdscore.org/

Risk of having Type 2 Diabetes within the next 10 years%Score of a typical person with the same age, sex and ethnicity%

In a crowd of 100 people with the same risk factors...... are likely to have Type 2 Diabetes within the next 10 years.

PHYSICAL HEALTH RECORD ("My Physical Health Explained")

Booklet provided YES/NO