The implementation of care pathways to improve children's allergy services

Thesis submitted for Doctor of Philosophy

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Declarations

Statement of originality

I declare that this thesis represents my own work – except where stated otherwise by reference or acknowledgement.

Copyright declaration

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Abstract

National reviews demonstrate quality deficiencies in UK health services for allergic children. In response, the RCPCH developed care pathways to improve the organisation and delivery of allergy care. However, care pathway interventions have variable success. Consequently, a literature review and four ethnographic case studies were conducted to theorise care pathway implementation and inform practical recommendations for health service improvements. This process followed the four stages of MELD dialectic: First Moment (1M) of (non-)being, Second Edge (2E) of becoming, Third Level (3L) of integrated totality, and Fourth Dimension (4D) of agency.

The 1M results define the mechanisms that cause allergy health service deficiencies and how to address them. Deficiencies were found to emerge from causal mechanisms interacting at physiological, inter-personal, and systemic levels. Care pathway interventions that address these mechanisms could improve the quality of children's allergy services. However, healthcare improvements also depend on the implementation process and contextual influences.

The 2E results describe the unfolding journeys of four teams improving their local health services for allergic children.

The 3L results integrate the 1M theoretical understanding and 2E empirical experiences into an advanced understanding of allergy care pathway implementation. The *improvement context totality* captures contextual factors that manifest differently depending on geohistorical contingencies. This creates unique local challenges and opportunities. The *child allergy intervention totality* integrates care pathway interventions implemented across case studies. What intervention elements are implemented and to what degree is negotiated based on local challenges and opportunities. The *improvement process totality* captures the quality improvement methods used to develop interventions and overcome contextual challenges. Children's allergy health service improvements emerge from the three totalities operating as a dynamic whole.

The 4D results discuss the resolution of dialectical contradictions related to the improvement of children's allergy services. They integrate contradictory theoretical insights identified across academic disciplines by grounding them in the 2L empirical case study experiences and relating them to the 3L structural understanding. These theoretical developments are subsequently translated into practical strategies to navigate and optimise local efforts to improve children's allergy services.

This study used MELD to make theoretical contributions in clinical allergy and improvement science with the aim to support the improvement of children's allergy services in practice.

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Table of contents

List of Tables

List of Figures

Appendices

Abbreviations

A&E – Accident and Emergency

AED – Action Effect Diagram

ARIA – Allergic Rhinitis and its Impact on Asthma

APC – antigen-presenting cell

BPR – Business Process Reengineering

BSACI – British Society for Allergy and Clinical Immunology

BTS/SIGN – British Thoracic Society & Scottish Intercollegiate Guidelines Network

C-ACT – Childhood Asthma Control Test

CCG – Clinical Commissioning Group

CCM – Chronic Care Model

CMPA – Cow's Milk Protein Allergy

CPM – Critical Pathway Method

CPSET – Care Process Self Evaluation Tool

CQC – Care Quality Commission

CQUIN – Commissioning for Quality and Innovation

CYP – Children and Young People

DCR – Dialectical Critical Realism

DH – Department of Health

EBM – Evidence-Based Medicine

ED – Emergency Department

ENT – Ear Nose Throat

E-P-A – European Pathway Association

FcƐR1 – high-affinity IgE receptor

GP – General Practitioner

HLP – Healthy London Partnership

HQIP – Healthcare Quality Improvement Partnership

IBM – International Business Machines Corporation

ICE – Integrated Clinical Environment

ICP – Integrated Care Pilot

IgE – Immunoglobulin E

IHI – Institute for Healthcare Improvement

IL – interleukin

IoM – Institute of Medicine

IT – Information Technology

ISAAC – International Study of Asthma and Allergies in Childhood

LOS – Length of Stay

MDT – Multidisciplinary team

MRC – Medical Research Council

MSI – Management Systems International

NHS – National Health Service

NICE – National Institute for Health and Care Excellence

NPfIT – National Programme for Information Technology

NPM – New Public Management

NRAD – National Review of Asthma Deaths

OTC – over-the-counter

PC – Personal Computer

PCT – Primary Care Trust

PDSA – Plan Do Study Act

PERT – Programme Evaluation and Review Technique

PLT – Practice Learning Time

PREM – Patient Reported Experience Measure

PRIS – Pediatric Research in Inpatient Settings

QIPP – Quality, Innovation, Productivity and Prevention

QI – Quality Improvement

QOF – Quality and Outcomes Framework

RCP – Royal College of Physicians

RCPCH – Royal College of Paediatrics and Child Health

SCG – Specialised Commissioning Group

SCN – Strategic Clinical Network

SHA – Strategic Health Authority

STP – Strategic Transformation Plan

SUM framework – Scaling-Up Management framework

T_h cell – T helper cell

TQM – Total Quality Management

UK – United Kingdom

WAO – World Allergy Organization

WHO – World Health Organization

Introduction

In 2003, *'Allergy: the unmet need'* was published by the Royal College of Physicians (RCP). It was a call to the Department of Health and the NHS for urgent action. The report discussed that the prevalence of allergic diseases had increased to 'epidemic' proportions and the presentation of allergic disease had become more complex. Luckily, the medical knowledge to diagnose, treat and manage children's allergies had also developed over the years. However, the report identified that this expertise was inaccessible to most children due to a lack of knowledge in the workforce and ineffective health services. As such, the RCP made recommendations to improve children's allergy services nationally. In 2010, they published another report that presented on the progress that had been made so far. This report was titled *'Allergy services: Still not meeting the unmet need'.* These findings reflect the experience in the United Kingdom (UK). However, the World Allergy Organization (WAO) identified similar deficiencies in allergy health services worldwide (World Allergy Organization, 2013).

These observations indicate that the quality deficiencies in children's allergy services are difficult to resolve. They reflect a complicated problem that involves many confluent issues. For example, children often present with multiple allergic comorbidities that need to be managed holistically based on their shared allergic pathophysiology. However, the healthcare system is organised by medical specialty, and most healthcare professionals have a limited understanding of allergies. Consequently, children often receive specialist treatment based on the symptoms they present, without learning about their allergy triggers and how to manage those. So, the improvement of children's allergy services requires an approach that accounts for the complexity of the problem. Accordingly, this study sets out to understand these complexities with the following purpose:

Study purpose: To support the improvement of children's allergy services in practice.

In an effort to resolve the complexity of quality problems in children's allergy services in the UK, the Department of Health commissioned the development of national care pathways. Care pathways are used to support the interdisciplinary planning and organisation of care (Vanhaecht, de Witte, & Sermeus, 2007). In 2011, the Royal College of Paediatrics and Child Health (RCPCH) published eight care pathways for the most common allergic conditions (Warner & Lloyd, 2011). The RCPCH care pathways embody the characteristics that are fundamental to care pathways. They define children's allergy care through a list of best practice and evidence-based healthcare activities that are organised in a sequence of healthcare stages. They also define competence and resource requirements at each stage, to structure the organisation of local allergy services. Accordingly, the RCPCH care pathways represent a comprehensive and multi-faceted approach to address the quality deficiencies in

children's allergy services. This work has influenced the focus of this study to investigate the potential of care pathway interventions to improve children's allergy services.

Proposition I: Care pathway interventions improve children's allergy services.

The potential of the RCPCH care pathways to improve the quality of children's allergy services in practice was demonstrated in the Itchy Sneezy Wheezy project. In 2011, this project was funded as part of a quality improvement collaborative by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care for North West London (CLAHRC NWL) (Caldwell & Mays, 2012). The NIHR CLAHRC NWL was a research programme studying the translation of research evidence into clinical practice. To support the process of evidence-translation, they developed a systematic approach, which was tested in the quality improvement collaborative (Howe, Randall, Chalkley, & Bell, 2013). The Itchy Sneezy Wheezy team applied the NIHR CLAHRC NWL systematic approach to translate the RCPCH care pathways into the local allergy services for children in north-west London. This process resulted in the development and implementation of the Itchy Sneezy Wheezy intervention, which demonstrated positive effects on the quality of local children's allergy services (Warner & Spitters, 2017). Consequently, in 2013, the Itchy Sneezy Wheezy intervention was implemented locally as a commissioned service, and the team spent time disseminating the findings and learning from the project at conferences and through professional networks. In 2014, several clinical teams were ready to adopt and implement the Itchy Sneezy Wheezy intervention in other regions. At the same time changes in the local context meant that, there, the Itchy Sneezy Wheezy service was decommissioned again despite its positive outcomes.

The Itchy Sneezy Wheezy project demonstrates that an effective care pathway intervention, alone, is insufficient to improve children's allergy services. Instead, the implementation process and contextual influences also play an important role in the achievement and continuation of health service improvements. This observation is reflected in the academic literature, which states that improvement outcomes depend on an intricate relationship between the content, process and context of healthcare improvement initiatives (Walt & Gilson, 1994). However, to understand the implications of this theoretical relationship for the practical improvement of local allergy services, it is investigated how the relationship operates in practice generally, and within the context of children's allergy services specifically.

Proposition II: Improvements in the quality of children's allergy services emerge from the interactions between care pathways interventions, implementation processes, and context.

So far, it is unclear how all these elements come together to support the improvement of children's allergy services. The academic literature indicates that the content of effective care pathway interventions should address the quality problems facing children's allergy services. However, they should simultaneously accommodate to local requirements and constraints, while also staying truthful to interventions that have demonstrated effectiveness elsewhere. In addition, the academic literature emphasises the importance of a systematic implementation process. However, there is no magic bullet approach. Instead, many efficacious approaches have been developed that might or might not effectively support quality improvement locally. These insights are collated from different academic disciplines with an interest in healthcare improvement – diffusion of innovations, implementation science and improvement science – which are all relevant, in principle, to the clinical scenario presented in this introduction. That is, to meet the needs of children with allergies, health services across the UK need to be improved. To support these improvements, the RCPCH care pathways were developed and implemented locally in the Itchy Sneezy Wheezy project. Lessons from the Itchy Sneezy Wheezy project then *diffused* to other clinical teams in the UK, who were now considering *implementation* of the Itchy Sneezy Wheezy intervention to *improve* their own local children's allergy service. However, guidance to support these teams in their decision-making and operational processes is inconclusive. The practical recommendations from the diffusion, implementation and improvement academic literature aren't specific to children's allergy care and, more importantly, they are often contradictory.

Accordingly, this study aims to improve these recommendations to better support the improvement of children's allergy services. The RCPCH care pathways were developed to support the improvement of children's allergy services by presenting an overview of best practice allergy care that can be integrated with local requirements. This study aims to subsequently understand how these care pathways are implemented by healthcare professionals to improve children's allergy services across different local areas. As such, the main question to be answered in this thesis is:

How can care pathways be implemented to improve children's allergy services in the UK?

To answer this question, it is broken down into the following five sub-questions

1. *What are the quality deficiencies in children's allergy services?*
2. *How are allergy care pathway interventions adapted during implementation?*
3. *How are quality improvement methods used to support the implementation of allergy care pathway interventions?*
4. *How are local children's allergy health service improvement experiences integrated?*
5. *What recommendations can support the local improvement of children's allergy services?*

These questions were developed and answered as part of the MELD dialectical process. MELD is an acronym for the four stages of Bhaskar's (2008b) dialectical process: the first Moment (1M) of (non-)being, the second Edge (2E) of becoming, the third Level (3L) of integrated totality, and the fourth Dimension (4D) of agency. A schematic overview of the four stages of MELD is presented in Figure 1. However, a more detailed explanation of each of the four stages follows in the main body of this thesis with an overview of MELD as a dialectical method presented in Chapter 3. MELD dialectic is the foundation for the analytical development and argumentative flow of this study. Dialectic evolved in philosophy as a structured process of reasoning to resolve contradictory ideas and theories (Nikulin, 2010). MELD is a development of this process, focusing not only on the understanding and resolution of contradictory ideas, but also of contradictory situations in the real-world (Bhaskar, 2008b). It is a meta-theoretical framework to systematically unpack why certain phenomena contrast our expectations by manifesting in contradictory ways, with the aim to inform action to change things in the real world. How comes, for example, that quality deficiencies in children's allergy services identified in 2003 had still not been addressed in practice by 2010 (RCP, 2003, 2010)? Or how comes that an intervention to improve children's allergy services implemented at one time was de-implemented only one year later (Warner & Spitters, 2017)? These are contradictory situations rather than theoretical contradictions that need to be understood and resolved in practice.

As such, MELD is applied in this study to guide the investigative process and unpack why health services haven't been meeting the needs of children with allergies and how this situation can be improved. To guide me through the MELD process and answer the above research questions, I performed a literature review and four ethnographic case studies. The results are presented in this thesis – structured by the four stages of MELD dialectic.

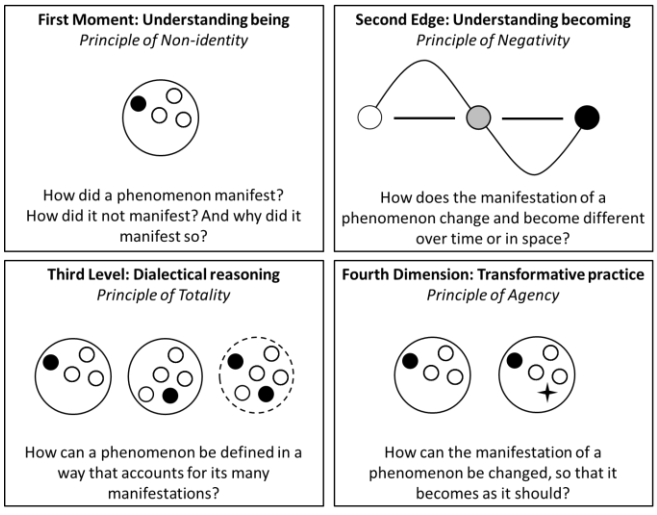


Figure 1. Schematic overview of the four stages of MELD dialectic.

Chapter 1 and 2 address the first Moment (1M) of MELD, which is focused on mapping the mechanisms that define and explain the phenomena being investigated. In Chapter 1, I define and discuss allergy care in the United Kingdom. This discussion also forms the background to this study, explaining how the study is situated within the broader context and concerns of children accessing healthcare to treat and manage their allergies. By defining the experiences of allergic children along multiple dimensions, this Chapter aims to determine the issues and mechanisms that explain the quality deficiencies in children's allergy services that were highlighted in the RCP reports (Royal College of Physicians, 2003, 2010). Accordingly, I first discuss the manifestation of children's allergies in the world. I describe how allergies manifest in children's physiology, how children experience allergy both physically and emotionally, and how the number of children with allergies has developed in society. Subsequently, I discuss the allergy care delivered to children by healthcare professionals. I discuss how allergy treatments developed over time and how evidence-based care was summarised in clinical guidelines. However, I also highlight that the majority of healthcare professionals don't deliver evidence-based care as such. I then describe how structural issues in the health services worsen the situation for children trying to access high quality allergy care. Finally, I discuss prior UK initiatives that have tried to improve children's allergy services within the NHS.

In Chapter 2, I define and discuss healthcare improvement, and I conceptualise the RCPCH care pathways and the Itchy Sneezy Wheezy intervention as vehicles for improvement. This discussion presents the theoretical understanding of healthcare improvement and children's allergy care pathway interventions that is further developed and elaborated in this study. It sets the RCPCH care pathways and Itchy Sneezy Wheezy intervention within the theoretical framework of healthcare improvement, using the theoretical concepts and explanations of healthcare improvement to describe and redefine them. This Chapter also demonstrate how the theoretical explanation of healthcare improvement needs to be advanced to better support improvement initiatives in practice. To achieve these aims, I first discuss how healthcare quality and quality improvement are defined. This discussion highlights the health policy triangle as the foundation for this study. The health policy triangle is a conceptual framework to understand implementation and improvement based on the content, process and context of change in improvement initiatives (Walt & Gilson, 1994). Next, I discuss how I applied this model to conceptualise implementation of the RCPCH care pathways as it happened in the Itchy Sneezy Wheezy project. That is, I discuss care pathway studies in the context of children's allergy. I briefly discuss integrated and chronic care studies to conceptualise the Itchy Sneezy Wheezy intervention. And I briefly discuss studies on the use Quality Improvement (QI) approaches to conceptualise the implementation process. Finally, I situate this theoretical framing of the Itchy Sneezy Wheezy project within the broader improvement science literature. Accordingly, I

discuss the theoretical insights from three improvement science disciplines. This discussion highlights contradictions and unresolved issues that are translated into the research questions of this study.

In Chapter 3, I discuss the research methods that were applied in this study to support the MELD dialectical process. I describe the methods and justify why they were selected to answer the research questions of this study. At the start of this Chapter, I briefly discuss how Dialectical Critical Realism (DCR) grounds this study and its methods. I specifically elaborate on MELD dialectics as an element of DCR philosophy, which is the foundational argumentative process to answer this study's research questions with the aim to support the improvement of children's allergy services in practice. I then specify how the design of this study aligns with the MELD process and with the DCR assumptions more generally. The research design includes a literature review to support 1M of MELD (presented in Chapters 1 and 2), and four ethnographic case studies that provide the empirical data to ground the dialectical reasoning at 2E, 3L and 4D of MELD (presented in Chapters 4, 5 and 6). Subsequently, I justify why this design is most appropriate to investigate this study's theoretical propositions and to answer its research questions. Finally, I describe the details of the ethnographic case study process.

Chapter 4 addresses the second Edge (2E) of MELD, which is focused on understanding the development of phenomena over space and time. This Chapter presents four individual case studies of children's allergy health service improvement initiatives. The four case studies demonstrate how the Itchy Sneezy Wheezy intervention develops over space across four different local areas. Each individual case study describes its development over time. The first purpose of the Chapter is to highlight the dynamic and processual unfolding of health service improvement initiatives in specific real-life settings without reducing these experiences to a static overview of themes and factors. The second purpose is to demonstrate how the theoretical explanations of healthcare improvement identified in Chapter 2 are situated in the real-life experiences of four improvement initiatives. For each improvement initiative, Chapter 4 presents a case narrative that describes the actual content of the intervention, the actual process of implementation, and the actual contextual elements that impacted the improvement initiative. Moreover, these descriptions demonstrate the actual interactions between the content, process and context of the improvement initiatives – how they changed over time in response to one another. Accordingly, the four case narratives demonstrate how contradictory improvement theories play out in practice – highlighting how, in reality, interventions were adapted and how QI methods were used in the implementation process.

Chapter 5 addresses the third Level (3L) of MELD, which is focused on the synthesis of different and contradictory expressions of phenomena in the world to understand how such differences come about and how they could be changed. Accordingly, I present a cross-case analysis in Chapter 5 that

presents an integrated understanding of children's allergy health service improvement. The analysis is grounded in the practical experiences of the four individual case studies. It clarifies how each individual improvement journey can be understood in relation to one another as part of a conceptual whole. The purpose of this Chapter is to demonstrate how the individual case studies can be integrated conceptually in a way that stays true to their unique complexities. This is achieved by first breaking each case study down into its component parts to understand the relationship between case studies. Next, this understanding is used to unite the case studies conceptually into a totality that better defines the general phenomenon of a children's allergy improvement initiative. The totality presented in Chapter 5 elaborates on the theoretical insights presented in Chapter 2. Accordingly, Chapter 5 discusses children's allergy improvement initiatives in terms of three sub-totalities: the child allergy intervention content, the improvement process, and the improvement context.

Chapter 6 addresses the fourth Dimension (4D) of MELD, which is focused on establishing real-world change informed by an empirically grounded theoretical understanding of phenomena. In Chapter 6, I return to the theoretical contradictions across improvement science disciplines identified in Chapter 2. I explore how each of the contradictory theoretical propositions are grounded in the 2L empirical experiences of children's allergy improvement initiatives (presented in Chapter 4) and how they relate to the 3L structural/theoretical understanding of children's allergy improvement initiatives (presented in Chapter 5). Based on these results, I present a set of practical recommendations to support the improvement of children's allergy services in practice.

In Chapter 7, the final Chapter of the thesis, I summarise and discuss the findings of this study and how they address the main of this study to support the improvement of children's allergy services. I discuss the research contributions this study has made in the field of clinical allergy and improvement science, and how the MELD dialectical process has supported these contributions to be developed. Then, I discuss the study limitations and future research directions, before presenting the conclusion of this thesis.

Chapter 1. Background

Defining children's allergy and their care

1.1. Introduction

This Chapter presents the background of this study and addresses the First Moment (1M) of MELD dialectic related to (non-)being. 1M of MELD aims to define real-world phenomena by exploring their presence vis-à-vis absence (Bhaskar, 2008b; Hartwig, 2007). Accordingly, the purpose of this Chapter is to develop a multidimensional understanding of childhood allergies to explain the quality deficiencies in children's allergy services. This Chapter addresses the first research question:

What are the quality deficiencies in children's allergy services?

More specifically, this Chapter describes how this study is situated within the broader context and concerns of children with allergies. A literature review was performed to develop a comprehensive understanding of childhood allergies. The findings reflect the experiences of allergic children along the following four dimensions of social reality (Alderson, 2016; Bhaskar, 2010).

Physical: how do allergies manifest within children's bodies and within the world?

Interpersonal: what care is delivered to allergic children by healthcare professionals?

Structural: how do health services support or prevent high-quality care?

Inner-subjective: how do children suffer from allergy symptoms and/or poor care?

Defining the experiences of allergic children along these dimensions supports the identification of mechanisms and issues that could cause the absence of quality in allergy healthcare delivery as discussed in the RCP reports (Royal College of Physicians, 2003, 2010).

This Chapter is structured as follows. First, I give a theoretical overview of 1M of MELD to set the interpretive frame for the literature review that follows. Then, I discuss the experiences of children with allergies within the physical world. In this section, I describe how allergies manifest in children's physiology; how children suffer from their physical allergy symptoms; and how the number of children with allergies has developed. As such, this section focuses on the physical and subjective experiences of childhood allergy. Third, I discuss healthcare provision for children with allergies. At the physical dimension, I describe the development of allergy treatments and evidence-based clinical guidelines. At the interpersonal dimension, I discuss contradictions between the evidence-based guidelines and the delivery of allergy care by healthcare professionals. At the structural dimension, I discuss issues in the organisation of children's allergy services that make it more difficult for children to access high-quality allergy care. Finally, I discuss how prior UK initiatives have tried to address the quality deficiencies and improve children's allergy services within the NHS context.

1.2. First Moment (1M) of MELD: non-identity to describe phenomena

The First Moment (1M) of MELD dialectics emphasises on the principle of non-identity to understand what real-world phenomena are like. 1M represents the moment to consider without judgement what is known about a certain phenomenon so far. This stage is focused on understanding the world as it is – understanding being. In MELD, being pertains to the concept of identity as well as non-identity, emphasising the importance of absence in relation to presence (Bhaskar, 2008b; Hartwig, 2007). To make sense of phenomena and their manifestations in the real-world, the presence of actual events, objects and actions is clearly important. They can be empirically observed, measured and analysed to build-up a picture of a phenomenon. However, focusing on presence alone concedes to mono-valence and is reductionist (Bhaskar, 2008b; Hartwig, 2007).

In the real world, things exist in relation to one another. This is true too for identity or being, which can only be fully understood in relation to non-identity or non-being. Non-identity refers to parts of phenomena and their manifestations that are not – not here, not anymore or not yet. It indicates the absence of things in space-time[1] (Hartwig, 2007). Absence, as such, creates difference – things being here, but not there. Non-identity as difference refers to the differences that exist in reality rather than theoretical differences between concepts. Differences in reality might include a child's awareness of their allergy triggers – limited initially, but more developed over time due to practical experience and medical assessments.

There is a dialectical relationship between absence and presence that helps to better understand phenomena (Bhaskar, 2008b; Norrie, 2010). For example, it becomes much easier to understand what consists a high-quality children's allergy service when contrasted to a poor-quality service. In this light, absence can be found in the suffering of children, which reflects an absence of wellbeing, or in the ills and problems of healthcare delivery, which reflects an absence of quality. As such, absence reflects the potential for healthcare professionals to address these issues and deliver the high-quality service that is not there yet. The relationship between absence, presence and difference is demonstrated in Figure 2.

[1] Note, things can also be present in space-time, while being absent from consciousness or they can be present in fantasy while being absent from existence altogether (Hartwig, 2007).

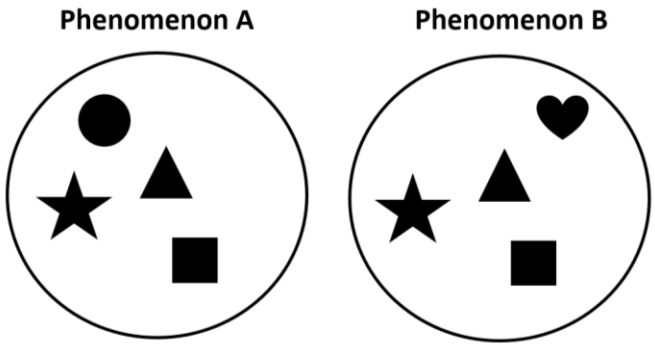


Figure 2. Presence, absence and difference. Phenomena A and B share the presence of three characteristics. However, they each have one additional characteristic present that is absent in the other, thereby establishing difference.

Absence also has causal powers that help explain phenomena. For example, the absence of coordination between system-based healthcare professionals (e.g. respiratory specialists and dermatologists) has consequences for the care a child with allergies receives. They might be prescribed too many medications by different professionals or receive conflicting self-management messages. Absence can also have positive consequences though. The absence of allergy triggers in a child's home, for example, can alleviate symptoms and reduce the need for medication.

In the next sections, I will present a literature review to understand allergy in children according to the principles of 1M of MELD. I will discuss what is already known about children's allergies – what is known about the physiology and subjective experiences of allergy in children, about the care delivered to allergic children by healthcare professionals, and about the organisation of children's allergy care in the United Kingdom. As such, I discuss what is known about the physical, inner-subjective, interpersonal and structural dimensions of allergy in children (Alderson, 2016; Bhaskar, 2010). In this discussion, I describe elements of allergic disease, health care delivery, and health service organisation and how the absence or presence of such elements impact how children experience allergies.

1.3. Children with allergies

1.3.1. The physiology of allergy

The World Allergy Organisation (WAO) defines allergy in their revised nomenclature as *"a hypersensitivity reaction initiated by specific immunologic mechanisms,[…] [where hypersensitivity refers to] objectively reproducible symptoms or signs initiated by exposure to a defined stimulus at a dose tolerated by normal persons"* (Johansson et al., 2004, p.833). Stimuli that cause allergic reactions are called allergens. Common allergens are found in: house dust mite, plant pollen, animal dander, moulds and foods (e.g. milk, egg, nuts or fish) (Arshad, Tariq, Matthews, & Hakim, 2001;

Kulig et al., 1999; Nwaru et al., 2014; Sampson & McCaskill, 1985). An allergen is a specific type of antigen, usually a protein, which causes an immunological hypersensitivity reaction. People suffering from allergies have a genetic predisposition to develop a hypersensitivity reaction to antigens that are harmless for others (Steinke & Borish, 2006). Gell & Coombs (1963) identified four types of hypersensitivity reactions. The majority of allergic reactions are classified as Type I hypersensitivity, which are mediated through the allergy antibody, Immunoglobulin E (IgE).

There are two key physiological phases underpinning IgE-mediated allergies: the sensitisation phase and the effector phase (Akdis, 2014). The sensitisation phase marks the development of allergen-specific IgE antibodies. When an antigen (e.g. a specific grass pollen molecule) enters the body it gets processed by antigen-presenting cells (APCs), such as dendritic cells (Lambrecht, 2014). Dendritic APCs transport the antigen to the lymph nodes where they encounter T lymphocytes or T helper (T_h) cells. In people that are allergic, the dendritic APCs present not only the antigen, but also co-stimulatory signals to T_h cells. This is necessary to activate naïve T_h cells (Mueller & Jenkins, 1995). Naïve T_h cells are mature cells that have not yet come into contact with their cognate antigen that they have been designed to recognise. When a naïve T_h cell binds to their cognate antigen and the co-stimulatory signals from an APC, the naïve T_h cell gets activated. Subsequently, a group of cytokines called interleukins (ILs), specifically IL-4, facilitate the differentiation of the activated T_h cell into a T_h2 cell (Poulsen, 2014). T_h2 cells then, produce their own ILs, IL-4 and IL-13, that induce antibody class switching in B cells (Gould & Sutton, 2008). This means that instead of making IgM antibodies, the B cell switches to making allergen-specific IgE antibodies (IgE antibodies specific to grass pollen molecules for example). The allergen-specific IgE antibodies then bind to other types of APCs and to high-affinity IgE receptors (FcƐR1) on the surface of mast cells and basophils, forming IgE-FcƐR1 complexes. This marks the end of the sensitisation phase.

The effector phase marks the immunologic response of a sensitised person, to subsequent allergen exposure, resulting in the symptoms of allergic disease (Akdis, 2014). When a sensitised person allergic to grass pollen gets exposed to grass pollen again, the grass pollen allergens will cause IgE-FcƐR1 complex cross-linking (Galli, 2014). This happens when an allergen binds to two or more allergen-specific IgE antibodies on sensitised mast cells and basophils. This way, the allergen literally links the IgE-FcƐR1 complexes on the cell. IgE-FcƐR1 complex cross-linking activates the mast cells and basophils and causes them to degranulate. During degranulation, the cell secretes inflammatory mediators that are responsible for the hypersensitivity reaction. Inflammatory mediators secreted during degranulation include histamine, but also certain cytokines, proteases, leukotrienes and prostaglandins (Creticos et al., 1984; Galli, 2014; Naclerio, Meier, Kagey-Sobotka, Adkinson, Meyers, Norman, & Lichtenstein, 1983). Most mast cell mediators are secreted into the surrounding tissue

within minutes, and contribute to the 'early phase' of an allergic reaction. However, through their effects on inflammation and on other cells, mast cell mediators also contribute to the 'late phase' chronic component of an allergic reaction (Galli, 2014).

The effects of mast cell secreted mediators in an 'early phase' allergic reaction are multiple. They first of all increase the vascular permeability and dilate the blood vessels, which increases the blood flow to the affected area, recruiting more immune cells to site (Galli & Tsai, 2012). The increased vascular permeability also allows fluid to flow more easily from the blood vessels into the interstitium, a fluid-filled space between cells. This contributes to the development of angioedema (swelling of the skin or mucous membranes) and urticaria (skin rash with red, itchy, raised patches). When this reaction is very severe and extensive fluid leak from the circulation will cause a fall in blood pressure and in the airways will cause obstructed breathing. This is life-threatening and defined as anaphylaxis. In allergic eczema (also called atopic dermatitis) there is a primary defect in skin barrier function which is enhanced by allergic inflammation. The impaired skin barrier is linked to an increased permeability, facilitating allergens and irritants to enter the skin and water to be lost through the skin (Novak, Bieber, & Leung, 2003). This leaves the skin dry and itchy. With scratching further damaging the skin, the condition aggravates, often resulting in a vicious cycle of itching and scratching. Increased blood flow and vascular permeability also contribute to the experience of rhinorrhoea (runny nose) and nasal itching in allergic rhinitis (Greiner, Hellings, Rotiroti, & Scadding, 2011). The mast cell secreted mediators also contract smooth muscles and enhance mucus secretion (Galli & Tsai, 2012). In allergic asthma, this leads to bronchoconstriction, which reduces the airflow and makes it difficult to breathe. Smooth muscle contraction can also contribute to abdominal symptoms, such as experienced in food allergy. In a group of asthmatics the airways become chronically inflamed, which can lead to airway remodelling (Galli & Tsai, 2012). This means that structural changes take place in the airways, such as thickening of the smooth muscle layers, which can permanently reduce air flow. The allergy symptoms described in this section range from relatively mild to life-threatening. In the case of anaphylaxis for example, the allergic reaction can prevent oxygen-rich blood from reaching vital organs, which if not treated, can cause death.

As demonstrated in the previous paragraph, allergies are associated with a number of allergic diseases or allergic conditions. Some of the most common allergic conditions include: asthma, eczema, rhinitis, conjunctivitis, urticaria, angioedema, anaphylaxis, food hypersensitivity, drug hypersensitivity, and insect sting or bite hypersensitivity (Hellings et al., 2014). These conditions are only considered to be allergic when they result from immunologic mechanisms, which can be IgE-mediated as described before. Alternatively, when different immunologic mechanisms are involved, the conditions are usually described as non-IgE-mediated allergic conditions (Johansson et al., 2004).

One study found 50% to 80% of adolescent eczema, asthma, rhinitis and food hypersensitivity to be IgE-mediated (Nissen, Kjaer, Høst, Nielsen, & Halken, 2013). If the conditions result from mechanisms other than IgE-immunologic mechanisms, the conditions are simply called non-allergic. For example, asthma can also be triggered by a viral illness and seborrheic dermatitis is a form of eczema usually triggered by a yeast overgrowth. However, when the underlying physiological mechanisms are not known, these conditions are often collectively referred to as allergic conditions for pragmatic reasons. I will also do so in this thesis.

1.3.2. The burden of childhood allergies

Allergies are a global problem and have even been described as a worldwide epidemic. The prevalence of allergic disease worldwide has been estimated by the WAO to be about 22%, making it the most common chronic condition in children (Warner et al., 2006). Similar results were found just for children in the International Study of Asthma and Allergies in Childhood (ISAAC), where 22% of 6-7 year olds and 26% of 13-14 year olds experienced allergic symptoms (Mallol et al., 2013). This large-scale study, involving about 1,120,000 children in 98 countries worldwide, used a patient survey method to capture the 12-month period prevalence for asthma, eczema and rhino-conjunctivitis. For the 13-14 year olds, the asthma prevalence was 12.6%, the eczema prevalence was 7.3%, and the rhino-conjunctivitis was 14.6%. In a UK study that followed a similar survey method, researchers found a slightly higher 12-month period prevalence in 11 year olds for eczema (18.4%) and rhinitis (20.2%), but they found a similar asthma prevalence (12.9%) (Belgrave et al., 2014).

Allergic conditions often coexist in the same person. In the ISAAC study, of the 13-14 year olds who experienced asthma, rhinitis and/or eczema symptoms, 26% suffered from two or more concurrent allergic conditions (22% suffering two and 4% suffering all three conditions concurrently) (Mallol et al., 2013). The coexistence of these conditions in the same child is more common than expected solely based on chance, which means that these conditions share common causal mechanisms (Pinart et al., 2014). IgE sensitisation (see previous section) explains part of this coexistence or comorbidity, but other factors (e.g. shared environments or genetics) also play a role. There is evidence that the comorbidity of rhinitis and asthma can be partly explained by the concept of the unified airway (Cruz et al., 2007; Meltzer, Szwarcberg, & Pill, 2004). The unified airway hypothesis puts forward the idea that rhinitis and asthma are linked, because they are both diseases of a continuous airway; rhinitis being a disease of the upper airway (nose and throat) and asthma of the lower airway (lungs). A key concept linking rhinitis and asthma as unified airway diseases is airway inflammation, but other anatomic and pathophysiological features also play a role. Another explanation for comorbidity was uncovered after observing a specific disease development pattern,

called the atopic march (Spergel, 2010; Zheng, Yu, Oh, & Zhu, 2011). At a population level, allergic people often experience eczema symptoms in infancy, and develop asthma and rhinitis later in life. On an individual level the same pattern is observed in a sub-group of allergy sufferers (Belgrave et al., 2014). The suggested mechanism explaining this developmental pattern involves defects in the skin barrier (Spergel & Palle, 2003). These skin barrier defects facilitate allergic sensitisation in the skin, which subsequently progresses to systemic sensitisation affecting the airways.

The prevalence of allergic conditions has steadily increased over the past few decades. Initially an upward trend in asthma, eczema and rhinitis prevalence was observed in Western and English speaking countries (Aberg, Hesselmar, Aberg, & Eriksson, 1995; Burr, Wat, Evans, Dunstan, & Doull, 2006; Downs et al., 2001; Ninan & Russell, 1992), but similar trends have since also been registered in other areas (Bouayad et al., 2006; Esamai, Ayaya, & Nyandiko, 2002; Zar, Ehrlich, Workman, & Weinberg, 2007). There have been indications that this upward trend is now plateauing (Bjerg, Sandström, Lundbäck, & Rönmark, 2010; Gupta, Sheikh, Strachan, & Anderson, 2007). However, when reviewing prevalence data of common allergic conditions worldwide, there still appears to be an overall increase. Findings do vary across geographical areas, likely due to lifestyle and environmental factors (Anandan, Nurmatov, van Schayck, & Sheikh, 2010; Asher et al., 2006; Wong, Leung, & Ko, 2013). Urbanisation, for example, has been associated with higher allergy prevalence compared to living conditions in rural areas (Heinrich et al., 2002; Majkowska–Wojciechowska et al., 2007; Viinanen et al., 2007). Not only these common allergic conditions, but also other potentially life-threatening allergic conditions, such as anaphylaxis, have become more prevalent (Gupta et al., 2007; Sheikh & Alves, 2000).

The high allergy prevalence means many children suffer from allergy symptoms that can influence their physical, social and emotional wellbeing Allergies impact children's health-related quality of life, both directly through the physical discomfort of allergy symptoms, but also indirectly (Covaciu, Bergström, Lind, Svartengren, & Kull, 2013; O'Connell, 2004). Indirectly, allergies can for example cause interrupted sleep and irritability, affecting children's psychology. Alternatively, allergic eczema can impact physical appearance, and allergic asthma might restrict activities, which can affect social relationships. The impact of allergic disease is different for different children, however. For some children, allergies manifest as an 'inconvenience', whereas for others, allergies manifest as a life threatening condition (Levy et al., 2014; Mukherjee et al., 2016). For example, children more often present to hospital with anaphylaxis due to foods, medicines, or insect venom compared to other allergens (Chung et al., 2020; Coutinho et al., 2020; de Silva, Mehr, Tey, & Tang, 2008; Hompes et al., 2011; Piromrat, Chinratanapisit, & Trathong, 2008). How much a child's quality of life is impacted depends on their condition and disease severity. Children with food allergies, for example, were

found to have a lower quality of life than children with Type I diabetes (Avery, King, Knight, & Hourihane, 2003; Flokstra-de Blok et al., 2010). And children with generalised eczema (severe eczema affecting the whole body) were found to have a lower quality of life than children with diabetes or children with asthma (Beattie & Lewis-Jones, 2006). This was not the case for children with mild eczema, however. Accordingly, the impact allergies have on children also depends on how well-controlled their allergic disease is. For example, asthma symptoms, like difficulty breathing, wheezing, or coughing can be minimised or completely eradicated, when a child's asthma is treated and managed appropriately (Cockcroft & Swystun, 1996). Unfortunately, many children suffer from uncontrolled asthma (Liu et al., 2010). Uncontrolled asthma can result in asthma exacerbations or asthma attacks, where symptoms suddenly worsen, which can subsequently cause death. The National Review of Asthma Deaths (NRAD), performed in the UK between February 2012 and January 2013, explored the causes of asthma-related deaths and identified that 46% of asthma deaths might have been avoided if people had received evidence-based care (Levy et al., 2014). Luckily, not many people die from their asthma, and the number of hospital admissions for children with asthma in the UK has stabilised since the 1990s (H. R. Anderson, Gupta, Strachan, & Limb, 2007; Liu et al., 2007; Mukherjee et al., 2016). However, due to the high prevalence of uncontrolled asthma, it is still one of the top causes for hospital admissions in children (Blair et al., 2017; Liu et al., 2007; Sands, Shanmugavadivel, Stephenson, & Wood, 2012). Moreover, hospital admissions for anaphylaxis and food allergy are still rising (Gupta, Sheikh, Strachan, & Anderson, 2004). A more in-depth discussion on the experiences of children with allergies is given in Appendix A. Here, the impact of allergies on children's wellbeing is discussed in more detail, and the explanation for the diversity of allergy experiences is expanded on. In this section, I discussed primarily the clinical perspective, which focuses on disease aetiology, -severity and -control to explain different allergy experiences. In Appendix A, this explanation is expanded by including the influence of psychological-, social-, and socio-economic factors.

In the next section, I will describe how health care for children with allergic disease is delivered and organised, and I will identify problem areas for meeting the needs of allergic children. First, I will describe how the scientific understanding of allergies and treatments evolved over time and how this knowledge is currently utilised in the delivery of care for children with allergic disease. Then, I will describe issues that have been identified in the organisation and delivery of paediatric allergy health services, which I will unpick by exploring underlying historic and political developments.

1.4. Healthcare for children with allergies

1.4.1. The delivery of evidence-based care

Symptoms of allergic conditions have already been described 2000 years ago in literature from Ancient times, and some of the terms introduced then are still in use today (Bergmann & Ring, 2014). The terms asthma, idiosyncrasy (food or drug hypersensitivity) and to a certain extent also eczema date back to approximately 300 BC, the time of Hippocrates, who is often regarded to be the father of medicine. In his work, the term asthmata is found in relation to breathing and was once described as *"as if somebody was whistling through a pipe"* (Bergmann & Ring, 2014, p. 8). This description fits what we now call wheezing. The term idiosyncrasy was used when patients experienced unexpected reactions to certain foods or drugs. Hippocrates' work also described *"itchy skin conditions which are excoriated and bloody"* (Bergmann & Ring, 2014, p. 10), which seem to describe the eczema skin. However, the term eczema was only first used roughly 1000 years later. Although symptoms of many allergic conditions were already described in Ancient times, it was not until the 20th century that significant progress was made in understanding the allergic underpinnings and in treatment developments.

The major advances in understanding allergy during the 20th century led to the development of allergy as a reputable specialty. The term allergy was first proposed by doctor Von Pirquet in 1906 to describe an organism's altered reactivity (J. Ring, 2014). He proposed this term after observations that some children suffering from diphtheria reported severe side effects after horse serum antitoxin administration (Bergmann & Ring, 2014). These side effects, resulting from anaphylaxis and/or 'serum sickness' caused several deaths in that time. Subsequently, the first scientific study successfully treating allergies in people by means of hypo-sensitisation was published in 1911 in the Lancet (Noon, 1911). In this study, progressively increased doses of pollen-based allergen were injected over time to people suffering from hay fever to induce tolerance (J. Ring & Gutermuth, 2011). Similar allergen immunotherapy is still used today. For diagnosing allergies, skin testing was introduced early 1900s, but the skin puncture or prick technique was only first used in the 1950s (Bernstein et al., 2008). Allergy skin prick testing is still the most common diagnostic method. Another major milestone was the organisation of diseases and symptoms related to hypersensitivity in the Gell & Coombs (1963) classification. However, it was not until 1965 that IgE was first identified in a patient (Johansson & Bennich, 1967). This discovery facilitated further understanding of allergy mechanisms and it gave rise to new diagnostics and treatment options. Among the latest advances in the field are component resolved diagnostics (Lloyd, 2015) and the development of anti-allergic monoclonal antibodies and small molecules (Landolina & Levi-Schaffer, 2016). The rapid scientific developments in the understanding of allergy mechanisms and corresponding treatment options,

specifically in the last 30 years, have facilitated allergy as a discipline to lose its reputation as being witch-doctory (Warner & Spitters, 2017).

The advancements in allergy diagnostics and treatments have led to the development of many clinical guidelines. Several institutions have contributed to the development of management guidelines for allergic conditions in the UK. The British Thoracic Society & Scottish Intercollegiate Guidelines Network (2016) published the latest UK adult and child asthma guidelines. These guidelines have been updated since the first asthma guidelines for children published in 1989 (Warner et al., 1989) and the first British asthma guidelines for adults in 1990 (Partridge, Harrison, Rudolph, Bellamy, & Silverman, 1998). The National Institute for Health and Care Excellence (NICE) published guidelines on eczema (2007) and food allergy (2011) for children. The British Society for Allergy and Clinical Immunology (BSACI) developed guidelines for many other allergic conditions, such as for anaphylaxis and rhinitis (Scadding et al., 2008). Besides clinical diagnostics and treatment options that directly act on the physiological mechanisms of allergic disease, these guidelines also include well-evidenced components related to self-management education. (Self)-management is particularly important for people with chronic diseases, which can only be controlled and not cured. Important self-management components in clinical guidelines include: establishing patient understanding and skills for using treatments (Cork et al., 2003; Klijn et al., 2017; Pinnock et al., 2017; Thompson & Thompson, 2014); agreeing written action plans with guidance on recognising when disease control has deteriorated (Chisolm, Taylor, Balkrishnan, & Feldman, 2008; N. M. Clark, Griffiths, Keteyian, & Partridge, 2010; Gibson & Powell, 2004; Pinnock et al., 2017; N. Ring et al., 2007); and having regular follow-up reviews (Gibson et al., 2002; Pinnock et al., 2017). Self-management education allows for the discussion of issues that are important to allergic children besides treating symptoms. For example, a plan could be made to allow asthmatic children to safely join in with physical activities, with follow-up reviews used to assess how the plan is working for the child. As such, self-management education is important for addressing the holistic needs of children with allergic disease.

Unfortunately, the implementation of clinical guidelines for allergic conditions is sub-optimal, especially in primary care where most patients are managed. In one Belgian study surveying 350 GPs in 2009, only 31% acknowledged they were aware of the global Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines that were first developed in 2001 (Van Hoecke et al., 2014). When scoring the GPs' responses to 4 rhinitis scenarios that were developed to test adherence to 4 ARIA standards, the researchers found only 48% of GPs sufficiently complied with the standards. A UK study that used a similar methodological approach, but focused on GPs with a special interest in respiratory conditions and/or allergies, found similar compliance rates (D. Ryan et al., 2005). Failure to comply

with management guidelines can have serious consequences. The National Review of Asthma Deaths (NRAD) identified that 60% of people who died from asthma in the UK between February 2012 and January 2013 could have lived if circumstances had been different (Levy et al., 2014). More specifically, the review identified that 46% of asthma deaths might have been avoided if people had received evidence-based care in accordance with clinical guidelines. For example, they identified that only 23% of people who died from asthma had an action plan, and only 43% had a review in the 12 months prior to their death. Other factors that might have avoided deaths included poor recognition of asthma control and adverse psycho-social circumstances. Despite this important publication, appreciation of poor asthma control amongst patients and healthcare professionals is still lacking (Menzies-Gow & Chiu, 2017), and many asthma guidelines are still not followed in primary care (Levy, Ward, & Nelson, 2018). This disconnect between the development of clinical knowledge and its implementation in practice is called the 'second translational gap' (Cooksey, 2006).

However, efforts to close the 'second translational gap' by implementing clinical guidelines have been increasing over the years with modest results. In their systematic review of asthma guideline implementation initiatives, Dexheimer et al. (2014) found that approximately two-third of initiatives measuring physician adherence, demonstrated an improvement, and about half of initiatives measuring patient outcomes were able to demonstrate an improvement. However, it should be noted that only 6% of studies focused on care settings outside of the hospital. The over-representation of implementation of clinical guidelines in hospital reflects a focus on treating the acute phase of allergic disease, such as asthma exacerbations or anaphylaxis. However, to address the holistic needs of children with allergies, these children also need support acquiring medical, lifestyle and psycho-social skills to self-manage their chronic condition(s) on a day-to-day basis. This type of support cannot be provided solely by medical doctors in hospital and requires input from other health and care services. For example, dietetic input can be needed to teach children and families how to avoid food allergens by reading food labels and to teach them what foods can be eaten as substitution. Or psychological support might be needed to support managing children's anxieties or insecurities. Health services need to be set up appropriately to provide this support. However, in the UK it has been demonstrated that the health services are currently not fit to meet the holistic needs of children with allergies as will be described in the next section.

1.4.2. The organisation of health services

Allergy health services issues play an important role in people with allergic conditions not consistently receiving best-practice care. The Royal College of Physicians (RCP) published a milestone report in 2003 titled '*Allergy: the unmet need*', which provided evidence that UK allergy services were

inadequate (Royal College of Physicians, 2003). The report highlighted a variety of issues. First of all, it showed a paucity of allergy specialist services unevenly spread across the country. Secondly, it highlighted that patients suffering from multi-system allergic problems were often managed by a variety of system-based specialists (e.g. dermatologists, Ear Nose Throat (ENT) and respiratory physicians) without a coordinated care plan. In addition, most system-based specialists had little or no training in allergies. Finally, the report highlighted poor management of allergies in primary care, where the majority of patients is managed, due to a lack of undergraduate and postgraduate training in allergy. As a result, allergy care is often fragmented and patients receive conflicting advice from health professionals. These findings have been endorsed and repeated in subsequent reports from the Department of Health (Department of Health, 2006a) and the House of Lords (House of Lords, 2007). Regrettably, the RCP follow-up report from 2010 showed that the issues were still not adequately addressed (Royal College of Physicians, 2010). It should be noted that these training and service issues are not just a problem in the UK, but are identified as global needs by the WAO (Warner et al., 2006; World Allergy Organization, 2013).

These service issues are also felt directly by healthcare professionals and patients. For healthcare professionals, there is an expressed need for health service solutions to improve allergy capacity in the workforce to deliver best practice care. A UK survey amongst GPs found that an *"overwhelming majority of GPs felt that current allergy services within the NHS is poor, citing lack of suitable training for primary care staff and difficulties in accessing specialists as important barriers"* (p. 518) (Levy et al., 2004). In alignment with the findings of the RCP (Royal College of Physicians, 2003, 2010), a follow-up survey identified similar GP perceptions, indicating an absence of service improvements in the UK between 2002 and 2009 when these surveys were administered (Hazeldine, Worth, Levy, & Sheikh, 2010). For patients, there is also a perceived need to improve allergy health services. A validated allergy specific Patient Reported Experience Measure (PREM) distributed in the UK amongst 253 allergic children aged 8-16 years and 250 parents of allergic children aged 0-7 years, highlighted several health service issues they experienced (Gore et al., 2016). The main issues were around accessing allergy care, information provision, and communication between healthcare professionals and schools (Gore et al., 2016). Problems accessing the right care are in line with the findings first identified by the Royal College of Physicians (2003) and are an indication for insufficient allergy capacity within the healthcare system. The communication issues identified in this PREM highlight care fragmentation along the full patient journey.

The allergy health services issues around capacity and fragmentation are exemplary of more general issues currently experienced in healthcare systems worldwide as they relate to the evolving healthcare needs from treating acute infectious diseases towards managing long-term conditions and

multi-morbidity. Similar to allergies, the prevalence of other chronic conditions is increasing worldwide (Yach, Hawkes, Gould, & Hofman, 2004). A cross-sectional study in Scotland using primary care data from 314 practices identified 42% of patients to have at least one long-term condition and 23% suffering from multi-morbidity (having two or more long-term conditions) (Barnett et al., 2012). However, healthcare systems, which are built over time, are not necessarily well-equipped to manage long-term conditions and multi-morbidity. The complexity of modern healthcare systems makes it difficult to adapt effectively and fast enough to meet the changing needs of the population. In their report *'Crossing the quality chasm: a new health system for the 21th century',* the Institute of Medicine (IOM) described this issue for the American healthcare system as follows: *"between the health care that we now have and the health care that we could have lies not just a gap, but a chasm"* (p. 1) (Institute of Medicine, 2001). In the UK such issues have also been identified, leading to reforms and initiatives to improve services (Wilson, Buck, & Ham, 2005). Such improvement initiatives do not start from scratch. They build on the political decisions and health system developments of the past. Reviewing some of the UK healthcare system's historic and political developments, can therefor help unpick some of the current issues related to managing allergies as well as other long-term conditions and multi-morbidity.

1.5. Improving children's allergy health services in the UK

1.5.1. The NHS context

Evolution of the UK health system has made it increasingly complex and fragmented. Medical science developed rapidly in the early 19th century, which resulted in the development of special hospitals and special hospital departments focused on the study of particular organs or conditions (Stevens, 1966). The medical doctors working in these hospitals were able to access the latest medical advances and gain expertise treating patients with special conditions. In time, hospital doctors would coordinate so that patients with specific conditions would be reviewed by doctors who had developed a special interest in their disease. This was the start of medical specialization. GPs, while maintaining a continuing relationship with the patient, would approach doctors with a special interest for a second opinion. With these arrangements in place, it was important for hospital doctors to keep good relationships with GPs, since most of their patients (and therefore most of their income) came via GP referrals. These informal professional agreements developed into the referral system between primary and secondary care that we know today.

However, over time payment structures and administration for GP practices and hospitals changed. When the NHS was first established in 1948, hospitals were brought together under common management and hospital doctors started receiving a salary ("National Health Service Act," 1946). As

a result, their income was no longer dependent on GP referrals, which slowly weakened the relationships between hospital doctors and GPs, with most communication occurring by letter only. At this point, the hospital has become a centre for diagnostic and specialist services – *"the hub of scientific medicine"* (p. 363) (Stevens, 1966), and the GP has become its gatekeeper (Stevens, 1966). These developments over time have led to fragmentation between primary and secondary care and between medical specialties. Since then, the increase in medical knowledge, technological advances, and the increased focus on public health and prevention have contributed to an increasingly complex web of services and practices for managing health and disease, which patients find difficult to navigate (Swain et al., 2007).

Fragmentation in the NHS continued when reforms were implemented to create an internal market. In 1989, the UK Government (under leadership of Conservative Prime Minister Margaret Thatcher) published the white paper *'Working for patients'*, which resulted in the separation of healthcare provision and purchasing (Klein, 1995). The white paper described a new vision for the NHS that resulted in major NHS reforms enacted through the "NHS and Community Care Act 1990". The NHS continued as a state funded service delivering free care at the point of access to ensure healthcare for all UK citizens independent of their income. However, to drive efficiency and innovation an internal market was created. Instead of managing hospitals and community services directly, local health authorities were now put in charge of purchasing health services from self-managed healthcare providers – both NHS and private. Likewise large GP practices were also empowered to become fund-holders and purchase health services for their patient population. The separation between healthcare provision and purchasing created additional complexities that increased the role of management in the NHS.

The realisation that health services had become fragmented and difficult to navigate for the modern patient with long-term conditions and multi-morbidity has put healthcare integration on the UK political agenda for some years. In 2000, the UK Department of Health (led by Labour Prime Minister Tony Blair) launched '*the NHS plan: a plan for investment, a plan for reform*', which marked the start of major NHS reforms and investment aiming to build health services around individual patient needs (Department of Health, 2000). Building on the achievements associated with this plan (e.g. shorter waiting times, improved staffing capacity, new services and a new commissioning and inspection framework), '*the NHS improvement plan'* was published (Department of Health, 2004). One of the main focus areas in this report was to improve the services for people with long-term conditions, aiming to provide more personalised support in the community or at home supported by better integration of health and social care services in order to improve their pathway of care. The next year a practical approach was published in the report *"Supporting people with long term conditions: An*

NHS and Social Care model to support local innovation and integration" on how this should be achieved (Department of Health, 2005). Integration of health and social care services had already been a UK policy goal for over 40 years (Humphries, 2015), and several legal structures to facilitate health and social care integration have been put in place. Most notably, the introduction of the ("Health Act 1999," 1999) made it possible for NHS and social care commissioners to jointly commission services by legally allowing them to pool budgets and transfer resources.

More structures aiming to promote integrated care were implemented after the change of UK government in 2010 to a coalition between the Conservatives and Liberal Democrats (led by Conservative Prime Minister David Cameron). In 2010, the Department of Health published their plans for NHS reforms in their report *"Equity and Excellence: Liberating the NHS"* (Department of Health, 2010). Initially, the plans did not focus on integrated care. Instead, the plans focused on increasing competition amongst NHS and social care providers by stimulating patient choice, with the aim to create a drive for providers to improve patient outcomes. There were also plans to move away from a centralised top-down governance structure and instead devolve power and responsibility for planning, purchasing and monitoring services to local GPs organised in Clinical Commissioning Groups (CCGs). However, these plans triggered major criticisms, which led the government to establish the NHS Future Forum to lead on a listening exercise around areas of concern (Ham, Baird, Gregory, Jabbal, & Alderwick, 2015). The feedback from the NHS Future Forum highlighted that many criticisms stemmed from concerns that the government plans would impede or discourage integrated working necessary for optimising health services around patients' needs (Field, 2011). This resulted in a number of amendments to the Department of Health plans that were adopted in the ("Health and Social Care Act 2012," 2012), most notably: the explicit inclusion of '*enabling integrated care*' as a duty of the NHS regulatory body Monitor; the establishment of multi-professional Clinical Senates to provide GP-led CCGs with advice; and the establishment of Health and Wellbeing Boards, hosted by local authorities, to promote integration and partnership across NHS, public health and social care by developing Joint Needs Assessments and Joint Health and Wellbeing Strategies for local populations.

The drive towards integrated care in UK policy continued and intensified since the 2012 Health and Social Care Act. In 2013, a number of national bodies, including the Department of Health, came together and published a report *"Integrated Care and Support: Our Shared Commitment"* which outlined their commitment to support healthcare professionals in providing integrated care locally (National Collaboration for Integrated Care and Support, 2013). That same year, the Department of Health established the Better Care Fund, which is a pooled budget for CCGs and local authorities to develop integrated spending plans to commission services spanning across health and social care

most appropriate to the needs of patients (Department of Health & Department for Communities and Local Government, 2017). The Better Care Fund spending plans are reviewed and signed off nationally, and the first wave of approved plans started implementation in 2015. 2013 was also the year that NHS England was established following implementation of the 2012 Health and Social Care Act. NHS England is a non-departmental public body of the Department of Health and Social care, tasked with leading the NHS. In 2014, NHS England presented their strategic vision for the NHS in their report *"Five Year Forward View"* (NHS England, 2014). They recognised that the current health system is not meeting the needs of patients with long-term conditions and multi-morbidity, stating that *"the NHS will increasingly need to dissolve these traditional boundaries [and overcome] providing single, unconnected 'episodes' of care"* (p. 16) (NHS England, 2014). To support healthcare practitioners achieve this vision, the NHS England report outlines six new care models, developed to integrate services around the patient and to move care out of hospital into the community where possible. The Nuffield Trust recognised that aside from some aspects of prevention, most of these new models of care did not focus on children and young people (CYP) (Kossarova, Devakumar, & Edwards, 2016). Subsequently, they sought CYP expert advice through a roundtable workshop and consulted the literature in order to collate and describe new models of care for CYP that have emerged across the UK, with the intention for them to be implemented more widely (Kossarova et al., 2016).

Several initiatives have been initiated by the Department of Health over the years to implement and test new ways of integrated working within the above legal and organisational frameworks. In 2009, the Department of Health set up the 2-year Integrated Care Pilots (ICPs) programme, supporting 16 areas across England to trial different types of integrated care models (Harris et al., 2012; RAND Europe & Ernst & Young LLP, 2012). The trialled approaches varied widely. Some sites tried setting up new integrated care organisations, some sites integrated processes within one existing organisation, but most sites trialled integrating care via the collaboration of healthcare practitioners from different organisations (RAND Europe & Ernst & Young LLP, 2012). In 2013, under new government, another programme was set up to trial integrated care models – the 5-year Integrated Care Pioneers Programme (National Collaboration for Integrated Care and Support, 2013). Fourteen Pioneers were initially selected and supported to test new models of 'whole systems' integration in line with the National Voices' definition of integrated care: *"I can plan my care with people who work together to understand me and my carer(s), allowing me control, and bringing together services to achieve the outcomes important to me"* (p. 7) (National Collaboration for Integrated Care and Support, 2013). The programme set out to actively learn from the experiences of these early Pioneers to inform and support future integrated care initiatives, with a second wave of eleven Integrated Care Pioneers

which started in 2015 (Erens et al., 2015). Finally, in 2015, NHS England also initiated the Vanguard programme, where a total of 50 Vanguard sites received three years of funding and support to implement one of the new care models described in the *"Five Year Forward View"* (NHS England, 2016). The intention of the programme was to capture learning from the Vanguard sites to develop practical guidance for national roll-out of the new care models.

The described historical and political developments form the national policy context where allergy health service issues were first discussed at government-level in the UK, where initial action was then taken. The realisation that health services had become fragmented and complex, and were not meeting the needs of people with long-term conditions and multi-morbidity had already led to a number of innovations by 2010, including case management as part of community nursing (Bentley, 2014), and self-management education via the Expert Patient Programme (D. Taylor & Bury, 2007). However, these initiatives had not yet resolved the issues around children's allergy services, first described by the RCP in 2003 and again in 2010 (Royal College of Physicians, 2003, 2010). A potential explanation could be the low priority of allergy in commissioning (Department of Health, 2006a). Moreover, a review of UK children's services highlighted that issues of low priority were also faced by other child health services (Kennedy, 2010). The review demonstrated that staff and organisations felt children's services were of low priority in the NHS, receiving disproportionally less support for service management and delivery, and less funding (Kennedy, 2010).

1.5.2. Improvement initiatives

Even though allergy and children's health services had not been a priority for health service developments, initial steps were taken by the Department of Health to address the issues that had identified in their review of the UK allergy services (Department of Health, 2006a). They specifically focused their efforts on two key issues: *"the knowledge and skills of clinical staff, and the systematic planning and commissioning of services for allergy"* (p. 65) (Department of Health, 2006a). Moreover, they identified three priorities for action. The first priority urged the commissioners of local health services, the Primary Care Trusts (PCTs), to explore local levels of need for allergy services. The second priority urged the regional Strategic Health Authorities (SHAs) to explore possibilities for increasing the specialist workforce. The third priority actioned the Department of Health to commission the development of guidelines and care pathways (Department of Health, 2006a).

To address their commissioning and workforce priorities, the Department of Health decided to support an allergy health service development pilot in the north-west of England. The pilot officially ran between 2009 and 2011 (Sinnott & Dudley-Southern, 2012). In 2001, however, the north-west Specialised Commissioning Group (SCG) already started creating a strategy to develop their regional

allergy services. At the time, the commissioning of allergy services was shared across local PCTs and the regional north-west SCGs. PCTs commissioned local primary and secondary care services, and they were responsible for the procurement of allergy health care activity. SCGs on the other hand commissioned regional specialist tertiary care services, including allergy and immunology services. In 2009, the north-west SCG committed £1.8 million to expand and improve regional allergy services. This initiative was supported by the Department of Health, who funded a project manager and a scientific evaluation.

The north-west of England allergy initiative first expanded the specialist centres in a large south-eastern-, south-western-, and northern city to act as clinical 'hubs', providing specialist allergy services for the regional population. Next, a regional allergy network was developed, connecting the specialist hubs, to support peer learning, to co-develop standardised clinical procedures and educational materials, and to perform regional audits. The network also created the space for other doctors, nurses and dietitians with an interest in allergy to attend, learn and collaborate to improve other local primary- and secondary care services across the region. To improve local services, the initiative also aimed to engage and train GPs and nurses to deliver more specialised allergy services in primary care.

The idea of specialist GPs, who take referrals from other local GPs in their area of interest, was first proposed in 'The NHS Plan' (Department of Health, 2000). Although initially implemented in other clinical areas, this model was tested for allergy in London in 2005 (Levy, Walker, Woods, & Sheikh, 2009). After two years of negotiations, a local London PCT funded a 6-month pilot for an allergy clinic in primary care, delivered by a GP with a special interest in respiratory and allergic disease and a specialist allergy nurse. The pilot demonstrated that a large proportion of children, who would otherwise be referred to secondary care services, could instead be managed safely and effectively in primary care.

In addition to supporting the allergy pilot in north-west England, the Department of Health also commissioned the Royal College of Paediatrics and Child Health (RCPCH) to develop care pathways for children with allergies. The project started in 2009, and finished in 2011 with the publication of integrated care pathways for the eight most common allergic conditions: anaphylaxis; food allergy; asthma and rhinitis; eczema; urticaria, angio-oedema and mastocytosis; and drug, venom and latex allergy (Clark et al., 2011; Cox et al., 2011; du Toit et al., 2011; Fox et al., 2011; Leech et al., 2011; Lucas et al., 2011; Vance et al., 2011; Warner & Lloyd, 2011). The care pathways were developed by six working groups, consisting of multi-disciplinary healthcare professionals and patient

representatives, based on evidence review, critical appraisal and expert opinion (Warner & Lloyd, 2011).

The care pathway for food allergy is shown as an example in Figure 3 (Fox et al., 2011). It shows the care pathway algorithm, which maps the stages of optimal care from the first presentation of allergy symptoms to ongoing management. For each care stage, it also lists the care activities and considerations for referral. Moreover, the pathway refers to the anaphylaxis, eczema, and urticaria pathways to support the appropriate management of allergic comorbidity. The care pathway in Figure 3 is accompanied by a food allergy competency document. The competency document details what knowledge, skills, and facilities are necessary to perform each of the care activities across the care stages. It also includes references to the underpinning evidence, and it points out key knowledge documents (e.g. clinical guidelines) that healthcare professionals should be aware of. The Department of Health did not, however, support the implementation of the allergy care pathways they commissioned.

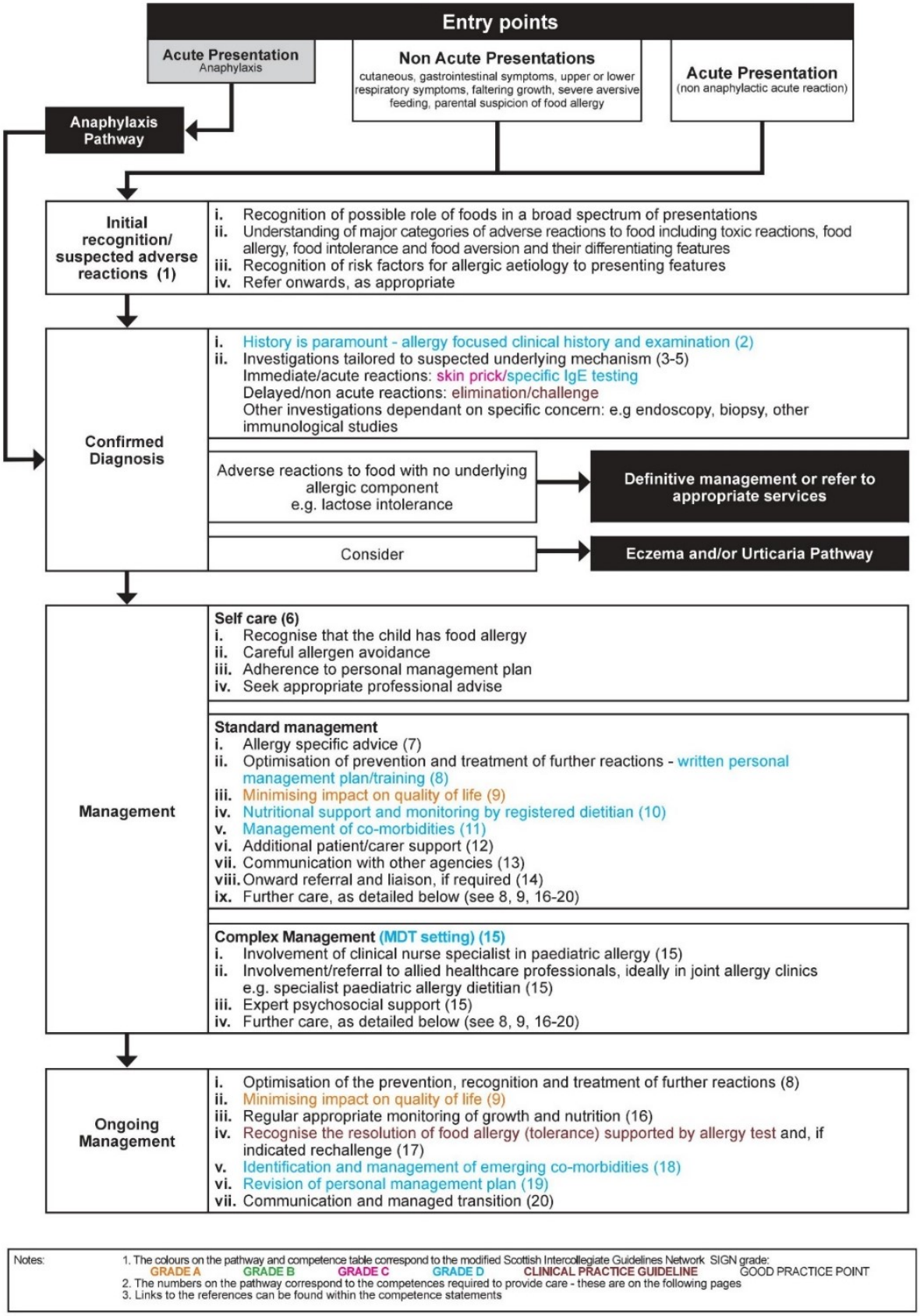


Figure 3. The algorithm of the RCPCH integrated care pathway for food allergies

The RCPCH team identified an alternative sponsor to pilot the implementation of the allergy care pathways, which resulted in the Itchy Sneezy Wheezy pilot project (Gore et al., 2016; Warner & Spitters, 2017). The project started in north-west London in 2011 and evolved into a commissioned children's allergy service in 2013. During the 2-year project phase, the Itchy Sneezy Wheezy team focused on building allergy capacity in their local area based on the competences set-out in the RCPCH care pathways. They developed a website with educational materials for healthcare professionals and self-care materials for children and their caregivers. They delivered allergy workshops targeting healthcare professionals in community-based roles, like GPs and health visitors, but open to all professionals interested in childhood allergy. And they delivered outreach clinics, run by allergy specialists in primary care to offer training opportunities and clinical advice. The outreach clinics evolved into a commissioned service. Initially, clinics were run by a tertiary allergy consultant, a specialist nurse, and a paediatric dietitian. Over time, with the appropriate training and clinical support, the specialist nurse developed the competences to deliver allergy clinics for children with simple allergies independently.

The Itchy Sneezy Wheezy pilot project was evaluated to assess its potential to be implemented into the NHS as a commissioned service. The evaluation was supported by Matrix Knowledge (TMKG Limited), who were contracted to perform an external evaluation and to assess the intervention's business case (Matrix, 2014). The evaluation of economic and health outcomes used the data infrastructure from the north-west London Commissioning Support Unit (CSU). CSUs were established in 2011 to support CCGs with business and commissioning support (Petsoulas et al., 2014). Accordingly, the north-west London CSU established a data warehouse to deliver decision-support and business analytics to CCGs across north-west London. The data warehouse included multiple linked data sets across the region with the CSU available to support information requests. In 2014, though, north-west London CCGs decided to bring commissioning support services in-house to save costs, which resulted in the abolishment of the north-west London CSU and its regional data warehouse thereafter.

The Matrix Knowledge evaluation demonstrated evidence for a positive impact of the Itchy Sneezy Wheezy pilot on hospital admissions. They identified that the number of hospital admissions had reduced since the start of the Itchy Sneezy Wheezy pilot compared to a baseline year. Moreover, to account for other factors that might have impacted the reduction in admissions, the data was compared to the other north-west London boroughs. Analysis demonstrated a 23% reduction in the allergy-related hospital admission rate per 1000 target population from March 2011 until September 2013 in the Itchy Sneezy Wheezy catchment area compared to a 9% reduction in other north-west London areas (Matrix, 2014). The report also demonstrated, based on a costing of the Itchy Sneezy

Wheezy outreach clinics and the 2012/13 average cost of an emergency admissions, that the Itchy Sneezy Wheezy pilot intervention would break even if it was responsible for 51% of the avoided hospital admissions.

The Itchy Sneezy Wheezy team also assessed the impact of the intervention on patient satisfaction. In collaboration with the Picker Institute, they developed and validated two allergy-specific Patient Reported Experience Measures (PREMs) for children aged eight to sixteen years and for parents of children aged zero to seven years (Gore et al., 2016). The PREM was subsequently used to audit patient satisfaction with the Itchy Sneezy Wheezy outreach clinics compared to the allergy clinics delivered in their local specialist hospital. Results indicated patients were equally satisfied with both clinical services – 23/36 (64%) of children rated the Itchy Sneezy Wheezy service as 'very good' compared to 20/35 (57%) rating the hospital service, and 12/36 (33%) of children rated the Itchy Sneezy Wheezy service as 'fairly good' compared to 12/35 (34%) rating the hospital service (Matrix, 2014).

Finally, the team evaluated the impact of the allergy training clinics and workshops on community-based healthcare professionals. Surveys administered before and after the allergy training workshops indicated that healthcare professionals felt more confident in their ability to manage children with allergic disease after the training. However, to evaluate whether the Itchy Sneezy Wheezy intervention had impacted the competence of healthcare professionals in the community, the team performed an audit of 100 GP referral letters (Taha, Patel, & Gore, 2014). The audit post-intervention demonstrated an improved recognition and communication of allergic comorbidities and disease complexity even though 69% of GP referral letters still didn't reflect disease complexity appropriately. Moreover, 56% of patients had not yet been treated prior to the referral even though only 13% of patients left the specialist clinic without treatment.

As such, the Itchy Sneezy Wheezy pilot project had demonstrated the feasibility of implementing the RCPCH care pathways. Different healthcare professionals had gained various levels of competency to identify and manage allergies, which created the opportunity for them to take more responsibility in the care for children with allergies accordingly. Most significantly, the specialist nurse who had been supporting the consultant-led outreach clinics was able to take over the clinics towards the end of the pilot and run community-based allergy clinics independently with mentoring support from hospital-based consultants. In 2013, these clinics and the allergy workshops were commissioned as a specialist nurse children's allergy service with clinical support from the local tertiary allergy service. The pilot evaluation had made a compelling case to continue the Itchy Sneezy Wheezy intervention as a cost-effective solution to improve children's allergy care. However, in 2014, after one year, the

service was decommissioned locally due to changing commissioning priorities, which prevented a more rigorous longitudinal evaluation of the intervention locally. Instead of continuing the consultant outreach or nurse-led children's allergy clinics, the CCG decided to commission a general paediatrician outreach clinics instead. Nevertheless, dissemination of the Itchy Sneezy Wheezy pilot evaluation had generated interest in other areas. In 2015, three healthcare teams in the UK had communicated their intention to implement the Itchy Sneezy Wheezy intervention locally. This situation reflects the context for the study presented in this thesis, which started in 2015 studying the spread of the Itchy Sneezy Wheezy intervention. Rather than building a more rigorous evidence-base for the Itchy Sneezy Wheezy intervention, this study uses the Itchy Sneezy Wheezy intervention as a case study to learn about the implementation of allergy care pathway interventions and the local decisions and efforts made by healthcare professionals to improve health services for children with allergies.

1.6. Conclusion

This Chapter has situated the study in a broad understanding of childhood allergy by discussing the experiences of children with allergies at different dimensions of social reality (Alderson, 2016; Bhaskar, 2010). At each dimension, elements and mechanisms were discussed that produce real consequences for how children experience their allergies. The discussion centred MELD's 1M principles by arguing how the presence vis-à-vis absence of these mechanisms generates differences in disease expression, differences and inequalities in care, and different models of healthcare organisation. This analysis highlights several contradictions in the reality of children with allergies.

At the physical dimension, I explained how children's allergy manifests in the natural world. I explained the pathophysiology of allergy, describing how children can become sensitised to substances in the outside world. After sensitisation, consequent exposure will lead to immune reactions that cause allergy symptoms – often multiple and across organ systems. I then discussed that the understanding of these disease mechanisms has improved allergy management. Nowadays, children can access medical treatments that reduce their symptoms, and they can access clinical tests to help them avoid allergens in their diets, homes, and neighbourhoods.

At the interpersonal dimension, I highlighted a contradiction between established evidence-based allergy care and the care that most children receive from their healthcare professionals. That is, I discussed clinical guidelines, which describe the care that allergic children should receive based on clinical evidence. These guidelines focus on clinical testing and medical treatments, while also emphasising the responsibility of healthcare professionals to educate and collaborate with children to empower them to self-manage their allergies over time. However, clinical guidelines are often not

implemented in practice, especially in primary care where knowledge about allergies tends to be limited. Consequently, the quality of care a child receives will depend on the competences of their local GP and their ability to refer children to appropriate specialists if necessary. However, due to a lack of allergy specialists in the NHS, most children don't have timely access to a paediatric allergist. Accordingly, many children are referred to system-based specialists to treat persistent allergy symptoms. However, many system-based specialists lack an integrated understanding of allergy across body systems. As a result, many children interact with multiple specialists to treat their system-based allergy symptoms without receiving integrated allergy advice on allergen avoidance for example.

At the structural dimension, I discussed how the organisation of the health system impacts the experiences of children with allergies. In this discussion, I argued that the above interpersonal issues tend to reflect health system issues around clinical capacity and fragmentation. Moreover, I highlighted that these issues affect all patients with chronic conditions and multi-morbidity, not just allergy. Accordingly, I discussed policy initiatives and health reforms that were implemented in the UK to better support such patients. The policies and reforms focused on improving the NHS by delivering more personalised care, closer to home, in well-integrated health and care services. These efforts seemed to have had little impact on allergy services. However, a few allergy improvement initiatives were supported after the review of allergy services by the Department of Health in 2006. In 2011, the RCPCH published eight care pathways to support the delivery of best practice care for the most common allergic conditions in children. In 2013, four of these care pathways were translated into the Itchy Sneezy Wheezy intervention and implemented in a local London area as a commissioned allergy service.

The above account of children's allergy demonstrates how the quality deficiencies in children's allergy services are caused by the interdependencies across all dimensions. More specifically, it highlights how children need access to evidence-based and holistic care to manage all of their allergy symptoms effectively. It also highlights that the delivery of such evidence-based and holistic care depends on the availability and coordination of allergy expertise in the health system. Accordingly, initiatives will have to address mechanisms across dimensions to improve children's allergy services. The Itchy Sneezy Wheezy intervention managed to do so successfully. However, despite successful outcomes, the Itchy Sneezy Wheezy intervention struggled to spread to other areas and was decommissioned locally in 2014. In the next Chapter, I aim to unpack and explain this contradiction based on a review of the improvement science literature.

Chapter 2. Theoretical Framework

Understanding improvement initiatives in children's allergy care

2.1. Introduction

This Chapter aims to unpack and explain quality improvement initiatives in children's allergy care. This discussion is a continuation of the First Moment (1M) of MELD dialectic from the previous Chapter. Here, I aim to explore why the quality issues in children's allergy services remain largely present and why the uptake of the improvement initiatives remains largely absent. As such, this Chapter aims to understand healthcare improvement and why it only manifests in some places sometimes, while having been absent for the majority of children's allergy services over many years (Royal College of Physicians, 2003, 2010). To achieve this aim, a review of the improvement science literature is presented in this Chapter. Doing so, this Chapter aims to develop a theoretical understanding of healthcare improvement and quality improvement initiatives in children's allergy care, while also identifying the explanatory gaps that will be addressed in this study.

Improvement science is defined as an interdisciplinary field of study that aims to support the practice of quality improvement by understanding how quality improvements can be made effectively and consistently (Marshall & Mountford, 2013). As such, it aligns with the main purpose of this study.

> *Study purpose: To support the improvement of children's allergy services in practice.*

Moreover, I described in Chapter 1 how the Itchy Sneezy Wheezy intervention improved the quality of children's allergy services by implementing the RCPCH care pathways in a local London area. However, I also described that the intervention was decommissioned after one year, which reflects an inconsistent improvement. Accordingly, improvement science could support the resolution of this contradiction.

> *Contradiction I: Despite achieving quality improvements, the Itchy Sneezy Wheezy intervention was decommissioned.*

This Chapter is structured as follows. First, I will elaborate on 1M of MELD and discuss its implications for understanding causality and empirical investigation, which grounds the interpretation of the improvement science literature that will be discussed thereafter. In the next section of this Chapter, I define healthcare quality and quality improvement. This effort is concluded with the selection of conceptual model that defines quality improvement initiatives based on the content, process and context of the changes that are implemented (Walt & Gilson, 1994). These concepts are applied in the remainder of the Chapter to structure the theoretical framework. In the third section of this Chapter, I unpack and define the Itchy Sneezy Wheezy improvement initiative. First, I discuss care pathway studies to make sense of the RCPCH care pathways. Then, I discuss integrated and chronic care studies to make sense of the Itchy Sneezy Wheezy intervention. I also discuss studies on Quality

Improvement (QI) approaches to understand the implementation process. In the fourth and final section of this Chapter, I make sense of quality improvement initiatives based on the insights from three improvement science disciplines. First, I discuss theories from diffusion of innovations. Subsequently, I discuss theories from implementation science, and I discuss the study of QI approaches. Then, I discuss the contradictions and knowledge gaps that are reflected in the amalgamation of theoretical insights. And finally, from these research gaps, the research questions are derived.

2.2. First Moment (1M) of MELD continued: non-identity to explain phenomena

In the previous Chapter, I discussed how reality at 1M of MELD is understood both in terms of presence and absence, which creates the opportunity for phenomena to manifest in different ways depending on what qualities are or aren't expressed. Here, I discuss further the importance of presence vis-à-vis absence in explaining phenomena, which involves the enactment of its generative mechanisms.

Generative mechanisms comprise causal powers that might or might not be exercised. If they are exercised they represent tendencies that might or might not manifest, actualise or express locally (Archer, Bhaskar, Collier, Lawson, & Norrie, 1998; Bhaskar, 2010; Hartwig, 2007). Causal powers usually need to be triggered, stimulated, released, enabled or otherwise activated to be exercised as tendencies. Tendencies subsequently have the efficacy to bring about material properties, events or patterns of events. Their manifestation (in actual reality) depends on their interactions with other tendencies which can reinforce, oppose or even completely cancel-out a causal tendency. Hence, the manifestation of mechanisms (causal powers and tendencies) depends on their interrelations, presence and absence.

This potentiality for mechanisms *not* to exercise their causal powers or *not* to manifest explains phenomena and their contingent nature. In real-life, mechanisms hardly ever operate independently. Instead, they exist in open systems where they operate conjointly with a variety of other mechanisms (Alderson, 2016). The manifestation or actualisation of mechanisms in open systems is therefore determined by their context – where they are situated in space and time.

The contingency of mechanism manifestation is demonstrated through an example of three children with cat allergies. A schematic overview of this example is shown in Figure 4. In allergic children, exposure to cat dander triggers immunological mechanisms with the potential to cause allergy symptoms. Two children live in a household with a cat, who's dander triggers these mechanisms. The third child, however, is not exposed to any dander in their home. The absence of dander means their

immune response is not activated and the powers of their immune system to cause allergy symptoms are not exercised. As such, the third allergic child lives at home symptom-free, while the two others have a tendency to experience allergy symptoms in their homes. However, one of the two children living with cats has recently been prescribed allergy medications. These medications, such as antihistamines or corticosteroids, suppress immune functioning. Hence, they oppose the activated allergic immune response and prevent the manifestation of allergy symptoms. By taking allergy medications, the second child now also lives symptom-free at home. So, even though all three allergic children in this scenario have the potential to experience allergy symptoms at home, only one child lives in the conditions where their symptoms manifest. This example clarifies how the local manifestation of 1M phenomena (i.e. allergies) depend on their generative mechanisms (i.e. immunological mechanisms) and their positioning in space and time (i.e. living conditions).

So, generative mechanisms are enduring causal powers with the efficacy or potential to manifest or actualise. Their expression is mediated by absence. Accordingly, whether the causal efficacy of generative mechanisms is actualised depends on where exactly the phenomenon manifests in time and space. Thus, reality and change at 1M are understood structurally as (non-)exercised causal powers generating different manifestations across time and space.

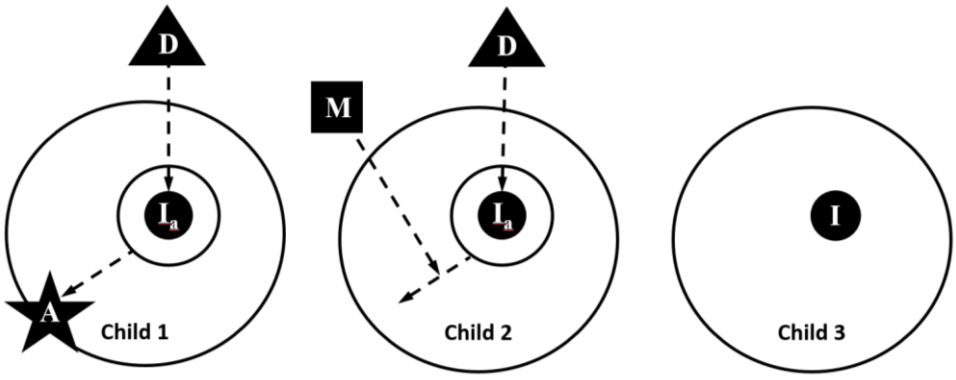


Figure 4. Symptom manifestation in allergic children. Immunological mechanisms (I) are activated when exposed to dander (D). Activated immunological mechanisms (I_a) have the tendency to manifest as allergy symptoms (A) unless suppressed by medication (M).

In the previous paragraph, I discussed how phenomena are understood in terms of generative mechanisms and their efficacy to manifest or actualise as material properties, objects, events or patterns of events. Many scientific studies focus their investigation on actual properties and events through empirical inquiry. Generative mechanisms, however, aren't necessarily actual properties or events. Nevertheless, they are important elements that explain phenomena and hence are part of the scope for scientific investigation.

To clarify the elements of scientific investigation at 1M and how they are interrelated, three levels of reality should be distinguished: the empirical, the actual, and the real (Bhaskar, 2008a). The three levels of reality are pictured schematically in
Figure 5 and explained as follows. The empirical level consists of human observations, perceptions and experiences. Even though empirical experiences are subjective to the individual, they refer to actual material properties and events.

At the actual level, properties and events might be observed or experienced, but many occur or exist independent from humans. Much scientific research has focused on understanding the world at the actual level, describing material properties and looking for patterns of events. Regular patterns of events or *constant conjunctions* have been used in actualist science to define causation. More specifically, this line of thinking indicates that one event causally determines another if the two events always co-occur (Eagle, 2007; Westhorp, 2012). However, critical realists emphasise that predicting events through constant conjunctions does not explain their occurrence (Archer, 2015).

Instead, critical realists look for causal explanations that reveal how actual events come about through the identification of real generative mechanisms (Archer, 2015; Mingers & Standing, 2017). Generative mechanisms have causal powers, and while many are without actual manifestation and empirically undetectable, they are real since they bring about real effects (Bhaskar, 2008a). In the same way that actual properties and events exist independent from human detection, causal mechanisms exist independent from the actual properties and events they manifest (Elder-Vass, 2004). The power of cow's milk protein to cause allergic reactions, for example, does not become less real when consumed by non-allergic people where its chemical structure does not trigger any allergies. As such, all causal mechanisms are real, some are manifested as actual properties or events, and some properties or events are empirically observed and detected.

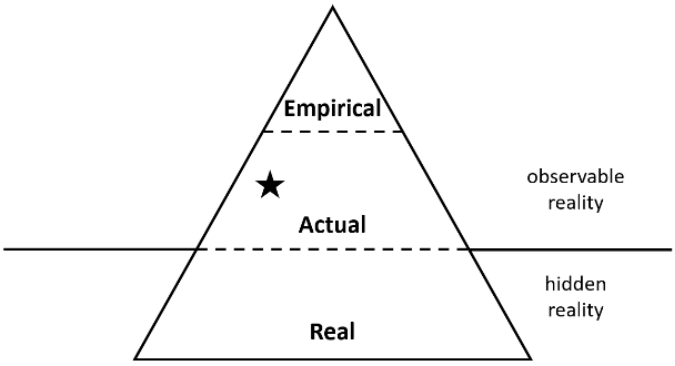


Figure 5. Three levels of reality. Empirical reality is part of actual reality, which includes all that could be observed. Actual reality is part of the real, which includes all that exists. For example, the star symbol represents a causal mechanism manifested as an actual event that hasn't been empirically observed.

So, at 1M, phenomena are described based on absence through the principle of non-identity and explained through the exploration of the absence vis-à-vis presence of real causal mechanisms and their actualisation or manifestation in reality.

In the next sections, I will present a review of the improvement science literature to better understand healthcare quality improvement. After defining quality improvement in healthcare, the review explores the Itchy Sneezy Wheezy improvement initiative and how it changed over time. As discussed in Chapter 1, the initiative manifested as a successful newly commissioned health service for children with allergies in London in 2013. However, when circumstances changed in 2014 the new service was decommissioned. In 1M terms, this meant that the initiative's potential to cause healthcare quality improvements that was demonstrated in 2013 was no longer exercised in 2014. The review aims to identify what generative mechanisms are most likely involved in the Itchy Sneezy Wheezy improvement initiative. The focus of the review is then broadened to explore more generally how quality improvements can come to actualise under certain conditions at certain points in time without actualising under different circumstances. Accordingly, the discussion moves on to evaluate insights about healthcare quality improvement from different improvement science disciplines which generates a set of knowledge gaps that this study aims to address to better support the improvement of children's allergy services in practice.

2.3. Defining quality improvement in healthcare

2.3.1. Healthcare quality

Definitions of healthcare quality vary widely. Yet, they often identify a number of quality dimensions associated to specific outcomes of care that are used to express whether certain quality goals are achieved. Definitions and measurement of healthcare quality build on definitions from industry that evolved during the 1980s quality movement (Cole, 1998). In industry, quality is often defined as achieving customer satisfaction at low cost (Dahlgaard, Kristensesn, & Kanji, 2002). A quality measure commonly used is Cost Of Poor Quality (COPQ), which is defined as *"the sum of all costs that would be saved if there were no quality problems"* (p. 50) (Juran, 1989). For healthcare, where services are meant to be accessible to everyone who needs them and where resources are limited, these definitions and measures of quality need to be further developed and adapted, which is still ongoing today (Donald M Berwick & Fox, 2016). The definition of quality commonly used in healthcare is from the IoM, stating that healthcare should be: safe, effective, patient-centred, timely, efficient and equitable (Institute of Medicine, 2001). This definition outlines certain qualities that are common across quality definitions. First, the IoM definition breaks-up quality into six different dimensions. It is important to balance these dimensions as their importance will be perceived differently by different

stakeholders based on their respective values, perspectives and interests (McGlynn, 1997). Care purchasers, like NHS commissioners, might for example over-emphasise (cost-)efficiency, whereas patients more likely value patient-centeredness and timeliness. So, *"[t]o some extent, quality is in the eye of the beholders"* (p. 9) (McGlynn, 1997). Second, the IoM definition focuses on outcomes of care as quality criterion. Care should be delivered in such a way that safety, effectiveness, patient-centeredness and the other quality dimensions are achieved. Their definition does not however, define what the care processes or care settings should look like in order to be of high-quality. Third, the IoM definition uses goals to define quality, aiming for improvements on the six quality dimensions. Quality goals can be operationalised using empirical or normative standards. Empirical standards are used in benchmarking, where quality goals are set based on measurement and comparison across care settings. A quality goal based on benchmarking could be 'to perform better than *x* percent of organisations'. Normative standards contrarily are independent of actual care performance. Normative quality goals can be set at different levels, aiming for 'best practice' or 'acceptable levels of care'. As such, quality goals represent measurement-based value judgement that help defining what is 'good' and 'bad' quality (Donabedian, 1966).

More comprehensive healthcare quality definitions also emphasise how care processes and care settings or structures relate to the achievement of outcome-based quality goals. Even though outcomes remain key indicators for understanding quality, Donabedian (1966) highlights two additional elements that should be assessed: care processes and care setting. Outcomes often express how effective care is at achieving positive health status and patient satisfaction, i.e. whether care has good results (Campbell, Roland, & Buetow, 2000; Donabedian, 1966). However, such measures are influenced by many factors and often don't reflect small changes in care delivery (Poots, Reed, Woodcock, Bell, & Goldmann, 2017). As such, it can be relevant to assess whether good care is being delivered, i.e. *"whether medicine is properly practiced"* (p.694) (Donabedian, 1966). Appropriateness and completeness of care processes can be assessed using evidence-based medicine or best practice guidelines. Care processes are assumed to be a means to achieving good outcomes. Following this line of argument, the care setting (i.e. care structure) is also assumed to facilitate or inhibit good care delivery and should therefore also be assessed to unpick quality (Donabedian, 1966). Care structure refers to the availability and organisation of contextual elements, such as physical resources (e.g. facilities and equipment) and staff characteristics (e.g. skill-mix and team functioning) (Campbell et al., 2000). Having more staff and physical resources does not simply lead to better quality, since the relationship between care structure and outcomes depends on the organisation of such structural elements and their interactions with care processes. However, having too little resources can most certainly prevent the achievement of specific quality goals (Donabedian,

1966). Donabedian's (1966) triad of structure, process and outcome can be said to form a framework for understanding, measuring and improving healthcare quality. Based on this framework, Campbell et al. (2000) provide the following definition of healthcare quality for individuals: *"individuals can access the health structures and processes of care which they need[,] and whether the care received is effective"* (p. 1614). For populations they define healthcare quality as: "*the ability to access effective care on an efficient and equitable basis for the optimisation of health benefit/well-being for the whole population*" (p. 1617). Analysing care processes and settings helps to understand their elements, their interactions and their holistic effect on outcomes. This is needed to establish accountability and make decisions for improving quality and achieving quality goals (Donald M Berwick & Fox, 2016).

2.3.2. Quality improvement

Improving quality is first and foremost a practical endeavour which involves making actual changes to care processes and structures. In healthcare, improvement efforts often focus on quality goals that are expressed in terms of closing the gaps between care processes and outcomes that could be, compared to the processes and outcomes that exist currently (Cooksey, 2006; Institute of Medicine, 2001; Junghans, 2018). To close these metaphorical gaps, actual changes to healthcare processes and supporting structures need to be made. This requires first and foremost commitment from everyone involved to deliver such changes and improvements:

> *"A genuine, persistent, unshakable resolve to advance quality must come first. If that is present, almost any reasonable method for advancing quality will succeed. If the commitment to quality is absent, even the most sophisticated methods will fail"* (p. 137) (Donabedian, 2003)

Focused on making such changes in practice, the following definition of quality improvement is given:

> *"better patient experience and outcomes achieved through changing provider behaviour and organisation through using a systematic change method and strategies"* (p. 8) (Ovretveit, 2009).

This definition is two-fold in that it focuses on what change to make *(changing provider behaviour and organisation)* and how to make that change *(using a systematic change method and strategies)*. The content of the change can involve either diagnostics and treatments (i.e. clinical changes), processes and systems (i.e. organisational changes), and/or values and team-working (i.e. sociocultural issues) (Bergman, Hellström, Lifvergren, & Gustavsson, 2015; Ovretveit et al., 2018; Wensing, Wollersheim, & Grol, 2006). For making those changes any systematic approach or process

can be used, including the systematic application of implementation methods and strategies (Powell et al., 2012, 2015). This highlights the close link between improvement and implementation (Perla, Provost, & Parry, 2013). However, a view of improvement solely focused on implementing (evidence-based) interventions is incomplete (Marshall, Pronovost, & Dixon-Woods, 2013). More often, systematic change methods refer to industrial approaches, like lean, Six Sigma or TQM, and adaptations thereof (Boaden et al., 2008; Marshall et al., 2013; The Health Foundation, 2013). The Institute of Healthcare Improvement (IHI) led by Don Berwick played a big role popularising methods from industry in healthcare since the 1990s, specifically the approach and lessons from Edwards Deming (Donald M Berwick & Nolan, 1998; Langley, Nolan, Nolan, & Norman, 2009; Marshall et al., 2013). While quality has been a priority for the NHS since the 1990s (Department of Health, 1998, 2008; Ham, Berwick, & Dixon, 2016; Leatherman & Sutherland, 2008; Nuffield Trust, 2019), the adoption of these methods, and the recognition that such practices should be taught to NHS staff to create capacity for continuous improvement happened only in the last 10 years (National Advisory Group on the Safety of Patients in England, 2013; The Health Foundation, 2013).

In the academic literature, quality improvement evolved from and replaced what was previously known as quality assurance. Donabedian (2003) defined quality assurance as *"all actions taken to establish, protect, promote, and improve the quality of health care"* (p. xxiii). However, recognising that quality can never be guaranteed (i.e. assured), he suggested a better term to use is quality improvement, or continuous quality improvement as a reminder to always strive for even better quality. To improve quality, Donabedian (2003) suggests a continuous performance of two activities: performance monitoring and readjustment. Based on monitoring activities, both preventative and corrective readjustments and changes can be made. Readjustments either focus on developing people directly (e.g. through education or motivation) or developing the health system's design and resources which indirectly influence behaviour. There is a clear connection between this description of quality assurance and the Ovretveit (2009) definition of quality improvement described in the previous paragraph. Readjustments are changes to "*provider behaviour and organisation"* (p. 8) (Ovretveit, 2009)), and quality monitoring is *"a systematic change method"* (p. 8) (Ovretveit, 2009) supportive of making that change. Initially, readjustments focused solely on clinical processes. However, supportive processes (e.g. housekeeping or administrative processes) soon also became subject to formal quality improvement.

In practice, however, both quality improvement and quality assurance are still actively used terms to indicate different practices. In the UK, improvements to care processes are usually made by healthcare provider organisations, while quality monitoring increasingly gets performed by other types of organisations. This split of activities has resulted in the term 'quality improvement' being

reserved for the improvement of local practices, while 'quality assurance' tends to refer to quality monitoring (Campbell, 2002; Donabedian, 2003; Ham et al., 2016). Nevertheless, it was acknowledged that quality improvement and quality assurance were overlapping systems, which were subsequently consolidated using the term clinical governance (Campbell, 2002; Department of Health, 1998). However, the split between monitoring and improvement activities still causes tension in practice. In the NHS for example, the Care Quality Commission (CQC) was brought into existence to assure provider organisations are delivering care of acceptable quality. They do so by setting requirements for improvement based on the (potential) problems identified in inspections. However, the CQC does not lead on any consequent quality improvement efforts (Ham et al., 2016). Similarly, Primary Care Trusts (PCTs) were set-up to implement clinical governance in primary care. Accordingly, PCT staff generally perceive their function to be both monitoring and improving quality. However, their activities tend to be skewed towards quality monitoring (Campbell, 2002). These PCT activities are currently performed by Clinical Commissioning Groups (CCGs), after PCTs were abolished in 2013 (Ham et al., 2015). The split between monitoring and improvement activities across organisations can create tensions, with provider organisations experiencing a lack of support to achieve the monitoring-based quality standards, and monitoring organisations struggling to engage care providers to make the quality improvements necessary to achieve the set standards (Campbell, 2002; Ham et al., 2016). This is why Donabedian (2003) emphasises the importance of provider organisations performing monitoring activities themselves as part of their responsibility and commitment to providing high-quality care. Ham et al. (2016) agree, urging for commitment to improvement and learning instead of compliance to external standards, and more effort put towards quality improvement activities.

2.3.3. Improvement initiatives

So, when defining quality improvement and describing quality improvement activities a distinction tends to be made between what clinical and organisational changes improve healthcare quality and how these changes are made (Donabedian, 1966; Ovretveit, 2009). This understanding of quality improvement was validated and elaborated when studies in change management and policy implementation started to explore how quality improvement unfolds in reality. These studies initially aimed to identify what organisational structures and policies were associated with positive outcomes, so they could be replicated to improve quality elsewhere. However, the results of the configurational research studies (Gresov & Drazin, 1997; Miller, 1987; Pettigrew, 1992; Short, Payne, & Ketchen, 2008) and top-down policy evaluations (Barrett, 2004; Hugh Heclo, 1972; Nilsen, Stahl, Roback, Cairney, & Ståhl, 2013; Sabatier, 1986) were often hard to apply in practice. Outcome associations were inconsistent across settings and many policy studies failed to implement policies in

the first place, giving it the nickname 'misery research' (Forte, Hoffman, Lamont, & Brockmann, 2000; Nilsen et al., 2013; Pettigrew, Ferlie, & McKee, 1992). The limited generalisability of study findings and the high rate of implementation failure slowly established a shift towards the study of contextual and processual elements of improvement. Improvement became recognised as a process unfolding in time and space which has to be managed. This increased interest into topics like organisational leadership, teamwork, context analysis, continuous innovation and learning, and knowledge management (Cool, Neven, & Walter, 1992; Pettigrew, 1992; Pettigrew et al., 1992). In addition, policy implementation became recognised as a social and political process. The realisation and actualisation of policies in reality requires the bottom-up actions and behaviours of implementers. The instructions of politicians and managers might be necessary to influence this process. Independently however, they are insufficient to make any actual changes to practice (Barrett, 2004; Hjern & Hull, 1982; Sabatier, 1986; Schofield, 2001).

These developments and insights are encapsulated in the health policy triangle (Walt & Gilson, 1994). The health policy triangle, shown in Figure 6 describes that healthcare improvements are influenced by the content, process and context of change, mediated by the actions of implementers. This model represent a holistic and dynamic view of improvement, it has strong empirical underpinnings and it has been widely applied (Gilson, Buse, Murray, & Dickinson, 2008; Iles & Sutherland, 2001). Consequently, the health policy triangle is used as the foundational skeleton to analyse the improvement of healthcare quality in this study and in the remainder of this Chapter.

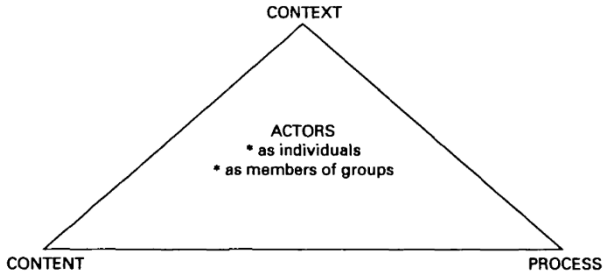


Figure 6. The health policy triangle. A model developed for health policy analysis adopted in this study for the analysis of healthcare improvement. From: Walt & Gilson (1994)

In the next section, I will apply the health policy triangle to analyse the improvement of children's allergy services. More specifically, I will use the health policy triangle to understand how the RCPCH care pathways can improve children's allergy services. As discussed in Chapter 1, they were commissioned in the UK as tools to address the quality problems that were facing children's allergy services in the UK (Warner & Lloyd, 2011). Subsequently, the RCPCH care pathways were implemented in a local London area as part of the Itchy Sneezy Wheezy project. The Itchy Sneezy Wheezy intervention had positively affected local allergy services. Still, the intervention wasn't

sustained and is yet to be replicated in other areas. In Chapter 1, I discussed how the RCPCH care pathways and the Itchy Sneezy Wheezy intervention were situated in a context of historical policy and health service developments in the UK. In the next section, I will first discuss how the RCPCH care pathways are situated within the scientific literature on care pathways to better understand their content. Then, I will touch on different scientific fields to make sense of the implementation of the RCPCH care pathways. First, I will discuss how the Itchy Sneezy Wheezy intervention, used to implement the RCPCH care pathways, is situated within the literature on integrated- and chronic care. Second, I will touch on the literature on industry-based quality improvement approaches, which had supported the development and implementation of the Itchy Sneezy Wheezy intervention. I will conclude the section by summarising key insights based on the health policy triangle.

2.4. Theorising the Itchy Sneezy Wheezy improvement initiative

2.4.1. Care pathways and their impact

Care pathways are defined broadly to encompass the variety of care pathway interventions embedded in practice. In the UK, the first care pathways were introduced in the 1990s (Zander, 2002). They derived from critical path methodology, which was used in industry to plan and standardise processes (Zander, Etheredge, & Bower, 1987). Over time, however, different stakeholders perceived care pathways as a potential means to achieve increasingly varied goals, which resulted in adaptations and different types of documents and interventions listed under the same care pathway umbrella (Allen, Gillen, & Rixson, 2009; Currie & Harvey, 2000; De Luc, 2000). On the one hand, this ambiguity around care pathways allows different types of stakeholders to buy-into the idea, which facilitates them coming together to collaborate. However, differences in understanding and expectations will still need to be resolved during the development of care pathways and their implementation into practice (Allen, 2009, 2010; Star & Griesemer, 1989). To get more conceptual clarity, a literature review was conducted to help define care pathways. As part of the review, 84 unique care pathway definitions were identified and used to abstract key care pathway characteristics (De Bleser et al., 2006). This literature review, together with a survey on pathway use and prevalence across 23 countries (Vanhaecht et al., 2006), and a consensus meeting resulted in the definition of care pathways held by the European Pathway Association (E-P-A), which reads:

> *"[Care pathways are] a methodology for the mutual decision making and organisation of care for a well-defined group of patients during a well-defined period. Defining characteristics of care pathways include: an explicit statement of the goals and key elements of care based on evidence, best practice, and patient expectations; the facilitation of the communication,*

> *coordination of roles, and sequencing the activities of the multi-disciplinary care team, patients and their relatives; the documentation, monitoring, and evaluation of variances and outcomes; and the identification of the appropriate resources. The aim of a care pathway is to enhance the quality of care by improving patient outcomes, promoting patient safety, increasing patient satisfaction, and optimizing the use of resources."* (p. 57) (Vanhaecht, de Witte, et al., 2007)

The RCPCH allergy care pathways for children embody this definition. The care pathways were developed to support care for allergic children from birth until 18 years old. They organise the process of optimal care in stages, from the first presentation of allergy symptoms to ongoing management. Moreover, they were developed and agreed by multi-disciplinary working groups. The RCPCH care pathways also reflect the key pathway characteristics that have been defined. Each stage of optimal care *explicitly states the care activities* that need to be performed. These activities are colour-coded *based on the strength of the evidence* that underpins them. The activities that reflect *good practice points* (not specifically based on scientific evidence or clinical guidelines) were *agreed by multi-disciplinary healthcare professionals and patient representatives*. Moreover, the RCPCH care pathways come with a competency document that outlines the knowledge, skills and facilities required to perform the clinical activities listed in the care pathway document. As such, the document *identifies the resources needed* to deliver optimal care. Moreover, it *facilitates the communication* within healthcare teams and organisations to design their allergy services effectively. More specifically, it helps them *coordinate roles and organise care activities* by providing the framework needed to evaluate which care settings and which professionals have access to the necessary facilities and capabilities to perform certain clinical activities, and which activities can be performed by the children or caregivers themselves as part of self-management. *Coordination within the multi-disciplinary care team* is further facilitated by listing referral considerations for managing single allergic conditions in each care pathway, and by internally signposting across care pathways to manage allergic comorbidities. Processes for the *documentation, monitoring and evaluation* of care are not, however, specified in the RCPCH care pathways.

As such, care pathways are designed to organise and coordinate resources, activities and behaviours of different types of healthcare professionals to improve a range of potential outcomes. Moreover, it was discussed that care pathways have been implemented flexibly to meet different stakeholder interests. Accordingly, care pathways are recognised as complex interventions (Vanhaecht, Panella, van Zelm, & Sermeus, 2010), because these characteristics correspond to the characteristics put forward by the Medical Research Council (MRC) to describe complex interventions:

> *"number of interacting components within the experimental and control interventions; number and difficulty of behaviours required by those delivering or receiving the intervention; number of groups or organisational levels targeted by the intervention; number and variability of outcomes; degree of flexibility or tailoring of the intervention permitted"* (p. 979) (Craig et al., 2008).

These characteristics of complex interventions can make it difficult to evaluate their effectiveness accurately and meaningfully. Regardless, many scientific care pathway evaluations have been performed that collectively suggest a positive effect of care pathway interventions on healthcare outcomes. An in-depth discussion of studies and systematic literature reviews on this relationship can be found in Appendix B. In sum, the evidence indicates that care pathways positively affect the E-P-A outcomes patient safety and use of resources, while a positive effect on patient satisfaction and health outcomes was not supported (Allen & Rixson, 2008; Banasiak & Meadows-Oliver, 2004; Chen, Chen, Liu, Tzeng, & Glasziou, 2014; Kwan & Sandercock, 2004; Leigheb et al., 2012; Phillips, Halcomb, & Davidson, 2011; Ronellenfitsch et al., 2008; Rotter et al., 2010). These results refer to the effectiveness of care pathways on the whole, indicating the overall or mean effect of care pathway interventions is cautiously positive (Borenstein, Hedges, Higgins, & Rothstein, 2009). Moreover, the E-P-A definition suggests that this effect might be mediated through the process of mutual decision-making and of care organisation (Baron & Kenny, 1986; Vanhaecht, de Witte, et al., 2007). Indeed, evidence seems to support the mediating role of these processes (Deneckere et al., 2012; Gholve, Kosygan, Sturdee, & Faraj, 2005; Leigheb et al., 2012; Manser, 2009; L. C. Price et al., 2006; Tallis & Balla, 1995; Vanhaecht, De Witte, Panella, & Sermeus, 2009). Knowing the mean effect of care pathways on outcomes and being aware that this relationship is mediated by mutual decision-making and care organisations is useful for understanding the effectiveness of care pathways. However, these general measures are derived from all types of care pathway studies, and obscure any structural differences that exist between these studies (Petticrew et al., 2013).

However, it's important to understand structural differences between care pathway studies and their effects on effectiveness, especially in the context of care pathways. As discussed, care pathways are highly variable. They evolved to achieve a mixture of goals, and they have been implemented in different clinical settings across many countries to improve the management of an array of clinical conditions (Currie, 1999; De Luc, 2000; Vanhaecht et al., 2006). These differences can affect whether or not care pathways improve outcomes or to what degree. That is, they can moderate the relationship between care pathways and outcomes (Baron & Kenny, 1986). Identifying potential moderating variables requires that the variability of the mean effect of care pathways on outcomes, as discussed in the previous paragraph, is further examined. Accordingly, one review study explored

not whether care pathway were effective, but under which circumstances they were (Allen et al., 2009). The authors identified that care pathway effects seemed different for care pathways with different purposes. They also identified that care pathways were particularly effective for patient groups with predictable care trajectories, and less likely to be effective for patient groups with more variable care trajectories. Moreover, care pathway interventions were most effective in situations where there were clear quality issues or where new professional roles were introduced in the service. In contrast, they were less likely to be effective in situations where evidence-based care and strong multi-disciplinary working were already in place. As such, care pathway purpose, the predictability/variability of care, and pre-existing levels of healthcare quality were identified as structures that moderate the relationship between care pathways and healthcare outcomes (Allen et al., 2009). How these moderators are reflected in the RCPCH care pathways is discussed in the following sections.

2.4.2. Care pathways in children's allergy services?

While the quality issues observed in children's allergy services suggest an opportunity for care pathways to make a difference, they have yet to be implemented and exploited in practice. In Chapter 1, I discussed how many allergic children in the UK don't receive the care they need to effectively manage their allergies. I discussed how these issues are partially due to individual healthcare professionals not delivering evidence-based care, and partially due to poor organisation of care. Moreover, I discussed that the high prevalence of uncontrolled allergic disease translates into high numbers of hospital admissions in children, especially for asthma. As such, I demonstrated there is room to improve pre-existing levels of quality in the care for allergic children, which suggests care pathways could be particularly effective (Allen et al., 2009). Accordingly, the RCPCH care pathways were commissioned as a mechanism to address the quality issues that the national allergy health service reviews had brought to light (Department of Health, 2006a; Royal College of Physicians, 2003, 2010). However, despite the potential of care pathways to improve healthcare quality, they have yet to be capitalised on in the context of children's allergy services. This was demonstrated in a review study on care pathways in the delivery of allergy and eczema services (Diwakar, Cummins, Lilford, & Roberts, 2017). The authors identified multiple survey studies and review reports that presented descriptive accounts of allergy services with recommendations for their improvement. However, very few studies were identified that discussed actual health service improvement efforts that changed the care pathways for allergic patients. Of those few studies, four were performed in the UK. These studies described evaluations of: a specialist allergy clinic in secondary care (O'Connor, & Kaminski, 2013); an allergy clinic delivered by a GP and specialist nurse in primary care (Levy et al., 2009); a roving allergy clinic delivered by a specialist nurse in primary

care (Brydon, 1993); and the north-west allergy pilot discussed in Chapter 1 (Sinnott & Dudley-Southern, 2012). It should be noted though that this review focused on care pathways in allergy and eczema services, excluding asthma services where the use of care pathways is more prevalent.

So, even though care pathways are underutilised in children's allergy services, they have been widely employed to improve the treatment of acute asthma in hospital settings. The use of care pathways had taken off in the 1990s in the UK (Currie, 1999; Karen Zander, 2002). A survey of 330 NHS trusts highlighted that 86% of trusts were using care pathways by 1998. However, 72% of those trusts reported still being in the piloting stages. The piloting of care pathways predominantly took place in acute care, where 48% of care pathways were situated. And while care pathways were developed for many clinical conditions, asthma care pathways were especially common. The development of asthma care pathways was reported by 12% of surveyed trusts, which made asthma the 5th most common clinical condition for care pathway development. In line with trends abroad, the implementation of asthma care pathways has likely also increased in the UK since 1998. In Canada, for example, a survey of 123 hospitals highlighted an increase in the use of asthma care pathways from 27% in 2006 to 86% in 2015 for treating inpatient children (Kaiser et al., 2017). However, despite their widespread use, asthma care pathways are predominantly implemented in hospital settings. This statement is supported by a review study that evaluated the implementation of asthma guidelines through computer- versus paper-based care pathways and protocols (Dexheimer et al., 2014). The review included 101 intervention studies, and highlighted that 94/101 interventions were implemented in a hospital setting (31 in ED; 18 in inpatients; and 45 in outpatients). Moreover, only 3/101 interventions were implemented across multiple healthcare settings (ED/outpatients; ED/inpatients; and outpatients/other setting).

The widespread adoption of care pathways to manage children's asthma in hospital settings can be explained, but not justified, through the care pathway moderator predictability of care. National asthma guidelines have been developed that describe high-quality asthma care (British Thoracic Society & Scottish Intercollegiate Guidelines Network, 2016). These guidelines are helpful in illuminating quality issues that can motivate healthcare professionals to improve their service. However, the process of evidence-based asthma care described in these guidelines is complicated. It involves alternative diagnoses to be ruled out; it involves prevention, pharmacology and self-management education to be integrated in a treatment plan; it involves asthma management to be monitored and updated over time; and it involves coordination of care between multiple healthcare settings. However, care pathways to improve asthma care in ED or the inpatient department, focus predominantly on the process of stabilising children with an acute asthma exacerbation. As such, these care pathways focus on a sub-group of asthma patients who attend a single healthcare setting

with the primary goal to treat their exacerbation. Accordingly, care pathways to treat asthma in hospital settings generally reflect a more predictable process, which was thought to positively affect care pathway effectiveness (Allen et al., 2009). This might explain why the implementation of asthma care pathways in hospitals is so much more common than the implementation of asthma care pathways across healthcare settings or the implementation of allergy care pathways more generally. Nevertheless, the reality of asthma is not limited to the acute phase. Instead, high-quality asthma care takes into account its chronic nature and the high prevalence of allergic co-morbidity. As such, while the treatment of acute asthma is relatively predictable, the care for children with allergic asthma or other allergies is highly variable. Children need different types of treatment and support at different stages of their disease progression and different stages of their personal development. Moreover, different allergy manifestations require different treatments and different self-management advice. This contrast between the predictability and variability of care is one reason explaining why care pathways seem much more common for treating acute asthma than for the long-term management of asthma and allergies.

2.4.3. The RCPCH care pathways

In addition to the comparison of care pathways based on their prevalence in practice, can care pathways also be distinguished by type. For example, it was identified that for care processes that are highly predictable, care pathways are often more prescriptive (Vanhaecht et al., 2010). These pathways outline the timings and sequences of clinical activities more precisely and specify professional responsibilities more concretely. For variable care processes, care pathways need to be structured more flexibly, in a way that supports selecting the right course of action on a case by case basis. The RCPCH care pathways incorporate such flexibility to accommodate for the variability of allergy care. This is done through its design around competences. The clinical activities in the RCPCH care pathways are themselves quite general and non-specific. However, they are connected to a more precise list of competences and facilities that are needed to perform the activities effectively. This structure embraces variability in allergy care, for example by supporting a flexible referral process. Instead of generically applying referral criteria, are healthcare professionals encouraged to assess whether they personally have the capabilities to deliver care in a particular case, or whether onward referral is necessary. The competence-based structure also supports a flexible division of labour, by encouraging roles to be allocated based on the capabilities people developed, rather than the job title they acquired. Moreover, the structure of the RCPCH care pathways allows health services to be designed flexibly. Listing what facilities and competences are needed for optimal care, without prescribing a particular health service model, encourages the development of innovative health services that creatively marry these care requirements with local skills and resources. As such,

the RCPCH care pathways describe allergy care at a generic level with the intention to be used nation-wide. However, other types of care pathways are developed for more specific purposes.

Accordingly, different types of allergy care pathways can be nested and applied simultaneously. As discussed, the RCPCH care pathways describe how allergy care should be delivered generally, based on scientific evidence and national working groups. Such care pathways are called *model pathways* (Vanhaecht et al., 2010). They can be used by clinical teams, organisations or regional partnerships to optimise their local allergy services, by developing a service that is both congruent with the evidence-based model pathway and tailored to local requirements and opportunities. Care pathways that specify the local organisation of children's allergy care are called *operational pathways*. For example, the competence-based design of RCPCH care pathways holds space for a variety of health service architectures. Consequently, to structure allergy services at a regional level, an architecture can be specified strategically based on alignment with existing services, skills and interests of local healthcare professionals, or financial opportunities. Moreover, the RCPCH care pathways describe all the stages for optimal care. To structure care at an organisational level, clinical teams might specify the stages that their organisation is responsible for delivering, by breaking down high-level clinical activities, specifying their order and timings, or assigning roles to them. As such, care pathways for treating acute asthma in hospitals can be understood as operational pathways that specify how the emergency care stage should be delivered in local hospitals. In the above discussion, these different types of allergy care pathways were considered interchangeably. For example, the RCPCH care pathways were juxtaposed with care pathways for treating acute asthma to compare the use of care pathways for variable versus predictable care processes. However, these contradictions between the RCPCH and the acute asthma care pathways can now be seen in a different light. That is, the acute asthma care pathways act as a mechanism to specify and implement the emergency care stage of the RCPCH care pathway for asthma. So, while the RCPCH and the acute asthma care pathways have different properties and functions, they both act synergistically to organise and improve asthma care for children (Bhaskar, 2008b). As discussed, however, asthma and allergy care still reflect great variability at the level of individual patient care, due to different disease manifestations and different individual needs.

So ideally, the implementation of the RCPCH care pathways is supported by specific patient-level care pathways, in addition to the care pathways at regional or organisational level. Patient-level care pathways can draw on the RCPCH care pathways to organise evidence-based care for individual children, describing the planned assessments, treatments and management strategies for a particular child, and assigning roles accordingly. As such, patient-level care pathways are equivalent to care plans (Layton, Moss, & Morgan, 1998). For example, hospital specialists might be requested

to confirm the clinical diagnosis and start initial treatment. For children with allergic comorbidities, several system-based specialists might be involved to treat their symptoms. When the initiated treatments have demonstrated positive effects, the responsibility for a child's care is usually handed back to primary care. Moreover, most stages of care require healthcare professionals to deliver some level of self-management support. Self-management support is meant to empower children and their caregivers to manage their condition in daily life. It does so by actively engaging them in the process of care, educating them about their condition and treatment options, and discussing which treatment options and behavioural interventions will most likely help them to achieve their personal allergy goals (Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002; Glasgow, Tracy Orleans, Wagner, Curry, & Solberg, 2001; Wagner, Austin, & Von Korff, 1996). The RCPCH care pathways emphasise the importance of self-management, both describing self-care activities for children and their caregivers, and describing the supportive and educational activities healthcare professionals should perform. This includes the development of a personal management plan for children to take home. Personal management plans are a summary of the patient-level care plan with a clear description of the agreed self-management strategies that is specifically developed for patient use. Both care plans and personal management plans describe the process of care that is planned for a specific patient. As such, they are sometimes called the *assigned pathways*, in contrast to the *completed pathways* that record at a patient-level what care has actually been received (Vanhaecht et al., 2010). Completed pathways can be used by multi-disciplinary care teams to hand-over relevant patient information in the process of care, or to collectively review and potentially adjust the process (Wilson & Tingle, 1998). Furthermore, when completed pathways are collated, they can be used to perform clinical audits (Layton et al., 1998). In the audit process, completed pathways are used to assess whether the healthcare provision in a specific allergy service meets certain clinical standards or benchmarking goals. This process helps to identify structural issues and variability in the delivery of allergy care that need to be addressed to improve quality (Bragato & Jacobs, 2003; Buetow & Roland, 1999; Wilson & Tingle, 1998). As such, allergy care pathways at patient-, organisational-, and regional- and national level express different types of care pathways that operate in a nested structure to improve care for children with allergies. Accordingly, implementation of the national-level RCPCH care pathways to improve children's allergy care takes place at multiple levels, potentially facilitated by the implementation of lower-level care pathways.

2.4.4. The Itchy Sneezy Wheezy intervention

As discussed, implementation of the RCPCH care pathways requires a multi-level approach. In addition, their implementation requires a multifaceted approach to address the array of issues they intend to resolve. As mentioned, the RCPCH care pathways have been designed as national tools to

integrate care for children with allergic comorbidities, to coordinate care across the acute and chronic stages of allergic disease, and to increase the delivery of evidence-based care (Department of Health, 2006a; Warner & Lloyd, 2011). However, the care pathway literature does not clarify how care pathways translate into the clinical and organisational changes needed to achieve these aims. Instead, the care pathway literature highlighted that the evidence supporting the use of care pathways for variable patient trajectories was uncertain (Allen et al., 2009). Moreover, it was identified that care pathways were not commonly implemented to manage multiple allergic conditions or to coordinate care across multiple settings (Dexheimer et al., 2014; Diwakar et al., 2017). Consequently, to understand what practical interventions are most likely to improve children's allergy care, it is necessary to review the scientific literature more broadly.

To understand what organisational changes are required to implement the RCPCH care pathways effectively, the literature on integrated and chronic care was explored. More specifically, three key reviews were identified, where the authors abstracted core integrated- and chronic care components from successful integrated- and chronic care interventions they had identified. One review focused specifically on chronic care interventions (Wagner et al., 1996), one focused on interventions to integrate primary and secondary care (Mitchell et al., 2015), and one focused on integrated care interventions for patients with chronic conditions (Ouwens, Wollersheim, Hermens, Hulscher, & Grol, 2005). The results from the chronic care review were developed further to form the Chronic Care Model (CCM), which has since been validated as an effective framework to improve health services (Coleman, Austin, Brach, & Wagner, 2009; Glasgow et al., 2001; Wagner et al., 1996). The intervention components identified in the three integrated- and chronic care reviews were different, but similar enough to classify them according to the CCM components. This classification is demonstrated in Table 1. It should be noted, that both integrated care reviews explicitly highlight the use of care pathways as a key component for successful integrated care interventions. However, the type of care pathway was not specified. In an integrated care context, different care pathway types could be beneficial. For example, regional-level pathways could be used to describe the design of an integrated healthcare service. Alternatively, organisation-level pathways could be used by healthcare professionals to navigate their clinical activities within team processes. Accordingly, I have classified the intervention component 'Care pathways' both under the CCM component 'Healthcare delivery system design' and 'Clinical decision support'. Moreover, care pathways are highlighted as one of multiple key integrated and chronic care intervention components. This supports the notion of nested care pathways, whereby the implementation of a care pathway can represent an independent intervention or be part of a larger intervention. Moreover, it supports the notion that to

address the complex issues affecting allergy care, a comprehensive multi-component approach is required (Coleman et al., 2009; Shojania & Grimshaw, 2005).

Table 1. Key intervention components for chronic and integrated care interventions.

Chronic care (Wagner et al., 1996)	Integrated care (Mitchell et al., 2015)	Integrated care for chronic conditions (Ouwens et al., 2005)
Self-management support		Self-management support and patient education
Clinical decision support	Training and education	Healthcare professional feedback, reminders and education
	Shared care guidelines or pathways	Multidisciplinary care pathways
Clinical information systems	Communication and information exchange	
Healthcare delivery system design	Interdisciplinary teamwork	A multidisciplinary care team
	Shared care guidelines or pathways	Multidisciplinary care pathways
	Access and acceptability for patients	Structured follow-up and case management
	Viable funding model	
Community policies and resources		

The Itchy Sneezy Wheezy intervention exemplifies such a comprehensive intervention. As discussed in Chapter 1, the Itchy Sneezy Wheezy pilot project was developed to implement the RCPCH care pathways for eczema, asthma and rhinitis, food allergy, and anaphylaxis. An overview of the Itchy Sneezy Wheezy intervention and its concordance with the CCM is demonstrated in Table 2. As shown, the Itchy Sneezy Wheezy intervention was multifaceted, drawing on a wide range mechanisms to implement the RCPCH care pathways. Moreover, the mechanisms address the

majority of CCM components, which has been found to increase the likelihood of success (Coleman et al., 2009). Accordingly, the Itchy Sneezy Wheezy intervention indeed demonstrated positive effects on the quality of care for allergic children (Warner & Spitters, 2017).

Table 2. Itchy Sneezy Wheezy intervention components classified against the Chronic Care Model.

Chronic Care Model (Wagner et al., 1996)	Itchy Sneezy Wheezy intervention
Self-management support	Website with self-management materials and educational videos for children and caregivers
	Access to allergy experts in primary care
	Access to longer appointment slots in primary care
Clinical decision support	Website with educational materials for healthcare professionals
	Allergy workshops for healthcare professionals
	Access to allergy specialists and experiential learning opportunities in primary care
	Professional development and clinical mentoring by a tertiary allergy specialist for a specialist nurse
Clinical information systems	
Healthcare delivery system design	Outreach allergy clinics run by a tertiary allergist, specialist nurse, and paediatric dietitian in primary care *Funded as a quality improvement project*
	Integrated specialist nurse allergy clinics: run in primary care and supervised in tertiary care *Funded as a commissioned service*
Community policies and resources	

2.4.5. The NIHR CLAHRC NWL systematic approach

As such, implementation of the RCPCH care pathways was achieved through the clinical and organisational mechanisms reflected in the Itchy Sneezy Wheezy intervention. However, the development and implementation of the intervention, was achieved through the use of an industry-based Quality Improvement (QI) approach. As discussed earlier, the definition of quality improvement highlights the process of "*using a systematic change method and strategies"* (p. 8) (Ovretveit, 2009). Sometimes, this involves the systematic use of known implementation strategies, such as health professional education, clinical audit, or financial incentives (Shojania & Grimshaw, 2005). However, the NHS and other healthcare systems are increasingly motivated to use QI methods and approaches from industry (Dixon-Woods & Martin, 2016; Ham et al., 2016; The Health Foundation, 2013). Such methods and approaches that have been applied in healthcare include: Plan-Do-Study-Act (PDSA) cycles as part of the model for improvement, Statistical Process Control (SPC), Six Sigma, lean, Total Quality Management (TQM), theory of constraints, mass customisation, business process re-engineering and experience-based co-design (Boaden et al., 2008; Howe et al., 2013; The Health Foundation, 2013). This overview, includes both approaches for both continuous incremental improvements and for more radical transformational change (Locock, 2003). QI approaches are methodological roadmaps that include various methods to describe a specific process to improve quality (Boaden et al., 2008; Dahlgaard & Mi Dahlgaard-Park, 2006). While some of the methods are unique to certain approaches, most are shared, but applied uniquely, across approaches (Ricondo & Viles, 2005). For example, lean relies heavily on analytical quality improvement methods, whereas Six Sigma relies more heavily on statistical methods, and TQM uses a mix of both (Andersson, Eriksson, & Torstensson, 2006). It is possible to explicitly follow specific QI approach. However, QI methods can also be used flexibly to improve quality in organisations (Dahlgaard & Mi Dahlgaard-Park, 2006).

So, the use of QI methods and approaches in practice is diverse. Accordingly, the effects of QI methods and approaches seem equally diverse. Systematic literature reviews of studies evaluating lean, Six Sigma and TQM indicate that more often than not, these approaches demonstrate positive effects on care processes and on patient outcomes (Dellifraine, Langabeer Ii, & Nembhard, 2010; Mason, Nicolay, & Darzi, 2015; Moraros, Lemstra, & Nwankwo, 2016; Nicolay et al., 2012; Ovretveit, 2009; Shortell, Bennett, & Byck, 1998). However, the reviews also highlight a significant lack of high-quality evaluation studies. Moreover, the high-quality RCTs that have been performed demonstrate that overall, QI approaches are not more effective than business as usual for improving quality. So indeed, no single QI approach seems to be uniformly effective or ineffective (Donabedian, 2003). Instead, research on the effectiveness of QI approaches has been summarised as *"Does it work? Well,*

sometimes it does and sometimes it doesn't, and a lot depends on who does it and how it is done" (p. 85)(Walshe & Freeman, 2002). So, rather than writing off the use QI approaches based on inconsistent effects, the variability of the effects should be further investigated (Grol, Berwick, & Wensing, 2008; Repenning & Sterman, 2001; Walshe, 2007).

One explanation for the variability in QI effectiveness involves diversity in the application process. More specifically, studies suggest that situations where the use of a QI approach fails to achieve improvements in healthcare quality, could reflect a lack of fidelity to its principles during the application process (Shojania & Grimshaw, 2005). It is acknowledged that the use of QI approaches and methods is flexible to a degree. However, it has also been identified that they tend to operate through similar principles. For example, most industry-based QI approaches were seen to operate based on the following shared principles: understanding systems and processes; managing process variation; managing supply, demand and flow; and understanding and involving patients (Boaden et al., 2008; The Health Foundation, 2013). As such, the selection of a specific compilation of QI methods in a specific QI approach is likely to matter less, than ensuring these principles are adhered to in the QI approach and its application (Hawe, Shiell, & Riley, 2004). Moreover, when an appropriate set of QI methods has been selected, their operational principles need to be adhered to also. For example, in one review study, it was identified that the PDSA method is based on five core principles. These principles, and the number of studies the authors identified that adhered to each principle, were as follows: iterative use of PDSA cycles (14/73), initial small-scale testing (2/73), prediction-based testing (4/47), use of data over time (7/47), and process documentation (49/73). Moreover, adherence to all five principles was only demonstrated in 2/73 PDSA studies included in the review (M. J. Taylor et al., 2014). As such, there are principles at the level of the QI approach and at the level of QI method that should ideally be adhered to, to increase the likelihood that a QI approach will be effective. However, in addition to these principles inherent to the QI approach, principles have also been identified at the level of local application. These include: appropriate quality definition and measurement; whole systems leadership and commitment to quality improvement; engagement of everyone involved in the change; selection and use of methods that align with local quality goals and problems (Boaden et al., 2008; The Health Foundation, 2013).

The Itchy Sneezy Wheezy project followed a QI approach that was tailored to the healthcare sector. More specifically, the approach was developed by the NIHR Collaboration for Leadership in Applied Health Research and Care for North West London (CLAHRC NWL) to study how a systematic QI approach could support the translation of research evidence into clinical practice and social care (Caldwell & Mays, 2012; Kislov, Wilson, Knowles, & Boaden, 2018). The study involved funding ten clinical project teams to create a quality improvement collaborative (Nadeem, Olin, Hill, Hoagwood,

& Horwitz, 2013; Ovretveit, 2002; Wells et al., 2017). The teams in the collaborative were then studied over an 18-month period, while they applied the NIHR CLAHRC NWL systematic QI approach to implement the research-based clinical improvements defined in their projects. The QI methods that comprised the systematic QI approach are outlined in Table 3. To understand how the QI approach was used, the NIHR CLAHRC NWL team collated data collected from two 18-month rounds of the improvement collaborative (Howe et al., 2013). Based on this data, they rated how the project teams interacted with each method in the NIHR CLAHRC NWL systematic QI approach. Three criteria were used: compliance with the method-level principles, cognitive engagement using the method, and method-related results. Within the improvement collaborative, all project teams received similar education and support to use the QI methods. Nevertheless, the ratings demonstrated that their interactions with the QI methods varied greatly. Some teams interacted productively with most methods. Some teams interacted productively with some methods, but not others. And some teams hardly interacted with any method. Moreover, some QI methods were generally better applied than others. However, each method was applied effectively by at least one team. So, improvement projects demonstrate variable levels of engagement with QI methods and approaches. Nevertheless, all improvement projects face challenges that need to be overcome.

Table 3. NIHR CLAHRC for Northwest London Collaborative methods. From: Howe et al. (2013)

Methods	Purpose of using the method	Key related references
Process mapping	To reveal the current working practices for all those affected by the multidisciplinary care or data processes. To support process design.	(Locock, 2003; NHS Institute for Innovation and Improvement, 2007)
NHS III Sustainability Model	To identify and collectively address the factors that may affect long-term success.	(Maher, Gustafson, & Evans, 2010; NHS Institute for Innovation and Improvement, 2007)
Action-Effect-Method (based on driver diagrams)	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.	(Reed, McNicholas, Woodcock, Issen, & Bell, 2014)

Model for Improvement including Plan-Do- Study-Act (PDSA) rapid cycle testing of change ideas	To establish and agree what is intended to be accomplished, how to demonstrate that the change is an improvement and to generate ideas for what those changes might be. To undertake systematic rapid iterative cycles of change.	(Langley et al., 2009; NHS Institute for Innovation and Improvement, 2007)
Measurement for improvement	To determine operational definitions of process and outcome measures to ensure that these are consistently used and understood within the work, with routine weekly use of the data to inform the project implementation.	(Boaden et al., 2008; NHS Institute for Innovation and Improvement, 2007; Tennant, Mohammed, Coleman, & Martin, 2007; Thor et al., 2007)
Stakeholder engagement	To identify and engage effectively with all key stakeholders and groups.	(Greenhalgh, Robert, Macfarlane, Bate, & Kyriakidou, 2004; The King's Fund, 2012)
Patient and public involvement	To engage with patients and the public to ensure the voice of the customer is clear in the work.	(Axelrod, 2010; Florin & Dixon, 2004; NHS Institute for Innovation and Improvement, 2007)
Dissemination of learning	To share and disseminate the experience and learning generated in the project internally and externally including through peer-reviewed journals.	

Accordingly, the NIHR CLAHRC NWL investigation into the process of healthcare improvement progressed from a primary focus on QI methods to a focus on navigating improvement challenges more generally. This effort generated a set of principles and strategies for healthcare improvement that transgress the method-level principles they studied so far. The principles and strategies they identified, are captured in the framework for Successful Healthcare Improvement From Translating Evidence into practice (SHIFT-Evidence) (Reed, Howe, Doyle, & Bell, 2018a, 2018b). Their three core principles for healthcare improvement summarise the SHIFT-Evidence framework as follows:

> *"to achieve successful improvements from evidence translation in healthcare, it is necessary to 'act scientifically and pragmatically' whilst 'embracing the complexity' of the setting in which change takes place and 'engaging and empowering' those responsible for and affected by the change"* (p. 4) (Reed, Howe, et al., 2018a).

The twelve strategies that have been suggested to enact these principles are demonstrated in Table 4. To implement these strategies into the quality improvement process, teams could use the QI methods encompassed in the NIHR CLAHRC NWL systematic QI approach. However, there are no set ways or methods that prescribe how these principles and strategies for improvement should be implemented. Moreover, it can be recognised that the principles and strategies in Table 4 overlap with the improvement principles discussed earlier, that were derived from other QI approaches (Boaden et al., 2008; The Health Foundation, 2013). This reinforces the statement that effective quality improvement tends to operate through a limited number of improvement principles, which could be established through different QI approaches, and also through other means.

Table 4. Principles and strategies for QI in healthcare. Adapted from: (Reed, Howe, et al., 2018a)

First principle: Act scientifically and pragmatically
1. Understand the problem and opportunities
2. Identify, test and iteratively develop potential solutions
3. Assess whether improvement is achieved, capture and share learning
4. Invest in continual improvement
Second principle: Embrace complexity
5. Understand practices and processes of care
6. Understand types and sources of variation
7. Identify systemic issues
8. Seek political, strategic and financial alignment
Third principle: Engage and empower
9. Actively engage those responsible for overcoming challenges
10. Facilitate dialogue

11. Build a culture of willingness to learn and freedom to act

12. Provide headroom, resources, training and support

2.4.6. Conclusion

So, in this section, I used the scientific literature to analyse and conceptualise the implementation of the RCPCH care pathways to improve children's allergy services. The RCPCH allergy care pathways were commissioned by the Department of Health as national tools for teams and organisations to improve their local children's allergy services. After publication, they were successfully implemented in a local London area as part of the Itchy Sneezy Wheezy project. To understand how this success could be replicated elsewhere and thereby support the improvement of children's allergy services more broadly, I used the scientific literature to understand and explain how the RCPCH care pathways and the Itchy Sneezy Wheezy project operated. This section highlighted this to be a multifaceted endeavour that can be summarised succinctly by discussing its context, content, and process of change (Walt & Gilson, 1994).

As such, I first discussed how the RCPCH care pathways need to be understood within the clinical and organisational **context** they were developed for. That is, I discussed characteristics inherent to the clinical context of allergic disease, and how these are accounted for by the RCPCH care pathways to effectively improve children's allergy services (Shojania & Grimshaw, 2005). I described that the RCPCH care pathways represent all stages of care to address the chronic nature of allergic disease, and they have internal references to address allergic comorbidities. Moreover, the RCPCH care pathways have a flexible design, so they can be implemented in local areas with different resources and requirements. Accordingly, the RCPCH care pathways have the appropriate characteristics to improve children's allergy care in different local areas. However, their implementation requires a comprehensive intervention, which can be difficult to commit to or implement.

Second, I discussed the **content** of the Itchy Sneezy Wheezy intervention that was used to implement the RCPCH care pathways into clinical practice. I demonstrated how the Itchy Sneezy Wheezy intervention embodies most evidence-based components to successfully deliver integrated and chronic care. However, I also noted that these evidence-based components could be embodied differently. Moreover, I demonstrated that different types of care pathways have different roles within an intervention due to their hierarchical or nested nature. Accordingly, an integrated/chronic care intervention to implement the RCPCH care pathways might include a care pathway that makes

clinical guidelines accessible to specific healthcare professionals, or a care pathway that organises the referrals between services.

Third, I discussed the NIHR CLAHRC NWL systematic approach that was used as the **process** to develop and implement the Itchy Sneezy Wheezy intervention. More specifically, I compared the NIHR CLAHRC NWL systematic approach to other QI approaches. This comparison highlighted that QI approaches generally operate through a small number of core principles and consist of multiple methods to enact these principles. However, as long as the core principles are enacted, the design of a QI approach can be flexible and engagement with its methods variable.

As such, I described what mechanisms explain the success of the RCPCH care pathways and the Itchy Sneezy Wheezy intervention to improve children's allergy services. However, this explanation holds uncertainty due to inconsistent intervention effects and a lack of corroboration. So far, the Itchy Sneezy Wheezy intervention had been successful locally. However, the intervention failed to sustain locally, as it was decommissioned after one year, and it hadn't yet been replicated in other areas. Moreover, there was a lack of studies evaluating care pathway interventions for children with multiple allergic comorbidities along different stages of their care. And studies evaluating different types of care pathway interventions, demonstrated that care pathway interventions are effective generally, but sometimes they're not. As such, both the Itchy Sneezy Wheezy experience and the scientific literature demonstrates contradictory care pathway effects. Accordingly, it is unclear whether the Itchy Sneezy Wheezy intervention or a different RCPCH care pathway intervention is likely to be effective elsewhere.

> *Contradiction II: While care pathway interventions have been demonstrated to improve healthcare quality generally, sometimes they don't improve quality*

Similar conclusions can be drawn regarding the use of a systematic QI approach to support the implementation of care pathways. The Itchy Sneezy Wheezy project demonstrated how the NIHR CLAHRC NWL systematic approach successfully supported implementation of the RCPCH care pathways. However, a research study showed that the NIHR CLAHRC NWL systematic approach was applied inconsistently across improvement projects (Howe et al., 2013). This aligned with the general scientific literature, which demonstrates that QI approaches are variably effective, while arguing that different types of QI approaches can be effective.

> *Contradiction III: While various systematic QI approaches have been demonstrated to achieve healthcare improvements, they do so inconsistently*

Rather than refraining from studying implementation of the RCPCH care pathways based on this empirical evidence, the mechanisms identified in this section suggest that the RCPCH care pathways can support the development and implementation of a complicated solution for a complicated problem. That is, the RCPCH care pathways organise the full patient trajectory of allergic children, which is necessary to effectively improve children's allergy services. However, it is a complicated effort that might include the implementation of multiple nested care pathway interventions that organise individual segments of the patient trajectory. Moreover, I identified that the Itchy Sneezy Wheezy intervention, used to implement the RCPCH care pathways, reflects an integrated/chronic care intervention. And generally, successful integrated/chronic care interventions are multi-component interventions that might include a care pathway component amongst other components. As such, to improve children's allergy services, care pathway interventions might be most effective when integrated into a complex integrated/chronic care intervention. So, rather than rejecting further study of the RCPCH care pathways based on insufficient care pathway evidence, I specified the proposition investigated in this study.

> *Proposition I: Care pathways improve children's allergy services as part of a complex integrated & chronic care intervention.*

In the next section, I take a broader view of healthcare improvement, to explain the contradictions identified in this section. Accordingly, I aim to understand why efficacious QI approaches and care pathway interventions might fail to achieve, sustain or replicate healthcare improvements. In doing so, I draw together the perspectives of three different improvement science disciplines: diffusion of innovations, implementation science and the study of QI approaches. I will describe and integrate key theoretical contributions from each discipline, aiming to develop the theoretical understanding needed to improve children's allergy services. That is, I aim to resolve the contradictions that have been identified, and I aim to identify the knowledge gaps that still need to be addressed. To understand the distinction between the three disciplines, and their distinction from the study on care pathways discussed so far, a short historical overview of each can be found in Appendix C.

2.5. Theoretical perspectives: diffusion, implementation and improvement

2.5.1. Diffusion of innovations

The concepts underpinning diffusion correspond with the concepts that describe quality improvement. Diffusion is commonly defined as *"the process by which an innovation is communicated through certain channels over time among the members of a social system"* (p. 6.) (Rogers, 1995). As such, diffusion describes how innovative ideas, methods and technologies spread, so they can get adopted into the beliefs and practices of people and organisations (Katz, Levin, &

Hamilton, 1963). Put simply, it describes *"how things, ideas and practices – get from here to there"* (p. 145) (Katz, 1999). In 1962, the first edition of *'The Diffusion of Innovations'* was published, which summarised a body of sociological studies on the diffusion of agricultural innovations. Its summary is based on four main organising concepts: the innovation that is diffused, the element of time in the diffusion process, the social system in which an innovation diffuses, and the channels through which the innovation is communicated (Rogers, 2003). These concepts map neatly onto the policy triangle components, respectively the content, context and process of improvement (Walt & Gilson, 1994). The only concept specific to diffusion of innovations is the notion of communication channels. Communication channels are the means through which people who have a practical or theoretical understanding of an innovation share their knowledge with people who don't (Rogers, 2003). The means used to share information can range from spontaneous personal conversations to detailed practical workshops to passive mass-media.

However, quality improvement has a slightly more specific focus. That is, quality improvement concentrates on people and organisations adopting innovations as a means to make improvements. In that sense, the focus is placed on gaining, processing and applying information about innovations, giving less priority to understanding how information about innovations should be shared. In this thesis, I have framed the problem of poor children's allergy services as a quality improvement problem. As such, I will approach the diffusion of innovations literature similarly. I focus on the active adoption rather than the active spread of innovations, while recognising these are two sides of a coin. With a primary interest to improve the adoption of innovations in the health sector, a comprehensive literature review was conducted to extend the review published in *'The Diffusion of Innovations'* (Rogers, 2003). This work was extended through an interdisciplinary literature search, including fields such as marketing, technology studies, organisational management, health promotion, and knowledge mobilisation. The findings of the review were summarised in the *"Conceptual Model for Considering the Determinants of Diffusion, Dissemination, and Implementation of Innovations in Health Service Delivery and Organizations"* (p.595)(Greenhalgh et al., 2004). This model is presented in Figure 7 to get an idea of the many different constructs involved in the adoption of innovations in healthcare.

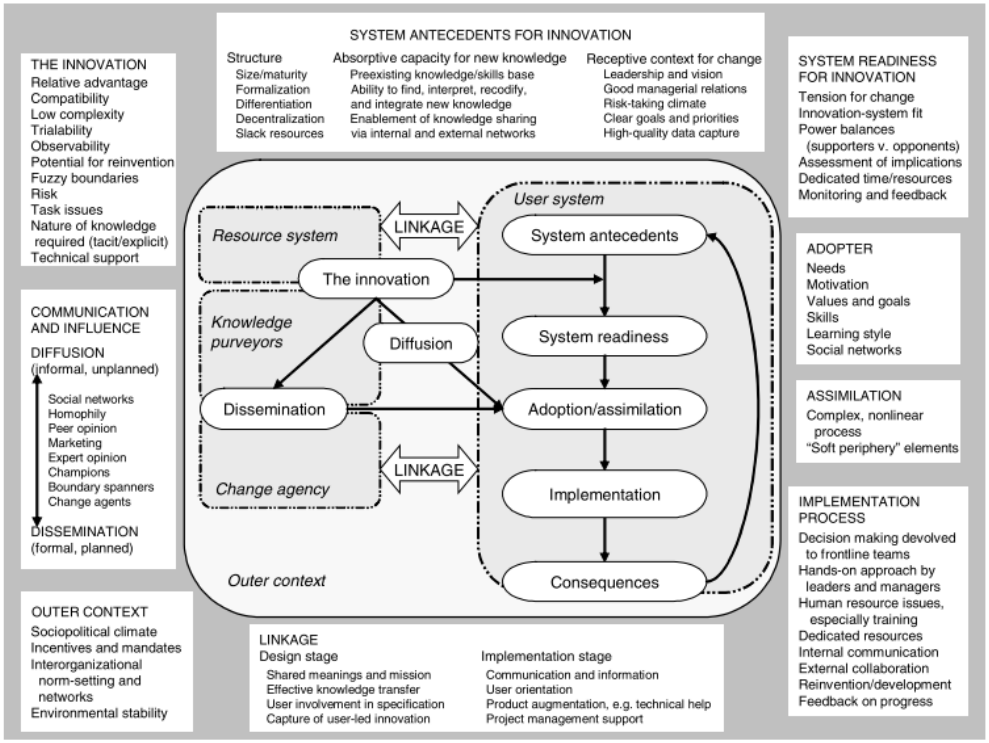


Figure 7. A model for the diffusion, dissemination and implementation of innovations in healthcare. From: (Greenhalgh et al., 2004).

In the study of diffusion, **the content of improvement** is conceptualised as an innovation with characteristics that influence diffusion. An innovation can be defined as *"an idea, practice or object that is perceived as new by an individual or other unit of adoption" (p. 49)* (Rogers, 2003). In health, innovations include new drugs, medical technologies, health interventions or new services. It is important to note that an innovation only has to be new to the adopting people or organisations, not newly discovered. Rogers (2003) identified five innovation characteristics that facilitate or impede diffusion: the innovation's perceived advantage compared to other solutions either in effectiveness or cost-effectiveness; the compatibility of innovation characteristics with norms, values, behaviours and needs of the adopters; the perceived complexity to understand and use the innovation; the ability to trial the innovation on a small-scale; and the ability to observe outcomes and consequences of innovation use. Over time and across fields of study, diffusion studies became more sophisticated. Studies initially focused solely on the direct relationship between innovation properties and adoption rate, while later studies also investigated innovation properties in relation to their context of use. In addition, the complexity of studied innovations increased over time. This led to the identification of additional innovation characteristics important for diffusion, including: the perceived innovation relevance to completing tasks, the ease of sharing theoretical and practical knowledge needed for innovation use, and the provision of additional technical support. The updated list of innovation characteristics is shown in Figure 7.

Despite conceptualising innovations based on characteristics, diffusion studies emphasise the dynamic nature of innovations. A key development in diffusions studies was the discovery that innovations are not invariant when diffused (Rogers, 2003). Instead, it was observed that innovations are often changed, adapted, or used differently than intended – they are re-invented. Re-invention or adaptation of innovations can facilitate their adoption by enhancing the 'fit' between an innovation and a new setting (Ansari, Fiss, & Zajac, 2010; Greenhalgh et al., 2004). New settings that adopt an innovation are likely to have different objectives, interests, values, norms, skills, resources, workflows and organisational structures compared to the setting where the innovation was originally developed and tested. Consequently, (perceived) misalignment with the innovation's characteristics, risks and benefits can prevent successful adoption and implementation in new settings (Denis, Hébert, Langley, Lozeau, & Trottier, 2002). Adaptation or re-invention might thus be needed to make an innovation more meaningful or suitable for new settings. Re-invention can be more or less extensive, planned or unplanned, with expected or unexpected consequences. Re-invention is influenced by the nature of innovations, with some innovations being very difficult to change while others are inherently more flexible (Rogers, 2003). In addition, some innovations have fuzzy boundaries meaning it is difficult to delineate innovation components and distinguish them from its context of use (Denis et al., 2002). Such ambiguity tends to exists when innovations are complex which often results in a degree of accidental re-invention. Furthermore, it was said that re-invention can facilitate innovation adoption. However, it is important to strategically plan adaptations as they might otherwise compromise innovation functioning resulting in the adoption of an innovation without achieving its desired effects (Elliott & Mihalic, 2004).

The process of improvement can be better understood through insights into the innovation-decision process that precedes commitment to the use of innovative solutions. Studies on the diffusion of innovations emphasise the importance of time. Time is inherent to diffusion and its role has been studied in several ways (Rogers, 2003). For various innovations the rate of adoption has been studied for example, and for individuals and organisations it has been studied how quickly they tend to adopt innovations. However, particularly relevant to improvement has been the study of the innovation-decision process, which describes the stages people or organisations tend to go through before using an innovation routinely (Rogers, 2003). Understanding the innovation-decision process can help to understand the process of improvement by highlighting why innovative solutions to quality problems might not be adopted and how adoption could be promoted. The innovation decision-process involves the following five sequential stages:

1) knowledge, gaining awareness of an innovation's existence and understanding of its functioning;

2) persuasion, forming a favourable or unfavourable attitude towards an innovation based on technical and social information about its potential consequences;
3) decision, choosing to adopt or reject an innovation based on its advantages for the individual person or organisation relative to existing or other solutions;
4) implementation, actively embedding an innovation into routine practice potentially including adaptation or re-invention of the innovation;
5) and confirmation, evaluating whether the previous adoption decision is still appropriate, potentially leading to delayed innovation adoption or conversely innovation discontinuance or de-implementation when dissatisfied with prior adoption or when a better solution is found.

These stages conceptualise the innovation-decision process as an information-seeking and information-processing trajectory to find out with increasing certainty whether an innovation is suitable to the circumstances of the person or organisation adopting the innovation. This process can either start with a specific quality issue that requires a solution, i.e. demand-pull. Or it starts with the development of an innovation that is superior to existing processes and solutions for resolving (potentially unrecognised) quality issues, i.e. supply-push (Abrahamson, 1991). In real-life situations, however, the ability to make rational innovation-decisions is usually limited by the complexity of the problem, incomplete information and a scarcity of time and resources (Simon, 1972). Most innovation-decisions are made in situations where such limits make fully rational decisions, based on complicated resource-heavy scientific predictions, inappropriate if at all possible. Instead, fast and frugal heuristics tend to be used to optimise the decision-making progress in complex real-life settings (Herwig, Hoffrage, & ABC Research Group, 2013). In diffusion, the *imitate-the-successful* heuristic is common for example, whereby innovation-decisions of successful competitors or opinion leaders are imitated based on the premise that by adopting their innovations, their success will follow. Another prevalent heuristic is *imitate-the-majority*, whereby innovations are adopted based on conformation to group norms (Abrahamson, 1991; Herwig et al., 2013; Katz, 1999; Rogers, 2003).

The context of improvement is conceptualised in the study of diffusion as a social system. A system can be loosely be defined as *"a whole made up of interdependent components in interaction"* (p.8) (Laszlo & Krippner, 1998). In the study of diffusion, the systems that tend to be focused on are systems of interconnected adopters sharing information between each other – i.e. social networks. An adopter can be any type of social unit, including clinical teams, organisations or local areas. However, the type of adopting unit most often studied are individuals. In social networks, diffusion can be conceptualised as a gradual learning process, where innovation expertise slowly accumulates through individuals sharing knowledge and skills amongst each other (Rogers, 2003). Both the

structural characteristics of the social network as a whole and the characteristics of the individual social units influence diffusion (Rogers, 2003; Scott, 2000). Characteristics of individuals that influence innovation adoption include both general and context-specific psychological traits, summarised in the diffusion model in Figure 7 under *'adopter'* (Greenhalgh et al., 2004). Characteristics of organisations that influence adoption include structural elements related to the general design, knowledge management and business management processes of organisations, summarised in Figure 7 under *'system antecedents for innovations'*. They also include organisational elements that are innovation specific, summarised in Figure 7 under *'readiness for innovations'*. However, to understand the social network influences in diffusion, it's insufficient to understand the characteristics of individual people or organisation that influence diffusion.

Instead, it's also important to understand how they operate collectively as a social network that also influences diffusion as a whole. That is, it's also important to understand what network characteristics influence diffusion. System norms for example influence diffusion (Rogers, 2003). Norms are patterns of acceptable behaviours within social systems that slowly develop over time as the aggregate of individual behaviours. Norms influence diffusion by defining whether performing the behaviours associated with implementing and using specific innovations is socially acceptable. Another structural element influencing diffusion is the social position of adoption units relative to one another creating both formal and informal power structures in a system (Porpora, 1989; Rogers, 2003). People in formal power positions tend to attain influence due to capabilities inherent to their social position. People in management positions for example can enforce the adoption of innovations as part of their role, making authority-based innovation-decisions. People in informal power positions however, tend to attain influence due to interpersonal relations. Such informal leaders are called opinion leaders (Rogers, 2003). Opinion leaders usually demonstrate behaviours in close alignment with system norms. In relation to others, they tend to be more exposed to external communications, have a somewhat higher socio-economic status, and be more innovative. Moreover, their position within the interpersonal network is highly central. Through these relational properties opinion leaders attain a highly influential social position as a respected social model.

In conclusion, the study of diffusion of innovations offers important insights that can support the improvement of children's allergy services. Diffusion explains how innovative ideas, tools and practices are shared between healthcare professionals and across health services. As such, it helps to explain how clinical teams and local health systems adopt innovative solutions, like the RCPCH care pathways and the Itchy Sneezy Wheezy intervention, to improve their local children's allergy services. Diffusion studies highlight that adoption of innovative interventions is influenced by the **content** of the intervention. Several intervention characteristics have been identified that influence

adoption. Interventions are not invariant however, as they are often adapted or re-invented to make them more appropriate for other settings. In addition, adoption is also influenced by the innovation-decision **process** that precedes the use of innovative interventions in routine practice. This process depends on communication, information-processing, social influences, and practical experience to decide whether the intervention is beneficial and worthwhile. This innovation-decision process is influenced by the context in which the intervention is adopted. In diffusion studies, **context** is conceptualised as a social system, most often a social network. Within a social network, adoption decisions aren't solely influenced by the characteristics of the people and organisations in the network. Instead, how innovations get adopted into routine practice is also influenced by their relationships and their positions respective to one another.

2.5.2. Implementation science

Due to its medical roots, implementation science focuses on achieving quality improvements through the implementation of evidence-based interventions. As discussed in Appendix C, implementation science is rooted in medical science, where modernist thinking has led to great scientific advances (Wieringa, Engebretsen, Heggen, & Greenhalgh, 2017). Modernist science evolved around the idea that understanding and predicting the world is possible through the identification of universal laws, which are, or depend on, empirical regularities – the constant conjunction of observable events (Bhaskar, 1998). This type of thinking underpins the research pipeline as a metaphor for quality improvement in healthcare, whereby: 1) the understanding of disease pathology leads to 2) the development of effective treatments that are 3) implemented in medical practice to 4) improve patient outcomes. However, this elegant linear trajectory from research to practice had to be reconsidered when the two translational gaps were identified.

> *"[The first translational gap concerns] translating ideas from basic and clinical research into the development of new products and approaches to treatment of disease and illness; and [the second translational gap concerns] implementing those new products and approaches into clinical practice"* (p.3.) (Cooksey, 2006)

The translational gaps were expressed in the research pipeline metaphor as pipeline leakages, which created some initial awareness that the linear causal model of translating research into practice might be an oversimplification (Cooksey, 2006; Green, Ottoson, García, & Hiatt, 2009). However, still rooted in modernist thinking, implementation science developed to understand and close the gap between the development of evidence-based treatments and their use in practice.

Accordingly, its perspective on the content, process and context of improvement was initially reductionist and static. The **content of improvement** comprised fixed evidence-based interventions to be implemented. The **process of improvement** was conceptualised through the research pipeline. The implementation process, more specifically, was seen as the application of practical strategies to navigate implementation barriers and facilitators (Brownson, Colditz, & Proctor, 2012). Accordingly, the **context of improvement** was conceptualised as the set of facilitators and barriers present in a particular settings that might support or constrain implementation. Over time, however, implementation science became more amenable to insights from other disciplines and the complexities of real-world clinical practice. Its scientific developments since have been captured and summarised in numerous frameworks (Moullin, Sabater-Hernández, Fernandez-Llimos, & Benrimoj, 2015; Nilsen, 2015; Tabak, Khoong, Chambers, & Ross, 2013). These frameworks can be classified as explanatory frameworks, process frameworks and evaluation frameworks (Nilsen, 2015). In the following paragraphs, I will highlight a specific implementation frameworks from each category to discuss how the conceptualisation of improvement content, context and process has evolved in implementation science.

The Consolidated Framework for Implementation Research (CFIR) is a distinguished explanatory implementation framework building on the diffusion of innovations knowledge base. More specifically, the CFIR is a determinant framework in which constructs that influence implementation are collated, organised and defined to provide a *"consistent taxonomy, terminology, and definitions on which a knowledge base of findings across multiple contexts can be built"* (p. 2) (Damschroder et al., 2009). As such, the framework provides a conceptual overview of the implementation literature. The literature review underpinning the CFIR, took the aforementioned synthesis on the diffusion, dissemination, and implementation of innovations from (Greenhalgh et al., 2004) as a starting point. This synthesis was subsequently extended with 17 additional frameworks (Damschroder et al., 2009). The synthesised frameworks mainly described which constructs influence implementation – not how, where or why. Consequently, no hypotheses or construct relationships were included in the CFIR. The CFIR includes many constructs from the diffusion of innovations literature. Having the same constructs influence both implementation and diffusion makes sense, since implementation is an important stage of diffusion (Rogers, 2003). Diffusion has a much broader focus however, and accordingly a more limited understanding of implementation specifically. It is no surprise then, that the five domains that categorise implementation constructs in the CFIR are highly similar to the four organising concept used by (Rogers, 2003) to explain diffusion. The five domains in the CFIR are: intervention characteristics, characteristics of the individuals involved, the process of implementation, the inner setting, and the outer setting (Damschroder et al., 2009). Since its

development, the CFIR has been widely applied by both scientists and practitioners. A review of 26/429 journal articles citing the CFIR found application of the framework across a variety of study objectives, methods and settings (Kirk et al., 2016). However, a lack of in-depth and meaningful application of the CFIR constructs means more theoretical developments based on the CFIR are yet to be made.

The way in which the CFIR conceptualises the content, context and process of improvement is specific to implementation of evidence-based interventions, yet heavily influenced by the diffusion literature. Similar to diffusion, the CFIR conceptualises the **content of improvement** as interventions with characteristics that influence implementation. The intervention characteristics domain contains the diffusion-based innovation characteristics from (Rogers, 2003) and (Greenhalgh et al., 2004), including adaptability in recognition of potential re-invention to meet local needs. Most notably, the CFIR adds the characteristic 'evidence strength and quality', highlighting the EBM roots of implementation science and of the healthcare professionals who practice implementation. The CFIR conceptualises **context of improvement** as inner and outer setting. This conceptualisation is somewhat different from the diffusion perspective despite including many of its ideas and constructs. Most diffusion studies focussed on adoption by individuals with insights from organisational studies only added later (Greenhalgh et al., 2004; Rogers, 2003). Accordingly, the CFIR recognises the importance of the characteristics of individuals. In implementation science however, individuals are the agents performing implementation and intervention behaviours, rather than the agents making innovation-decisions. The CFIR recognises also that implementation in healthcare is often not personal, but performed by clinical teams, departments, or organisations – which are all hierarchically organised systems (Damschroder et al., 2009). These systems, where implementation takes place, form the inner setting of implementation which is influenced by factors in the outer setting. Social networks, which have been described as the context for the diffusion of innovations, are included as a construct in the CFIR's inner setting domain. The organisational-level insights from later diffusion studies are included in the CFIR's outer setting domain (Damschroder et al., 2009; Greenhalgh et al., 2004; Rogers, 2003). As a determinant framework however, the CFIR does not elaborate on the implications of conceptualising the inner setting as a system. Moreover, it presents the constructs that make-up the inner setting domain without explaining their relationships, which is key for understanding systems (Laszlo & Krippner, 1998; Macy, 1991; McDaniel & Driebe, 2001; Schein, 2010). The **process of improvement** that the CFIR conceptualises is the process of implementation. Even though implementation is a stage within the diffusion process, it is usually not further explored in diffusion studies. It is, however, the main focus of study in implementation science. Many methods and approaches exist for implementation. The CFIR does not promote any

specific method. Instead it defines the implementation process through four mechanisms that influence implementation success: planning, engagement, execution, and reflection and evaluation (Damschroder et al., 2009). The way in which these mechanisms are activated is highly flexible, ranging from prescriptive research protocols to informal rapid testing of small-scale changes. Furthermore, specific implementation approaches do not necessarily enact all four mechanisms, neither do the mechanisms have to take place in order or occur only once (Damschroder et al., 2009). Note that the QI approaches from industry form a specific type of implementation approach in the CFIR process conceptualisation.

Implementation science also conceptualises the **process of implementation** in other ways, in terms of implementation strategies or implementation stages. First, discrete implementation strategies have been identified as practical guidance for the implementation process. Early implementation studies generally focused on developing and testing implementation strategies as part of effectiveness studies (Brownson et al., 2012). However, poor descriptions, inconsistent terminology and a lack of explicit incremental development resulted in a large and confusing knowledge-base of potential implementation strategies. To support researchers and practitioners navigate this knowledge-base, available implementation strategies have been compiled, defined and classified (Powell et al., 2012, 2015; Waltz et al., 2015). The result has been a consolidated compilation of 73 discrete implementation strategies organised into 9 categories: evaluative and iterative strategies; interactive assistance; adaptation and tailoring to context; stakeholder relationship development; stakeholder training and education; clinician support; consumer engagement; financial strategies; and change infrastructure. All strategies come with clear definitions and examples to enable consistent use of terminology and the replication of strategies in practice. Implementation strategies might involve a single process or action (e.g. a reminder or educational meeting) or a combination of multiple processes or actions, with multi-faceted implementation strategies generally being more effective (Shojania & Grimshaw, 2005). Second, comprehensive process frameworks have been developed to guide the implementation process. An example of an extensive process framework that is specifically focused on practical actions to support implementation, is the Quality Implementation Framework (QIF) (Meyers, Durlak, & Wandersman, 2012). The QIF consists of 14 critical steps for high-quality implementation, performed over four implementation phases: initial considerations regarding the host setting, creating a structure for implementation, ongoing structure once implementation begins, and improving future applications. QIF synthesises action-oriented elements from 25 implementation frameworks to address the lack of practical implementation how-to knowledge (Gibbons et al., 1994; May, 2013; Nowotny, Scott, & Gibbons, 2003; Pettigrew, 2001). To support the execution of each of the 14 critical step, Meyers et al. (2012) highlight key questions to

be answered. Despite its comprehensive multi-level practical guidance, the QIF still needs to be applied and tested in practice to understand what low-level actions are needed to execute all 14 steps, to understand the interactions between steps, and to assess the impact on implementation.

Evaluation plays a key role in implementation science. Although slowly changing, the research pipeline has long been the dominating model in evidence-based medicine and implementation science (Braithwaite, Churruca, Long, Ellis, & Herkes, 2018). The research pipeline conceptualises the process of quality improvement in healthcare as a linear progression of scientific developments – from fundamental discoveries in the life-sciences to actual healthcare improvements (Cooksey, 2006). Every stage in this process is underpinned by rigorous health research, evaluation studies forming an important group. Different types of evaluation studies exist. Efficacy studies are designed to assess whether interventions tend to have positive outcomes under ideal circumstances, often studying intensive interventions implemented in optimised settings (Flay, 1986; Glasgow, Vogt, & Boles, 1999). Generally though, healthcare settings are strained for resources, clinicians are juggling care priorities, and patients are not similarly motivated to participate. Implementation activities might also not be well-executed and interventions might be adapted during implementation. Which is why effectiveness studies test interventions in real-world conditions, often finding outcomes very different from efficacy studies (Flay, 1986). The Medical Research Council (MRC) has provided guidance on evaluating complex interventions through effectiveness studies, encouraging the use of RCTs whenever randomisation is possible (Craig et al., 2008). RCTs, when well-executed, have high internal validity, reflecting high confidence in the study results (Cartwright, 2007, 2010). However, their external validity is often narrow, since RCTs tend to have many inherit assumptions about its target population. This means that RCT conclusions can usually not be applied reliably to most other settings (Parry, Carson-Stevens, Luff, McPherson, & Goldmann, 2013). Moreover, RCTs intend to evaluate the effectiveness of interventions. Accordingly, they are designed to separate intervention effects from the influence of contextual factors. Context was therefore usually seen as a form of bias, which confounded intervention effects, and had to be controlled for through strategies like randomisation (Craig et al., 2008; Skelly, Dettori, & Brodt, 2012). So, while RCTs are useful for evaluating complex interventions, they tend to inadequately address the complexities of implementation in real-world settings. Additional insights are required to help policy-makers and healthcare professionals understand whether an 'effective' intervention can have similar positive outcomes in their setting, and how exactly these outcomes can be achieved. Implementation evaluation frameworks have been developed to address these issues and attain such knowledge (Nilsen, 2015).

Implementation evaluation frameworks provide additional insights into the conceptualisation of the content, context and process of improvement in implementation science. Evaluations in implementation science assess implementation as a means to explain intervention outcomes, i.e. to explain how and why interventions work (Craig et al., 2008; Nilsen, 2015; Oakley, Strange, Bonell, Allen, & Stephenson, 2006). Process evaluations are a good example, aiming specifically to *"assess fidelity and quality of implementation, clarify causal mechanisms, and identify contextual factors associated with variation in outcomes"* (p. 982) (Craig et al., 2008). The MRC developed guidance on performing process evaluations, augmenting its guidance on evaluating complex interventions (Moore et al., 2015; Moore, Audrey, Barker, & Bond, 2014). The process evaluation framework produced and shown in Figure 8 outlines three interrelated components to be studied: mechanisms of impact *"through which intervention activities produce intended (or unintended) effects" (p.8)*; contextual factors, *"which may influence its implementation, or whether its mechanisms of impact act as intended" (p.8)*; and implementation (Moore et al., 2014). Both implementation processes (i.e. how intervention delivery is achieved) and implementation quality (i.e. what intervention is delivered) require assessment. Several measures and measurement instruments exist to assess implementation quality (Lewis et al., 2015; Proctor et al., 2011; Rabin et al., 2016). Moore et al. (2014, 2015) emphasise the following four: fidelity, adaptations, dose and reach. Even though the potential need for intervention adaptation is acknowledged, intervention fidelity is encouraged to increase the likelihood of replicating positive outcomes achieved in previous studies (Durlak & DuPre, 2008; Elliott & Mihalic, 2004; Moore et al., 2015). As such, process evaluations use implementation quality in addition to the aforementioned implementation stages and activities to conceptualise the **process of improvement**. For conceptualising the **content of improvement**, process evaluations highlight the importance of understanding the causal mechanisms of impact in addition to intervention characteristics. Note that causal mechanisms are distinct from intervention activities. Causal mechanisms are the underlying factors that explain empirical regularities (Pawson & Tilley, 1997; Weiss, 1997). For interventions, these are the mechanisms triggered by intervention activities that explain the observed relationship between intervention activities and outcomes. Underlying the effects of medical training for example, are causal mechanism, like knowledge, practical skills and confidence. These are triggered by training activities, and they explain the quality of patient care. Such causal mechanisms can be seen as mediators (Moore et al., 2014). Process evaluations also elaborate on the conceptualisation of the **context of improvement** as a set of influencing factors. Contextual factors are recognised to affect the relationship between intervention and outcome, both directly and indirectly, through their effect on implementation. Such contextual factors are moderators (Moore et al., 2014). They can sustain the status quo by acting as negative forces or intensify intervention effects by acting as positive forces. This creates contextual contingencies,

meaning that interventions work differently in different contexts, depending on what contextual factors are present. So essentially, process evaluations explain intervention-outcome associations by exploring how implementation, contextual factors and intervention-triggered causal mechanisms influence the relationship.

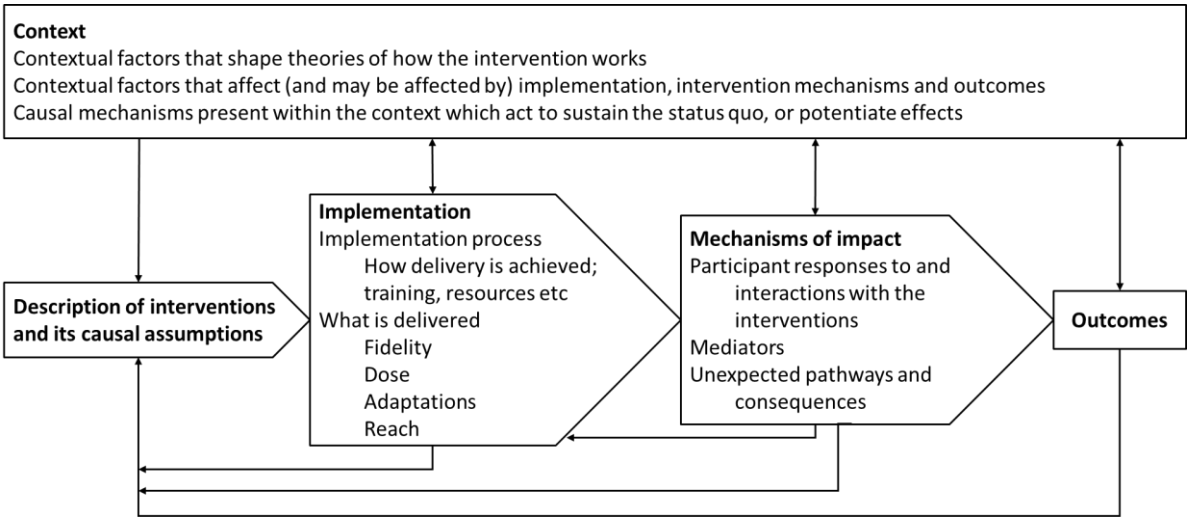


Figure 8. MRC process evaluation framework. From: Moore et al. (2015)

So, in conclusion, implementation science extends and supplements the insights on healthcare improvement from the literature on diffusion of innovations. Implementation is an important stage in the innovation diffusion process. Accordingly, the way in which the content, process and context of improvement are conceptualised in implementation has many similarities with the diffusion perspective. These similarities are clearly visible when comparing the CFIR with diffusion models (Damschroder et al., 2009; Greenhalgh et al., 2004; Rogers, 2003). However, rather than focusing on innovations generally, implementation science focuses on the implementation of evidence-based interventions as the **content of improvement**. Consequently, implementation science tends to prioritise fidelity to the 'tried-and-tested' evidence-based intervention, over interventions being adapted and re-invented, as is naturally assumed in the field of diffusion. Moreover, in the field of diffusion, implementation is studied as part of the natural unfolding process of diffusion. In implementation science, however, implementation is understood as the **process of improvement**, through which evidence-based interventions can achieve their improvement outcomes in clinical practice. So, implementation is seen as the process that closes the second translational gap. Accordingly, implementation science aims to optimise the process of implementation by developing evidence-based practical guidance. This included the identification of implementation strategies to increase the likelihood of implementation success. It also included the development of process frameworks that identify stages, steps, tasks and actions to follow. Finally, CFIR and other implementation frameworks describe the **context of improvement** as social systems in the same way

context is understood in the field of diffusion. However, empirical implementation studies tend not to reflect this understanding, instead reducing context to lists of variables, facilitators and barriers, without sufficiently accounting for their interconnectedness and their holistic influence. Nevertheless, some studies have focused on the interactions between contextual barriers and facilitators and implementation in acknowledgement of this issues (Bate, Mendel, & Robert, 2008; Pfadenhauer et al., 2017). In general, though, implementation scientists are encouraged to take-on more of a *systems mind-set*, to unpack the dynamic interactions between activities and mechanisms in the content, process and context of implementation (Braithwaite et al., 2018; Greenhalgh & Papoutsi, 2018; Moore et al., 2015).

2.5.3. Study of QI approaches

In contrast to the positivist philosophical roots of implementation science and diffusion studies, is the study of (Quality Improvement) QI approaches rooted in pragmatist beliefs. QI approaches developed in industry due to a relentless commitment towards quality to attain competitive advantage and business survival (Dahlgaard & Mi Dahlgaard-Park, 2006). The means for improvement were therefore less important than the ends. This type of approach builds on key assumptions from philosophical pragmatism (Perla et al., 2013). Since this thesis is mainly aimed towards health researchers who are usually not socialised into pragmatism, I will elaborate here briefly on pragmatist philosophy. A key pragmatist assumption states that knowing cannot be separated from doing. This relates to the *pragmatist maxim*, which expresses that the meaning of concepts can only be fully grasped through practical experience (Peirce, 1955). Like the positivist philosophy underpinning diffusion and implementation science, pragmatism assumes knowledge is gained empirically through experience. However, pragmatism emphasises the need for practical transactional experience, and does not accept observation and representation as the sole empirical mechanism for developing knowledge (Peirce, 1955). A second key assumption refers to a pragmatist understanding of truth as instrumental, or practically useful (James, 2000). Here, pragmatists emphasise again the role of action or agency, which is lacking in positivist conceptions of truth as empirical regularities. Roughly, pragmatists view things as true if they make a difference, i.e. if they can guide behaviour towards what is right (James, 2000). On an individual level this can be said to mean that 'whatever works for you, is true to you'. Truth in general terms though, is not perceived as relative to the individual and his context (Thayer-Bacon, 2003). That is, pragmatists don't believe that 'whatever works for you' is true and 'whatever works for me' is per definition also true. Instead, both at the individual level and in general terms, truth is seen as developmental, evolving with experience. Experience in this sense can be interpreted as making new theory-action and action-consequence connections (Dewey, 1997) through a continuous process of assimilation, validation, corroboration

and verification (James, 2000; Thayer-Bacon, 2003). Historically, pragmatist beliefs and practices are well-aligned with healthcare or medical practice. Medical practice is based on the Hippocratic tradition, where physicians use their experience examining, observing and treating patients to infer theories about disease mechanisms and effective treatments which subsequently informed their practice (Gillett, 2006; Marcum, 2017). The rise of EBM, however, where practical experience and mechanistic reasoning were devalued in favour of 'rigorous' scientific evidence from RCTs (Howick, 2011; W. Rogers & Hutchison, 2017), resulted in the assimilation of many positivist principles, practices and beliefs from the medical scientific community into the epistemic culture of the medical professional community (Cetina, 2007; Gillett, 2006; Kastenhofer, 2007; Mørk, Aanestad, Hanseth, & Grisot, 2008).

However, QI approaches and methods can be used both rigorously and pragmatically to improve healthcare quality. Earlier, I introduced QI approaches and methods as a *"systematic change method"* (p. 8) (Ovretveit, 2009) to conceptualise the process of improvement. Moreover, I discussed that the effectiveness of QI approaches tends to relate more strongly with the activation of core improvement principles than with their specific composition of QI methods. The mechanisms underpinning effective QI approaches in industry were first abstracted into 14 principles for as part of the Deming management approach (Deming, 1982). His approach to management is summarised as *"**leadership** efforts toward the simultaneous creation of a **cooperative** and **learning** organization to facilitate […] **process management practices**, […] **customer satisfaction** and organizational survival through sustained **employee fulfilment** and **continuous improvement** of processes, products, and services [emphasis added]"* (p. 480) (Anderson, Rungtusanatham, & Schroeder, 1994). The concepts in this definition that I emphasised in bold, are very similar to the principles for quality improvements discussed earlier in this Chapter. To implement these principles into practice, the IHI developed a systematic QI approach. The IHI systematic QI approach developed from Deming's management approach over 30 years of practical experience in healthcare improvement. Accordingly, the IHI approach reflects a grounded and rigorous QI approach that can be used by healthcare teams to systematically improve their health services. Still, the IHI approach has a pragmatic design that requires clinical teams to actively problem-solve, learn, and experiment within their local clinical practice.

The QI approach that was adopted by IHI is the Model for Improvement, which is also incorporated in the NIHR CLAHRC NWL systematic QI approach. The Model for Improvement, is made up of three questions and Deming's Plan-Do-Study-Act (PDSA) cycles (Deming, 1982; Langley et al., 2009). This model, presented in Figure 9, is meant to transform knowledge-based theories into actual changes and improvements. Answering the questions effectively depends on a combination of professional

and improvement knowledge, adoption and adaptation of known ideas, and creative thinking (Batalden & Stoltz, 1993; Deming, 2000; Langley et al., 2009; Rogers, 1995; Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996). To acquire such knowledge, formulate theories, and encourage creative thinking, different QI methods can be used. For example, process maps can be used to understand systems and processes, Shewhart charts to understand process variation, and surveys to understand patient needs (Doyle, Reed, Woodcock, & Bell, 2010; Jenkinson, Coulter, & Bruster, 2002; Langley et al., 2009; Perla, Provost, & Murray, 2011; Trebble, Hansi, Hydes, Smith, & Baker, 2010). These types of insights help identify potential mechanisms that underlie quality issues, and the types of changes that might improve quality by addressing these mechanisms. When change ideas have been selected, they can be tested and implemented using PDSA cycles. PDSA cycles structure experiential learning as a *"trial-and-learning methodology"* (p.24) (Langley et al., 2009). They involve experimentation, whereby change ideas are executed on a small scale initially, and then developed iteratively by analysing their impact and adjusting the change accordingly. By starting small, the risk of extensive harm to the organisation is limited, keeping in mind that change will not always lead to an improvement. However, after recognising that the model for improvement and other quality improvement lessons were not being applied in practice, the IHI developed the Breakthrough Series (BTS) (Kilo, 1998). This is a model aiming to increase the scale and pace of healthcare improvements by supporting organisations to learn collaboratively around understanding and improving a specific topic area, such as diabetes care or child allergies. With the model for improvement as its *"engine for change"* (p. 7) (Kilo, 1998), the BTS incorporates team formation, planning, learning sessions, and improvement support, to facilitate its use in practice and for making quality improvements in care. The NIHR CLAHRC NWL systematic QI approach, that was used to implement the Itchy Sneezy Wheezy interventions, adapted the IHI approach for local use. It included the IHI model for improvement within their compilation of eight QI methods. Moreover, it also used the collaborative model to support clinical teams to use the QI approach in their improvement projects. However, as discussed, project teams still expressed various levels of engagement with the NIHR CLAHRC NWL systematic QI approach despite being exposed to the same supportive structures as part of the quality collaborative (Howe et al., 2013).

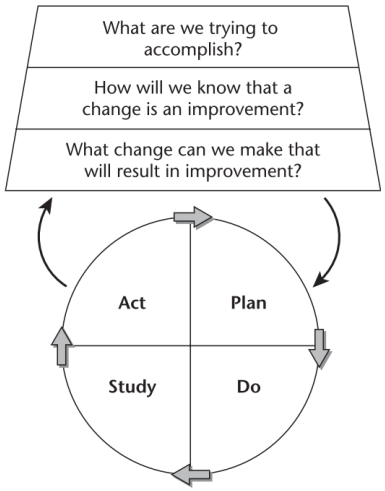


Figure 9. The model for improvement. From Langley et al. (2009)

A lack of engagement with and fidelity to QI approaches is often ascribed to a lack of capability or commitment. However, management studies found a more elegant explanation for poor-fidelity quality improvement, called *"the capability trap"* (p. 72) (Repenning & Sterman, 2001). Repenning & Sterman (2001) visualised the dynamics of improvement through a causal loop diagram, found in Figure 10. It highlights two key processes that are generally employed to improve performance: working harder (B1) and working smarter (B2). Working harder involves more time spent on work activities. Working smarter involves more time spent on improvement activities to increase the capabilities of processes and people, which subsequently allows reinvestment of resources for further improvements (R1). However, the positive effects of working smarter are usually delayed, while the positive effects of working harder are instant. As such, when pressured for immediate performance improvements, people often resort to working harder. And to increase the time available for work harder, time for improvement tends to be cut (B3). However, shortcuts to improvement eventually lead to capability deterioration with adverse effects on performance – which subsequently requires working even harder to achieve performance goals. The capability trap is this downward spiral of working harder and harder, which explains shortcuts, disengagement, and poor fidelity to QI approaches and methods. Improving the application of QI approaches requires the enabling of practitioners to invest time in QI approaches and learning how to apply them. Accordingly, freeing up this type of headspace was also identified by the NIHR CLAHRC NWL team as a key strategy to implement quality improvement principles (Reed, Howe, et al., 2018a, 2018b). Doing so requires supportive management and organisational structures to be in place, which highlights the importance of context to successfully use QI approaches.

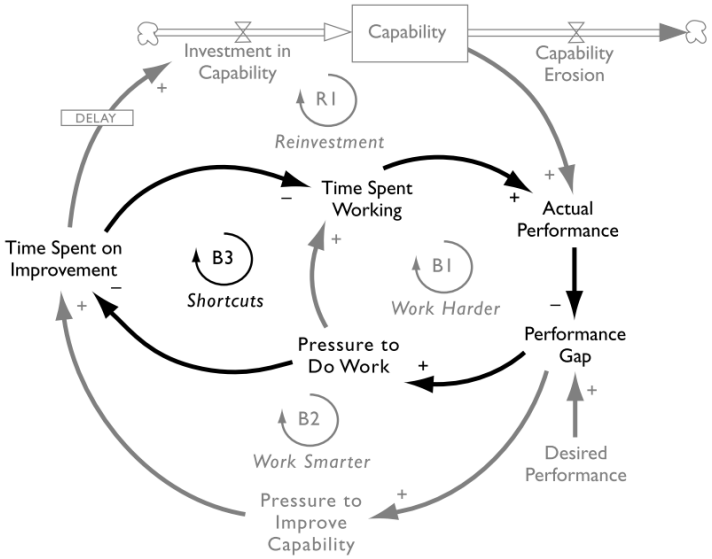


Figure 10. The capability trap. From Repenning & Sterman (2001)

To understand how context influences quality improvement success, the healthcare and business literature was reviewed and synthesised into the Model for Understanding Success in Quality (MUSIQ). The authors of this literature review acknowledged that contextual differences might explain why QI approaches and methods have inconsistent outcomes. Accordingly, they identified and collated contextual factors from quantitative studies that evaluated healthcare improvement efforts where QI approaches or methods were applied (Kaplan et al., 2010). This distinguished the review from implementation science and diffusion studies, which had already collated contextual factors to understand the influence of context on healthcare improvement (Damschroder et al., 2009; Greenhalgh et al., 2004). However, the authors acknowledged that to optimise context for improvement, healthcare professionals and organisations need to understand how the contextual factors relate to each other and to improvement outcomes. Accordingly, the authors used expert opinion to hypothesise relationships between contextual factors, drawn together in the MUSIQ, shown in Figure 11. The model consists of 25 factors organised hierarchically on three levels: the team or microsystem, the organisation, and the external environment (Kaplan, Provost, Froehle, & Margolis, 2012). The microsystem- and organisation level align with the CFIR construct of inner context, whereas the external environment aligns with the CFIR construct of outer context (Damschroder et al., 2009). Revisions of the MUSIQ identified different context types in addition to these levels: 1) the context of care, 2) the context of an improvement project or work stream, and 3) the wider context of quality improvement (Reed, Kaplan, & Ismail, 2018a). As depicted in Figure 12, the model revisions explain how QI approaches and methods operate. QI approaches enable

improvement by actively changing the context of care, while the effective use of QI approaches is influenced both by the project context and the wider improvement context.

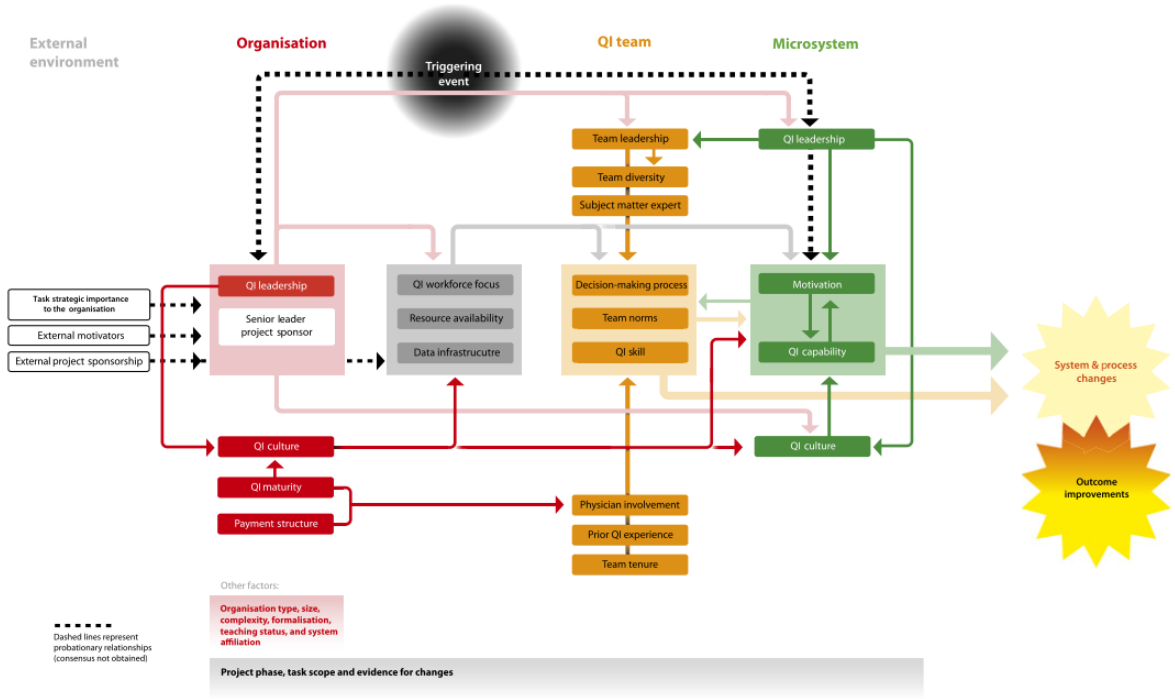


Figure 11. The Model for Understanding Success in Quality (MUSIQ). Describing contextual influences on the application of QI approaches and methods. From Kaplan et al. (2012).

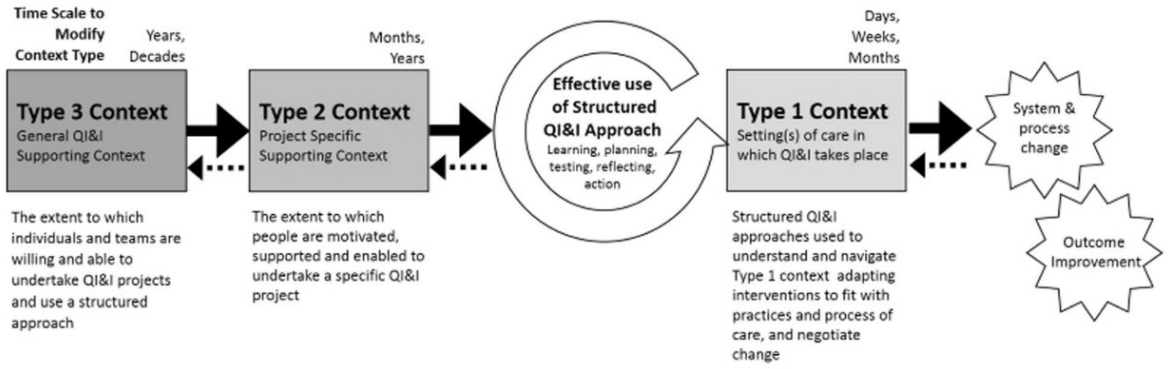


Figure 12. Revisions of the MUSIQ. Describing interactions between three types of context and QI approaches and methods. From Reed, Kaplan, et al. (2018).

The above discussion demonstrates how the content, process and context of improvement are conceptualised in the study of QI approaches and methods. The study of QI approaches and methods in healthcare evolved from industry. Both in industry and in healthcare is the achievement of actual quality improvements prioritised, for competitive advantage and for public health respectively (Batalden & Stoltz, 1993; Donabedian, 2003; Marshall & Mountford, 2013; Ovretveit, 2009). How such improvements are achieved, is generally seen as less important. *'Do whatever works'* is how pragmatist James (2000) would put it. This sentiment is expressed in the IHI model through its third

question – *'what change can we make that will result in improvement?'.* This question indicates that the **content of improvement** should be selected based on its ability to address local quality issues and achieve outcomes (Langley et al., 2009). Accordingly, and as a result of the EBM movement, improvement teams are usually encouraged to start with an evidence-based interventions as their initial change idea (Ovretveit, 2009; Reed, Howe, et al., 2018a). However, in line with pragmatist thought, teams are simultaneously encouraged to use mechanistic reasoning and creative thinking to make any adaptations needed to increase the likelihood of intervention success (Castro, Barrera, & Martinez, C. R., 2004; Parry et al., 2013). Moreover, change ideas are dynamic, continuously evolving based on experiential learning and development, which is formalised in the IHI model through the PDSA methodology (Deming, 2000; Donabedian, 2003; Langley et al., 2009).

The **process of improvement** is similarly conceptualised as flexible and dynamic in the study of QI approaches and methods. As discussed in Appendix C, a variety of well-established QI approaches have evolved since they were first developed in 1950s Japan, including the IHI model for improvement (Anderson et al., 1994; Dahlgaard & Mi Dahlgaard-Park, 2006). As such, in contrast to positivist aims, the evolution of QI approaches did not converge into an evidence-based recipe for successful improvement (Shortell et al., 1998; Walshe & Freeman, 2002). Instead, pragmatists beliefs prioritise *"improving what we do, not doing improvement"* (p. 438) (Batalden & Stoltz, 1993). Accordingly, different QI approaches can co-exist and adaptations are encouraged as long as improvements achieved. To achieve improvement, studies identified that QI approaches should implement certain key improvement principles (Boaden et al., 2008). They should include both analytical methods to understand contextual mechanisms, and statistical methods to monitor processes and outcomes (Antonacci, Reed, Lennox, & Barlow, 2018; Benneyan, Lloyd, & Plsek, 2003; Dahlgaard & Mi Dahlgaard-Park, 2006; Davidoff, Dixon-Woods, Leviton, & Michie, 2015; Perla et al., 2011; Portela, Pronovost, Woodcock, Carter, & Dixon-Woods, 2015; Reed et al., 2014; Thor et al., 2007; Trebble et al., 2010). And QI approaches should facilitate a continuous process of experiential learning and improvement, in alignment with the pragmatist understanding of truth as developmental in nature (James, 2000; Langley et al., 2009). However, despite the flexibility of QI approaches to adapt to local requirements, it was still identified that engagement with, fidelity to, and success of QI approaches was also highly variable (Dellifraine et al., 2010; Howe et al., 2013; M. J. Taylor et al., 2014).

To understand this variability efforts were made to understand the **context of improvement** projects, which resulted in the MUSIQ. The MUSIQ and its revision represent a key progression in the way context is understood, from a set of independent and stable contextual factors, towards a system of interrelated and hierarchically organised factors that change within the process of

improvement over time (Kaplan et al., 2012; Reed, Kaplan, et al., 2018a). This understanding of context represents a true complex system in line with complexity theory. The revised MUSIQ also extends a complexity-consistent view of the relationship between the improvement process and context. That is, by using a QI approach to intervene within a particular context, the context will influence how the QI approach is applied, while application of the QI approach will simultaneously manipulate the context (Bhaskar, 2008b; Braithwaite, 2018; Braithwaite, Clay-Williams, Nugus, & Plumb, 2013; Greenhalgh & Papoutsi, 2018; Pettigrew, Woodman, & Cameron, 2001; Reed, Howe, et al., 2018a).

2.5.4. Conclusion

In this section, I reviewed the improvement science literature to make sense of healthcare improvement initiatives and the inconsistent evidence on care pathway interventions and QI approaches. Accordingly, I examined how the content, process and context of healthcare improvement initiatives are understood in three improvement science disciplines: the diffusion of innovations, implementation science, and the study of QI approaches. One important conclusion from this literature review was that the search for universally effective healthcare interventions and improvement processes is fundamentally flawed for the reason that healthcare improvement takes place in settings, which are best conceptualised as complex systems where law-like regularities are highly unlikely (Bhaskar, 2008a; Braithwaite et al., 2013). Accordingly, implementation and improvement outcomes cannot be predicted based on a list of independent, yet evidence-based, implementation barriers, facilitators and strategies. Instead, improvement interventions and processes need to be sensitive to the specific pattern of causal mechanisms that exists locally, and adaptive to the local changes and developments over time. This supports the proposition based on the health policy triangle, which stated that improvement outcomes depend on an intricate relationship between the content, process and context of healthcare improvement initiatives (Walt & Gilson, 1994). This study further investigates how this proposition operates within the context of children's allergy services:

> *Proposition II: Improvements in the quality of children's allergy services emerge from the interactions between care pathways interventions, implementation processes, and contextual influences.*

The investigation of this proposition is informed by this Chapter's review of the diffusion of innovations literature, the implementation science literature, and the literature on QI approaches. On the one hand, the review highlighted unique disciplinary contributions that were consistent with or complementary to the insights from other disciplines. For example, QI methods have also been

studied in implementation science as a means to implement interventions. Likewise, the scientific rigour underpinning evidence-based interventions, as emphasised in implementation science, can be reason to push evidence-based interventions for diffusion or prioritise them as change idea to be tested locally as part of a QI approach. On the other hand, the literature review also highlighted contradictory insights across disciplines, many of which could be traced back to their different historical and philosophical roots, discussed in Appendix C. Consequently, to develop a theoretical understanding of quality improvement initiatives that could support the local improvement of children's allergy services, these contradictions will have to be resolved. As such, they express the main research gaps that will be addressed in this study.

2.6. Research gaps and research questions

This Chapter has presented the theoretical framework that underpins this study. Based on this theoretical understanding, two theoretical propositions were presented in the conclusion sections that will be further investigated in this study. However, the improvement science literature review also highlighted contradictory perspectives that need to be resolved to achieve the purpose of this study. More specifically, three contradictions were identified across improvement science disciplines, which reflect three research gaps that will be addressed in this study. Moreover, these research gaps informed four of five research questions that are answered in this thesis. Together, these five questions help answer the main question of this thesis.

How can care pathways be implemented to improve children's allergy services in the UK?

The first sub-question to answer the main question has been addressed in Chapter 1.

Question 1: What are the quality deficiencies in children's allergy services?

The remaining four questions have developed from the contradictions and research gaps identified in this Chapter. Accordingly, they are presented and discussed collectively below.

Contradiction IV: Intervention adaptations generally enhance implementation, while intervention fidelity generally enhances healthcare improvements

First research gap: Although all disciplines acknowledge that intervention adaptations are inherent to most quality improvement efforts, it is yet unclear what adaptations are appropriate, how adaptations are practiced, and via which mechanisms they support or hinder improvement.

Question 2: How are allergy care pathway interventions adapted during implementation?

The first research gap is associated to the **content of improvement** and involves the contradiction between intervention adaptation and fidelity. The importance of adaptation as a construct in healthcare improvement is acknowledged in all three disciplines. However, how this construct is approached and understood varies. In short, in the study of diffusion, adaptation is understood as likely to happen for better or worse (J. E. Moore, Bumbarger, & Cooper, 2013). It is a mechanism used to make interventions more suitable and meaningful to the settings in which they become adopted (Barker, Reid, & Schall, 2016; Cooley & Ved, 2012; Simmons, Ghiron, Fajans, & Newton, 2009). In implementation science, adaptation is understood as 'necessary evil' that should be avoided when possible in favour of fidelity to evidence-based interventions (Elliott & Mihalic, 2004). Intervention adaptations have not been tested in RCTs and are thus not supported by the highest level of evidence (Howick, 2011). Fidelity is therefore encouraged to increase the likelihood of achieving the outcomes associated with intervention implementation (Durlak & DuPre, 2008). It is acknowledged, however, that adaptations might be necessary in contexts that deviate from the studied population in significant ways (Castro et al., 2004; Parry et al., 2013). In the study of QI, adaptations are seen as inherent to a process of continuous local improvement. Interventions should be tailored initially to ensure they address local problem mechanisms (Cheater et al., 2010). Subsequently, they should be continuously updated and adapted based on an evolving understanding of intervention effects and how the intervention operates in a specific local context (Langley et al., 2009). As yet, it is unclear how these varying approaches to intervention adaptation are demonstrated and integrated in practice. Furthermore, a lack of practical how-to knowledge regarding adaptation-decisions is identified across disciplines (Barker et al., 2016; Lee, Altschul, & Mowbray, 2008; Ovretveit et al., 2018).

> *Contradiction V: QI methods are used for implementation even though implementation and improvement are based on contradictory underlying principles and assumptions.*
>
> *Second research gap: Although quality improvement methods are increasingly promoted as a means for implementation, both constructs are based on fundamentally different underlying assumptions. Consequently, it is yet unclear whether the practical integration of quality improvement methods in implementation brings about any tensions, how these tensions are resolved and through which mechanisms quality improvement methods contribute to implementation and improvement.*
>
> *Question 3: How are quality improvement methods used to support the implementation of allergy care pathway interventions?*

The second research gap is associated to the **process of improvement** and involves the contradiction between the implementation and improvement process. As discussed, the study of diffusion describes how interventions spread and then get implemented into local practice (Rogers, 2003). Implementation science and QI studies, though, explore how this process can be actively supported and optimised. QI approaches are flexible and have accordingly diversified over time (Anderson et al., 1994; Dahlgaard & Mi Dahlgaard-Park, 2006). Implementation science, also, has come up with a plethora of strategies and frameworks to support implementation (Damschroder et al., 2009; Meyers et al., 2012; Powell et al., 2015). However, it was demonstrated that implementation strategies and QI approaches and methods work only sometimes. There is no magic bullet (Shojania & Grimshaw, 2005; Walshe & Freeman, 2002). Within a positivist beliefs framework, these findings are difficult to integrate into practice. Positivist beliefs encourage practitioners to select implementation methods that are evidence-based. However, the evidence is ambiguous, meaning that local improvers are left without any real guidance on how to proceed with implementation (Moullin et al., 2015; Nilsen, 2015). Instead, QI approaches and methods might be more helpful to practitioners. They are also no magic bullets. However, their pragmatist underpinning has made them inherently flexible. They encourage practitioners to learn and adapt based on experience over time. In some occasions, QI approaches and methods have been used to close the second translational gap – to implement evidence-based interventions (Damschroder et al., 2009; Howe et al., 2013; Oborn, Barrett, Prince, & Racko, 2013). However, studies have yet to explore how potential tensions are resolved in practice when ideas from a positivist implementation science are integrated with ideas from the pragmatist study of QI approaches and methods. There is also a need to further explore through which mechanisms QI approaches and methods support the implementation of evidence-based interventions (Ramaswamy et al., 2018; Walshe, 2007).

> *Contradiction VI: A theoretical understanding and awareness of mechanisms is often not necessary nor sufficient to manage and manipulate them in practice and achieve the desired consequences.*
>
> *Third research gap: Although it is accepted that improvement efforts should be informed by learning, knowledge and understanding, it is yet unclear how practical and theoretical knowledge conjointly contribute to local practical improvement efforts.*
>
> *Question 4: How are local children's allergy health service improvement experiences conceptually integrated?*
>
> *Question 5: What recommendations can support the local improvement of children's allergy services?*

The third research gap is associated to the **context of improvement** and involves the contradiction between theory and practice. In healthcare, RCTs are generally seen as the gold standard for learning about improvement (Howick, 2011). Well-executed RCTs are a rigorous method with high internal validity, meaning confidence is warranted to believe its conclusions are true (Cartwright, 2007, 2010). However, RCTs are based on assumptions about its target population that often make it difficult to generalise their conclusions reliably to other settings (Parry et al., 2013). Such narrow external validity is not necessarily a problem when science is perceived as an endeavour to uncover truth reliably. Improvement science, however, is also highly committed to benefitting patients by supporting actual healthcare improvements to be made (Marshall & Mountford, 2013). To achieve this pragmatic purpose, science should aim to develop knowledge that is useful to practitioners in addition to knowledge that is 'true' in a positivist sense (Starkey & Madan, 2001). Knowing that certain interventions are associated with positive outcomes in certain specified situations is insufficient information for practitioners to improve healthcare quality. They also need information to decide what changes are most appropriate for their specific setting and local problems and how they could best manage the process of change and improvement (Gibbons et al., 1994; Nowotny et al., 2003). Basically, instead of knowing 'what works', practitioners need to know 'what works for me' and 'how to make it work here' (Pawson & Tilley, 2004; Pettigrew, 2001). RCTs and other positivist methods that emphasise consistency and stability of the natural world, insufficiently address the complexities and dynamic nature of real-world quality improvement (Bhaskar, 2008a; Braithwaite et al., 2018). Healthcare improvement involves making changes in complex systems, which requires both theoretical knowledge *(episteme)* and practical expertise *(techne)* on how to do so (Feibleman, 1961; Langley et al., 2009). More specifically, the types of knowledge needed for improvement have been specified as: generalisable scientific evidence, local context awareness, analytical and measurement knowledge, knowledge of plans and approaches for improvement, and strategic and operational knowledge to execute changes (Batalden & Davidoff, 2007). Improvement science focuses on developing these types of knowledge, which requires close collaboration between academics and practitioners working at the intersection of healthcare and health research (Marshall & Mountford, 2013). As such, improvement science is positioned at the intersection of practice-focused pragmatism and health-science-focused positivism. However, there is a need for improvement science studies to integrate both pragmatist and positivist approaches in innovative ways. Innovative ways of studying and conceptualising healthcare improvement in complex systems might lead to the development of theoretical knowledge and practical expertise that is both reliable and useful. In the next Chapter, I discuss the methodology that was used to address these research gaps and answer these research questions.

Chapter 3. Research Methods

Going through the MELD dialectical process based on four ethnographic case studies

3.1. Introduction

This Chapter presents the research methods that were applied in this study. More specifically, this Chapter aims to describe and justify how the research methods contribute to answering the research questions and to achieve the purpose of this study. The purpose of this study is ultimately practical – to support the improvement of children's allergy services. To achieve a practical understanding able to resolve the contradictions identified in the previous Chapters, this study uses dialectic. Dialectic has evolved in philosophy from the discussion of ideas through dialogue to a structured process of reasoning aimed to resolve contradictory ideas (Nikulin, 2010). In Dialectical Critical Realism (DCR), this tradition resulted in the development of MELD dialectic, which extended the traditional dialectical method to address contradictions in practice and not just in theory (Bhaskar, 2008b). Accordingly, this Chapter starts with a short discussion of DCR philosophy, the MELD dialectical process, and how they ground this study. Next, I justify the research design of this study, which includes a literature review and four ethnographic case studies. First, I justify how these methods address the stages of MELD dialectic and how they align with DCR assumptions. Then, I justify how this design is particularly suitable to investigate the theoretical propositions and answer the research questions defined in Chapter 2. Finally, I describe the ethnographic case study process that was followed to learn about the improvement of children's allergy services. Here, I describe the case selection-, data collection-, and analysis processes amongst other things. Before moving on to the main section of this Chapter, it should be noted that in Chapter 2, I traced several of the contradictions between improvement science disciplines back to differences between positivist and pragmatist assumptions held across disciplines. This study is instead grounded in DCR assumptions. In Appendix D, I describe the differences between positivist, pragmatist and DCR philosophies that underpin the decision in this study to adhere to DCR assumptions.

3.2. Philosophical grounding

3.2.1. Dialectical Critical Realism

This study is positioned within the philosophical assumptions of Dialectical Critical Realism (DCR). The assumptions and qualities of the DCR philosophical system make it particularly useful to study healthcare improvement. Critical realism (CR) emphasises metatheory, which facilitates the comparison and evaluation of the contradictory theories and ideas expressed in different improvement science disciplines. Metatheory also facilitates the analysis of philosophical assumptions. Such analyses have allowed critical realists to clearly argue why some ontological and epistemological assumptions from positivism and pragmatism should be taken on board while others should be dismissed (Bhaskar, 2010; Porpora, 2015). As such, CR integrates the legitimate positivist

and pragmatist beliefs. Moreover, DCR extends the CR philosophy through dialectics. Dialectics includes rationality and reason in the scientific endeavour as a means to resolve contradictions (Bhaskar, 2008b, 2010; Norrie, 2010). Accordingly, it can guide this study to address and resolve the contradictions expressed in Chapter 2. DCR is also methodologically pluralist (Hartwig, 2007; Porpora, 2015). This means that DCR explicitly acknowledges the value of different types of methodologies. Rather than prioritising methods to study a particular topic, DCR promotes the integration of insights derived from multiple methods to account for their unique benefits and limitations. As such, DCR defends the use of ethnography in healthcare, where qualitative social science methods are traditionally devalued (Albert, Laberge, & Hodges, 2009; Albert, Laberge, Hodges, Regehr, & Lingard, 2008; Napolitano & Jones, 2006; Niklas, 1982; Strong & McPherson, 1982). The integration of different types of empirical studies requires rational thought and critique. In DCR, rationality acts as the mediator between empirical observations and scientific theories, using empirical observations to assess whether theories should be elaborated, refined, changed or completely rejected (Fisher & Aguinis, 2017; Lakatos, 1968). More specifically, DCR assumes judgemental rationality, using rationality to judge which theories are more likely to represent reality than others (Bhaskar, 2008a). However, judgemental rationality is not only assumed to resolve epistemic/knowledge questions. It is also assumed in the context of ethics and morality, where judgemental rationality helps to evaluate which actions are most likely *right* and which are most likely *wrong*. This DCR contribution is very useful in the context of healthcare improvement, which focuses on implementing actions to improve health services – to make health services *right*. These DCR characteristics are all based on three core assumptions: ontological realism, epistemic relativism, and judgemental rationality (Bhaskar, 2008a). Together, these assumptions form the DCR *holy trinity*, which is discussed in more depth in Appendix D. The DCR ideas and assumptions have guided the methodological choices in this study, and delivered the structure to defend these choices – to convince readers of the credibility, integrity and value of this study, even if they hold different philosophical beliefs. As such, DCR serves an *'underlabourer'* role (Benton & Craib, 2011; Bhaskar, 2011). However, DCR also provides this study with MELD dialectic that guides the process to resolve the contradictions reflected in the research gaps and questions presented in Chapter 2.

3.2.2. The MELD dialectical process

In this study, I used the dialectical process MELD to study healthcare improvement. As discussed, dialectics introduces rationality and reason into scientific practice to resolve dialectical contradictions. The DCR process MELD adapted and elaborated Hegel's dialectic to resolve practical contradictions in addition to theoretical contradictions (Bhaskar, 2008b, 2010; Hartwig, 2007; Norrie, 2010). This means that Hegel's dialectic uses rationality to improve our understanding of the world,

whereas MELD draws on rationality to improve the world itself. As such, both dialectical processes could be applied to resolve the contradictions, described in Chapter 2, between the scientific ideas from different improvement science disciplines. However, only MELD can be used to resolve these contradictions in practice, where the conflicting ideas express tensions that need to be resolved to optimise the practice of healthcare improvement. A schematic overview of Hegel's dialectic is presented in Figure 13. It demonstrates a cyclical process from understanding via dialectical reasoning to speculative reasoning by which a greater understanding is created (Bhaskar, 2008b; Hegel, 1830, 1969). As such, the process reflects how our understanding of the world develops progressively. It starts at the first moment of understanding, where the identity of a phenomenon is defined. This means that concepts and theories are used to label and define the objects, events or situations that exist or take place in the world. Then, at the moment of dialectical reasoning, negativity is introduced by examining contradictory ideas and observations. Negativity, as used by Hegel, explains contradiction, which is the conjunction of opposites. This means that a contradiction involves a statement or idea that is defined as true, in opposition to a negative statement (i.e. a contradictory ideas and observations) that indicates the first statement is *not* true. When contradictions have been defined, the opposing statements and ideas are evaluated and critiqued with the aim to improve our understanding of phenomena. These improvements develop at the moment of speculative reasoning. Speculative reasoning defines the interdependencies between opposites, so that they can be integrated into an understanding that better reflects the true nature of a phenomenon than either opposite independently does. Hegel (1969) describes this process as the *"grasping of opposites in their unity"* (par. 69). As such, Hegel's dialectic supports the development of theories that define what the world is like.

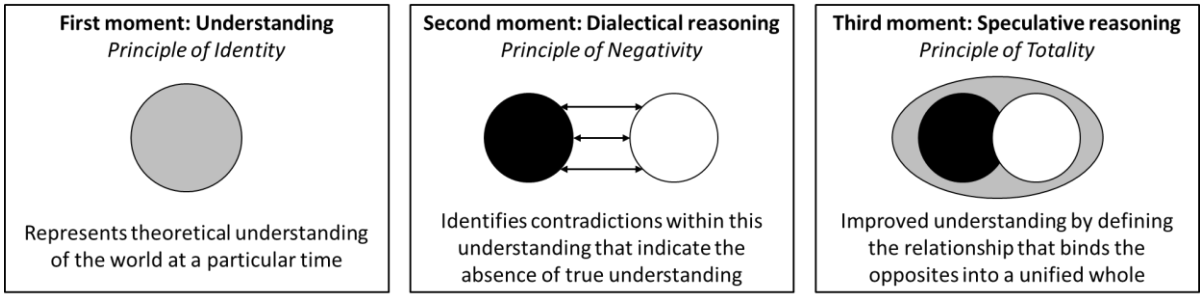


Figure 13. Schematic overview of Hegel's dialectic.

However, Hegel's dialectic is less appropriate for understanding and resolving contradictions in practice. The way Hegel's dialectic operates is demonstrated with an example in Figure 14. The example describes how Hegel's dialectic resolves a contradiction that is commonly experienced in practice as *'the data says the quality of our health service is poor, but our team works really hard'.* This statement is based on the common understanding that hard work leads to good quality.

However, the experience of this team contradicts that understanding. In fact, empirical observations highlight many hard-working teams that operate health services with quality problems, while also highlighting plenty of hard-working teams that operate high-quality services. As such, the initial understanding *of* the world is contradicted by data *from* the world. To account for the empirical observations, the relationship between hard work and quality is updated. It is now defined in terms of effectiveness, highlighting that hard work is effective when it achieves good quality. This definition reflects the experiences of healthcare teams and is therefore a better representation of the world. Nevertheless, the definition is rather useless to the ineffective hard-working teams that want to improve the quality of their services. As such, the example demonstrates that Hegel's dialectic resolved contradictions theoretically, in the mind, while MELD was developed to resolve contradictions practically, in the world (Bhaskar, 2008b; Hartwig, 2007; Norrie, 2010). The resolution of practical contradictions is supported by a good theoretical understanding. However, a practical issue can be understood without taking action, and some actions might not be able to resolve the issue (Norrie, 2010). Accordingly, the resolution of practical contradictions requires successful action, which is supported by a theoretical understanding of the situation and a strategic plan for change. MELD dialectic reflects this process (Alderson, 2021; Bhaskar, 2008b).

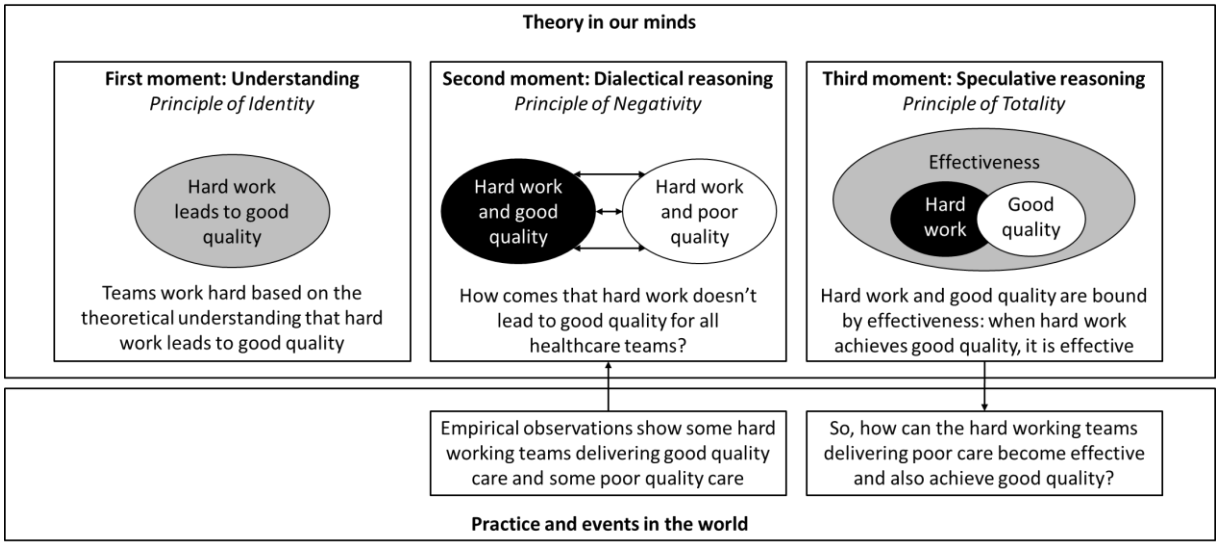


Figure 14. Demonstration of Hegel's dialectic.

To resolve contradictions within the world, the three moments of Hegel's dialectic were developed into the four moments of MELD. A schematic overview of MELD is presented in Figure 15, which highlights the similarities and differences with Hegel's dialectic (Bhaskar, 2008b; Hartwig, 2007; Norrie, 2010). The first moment (1M) of MELD also involves defining our understanding of the world. However, MELD emphasises that our understanding of phenomena is not just based on positive qualities and causes, but their absence also. For example, our understanding of healthcare quality is markedly based on the identification of quality problems, which refer to the absence of quality rather

than its presence. Accordingly, the identity of a phenomenon is also defined by its *non*-identity. So, at 1M, phenomena are defined based on absent versus present qualities. Moreover, definitions include the causal mechanisms that explain why a quality is absent in one manifestation, yet present in another. At the second edge (2E) of MELD, negativity is introduced as a reflection of the contradictions that exist in the world, rather than to reflect the contradiction between ideas. For example, the Itchy Sneezy Wheezy intervention was decommissioned, even though the intervention successfully improved quality. Such contradictions become apparent in the process of change and development. How comes that the Itchy Sneezy Wheezy intervention was present in 2013 and *not* present or absent in 2014? Accordingly, at 2E, the process of change is defined to identify and understand dialectical contradictions in the world. Accordingly, totalities at the third level (3L) of MELD are grounded in reality. Only when phenomena are contextualised in space and time do their contradictory manifestations become apparent. As such, dialectical contradictions are identified as manifestations within context. At 3L, rationality is used to understand the relationships between dialectical opposites, that is, between the contradictory manifestations that express in different context. Based on the definition of these relationships, the contradictory manifestations are then unified again in a totality that represents the phenomenon as a whole. For example, in Chapter 2, I argued that contradictory care pathway manifestations reflect care pathways as a hierarchically nested phenomenon of patient-, organisation-, regional-, and national-level care pathways that can operate synergistically. In MELD, totalities demonstrate contextual and structural contingencies just like real phenomena in the world. Finally, MELD includes the fourth dimension (4D) to resolve dialectical contradictions not only rationally, but practically as well. This final stage describes how contradictory situations can be changed through transformative practice or agency informed by the theoretical understanding developed in 3L. This stage is key to the purpose of this study to support the improvement of children's allergy services, rather than simply to understand it. Next, I will discuss the methods of this study, and how they supported the application of MELD.

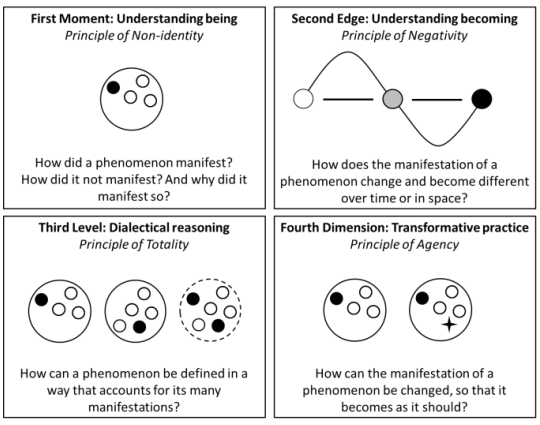


Figure 15. Schematic overview of the four stages of MELD dialectic.

3.3. Justification

3.3.1. Research design

This study has been designed to achieve its main purpose of supporting the improvement of children's allergy services. At its most basic level, this purpose reflects the contradiction that a well-intentioned workforce is delivering health services that are not addressing the needs of allergic children. Accordingly, I applied the MELD dialectical process to learn about this contradiction and how it might be resolved. To proceed through the four stages of the MELD dialectical process, I reviewed the academic literature and I performed multiple case studies. An overview of this study is shown in Table 5. This overview demonstrates that a literature review was used as the primary method to address 1M of MELD, while ethnographic case study methodology was the primary method to address the remaining three stages of MELD.

The ethnographic case studies were informed by the results of 1M of MELD presented in Chapter 1 and 2. More specifically, these Chapters discussed the subject of this thesis, 'quality in children's allergy health services', and explained its causal mechanisms. This discussion was based on a literature review and a retrospective exploratory case study of the Itchy Sneezy Wheezy project. Moreover, it was contextualised to the United Kingdom. In Appendix E, I describe how the 1M literature review evolved, informed by the Itchy Sneezy Wheezy case study. Together, they represent the exploratory work that informed the four ethnographic case studies. Exploratory work can support the design of case study methodology by providing a sense of direction throughout the continuous process of data collection, interpretation and potential design adaptations (Yin, 2018). This aligns with the type of ethnography practiced by Malinowski, who used theoretical training to identify foreshadowed problems and sensitising concepts to guide his attention and data collection techniques in the field. Foreshadowed problems and sensitising concepts need to be continuously revisited and developed along the course of the ethnography (Firth et al., 1960; O'Reilly, 2009). In this study, implementation, improvement, and diffusion were key sensitising concepts that were discovered early. Moreover, variety and adaptations of care pathway interventions and the use of quality improvement methods as implementation strategy were identified in the literature review as two specific foreshadowed problem areas to investigate in-depth in the ethnographic case studies.

Ethnographic case study methodology supports in-depth investigation to grasp and make sense of the reality of care pathway implementation. More specifically, a case study can be defined as *"an empirical method that investigates a contemporary phenomenon in-depth and within its real-world context, especially when the boundaries between phenomenon (the "case") and context may not be clearly evident"* (p. 16) (Yin, 2018). Different types of qualitative and quantitative methods can be

used to compose a case study. The main case studies presented in this thesis are ethnographic, which involves *"the researcher participating, overtly or covertly, in people's daily lives for an extended period of time, watching what happens, listening to what is said, and/or asking questions through informal and formal interviews, collecting documents and artefacts – in fact, gathering whatever data are available to throw light on the issues that are the emerging focus of inquiry"* (p.3) (Hammersley & Atkinson, 2007). Ethnography as such, has much in common with the type of sense-making people do in their daily lives. However, ethnography distinguishes itself from this type of sense-making by becoming increasingly systematic and deliberate over time. Ethnography is developmental in that the research purpose, the questions, the study design and the data analysis all become more clear and more defined over time. Accordingly, the study also becomes increasingly rigorous, relying on rationality to compose explanatory accounts, with clear connections to empirical evidence that is carefully collected and recorded (Hammersley & Atkinson, 2007; Yin, 2018). Usually, ethnographic case studies are limited to a single or small number of cases to allow for an in-depth investigation, embracing the full complexity of variables and relationships that make-up real world phenomena (Hammersley & Atkinson, 2007; Yin, 2018). To support the ethnographic process, I continued my literature review in parallel. This parallel relationship between theoretical and empirical learning reflects a dialogue between reality (ontology) and our knowledge and understanding of reality (epistemology) (Bhaskar, 2008a; Lakatos, 1968). It reflects an iterative cycle of collecting empirical information to critique the validity of scientific theories, followed by theoretical elaboration and refinements, that encourage the collection of more empirical information, to critique and refine the theoretical developments, and so on. As such, this study reflects the critical realist perspective of science as a continuous developmental process (Bhaskar, 2008a; Hartwig, 2007; Porpora, 2015).

Table 5. Study overview

Primary method	Supportive method	MELD stage	Purpose	Research questions	Results	Chapter
Literature review	Single case study	1M	Define the subject	What are the quality deficiencies in children's allergy services?	Literature review	Ch. 1, Ch. 2
Four ethnographic case studies	Literature review	2E	Describe how care pathway interventions change and evolve	How are allergy care pathway interventions adapted during implementation? How are quality improvement methods used to support the implementation of allergy care pathway interventions?	Single case descriptions	Ch. 4
		3L	Explain the implementation of allergy care pathways	How are local children's allergy health service improvement experiences conceptually integrated?	Cross-case theory development	Ch. 5
		4D	Make practice recommendations to support the local improvement of children's allergy services	What recommendations can support the local improvement of children's allergy services?	Practical recommendations	Ch. 6

3.3.2. Philosophical assumptions

Ethnographic case study methodology aligns with the DCR philosophical assumptions more broadly. In quantitative research communities, ethnographic case studies are often falsely perceived as less valuable and less scientific than social experiments. This perception can be traced back to ontological and epistemological assumptions. Social science experiments are designed to test causal theories by translating social constructs into measurable variables and using statistical analysis to identify constant conjunctions and other regularities (Dooley, 2009). This is modelled on scientific experimentation in the natural sciences, where positivism has historically been the "*standard philosophical view"* (p.21) (Robson & McCartan, 2016). And even though researchers might not be aware of or concerned with the philosophical underpinnings of their preferred research methods (Bryman, 2006), it does impact their ideas and beliefs of what consists *good* science. Positivism holds the assumption that in theory it is possible to learn the truth about reality, while acknowledging that in practice science is fallible (Benton & Craib, 2011; Popper, 2002). As such, positivist scientists strive for certainty, for truth, mitigating for the fallibility of science by using the most rigorous and objective scientific methods available. Experiments are consequently highly regarded, since their finding and conclusions carry a high likelihood to be true when they are performed well (Howick, 2011). Their quality, however, depends on the reliability and validity of its measures. Reliability indicates a measure is free from error, while validity indicates that a measures is an appropriate, meaningful and accurate representation of its social construct (Dooley, 2009; R. M. Kaplan & Saccuzzo, 2009). These constructs don't translate well to ethnographic case studies or other types of qualitative research, where different interpretations of validity and rigour are needed (Creswell & Miller, 2000; Tobin & Begley, 2004; Yin, 2018). Moreover, the findings from ethnographic case studies are case specific and lack statistical generalisability. As such, the scientific contributions from ethnographic studies lack epistemic certainty compared to experimental studies, which causes scientists with positivist beliefs to devalue ethnography. Critical realists, however, take a more egalitarian stance towards scientific methods (Porpora, 2015). This stance follows the critical realist assumption that it is theoretically impossible to know truth with certainty since the world (ontology) and our knowledge of the world (epistemology) are separate. As such, critical realists strive for continuous scientific development, development of our *'best guess'* of what the world is like, based on empirical information and judgemental rationality (Lakatos, 1968; Porpora, 2015). From that viewpoint, scientific methods have different strengths and weaknesses, without one method being categorically better than another. As such, critical realists can appreciate the scientific contributions of ethnography alongside the contributions of experimental studies.

3.3.3. Theory elaboration

Accordingly, social experiments are appreciated for their capability to produce reliable and generalisable findings, while their causal insights are limited. Scientific experiments focus on constant conjunctions to explain phenomena, which highlights a view of causality that is based on co-occurrence and statistical generalisation (Dooley, 2009; Eagle, 2007; Westhorp, 2012). Simply said, if healthcare improvement in a particular type of situation always occurs after care pathway implementation and not without it, then it might be concluded that care pathway implementation causes healthcare improvement. However, in real-world situations, such causal relationships often don't occur or actualise, due to the interplay with other causal mechanisms, which are controlled for in experimental studies (Porpora, 2015). Accordingly, most causal relationships reflect causal tendencies that might not always actualise in reality (Porpora, 2015). Such causal tendencies are measured in social experiments to validate law-like causal relationships between social constructs (Dooley, 2009). This was demonstrated in the literature, showing that care pathway interventions had a mean positive effect rather than a universal effect, which means there was a tendency for care pathway interventions to be followed by quality improvements. This general tendency is expressed in the first hypothesis of this thesis, which states that care pathway interventions improve children's allergy services. However, causality in the real-world is more complicated as expressed in the second hypothesis. Accordingly, the second hypothesis states that quality improvements emerge from the interactions between care pathways interventions, implementation processes, and contextual influences.

However, ethnographic studies can complement social experiments and elaborate these hypotheses, by contributing a more holistic, yet contextual, understanding of causality. That causality is more far-reaching than patterns of co-occurrence is exemplified in MELD (Bhaskar, 2008b; Hartwig, 2007; Norrie, 2010). 1M explains how causal mechanisms, when activated, co-determine the local expression of phenomena. 2E explains change as the rhythmic unfolding of causality over time and space. 3L explains how phenomena can express emergent properties, generated through the holistic causality of multiple mechanisms operating collectively. Finally, 4D describes intentional agency as a specific mechanism of causation that influences societal change. A more elaborate description of causality in MELD is presented in Appendix E. Accordingly, there is more to consider in explanatory studies than the identification of event(s) that systematically covary with and precede the events that are to be explained (Dooley, 2009; Porpora, 2015). Instead, studies should also aim to identify why these events co-occur (i.e. their generative mechanisms) and in which situations (i.e. their contextual contingencies) in order to understand how the observed relationship can be influenced locally (Archer, 2015; Bhaskar, 2008a; Mingers & Standing, 2017; Walshe, 2007). Ethnographic case

studies are specifically suitable for addressing this explanatory gap. By focusing on the in-depth and comprehensive study of a single or small number of cases, it is possible to develop a more holistic explanation of how phenomena manifest in reality. More specifically, ethnographic case studies are contextual and temporal, which allows them to investigate how a phenomenon develops over time within a particular context. Moreover, ethnographic case studies can access information on different types of generative mechanisms, including material objects and processes, subjective thoughts and values, and socio-cultural practices and tools (Popper, 1987). Their causal properties are based on the DCR ontological assumptions discussed in Appendix D. As such, ethnographic case studies support a holistic investigation of allergy care pathway interventions that can elaborate the two hypotheses described earlier – by exploring generative mechanisms, contextual influences, the interactions between them and their developments over time.

3.3.4. Answering research questions

Finally, these methodological properties help answer the research questions that this study sets out to address. As discussed, the first research question, aligned to 1M of MELD, was answered in Chapter 1 and 2 through a literature review and a single exploratory case study. The literature review allowed me to gain a comprehensive overview of generative mechanisms across studies, while the exploratory case study demonstrated how these mechanisms were expressed in a particular situation.

1. *What are the quality deficiencies in children's allergy services?*

The other research questions were answered through the ethnographic case studies. The temporal and contextual nature of ethnographic case studies allowed me to answer the second and third research questions as part of 2E of MELD. That is, they allowed me to explore how change unfolds over time – how care pathway interventions develop holistically over time as part of a dynamic implementation process shaped by contextual influences (Hammersley & Atkinson, 2007; Porpora, 2015; Yin, 2018).

2. *How are allergy care pathway interventions adapted during implementation?*
3. *How are quality improvement methods used to support the implementation of allergy care pathway interventions*

The holistic nature of ethnographic case studies allowed me to answer the fourth research question as part of 3L of MELD. So far, scientific studies focused on the discovery of independent mechanisms that affect the relationship between care pathway interventions and healthcare quality, including care pathway mechanisms, implementation strategies, and contextual barriers and facilitators (Grimshaw et al., 2006; Kaplan et al., 2010; Powell et al., 2015; Vanhaecht et al., 2010). However,

these mechanisms in isolation, are insufficient to explain improvement outcomes (Bate et al., 2008). Instead, improvement outcomes are explained through holistic causality, because causal mechanisms operate and unfold holistically, in interaction with one another, which creates emergent affects (Bhaskar, 2008b). Ethnographic case studies give access to the holistic operation and unfolding of intervention, process and contextual mechanisms. As such, they provide the empirical grounding to theorise causal relationships and synthesise different local experiences accordingly.

4. *How are local children's allergy health service improvement experiences integrated?*

Finally, the capability of ethnographic case studies to capture different types of causal information allowed me to answer the fifth research question as part of 4D of MELD. More specifically, studying thoughts and actions over time through interviews and participant observations, helps to understand the non-deterministic interplay between structure, culture and agency (Archer, 1995, 1996; Hammersley & Atkinson, 2007; Porpora, 2015). This information can subsequently be used to develop case narratives that express how change *can* unfold. However, this also creates the awareness that change can unfold differently, highlighting opportunities where different actions might be taken. Moreover, the in-depth understanding that develops from case study analysis forms the theoretical grounding to inform actions strategically.

5. *What recommendations can support the local improvement of children's allergy services?*

In the next sections, I will describe in more detail how the four ethnographic case studies were performed.

3.4. Ethnographic case studies

3.4.1. Case selection

The ethnographic study comprised a multiple case design of four different cases. A case study was defined earlier as *"an empirical method that investigates a contemporary phenomenon in-depth and within its real-world context"* (p. 16) (Yin, 2018). This might involve the study of a single case – a single manifest phenomenon. Studying multiple cases, however, allows for building stronger theories (Eisenhardt, & Graebner, 2007). A multiple case study design incorporates a greater variety of empirical evidence that needs to be accounted for, thereby increasing the robustness of the theoretical findings. Moreover, multiple case studies can increase external validity or generalisability by assessing to what extend the emergent findings from one case can be replicated in other cases. To facilitate this process, cases need to be selected based on a replication logic and a sampling strategy (Yin, 2018). In this study, I used theory-based and heterogeniety sampling and I applied a literal replication logic, which means I didn't anticipate the sampled case studies to have contrasting findings (Patton, 2002; Yin, 2018).

The exploratory phase of this study had specified 'the implementation of allergy care pathways for children' as the phenomenon to be studied in more depth. Moreover, it specified intervention variety and adaptations and the use of quality improvement methods as theoretical areas of interest. I used these theoretical constructs as sampling criteria, so I could further examine them in the case studies and elaborate their theoretical understanding (Fisher & Aguinis, 2017; Patton, 2002). So, the four cases I sampled were different manifestations of child allergy care pathway implementation, conducted in healthcare improvement projects as the unit of analysis. Furthermore, cases were sampled based on the manifestation of the above theoretical constructs. Sampled cases had to intent to implement the Itchy Sneezy Wheezy pathway intervention, so I could monitor intervention adaptations within cases and compare intervention variety across cases. Moreover, selected cases had to use quality improvement methods as part of their implementation strategy.

Subsequently, heterogeneity was introduced to the sampling strategy. This aims to strengthen analytical generalisability by making it possible to distinguish case study findings that are case-specific from findings that represent a pattern across different types of cases (Patton, 2002; Yin, 2018). The first two cases were identical in relation to the sampling dimensions. Both cases were based in London, their lead organisation was the local hospital, and their use of quality improvement methods was part of a comprehensive quality improvement approach facilitated by an external organisation. The third case was also based in London. However, the lead organisation was the local CCG, who facilitated the use of quality improvement methods as part of their internal project management approach. The fourth case was also led and supported by their local CCG, but based in the North-west of England. The characteristics of the four cases studied are represented in Table 6.

Table 6. Case characteristics.

Case	A	B	C	D
Geographical area	London	London	London	North West England
Lead organisation	Hospital	Hospital	CCG	CCG
Implementation strategy	Systematic quality improvement approach	Systematic quality improvement approach	Internal project management approach	Internal project management approach
External QI support	Yes	Yes	No	No

3.4.2. Gaining access

Access to the case study improvement projects had been facilitated by my PhD supervisor, Prof Warner, who acted as gatekeeper to improvement projects implementing the Itchy Sneezy Wheezy intervention. As discussed above, one of the case criteria was an intention to implement the Itchy Sneezy Wheezy intervention. Prof Warner was named on the Itchy Sneezy Wheezy project website. He also took an active role in project dissemination by presenting at conferences, meetings and events; networking with colleagues; publishing in scientific journals; and writing project descriptions for websites. As such, Prof Warner was a project champion, committed to engage and enthuse stakeholders locally as well as nationally (Leeman, Baernholdt, & Sandelowski, 2007; Rogers, 2003). Moreover, he was an allergy expert with a long-standing academic and clinical career. Through these roles, Prof Warner helped to facilitate connections with the Itchy Sneezy Wheezy team and other local teams interested in implementing the Itchy Sneezy Wheezy intervention.

In some cases, dissemination efforts from the Itchy Sneezy Wheezy team directly engaged other healthcare teams to motivate them to improve their local allergy health services.

> *"I was invited I think by [the Itchy Sneezy Wheezy clinical lead], and attended a meeting in January in [X] hospital. And also at that meeting was a commissioner for [case B] services who, I can't remember her name now […]. So, the two of us met at that meeting and that was the very first start of it." (Clinical Lead site B, interview)*

In other cases, teams reached out themselves.

> *"[through the] service in [city X], we identified London, in fact, [the Itchy Sneezy Wheezy clinical lead] through this as well, and yourself. […] It was through a literature search, and then [our Project Manager] happened to know one of the GPs who works there, and then [she] organised for, because I couldn't go, [our paediatric allergist] and a few others to visit the service." (Clinical Lead site C, interview)*

Prof Warner and the Itchy Sneezy Wheezy team not only enthused allergy teams to improve their local allergy health services and implement the Itchy Sneezy Wheezy intervention. They often maintained relationships offering advice and support. This network of relationships allowed Prof Warner to act as gatekeeper to the improvement projects studied in this research project. Moreover, he encouraged my research organisation to partially sponsor two of the projects studied, which also supported access negotiations (Hammersley & Atkinson, 2007; O'Reilly, 2009). In these two cases, two Itchy Sneezy Wheezy team members were active members of the Project Board, where they introduced my research and invited me to join the projects. In the other two cases, the project leads

invited the Itchy Sneezy Wheezy team to present on their project and to advise them on their local improvement efforts. In both cases, the Itchy Sneezy Wheezy team requested an extra invitation for me to attend the meeting. In each meeting, the Itchy Sneezy Wheezy facilitator highlighted areas in which we might be able to provide support and asked directly if the teams would participate in my study. In both cases, I followed-up his request after the meeting to negotiate access directly with the project managers and clinical leads. However, the Itchy Sneezy Wheezy team was not only able to help me gain permission to study the four improvement projects. Prof Warner's status and the quality of his relationships also facilitated access beyond permission, supporting a rather smooth and warm welcome by the project teams (Hammersley & Atkinson, 2007).

> *"For me this has been a very nice process and I really felt the facilitation of my supervisor was crucial. Since, both teams [C and D] do look up to him and could gain from his participation, I think it was easier for them to accept my attendance to return the favour." (Reflexive notes)*

3.4.3. Observer-participant role

My position in all four improvement projects was as a student to learn and my role in the field was as observer-participant. The role ethnographers take in the field can be more or less involved depending both on their beliefs about rigorous research and the nature of their situation. Generally, ethnographers navigates between the role of complete observer and complete participant (Hammersley & Atkinson, 2007; Labaree, 2002; Styles, 1979). As complete observer, the ethnographer positions themselves as a group outsider to avoid bias caused by their emotional commitment to the group, their interpersonal relationships with group members, or their social position within a group dynamic. As complete participant though, the ethnographer positions themselves as an insider, becoming a completely immersed group member, to attain a level of intimacy and experiential learning needed to fully appreciate and understand the group's social life. Privileging one role over the other has, however, been criticised. Ethnographic research is always convoluted by preconceived values, biases, and ideas. Yet, both observers and participants can perform fieldwork that illuminates and tests preconceptions so they can be changed to align with reality (Styles, 1979). In reality, the role of researchers often sits somewhere on a spectrum between being a complete outside observer and a complete inside participant and it tends to change over the course of the study (Labaree, 2002; Styles, 1979). This was also true for myself in this study. In all four improvement projects, I negotiated access as a student researcher, interested in both allergy health services and quality improvement practices. These intentions seemed to be understood and accepted.

> *"By sharing local experiences (that are in the research combined with findings from other settings) we can achieve empirically grounded, yet practical recommendations for other NHS organisations on what service models could be fruitful as well as what strategies and actions can support putting these models in place." (site C, committee paper)*

As a student researcher, I was allowed the position of being acceptably incompetent (Hammersley & Atkinson, 2007). This means I was allowed to be a novice, an outsider coming in, who could sit in on conversations and ask questions as a way to learn and become familiar with how thing work. However, as an outsider not only to the project teams, but also to the NHS and the UK more generally, I initially struggled to keep up with conversations and I felt I was stretching the team's tolerance and patience for a 'novice student'.

> *My first team meeting I was asked to take minutes by [the external QI lead]. On the one hand, I think this got me truly involved in the team sort of immediately, because I was showing goodwill, contributing, and it forced me to get involved in the conversation. On the other hand, though, it really put me on the spot. I didn't know the project, team members' names, the names of local organisations, NHS abbreviations, and I felt like this lack of understanding undermined my intelligence as a researcher in the eyes of the people attending the meeting. It basically was impossible for me to make notes. I could only write down some scribbles and action points, and for each action point I had to interrupt the meeting to ask if the action and the name of the person it was assigned to could be repeated. And not only that. I often asked for abbreviations to be defined. However, when I asked the definition of 'GP' and I heard the meaning, and I saw the face of the Chair, I felt so embarrassed and disruptive that I stopped asking. (Site A, Reflective notes)*

So, I was immediately positioned in a participatory role as a 'novice outsider'. My personal circumstances, though, made this level of participation at this stage of the research highly inappropriate. Moreover, by taking meeting notes I had to focus my full attention on the content of the discussion without being able to observe any other (nonverbal) communication and dynamics. As such, this type of participation prevented me from doing necessary fieldwork and writing field notes. Moreover, I was asked to help with many different types of administrative tasks that I felt were time consuming and preventing me from both fieldwork and academic reading. I continued to help with meeting preparations – printing paperwork, sorting out IT on site, and writing minutes. I also helped with the evaluation of education sessions – printing questionnaires, collecting responses, entering data, analysing findings, and feeding back the results to the team. It felt like my role within the project wasn't right. It felt I was participating too much, which prevented me from being able to

process and reflect on my experiences, which is actually what differentiates ethnography from normal life (Hammersley & Atkinson, 2007).

> *"I got involved via [the external QI lead] with entering data that the team collected at education events, which I did not appreciate and even flagged as an issue to my supervisors. I felt like it ate away my time and I had so much to learn and to catch-up on. [One supervisor] noted that these things might not be great, but that they're normal and that they help to access the team. [My other supervisor] added he thought things would get better when the new project manager was in place." (Site A, Reflective notes)*

This felt imbalance was later confirmed by the new project manager. When I asked her how herself, myself and the external QI lead were working together, she said:

> *"I thought you were doing way too much initially when I came in. I think you were taking over a lot of stuff. […] Obviously you're not going to get, you're not going to be doing all the project managing work, but I felt like initially you were quite, probably, relieved that I came in." (project manager Site A and B, interview)*

In hindsight, I agree with my supervisors that this experience helped me to build stronger relationships with the team. My participation allowed me to be seen and valued as project member. It also gave me an opportunity to interact with team members and ask questions, which can otherwise be more difficult, especially in a team of healthcare professionals who often attend meetings late or leave early due to clinical commitments.

Nevertheless, it was necessary to negotiate a less participatory role to allow more focused time for field observations, reflexivity, and sense-making. As such, I highlighted that taking meeting notes conflicted with my role as researcher, explaining I needed to write observational notes, which were different from meeting notes. Moreover, when the new project manager was in post and when I became more familiar with the project things slowly improved. Over time, I could volunteer strategically for tasks directly benefitting my fieldwork and reduce time-consuming tasks done merely to demonstrate goodwill and engagement. Initially, the tasks I volunteered for were still predominantly administrative, but allowing me to explore and observe.

> *"I helped the project manager with visualising the process in PowerPoint. And while we sat together behind the computer moving around boxes and arrows and fiddling with the software, I could ask her many questions about healthcare processes more generally. What do these boxes mean? What do the people actually do? So, how does that work normally in hospital?" (Site A, Reflective notes)*

When I gained more experience though, my volunteering became more participatory. As a non-medical researcher not affiliated to any healthcare organisation, I did not have the skills nor the authority to participate in the clinical interventions. However, with my MSc degree in Human Factors and Engineering Psychology and having finished the CLAHRC NWL in-house quality improvement training, I was able to participate in the use of quality improvement methods that were part of the teams' implementation strategies.

My level of participation varied, depending on the strategic and operational implementation approach across sites and my relationship with the project manager. In site D, for example, the project manager had significant experience in quality improvement methods. She had previously been employed as an NHS England quality improvement lead after a decade long clinical career that was packed with different types of service improvement initiatives and accompanied by training in quality improvement methodology. Consequently, quality improvement methods had a clear role within the team's implementation plan, which she confidently operationalised. She was comfortable to use quality improvement methods to brainstorm and plan, to get input from the team, and to allocate roles and project tasks to team members. As such, my participation was limited. When asked, I offered feedback based on the experiences of the sites I studied prior, and I helped to facilitate a driver diagram workshop during one of the stakeholder meetings. Otherwise, my role was mainly observational and involved asking follow-up questions. In site C, the project manager was similarly experienced. She had been working in commissioning and performance management in the NHS for almost a decade, she attained an MSc degree in commissioning and completed a program management course. As such, she was similarly confident developing and executing a project implementation plan. Nevertheless, quality improvement methods were not explicitly the focal point of her implementation plan. They tended to be workstream activities that were allocated to specific team members just like other workstream activities. This structure allowed me to participate more actively, where I could volunteer for quality improvement activities and the project manager could employ me strategically to support the project.

> *"So, when you approached us and you were like 'yeah can I study this project', we were like yeah. Because that for us was extra resource and you helped a lot with the pathways. So, that's like a, and that's a whole work stream, because you know all that's a lot of work. So, then we can say, yourself, [the clinical lead] and [that doctor], I had the three of you down against the pathway section with that [GP from the CCG pathway committee], who helped." (Project Manager site D, interview)*

Although at an earlier stage in her career, the project manager for Site A and B also had both management and quality improvement experience. As a nurse, she had been managing a clinical team. And during her MSc degree in paediatrics and child health, she learnt about quality improvement methods, which she applied in a practical improvement project. Even so, the projects in Site A and B were a great opportunity for her to learn more about quality improvement methodologies and managing improvement projects. This allowed us both to learn together about quality improvement methods as an implementation strategy. We would often collaborate during quality improvement workshops. Moreover, we had a weekly quality improvement meeting, where we would prepare for workshops and team meetings, process the data and information collected, and strategise about next steps.

> *"I think it was also helpful in terms of discussions, just prepping for the meetings. So, not just translating what we've done in the meeting into something tangible, but also prepping how we're going to interact. We know that that person is probably going to not be very receptive about this, how do we introduce the topic? How am I going to talk about process maps without talking about process maps, how, what? And, also, I think, we, it was good in terms of trying to identify what tool would fit best. So, for the meeting or for, or… OK, so I think we should be doing some PDSAs, how are we going to do that and how are we going to deliver that?" (Project Manager site A and B, interview)*

This process of shared learning felt mutually very productive. I was able to learn about the projects through active participation and I could ask questions and reflect with a key informant. On the other hand, my theoretical learning, my critical reflections, and my questions could help the project manager to develop her implementation strategy. Nevertheless, it had the unintended consequence that we became self-reliant.

> *"I think what wasn't managed so well, was the fact that we ended up being happy being just the two of us. And eventually this QI thing became just you and me. And we didn't have the [external QI lead], who actually, in theory, should have been the one promoting those, maybe, those QI sessions and having that role. But then at the same time, I was quite happy. And I knew that that [external QI lead] had so much other work to get on with. So, it's about being a team" (Project Manager site A and B, interview)*

So, my role as researcher developed over time, across projects, and across activities. From the start, I have taken a participatory role. In project A and B, my level of participation was particularly high. With my office on the same floor as the project manager and the external QI lead, it was easy to get involved myself and to be involved by them. This spatial proximity helped me to become an insider

quite naturally. Moreover, these were the first two projects I studied, which involved a steep learning curve that was facilitated by participation as an active learning strategy.

This allowed me to decrease participation intensity in project C and D. Since, I was more aware of these types of projects, I was better able to filter and select situations and activities that were important to be involved in. Moreover, the context of these projects made me more of an outsider than I was in project A and B. Projects C and D were managed from different offices, they were part of a larger improvement strategy with a much longer timeline, and they were well-integrated in the governance structures of the lead organisations. I wasn't part of these more enduring structures and as such, I wasn't naturally involved in the organisational nitty gritty that went on outside of scheduled project meetings. Instead, I had to learn about these things through update phone calls, forwarded 'FYI email threads' and by attending meetings early or staying late for informal conversation. Moreover, over time I learnt what roles were best to take on in different situations. During meetings, which were often fast-paced, I tended to take on an observational role. When collaborating on quality improvement activities, I would combine participation with informal interviewing. Finally, my role during independent quality improvement tasks was fully participatory, giving my own input based on my personal interpretation of the task.

3.4.4. Critical stance

During my fieldwork I took a critical stance, which I tried to maintain during active participation. Critical ethnography builds on an ethical responsibility, whereby *"the researcher feels a moral obligation to make a contribution toward changing those conditions toward greater freedom and equity"* (p. 5) (S. Madison, 2005). Allowing a place for this sense of moral obligation as part of my ethnographic study aligns with my DCR ontological and epistemological assumptions. I highlighted that DCR assumes moral truth, whereby moral viewpoints held by people might be wrong. Epistemologically, however, moral truth cannot be known with certainty. Nevertheless, moral standpoints can be critiqued, rejected, and refined based on judgemental rationality, thereby inspiring emancipatory actions that are more likely to contribute to greater freedom and equity – a morally better world (Bhaskar, 2008b; Norrie, 2010). Ethnographers can do this type of work by using their skills, resources and privileges to question taken-for-granted assumptions, to give voice to the experiences of people who might usually remain unheard, and by unpicking generally accepted operations of power and control (Madison, 2012; S. Madison, 2005). They can *"[q]uestion truth as truth operates through power and to question power as it operates through truth"* (p. 6) (Madison, 2012). As such, this moral obligation does not negate objectivity, nor does it introduce (extra) bias. Instead, it helps to identify the assumptions and values held by the researcher and by the

participants, which are subsequently explored and tested using empirical investigation (Hammersley, 2017; Styles, 1979). There were situations where I felt, the team and I could have acted more critically.

> *"The process map that [the doctor] developed was really good. However, I found it interesting she developed it on her own. It was not surprising to me that the first few questions immediately evolved around the role of health visitors and school nurses, because [the doctor] had less knowledge about these processes being a hospital consultant. So, these roles were largely left out, which made the people in the room wonder what their role was or would be within this process. So, when [the doctor] asked if someone would be able to help her drawing the process map on the computer, I immediately volunteered. I think this will be a great opportunity to learn more from [the doctor] about her insights into the processes of the healthcare system in [site D], to form a closer relationship, and to use my critical voice as an ethnographer. I intend to ask her how other stakeholders and their processes fit into this existing process. I expect that after these probing questions, we will either have to contact the different stakeholders individually to find out more or that we can conclude we need a separate session making the process map all together." (Site D, Reflexive notes)*

After this meeting, where I volunteered to improve the project's first process map, the clinical lead phoned me to talk me through his interpretation of the process map and the patient pathway more generally based on his understanding of the clinical guidelines, his professional role as GP, and the understanding he had as project lead of the community nursing role implemented in the project. To validate my understanding of the patient pathway and our conversation, I studied the clinical guidelines he mentioned. Moreover, I scheduled a follow-up meeting with the two community nurses to hear about their experiences in their own 'voice'. Consecutive these individual interactions, I met up with the doctor to work on the process map she had made. During this meeting my probes were indeed able to highlight the need for input from more stakeholders. However, rather than organising a collaborative process mapping workshop, more familiar channels were used to get input.

> *"Dear all, Sophie and myself have been busy working hard developing pathways for asthma and eczema. In order to ensure that we are clear about what the roles of different professionals in the pathway are, it would be really helpful if you could email me back with answers to a few brief questions." (Hospital Doctor Site D, team questionnaire)*

Subsequently, I collated all this information in a new version of the project process map. And although I had tried to capture more team voices in the development of the process map, I didn't

feel this was yet successfully achieved. However, I didn't want to interfere with the team's implementation strategy too much, as this was a specific area I was studying. So, I waited to see what happened next.

The two new process maps were presented at the following team meeting. They were stuck on the wall and the team was asked to split in two groups, discussing and writing down comments, which were consolidated and fed back to the group at large at the end of the meeting. And while this exercise again was intended to hear more voices, from my stance as critical ethnographer, this was still not sufficiently achieved.

> *"By the end of the session people were really positive, the clinical lead especially. When he talked to me about it, though, I felt he was surprised that I wasn't super enthusiastic. This had several reasons. One reason was that I wasn't in a great mood generally. But the more important reason was that I believe people commenting on existing content doesn't encourage diverging ideas. People tend to focus on what is there and don't think outside of the box as much. And because [the doctor], [the clinical lead] and myself made the map initially, it was us who decided the skeleton." (Site D, reflexive notes)*

Again, though, I tried to practice criticality within the operational framework of the project team. That is, during the meeting, I tried to use my skills as critical ethnographer to question the dominant assumptions and to give voice to the experiences of the people who were yet unheard.

First, I tried give voice to the school nurses. They were there, part of the project team, trying to improve children's allergy services. However, they commented on a process map outlining primary care, community nursing, and referral criteria to more specialist care. As such, the three people who developed the map, one of them being me, were inadvertently given the power to pre-define the scope of project discussions, thereby directing subsequent project actions. As critical ethnographer, though, I felt obligated to question this, to "*question [this] power as it operates through truth"* (p. 6) (Madison, 2012). As such, I questioned the school nurses about their services and their ideas about the project. I initially did so during the meeting, but then decided to follow-up with a more extensive interview which provided me the details needed to add their services and their intervention ideas on the process map. Thereby, I could represent their truth, giving back some power to influence the project. These actions also helped me to realise that much of the power in delivering allergy care to children is held by GPs and hospital doctors. More specifically, the project GP noted that the way I represented the patient pathway was new to him. Instead, he was used to seeing it from a primary care perspective (team meeting fieldnotes). Moreover, the hospital doctor claimed power to the

extent as to request removal of the hospital services from the process map altogether, since these were of specialist nature and managed internally (informal meeting fieldnotes).

Second, I tried to give voice to the parents of allergic children who were invited to the meeting. The process map was developed using the information provided by healthcare professionals delivering health services to children with allergies. As such, the representation of what allergy care looks like, the 'truth' of allergy care delivery, was defined by the people who control what care is delivered to reflect their experiences. As such, I felt the need to *"[q]uestion truth as truth operates through power"* (p. 6) (Madison, 2012) by asking the patient representatives whether the process map represented their personal experiences. In my field notes I captured their responses as follows:

> *[Patient rep1:] "for me, no, I got into a void" [they moved to a different borough and the communication of the GP in the new borough and secondary care in the old borough was not good, which also shows the importance of informal communication] […] "we're left out to dry" [re: patient resources, and also mentioning the different GP skill levels].*
>
> *[Patient rep2:] "to see it so structured, that would be great, wow. It would be great to experience that structure. But for me it didn't happen like that." (Site D, team meeting fieldnotes)*

Despite my critical stance, I tried to remain humble, reminding myself that the team members were the experts, who so kindly allowed me to study them and learn from them. That is, I tried to stay positively naïve, *"acknowledging that [I] do not know and that [I] must rely with humility on others and trust upon the knowledge of knowers"* (p 39) (Madison, 2012). For example, when I mentioned to the clinical lead the discrepancy between the patient pathway represented in the process map and the experiences of the patient representatives, he explained that this was to be expected. The reason was that the process map was not intended to be a perfect reflection of the health services that are delivered. Instead, it was intended to support healthcare professionals doing their jobs delivering high-quality care to their patients.

Moreover, my critical stance towards knowledge and how it relates to power also clarifies my stance towards the Itchy Sneezy Wheezy intervention. As discussed in Chapter 1, the Itchy Sneezy Wheezy intervention demonstrated to be a feasible solution to implement elements of the RCPCH care pathways into local practice. The RCPCH care pathways were developed through a literature-based evidence review and input from a multi-disciplinary stakeholder group. The Itchy Sneezy Wheezy intervention had been evaluated during its pilot phase to understand its feasibility in practice. Outcomes of this evaluation indicated its potential as a cost-effective way to implement the RCPCH

care pathways. This type of evidence is useful, yet not as robust as the evidence generated through well-executed experimental study designs, like RCTs (Cartwright, 2007, 2010). As such, I was aware of the meaning and value of the evidence for the RCPCH care pathways and the Itchy Sneezy Wheezy intervention within the scientific improvement science community. However, as part of this study, I aimed to understand the local meanings and values that healthcare teams attributed to the RCPCH care pathways and the Itchy Sneezy Wheezy intervention and how that influenced improvement decisions locally. As discussed in Chapter 2, there are different ways of knowing that are considered more '*true*' across different improvement science disciplines. In this study, I aimed to explore how these different and contradictory stances towards knowledge manifest in practice, rather than applying or prioritising any personal preferences. For example, a discussion in site C clearly demonstrated the importance of local evidence to support local action plans.

> *[Clinical lead]: "We can only deliver a service if we can make a financial case for it. The quality case is quite easy to make, but the CCG is running into a financial deficit, so we need to make a financial case as well". [Consultant]: "Why can't we just extrapolate from Itchy Sneezy Wheezy, which had good quality data". […] [Clinical lead]: "that's why we're asking you to give us everything you got. We can then extrapolate from that instead of just relying on national estimates [and other projects], which just isn't good enough to make our case" (Site C, team meeting field notes)*

As such, I aimed to empathise with the case study sites to understand their intervention decisions, their deliberations, and their actions. My critical stance subsequently made me question which voices and what knowledge (or evidence) had power in the case study sites. As such, I questioned the role and the impact of the RCPCH care pathways and the Itchy Sneezy Wheezy intervention in local improvement initiatives rather than being attached to their (high-fidelity) implementation.

3.4.5. Reflexivity

To maintain rigour, I reflected on how my stance, actions and assumptions influenced the research process. Ethnographic studies focus on understanding the social world of which the researcher is a part (Hammersley & Atkinson, 2007). Consequently, it cannot be denied or avoided that the researcher will have an influence on the participants being studied. Moreover, it is usually undesirable to minimise researcher–participant interactions, since these tend to provide the data needed to fully appreciate and understand social reality. As such, both observational and participatory roles can be adopted in rigorous ethnographic studies. What is important, though, is developing awareness of how an ethnographer was likely to have influenced the participants for this to be considered when interpreting the study results. Furthermore, the researcher's personal

thoughts, experiences, values, and assumptions influence the interpretation of the social life that is studied. And while these influences should be mitigated wherever possible by aiming to remain neutral and curious, they cannot be ignored (Hammersley, 2017). Here too, it is important that to use the process of fieldwork to become aware of personal biases and assumptions, which can then be explicitly tested against the data being collected (Styles, 1979). Developing such awareness of researcher influences is done through reflexivity (Hammersley & Atkinson, 2007; O'Reilly, 2009).

In my study, for example, I noticed how my academic background influenced my participation in the case study projects. More specifically, most team members have been medically trained. Whereas, I have been trained as a human factors specialist, often consolidating qualitative and quantitative data in a variety of charts. Consequently, I felt comfortable participating in project activities associated to the use of quality improvement methods. Nevertheless, I noticed over time that my approach, which felt 'natural' to me, was not necessarily aligned to the established customs and norms. For example, when asked to support the development of a patient pathway, I created a process map which had separate boxes for different professional settings and demonstrated the connections between settings. This is what I considered to be 'the task' based on the discussion that took place around the pathways that had been developed by the hospital consultant:

> *[Consultant:] I drafted different pathways, because there is a need for a dietetic element in the under six months. This is based on the asthma BTS guidelines, NICE guidelines for eczema and a bit of my own opinion. [she laughed when stating she also used her own opinion indicating that she might have felt this was knowledge of less value]. "And I learnt something about flow charts in the past 3 days"*
>
> *[A discussion of the process maps followed]*
>
> *[Health visitor:] "do you think health visitors could do anything?" [Consultant:] "Yes, that would be good! [then laughs]" (Site C, team meeting field notes)*

From this discussion, I concluded it was desired to integrate the different pathways created so far and to add the health visitor processes in the chart also to be able to visualise and discuss their potential contributions to the project. However, the feedback given made me realise I had assumed the task was to develop a whole systems pathway, which in reality was not the case.

> [Clinical lead:] *"This is not what I am used to seeing from a primary care perspective, but I actually think it's really great to see the whole pathway" (Site D, work meeting field notes)*

"OK, so, there's two bits of this pathway thing. So, in one way most pathways look at the GP decision making. So, the pathways we usually develop with the GP in mind. It's a clinical decision tool to say to a GP 'you've got a patient presenting how do you manage this', it's almost like a protocol. We call it pathway, but sometimes it's a bit more protocol. […] But again, because of the asthma thing we said no, we need to deal with the whole system pathway. Is this thing joined up or not, where's all our care being delivered? So, what you did was a bit more extreme, was looking at how everything linked up, what are the nurses doing, how did they get from the nurse to the GP, when does hospital get involved, would you send them back with a nurse, what are the alternatives, what is the self-help offer? So that was interesting, and it was so funny, well you were at the meeting. […] And then the big discussion happened, I didn't even say that much. 'It's too complicated. No, but we need more information.' And it was that big struggle, and I think even the Chair struggled. […] So, I think we decided we were going to have a layered approach." (Project manager Site D, interview)

As such, due to my professional training in human factors and my lack of experience in the NHS, I had false pre-conceptions of what it meant to develop 'pathways', which consequently influenced the team members and how the project was taken forward. More importantly, though, this experience allowed me to elaborate my understanding of 'pathways' and reflect on the notion that pathways have different meanings to different people in different settings (Allen, 2009). This example also demonstrates that my 'mere execution' of a quality improvement task, in reality went beyond the expectations of the team, something which had also been mentioned by others in different case study projects. As such, when analysing and interpreting the use of quality improvement methods as part of the implementation process, I tried to stay conscious of my influence in this process.

Moreover, being new to the UK and the NHS, I had to rely on my supervisors at the start of my PhD to tell me about allergy care in the NHS and guide me to relevant reading materials. During this initial phase, I had several conversations with Prof Warner, who could tell me about the development of the RCPCH care pathways and the Itchy Sneezy Wheezy project from personal experience. Being able to ask questions was very helpful to gain an initial understanding. Soon thereafter, I was able to triangulate his narrative with published reports, project documents, and conversations with other Itchy Sneezy Wheezy members. Learning about the Itchy Sneezy Wheezy project early on helped me to make sense of the academic allergy and care pathway literature, while also helping me define my research focus and design. The professional relationships of my supervision team gave me access to study the future unfolding of this work, which was an opportunity I was keen to explore. Moreover, by studying pre-existing healthcare improvement teams, I felt mostly free to design the research and to define my role as ethnographic researcher without having to navigate nested interests between

the research and improvement efforts. Prof Warner had been heavily involved in the Itchy Sneezy Wheezy project which informed my understanding of allergy health service improvement. However, his involvement was limited in the case study sites. He was a member of the advisory board in two case study sites, and he had no active involvement in the other two case study sites. Accordingly, I developed a deeper understanding of allergy health service improvement through my involvement in the case study sites as an independent researcher.

During the research process I felt supported in making independent research decisions. The development and implementation of the RCPCH care pathways and the Itchy Sneezy Wheezy intervention were heavily reliant on stakeholder engagement, something that was emphasised by Prof Warner during our conversations. Accordingly, I felt his role as my PhD supervisor emulated his role as advisor in the case study projects, which focused on supporting and enabling people. He was happy to talk about his experiences, share his vision, answer questions, give suggestions, and facilitate relationships. However, his involvement in the Itchy Sneezy Wheezy project made him aware that changes in practice need to be supported bottom-up with local leadership. Accordingly, I felt encouraged to make independent and non-biased research decisions, while also feeling enabled in realising my research decisions through facilitation around access negotiations. Moreover, as I became more involved in the case study sites, I gained more personal experiences and a deeper understanding of allergy improvement initiatives. Accordingly, the relational dynamic with my supervisors changed over time with me taking a progressively more leading role during our conversations based on the specific research and sense-making support I required.

3.4.6. Data collection

While observing and participating in the project teams, I collected different types of data. I wrote observational fieldnotes, I collected project documents, and I audio-recorded interviews, thereby triangulating different types of methods for data collection (Kimchi, Polivka, & Stevenson, 1991). Such triangulation makes it possible to assess whether different methods will bring me to make the same conclusions about care pathway implementation, which strengthens the validity of the study findings (Yin, 2009). Moreover, these methods all have somewhat different strengths that can mitigate the limitations of the other methods. Observational fieldwork, for example, which is the main method of ethnographic research, gives direct access to everyday behaviours and conversations without having to rely on second-hand accounts (Hammersley & Atkinson, 2007). This is important, because human accounts of real-life event are by nature selective and inaccurate due to the cognitive processes that underpin memory storage and retrieval (Kalat, 2009). As such, direct observation allows researchers to be purposefully selective, focused on capturing behaviours and

conversations that are relevant to the study. Moreover, writing down fieldnotes mitigates the issues related to memory retrieval to some degree. These strategies facilitate a rather objective representation of the actual activities and conversations people engage in. As such, observational fieldwork gives insight into the actual *'work'* that is done to implement allergy care pathways. This methodological strength supports theory development by grounding it in the reality of work, the reality of social and material practice, which makes-up implementation and improvement as organisational phenomena (May et al., 2009; May, Sibley, & Hunt, 2014; Nicolini, 2009, 2012). Observational fieldwork not only captures work activities, but also work conversations. In fact, most fieldwork involved attending meetings and events to record both formal and informal group discussions. Formal discussions that were itemised on the meeting or event agenda were structured in the sense that they were often timed and chaired. Whereas informal discussions were unstructured, taking place over coffee or lunch or happening spontaneously between agenda items. During my observations I wrote down fieldnotes which were stored in my case study database and analysed using the software programme N-Vivo. A summary of my fieldnote database is presented in Table 7.

Occasionally, I had the opportunity to extend my fieldwork beyond the passive recording of conversations by asking people more reflective questions to access their personal thoughts and perspectives during informal interviews. I tried to create such opportunities by arriving at meetings early, staying late, or by volunteering to work together with individuals on project tasks. Even so, these informal interviews were influenced and restricted by the circumstances. These predetermined which individuals were available for questioning; which subject areas were appropriate to discuss; what depth and length of questioning was permissible; and what level of notetaking was possible. Project managers, for example, would usually attend meetings early to prepare and set-up, which made them accessible for questions about the meeting ahead or recent events while lending a hand. Moreover, I would approach people arriving early either to introduce myself, ask questions based on the upcoming agenda, or to catch-up if our relationship was more established. However, some people would not arrive early, stay late, or attend networking events. Networking conversations would usually be a continuation from the presentations and workshops that had just been attended. During such conversations, people would usually share and compare their experiences of the sessions, which could include reflections of how the session relates to their own work or criticisms as to how the content did not relate to their own knowledge and experiences. These conversations usually flowed naturally with the topic of discussion predetermined by the event sessions that were attended. My role as such, would be limited to probing people to elaborate and reflect more deeply. Moreover, note-taking was difficult in such situations. Firstly, because these conversations took place

standing-up. More importantly though, because they took place in busy environments, where it was important to practice active listening with lots of eye contact and validating body language to keep people engaged and to create the safety needed to share personal reflections. It was easier for me to take notes during work meetings, where note taking is common practice. Nevertheless, when I would ask more reflective questions, asking people to share their personal thoughts and judgements, this would create a more intimate atmosphere where I would often prioritise listening over notetaking. The need to do so was confirmed to me when I asked one of the project managers how she felt about us working together. She replied:

> *"Not in a horrible way, but it felt sometimes a bit intrusive. Obviously, because you just feel like you're being analysed constantly. So, many times you would take your little book and write something down. So, sometimes it felt intrusive. But I knew, I felt comfortable, because I knew what it was for. But it does feel a bit intrusive in terms of work. Oh, I've just said something, what's she writing down now? That's how it felt." (Project manager Site A and B, interview)*

Regarding this relationship specifically, and managing the balance between my role as researcher aiming to collect high-quality data and my role as 'person' aiming to maintain loving relationships, I had reflected:

> *"With most people I was friendly, but our roles were clear. They were there to deliver the project. I was there to collect data for my PhD and help-out where I could. But with [the project manager], we weren't friendly, we were friends. I sometimes realised she forgot I was collecting data for my PhD at the same time as being her friend. She would make comments about me taking out my notebook or her being a lab rat. She would say this light-heartedly, making a joke rather than actually feeling disturbed. Still, for me, writing down everything she said to me on a day-to-day basis felt like betraying our friendship. So, I usually just stuck to using our meetings for making notes and other than that only writing down things that hit me as extremely relevant, remarkable or interesting." (Reflective notes)*

Table 7. Summary of the case study database: observational fieldnotes

Site A	Site B	Site A and B collaborative	Site C	Site D
Type (hours; number)	*Type (hours; number)*	*Type (hours; number)*	*Type (hours; number)*	*Type (hours; number)*
Team meetings (12.5; 9)	Team meetings (4; 3)	Board meetings (11.5; 5)	Board meetings (7.5; 2)	Board meetings (10.5; 7)
External stakeholder meetings (1.5; 1)	External stakeholder meetings (4; 3)	External stakeholder meetings (5; 3)	External stakeholder meetings (4; 3)	External stakeholder meetings (2; 2)
Informal team member meetings (2; 2)	Informal team member meetings (3.5; 3)	Informal team member meetings (8; 7)		Informal stakeholder meetings (3; 4)
Review meetings (4; 2)	Review meetings (4; 2)	Steering group meetings (13; 7)		Events (12; 2)
Intervention observations (7; 3)	Intervention observations (4.5; 2)			
Total (27; 17)	Total (20; 13)	Total (27.5; 22)	Total (11.5; 5)	Total (27.5; 15)
				Total (113.5;72)

These limitations of fieldwork to capture deeper personal thoughts and reflections were mitigated by inviting people for in-depth interviews that were audio-recorded and transcribed. Fieldwork has the benefit of being able to accurately record behaviours. As noted in the stages of MELD, however, implementation behaviours are a type of agency performed under particular socio-cultural conditions (Archer, 1995, 1996; Porpora, 2013). Human agency is intentional and subjective,

influenced by people's thoughts, experiences and deliberations (Archer, 2003, 2004; Emirbayer & Mische, 1998; Porpora, 2015; C. Smith, 2010). Interviews are a way to access such subjective thoughts and experiences to understand what motivates human behaviour. As such, interviews provide important information needed to explain behaviour and move beyond behavioural descriptions. In-depth interviews are facilitated by the ability to ask meaningful questions (O'Reilly, 2009). This ability can be strengthened with fieldwork over time, by building rapport with interview participants and becoming more aware of their language and cultural rules of engagement. Time in the field also helps to develop a basic theoretical understanding of what is going on, which can help to structure the interview process. Interviews can be used to inspire, validate, falsify or refine theories (Manzano, 2014; Pawson, 1996; Pawson & Tilley, 1997). In my research, I used formal semi-structured interviews several months after my fieldwork ended as an opportunity for in-depth meaningful conversations reflecting on the project with hindsight and to discuss developments that happened since. I had developed a generic interview guide with 15 open-ended example questions to discuss five topics: intervention, engagement, impact, implementation, and sustainability. The interview guide can be found in Appendix F. For each individual, however, I developed a more specific interview guide with questions that were attuned to their role and expertise. More specifically, these questions were designed to obtain information that would strengthen my theoretical understanding developed so far. This is exemplified in Table 8. The interview participants were purposively selected based on their role within the project. More specifically, I aimed to get a wide range of professional perspectives by interviewing team members with a variety of professional roles. Consequently, I interviewed team members with whom I already had a close relationship with prior in-depth conversations. Moreover, I interviewed team members with whom I had yet established a collegial relationship without having had in-depth one-on-one conversations. Finally, I also interviewed team members who had been involved in the project on the periphery and who I had not yet met in person. These semi-structured interviews followed a formal process, which demonstrates a degree of respect and ethical responsibility that was especially important to develop trust in the last group of participants, needed to have an open and honest in-depth conversation (O'Reilly, 2009). Across the four case study projects I interviewed 38 people, with 14 different primary professional roles. All semi-structured interviews were audio-recorded and professionally transcribed. The transcriptions were subsequently stored in my case study database and analysed in N-Vivo. A summary of my transcription database is presented in Table 9.

Table 8. Example interview questions and their underpinning strategy for theory development. Taken from the individual interview guide for the community/hospital nurse in Site B.

Question	Purpose
"Can you tell me again how you selected those two sites?"	Validate or refine theoretical propositions directly
"In his presentation, the clinical lead mentioned how useful the relationship was that you established with the welfare assistants. Can you tell me a bit more about this?"	Validate or refine theoretical propositions by triangulating different participant perspectives
"During earlier meetings, uncertainty was expressed about one person delivering a clinic in the community, because in the hospital it was really easy to get a hold of expertise (a test or a consultant) if there were difficulties or questions. What do you think about that now that you have been running the clinics?"	Validate or refine theoretical propositions by testing hypothetical assumptions against actual experiences
"You have done a prescribing course and the allergy course, right? How were these relevant to you?"	Refine theoretical propositions by unpicking an identified causal mechanism in more depth
"Were there any other ways that you have developed your clinical skills?"	Refine theoretical propositions by identifying additional causal mechanisms and exploring their interactions

Table 9. Summary of the case study database: interview transcriptions

Primary project role	Site A	Site B	Site A and B collaborative	Site C	Site D
	Minutes	*Minutes*	*Minutes*	*Minutes*	*Minutes*
Project lead			115		
Project manager			80 *	80	115
Clinical lead	130	80 *		70	95
Community/hospital nurse	65	110 *		30	120
Hospital doctor	75		70 *	70	50
Hospital nurse		60			
School nurse	70	60			60
Nurse manager				100	75
Hospital manager	95 *			35	60
Dietitian	60			60	
GP	65			40	50
Commissioner		90			
Project support staff				45	
Biochemist				55	
External QI lead			-- *		
PhD student (me)			-- *		
Total					
Hours (number of interviewees)	9.5 (8)	6.5 (6)	4.5 (3)	10 (11)	10.5 (10)
					41 (38)

* These participants were interviewed twice as part of the research programme this study was a part of, once by me as part of this study and once by a colleague as part of a study on sustainability in healthcare. Both interview transcripts were included in the case study database.

Besides fieldnotes and interview transcriptions, I collected a broad array of project documents. Field observations were said to be able to capture the 'work' as it is done in a relatively objective manner. Semi-structured interviews on the other hand capture people's subjective thoughts and experience, which can both validate field observations and provide additional insights into people's motivations and strategies. Documents, then, are cultural artefacts which are meaningful content produced with social intention which can be understood by others through subjective interpretation (Archer, 1996; Porpora, 2016). I have collected documents throughout my fieldwork, which helped me gain a third perspective on the work that was done to implement care pathways in child allergy health services. For example, I would usually review the meeting minutes that were sent through to all team members and cross-compare them with my observational notes. As such, I could use the minutes to validate my notes, to check for any important omissions, and to get an idea of which issues were particularly important to the team by being 'noteworthy'. Moreover, project reports and presentations developed to communicate completed or planned work were useful artefacts for expressing high-level project vision, strategies, and activities. As such, they represented the consolidation of strategic and sense-making discussions and a compressed overview of implementation activities that occurred over time. Moreover, they made explicit a high-level project understanding, which was the shared foundation implicitly underpinning the operational discussions that took place during regular meetings. Consequently, publication of these reports and presentations were important aids for me to stop and reflect to assess whether the messages they expressed aligned with my own understanding of the project and whether I thought this understanding was shared by the other team members. For example, as expressed earlier in this Chapter, I initially struggled to understand how my case study projects were related to the RCPCH care pathways (Warner & Lloyd, 2011) and I doubted whether this understanding of project purpose was shared across the team members. As such, I asked one of the hospital consultants during a work meeting:

> *[Me:] "Would you say that in [the original Itchy Sneezy Wheezy and the case study projects], the projects actively try to implement the RCPCH care pathways?" [Consultant:] "if [the project lead] would be in the room, then I would definitely say yes. But if not, I don't think so, we are just trying to increase capacity." [Me:] "Okay, but isn't that kind of what the pathways try to do as well?" [Consultant:] "I guess so. The pathways are competence based, so that not only specialists can deliver the services, but anyone who has the appropriate competences. I haven't been personally involved in developing the pathways, but I do know them by heart. So, yes, I guess you can say that the projects have been influenced by the pathways, sort of" (Site A and B, work meeting fieldnotes)*

This example demonstrates the intricacies of language used in documents, and how this language relates to the intended meanings, the interpreted understanding, and the reality it represents. This consultant had a deep understanding of both the meaning of the RCPCH care pathways and the reality of the case study projects. Initially, she considered the two to be separate. However, after some reflection she could see how the two overlapped. That is, through the mechanism of competence-based allergy services that can be delivered by a variety of qualified healthcare professionals. Such clarification helps me connect my interpretation of the project documents as cultural artefacts, the intended meaning expressed by the project developers, and the project understanding expressed by the team members. Similarly, when using quality improvement methods documents were often produced that integrated several ideas, processes, and activities. Many such documents were visual, including process maps, Action Effect Diagrams (AEDs) or driver diagrams, and data charts or graphs. As such, these documents helped me to consolidate and validate my understanding of the project by integrating and connecting project information. Similarly though, I had to stay vigilant and assess to what extend these documents reflected the collective understanding of the team. During one meeting for example, the chair put up an AED that was developed at the start of the project with the aim to discuss project progress. Before starting the discussion, she asked whether people were familiar with the chart to which the response was:

> *[Clinical lead:] "It's a reminder from some distant memory [laughter]. I wouldn't say it's our mantra that's on the wall [laughter]. But we refer to it on a daily basis, in fact it's quite interesting that you've put it up." [Community/hospital nurse:] "I've never seen it. Must be new*." (Site A, meeting fieldnotes)

This conversation continued with the clinical lead explaining how the project had developed since the development of the AED. He explained how the project activities mapped to the diagram and why these activities only represented part of the diagram. The team then continued the conversation reflecting on their intention to implement the other AED activities. This example demonstrates again how I tried to review and interpret project documents within their wider cultural context. Doing so, I tried to understand the meaning embedded into a document during its development by exploring for example who developed the document and for what purpose. Subsequently, I would try to understand how such documents and their meaning related to the actual experiences of the other team members and their sense-making processes. As such, I used these project documents as a vehicle to understand team culture more broadly, as something shared, that lies beyond my individual sense-making of the documents (Porpora, 2015). Throughout my fieldwork I collected many documents, including meeting agendas, minutes, quality improvement charts, project reports, presentations, and news articles. I primarily used these documents during my fieldwork to validate

my fieldnotes and to support sense-making captured in my field reflections. Nevertheless, I stored all documents in my case study database and uploaded them to N-Vivo, where I referred to key documents for analysis. A summary of my document database is presented in Table 10.

Table 10. Summary of the case study database: project documents

Site A	Site B	Site A and B collaborative	Site C	Site D
Type (number)	*Type (number)*	*Type (number)*	*Type (number)*	*Type (number)*
Meeting (29)	Meeting (10)	Meeting (61)	Meeting (5)	Meeting (20)
QI (17)	QI (20)	QI (26)	QI (7)	QI (36)
Other (23)	Other (28)	Other (29)	Other (33)	Other (33)
Total (69)	Total (58)	Total (116)	Total (45)	Total (89)
				Total (377)

3.4.7. Ethics

This study involved the participation of NHS staff being observed and interviewed about their professional role and healthcare improvement activities. To take care and responsibility for their experience, I applied for ethical approval and took measures accordingly. This study was part of a larger research study on healthcare quality improvement, approved by the NHS Health Research Authority (IRAS 188851). As part of the internal governance processes, I applied a sub-project ethics application, which was approved after internal review. To ensure confidentiality, all recorded and transcribed information was kept on secure servers, that could only be accessed by approved researchers. Moreover, information that could lead to the identification participants' identity was removed prior to publication. This information was communicated via a participant information sheet and verbally by me. For the observational fieldwork, written informed consent was given by the clinical lead and the project manager, while consent was negotiated orally with individual team members during team meetings. In meetings, I would introduce myself overtly as studying the project and taking research notes, highlighting I could stop recording at any time if people felt uncomfortable or for any other reason. Moreover, I highlighted I was available to provide more information or discuss concerns at any time during the study. In a handful of instances individual consent was withdrawn during meetings, when participants stated that what was said was not for minuting. Moreover, individual consent was re-negotiated in a handful of instances and a couple of

times withdrawn during one-on-one project meetings. In some such situations, I was asked if I was writing things down. This would lead me to pause my role as researcher and open-up re-negotiation of consent by suggesting I could stop my fieldwork or stop the conversation. In other situations, I would sense a sudden hesitancy for people to speak openly, which also led me to ask whether they wanted me to change the topic or stop taking notes. For the audio-recorded interviews, written informed consent was given by each participant.

3.4.8. Data analysis

My data analysis consisted of roughly three phases: problem definition, individual case description, and cross-case theory development. This neat description of my analysis process does not, however, fit my experience of data analysis. My experience is better described by other ethnographers:

> *"Ethnographic analysis is something of a messy business that ethnographers learn through practice and experience. Largely, it comes down to having an inquisitive mind and imaginative sensibility, as well as a strong desire to explore various aspects of the social world and make some sense of it all"* (p. 13) (O'Reilly, 2009)

> *"In ethnography the analysis of data is not a distinct stage of the research. In many ways, it begins in the pre-fieldwork phase, in the formulation and clarification of research problems, and continues through to the process of writing reports, articles, and books. Formally, it starts to take shape in analytic notes and memoranda; informally, it is embodied in the ethnographer's ideas and hunches."* (p.158) (Hammersley & Atkinson, 2007)

This contrived identification of distinct phases is useful to describe my analysis process. Nevertheless, it should be considered that in reality the phases were overlapping and my experience of these phases of analysis was largely subconscious. That is, I was aware that these phases were part of the ethnographic process. Most times, however, I was not aware of what phase I was in or how my analysis actions were connected to the purpose of each phase. This was similarly true for the distinction between the exploratory phase of this study described previously and the main phase of this study comprised of the four ethnographic case studies discussed in this section. I continued the literature review until the stage of writing-up and I often went back to the exploratory Itchy Sneezy Wheezy case study with new perspectives and new insights gained from the ethnographic case studies to cross-compare. Moreover, the exploratory phase was primarily oriented towards defining the research problem, which can be seen, is also the first phase of my ethnographic analysis.

Each phase of my analysis was dominated by a specific analytic strategy which I subconsciously adopted while creatively trying different analysis techniques. In his case study approach, Yin (2018)

defines four general theories to analyse case study evidence: relying on theoretical propositions, working your data 'from the ground up', developing a case description, and examining rival explanations. Alternatively, he highlights starting the analysis by playing with the data to look for significant concepts and patterns. Such playfulness encompasses creativity and imagination, which plays an important role in ethnographic analysis that is often described as an elusive and mysterious process (Hammersley & Atkinson, 2007). In reality, I found that by creatively playing with the data and trying different data analysis techniques, I intuitively moved towards techniques that roughly aligned with one of the above four general analytical strategies. I would follow this strategy, becoming increasingly structured in my analysis, until I experienced some sort of 'Eureka' moment, arriving at a key insight. Then, I would move to big-picture thinking, figuring out how these insights fitted with and contributed to the academic literature, and how they could be useful to healthcare practitioners. The answers would usually be unsatisfying which motivated me to continue my analysis. Driven by a combination of enthusiasm, having found an interesting angle to explore further, and anxiety, having (in my opinion) not yet made any significant contributions, I would return to the field and return to my data. Trying different analysis techniques, I would unconsciously change my analytic strategy to move to a deeper and more focused level of analysis. I will describe this process in more detail in the following sections.

Problem definition

In the first phase of my analysis, the problem definition, I moved from the analytic strategy working from the ground up to the strategy relying on theory. Generally, the first step in ethnographic analysis is to familiarise with the data and to identify concepts that help structure and understand the studied phenomena in a way that is novel or otherwise analytically interesting (Hammersley & Atkinson, 2007). And while the case study approach by Yin (2018) encourages an in-depth literature review prior to data collection, ethnographic analysis often doesn't start with a well-defined theory (Hammersley & Atkinson, 2007; Yin, 2018).

Personally, I started my PhD completely new to the implementation and improvement science literature. Eight months in, I was conscious of many key academic ideas and concepts and I had spent six months in the field collecting data in sites A and B. At this point, I started re-reading and coding my data inductively looking for significant themes and issues (Braun & Clarke, 2006; Ely, Vinz, Anzul, & Downing, 1997). Key high-level themes I identified at this stage were: integrating Itchy Sneezy Wheezy learning; clarity of aim and scope; organisational readiness for change; supportive organisational structures and processes; stakeholder engagement; and feedback on progress. I noticed, however, that these themes represented common theoretical concepts from a variety of implementation models. This made me question whether I was about to reinvent the wheel –

developing yet another conceptual implementation model in a field where multiple efforts had already tried to organise and consolidate the large amount of existing models (Damschroder et al., 2009; Nilsen, 2015; Tabak et al., 2013).

Consequently, I decided to change my coding strategy to a deductive strategy, using the Consolidated Framework For Implementation Research (CFIR) domains (Damschroder et al., 2009) to organise and interpret my data aiming to elaborate current theoretical developments (Fisher & Aguinis, 2017; Yin, 2018). However, such a framework analysis tends to be a focused approach best suited for descriptive purposes (Smith & Firth, 2011; Srivastava & Thomson, 2009). This reflected my experience, realising I started to gain a structured descriptive overview of the case study projects, while unsure if I was getting any closer to understanding their processual and causal developments (Walshe, 2007). I figured this might be due to CFIR being a descriptive rather than an explanatory model. Consequently, I went back to the literature where I identified Normalisation Process Theory (NPT), a theory explaining the implementation and routine incorporation of interventions into everyday clinical practice (Murray et al., 2010). More specifically, NPT was developed to understand *"how and why things become, or don't become, routine and normal components of everyday work"* (p.535) (May et al., 2009) – very much in line with my literature-based problem definition (Walshe, 2007). Integrating my understanding of NPT (May, 2006, 2013, May et al., 2007, 2009; May, Johnson, & Finch, 2016; Murray et al., 2010) with other relevant models (Damschroder et al., 2009; De Luc & Kitchiner, 2001; Kaplan et al., 2012; Walt & Gilson, 1994), I developed the conceptual model (Miles & Huberman, 1994), shown in Figure 16, accompanied by a list of codes and code definitions attached in Appendix G. However, this conceptual model was abandoned once more when I encountered MELD dialectic as discussed later in this Chapter.

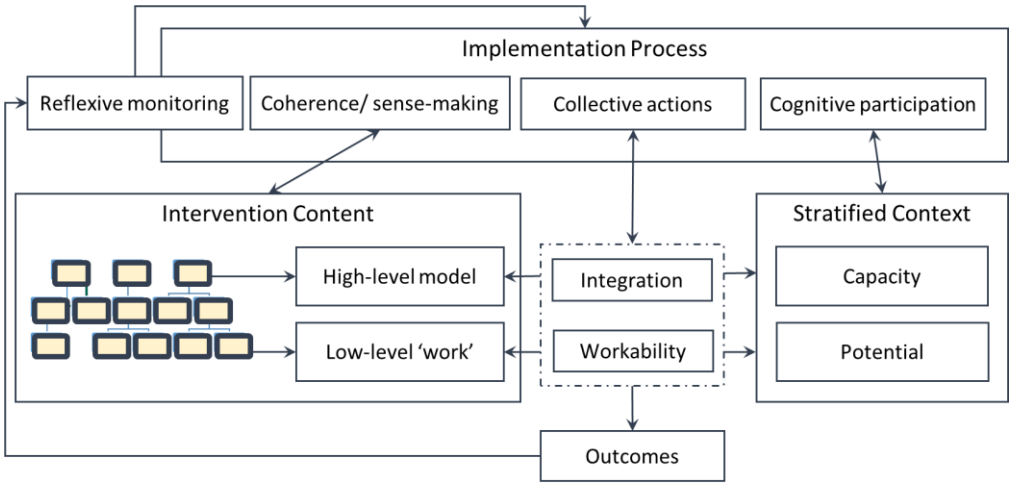


Figure 16. Conceptual model underpinning my deductive coding. Based on concepts from the Health Policy Triangle (Walt and Gilson, 1994) and Normalisation Process Theory (NPT) (May, 2013)

The literature review and the Itchy Sneezy Wheezy case study had helped me to define an initial problem definition to focus my fieldwork. In ethnographic research, this is called *foreshadowing problems*, which means:

> *"specifying issues in which one is interested in advance of entering the field. […] Thus, unlike the open-ended approach that is sometimes advocated by qualitative researchers, Malinowski and others who have followed him recommended coming to the field with an awareness of certain issues that require investigation [by means of theoretical studies]."* (p. 402) (M. Lewis-Beck, Bryman, & Futing Liao, 2004).

The foreshadowed problems I had identified in the exploratory phase of this study were the potential for care pathway interventions to support allergy management; the mechanisms that define allergy care pathway interventions; the use and usefulness of quality improvement methods for implementation. Starting my fieldwork and the initial phase of my analysis, led me to focus this research problem more. After deductively recoding my initial data based on the Figure 16 conceptual model, I realised that much data was coded as 'integration'. As shown in Appendix G, I had defined this code as *'negotiations around the interactions between context of use & the intervention model (does it fit within our organisation, practice & roles; can we do it, who is accountable)'.* Moreover, I noticed I had already identified this as an important theme. That is, through my inductive coding I identified 'integrating Itchy Sneezy Wheezy learning' as a key theme. My notes defined this theme as follows:

> *"The teams find it difficult to integrate learning from [the Itchy Sneezy Wheezy project] appropriately. This involves learning regarding specific implementation barriers as well as learning which intervention components are most suitable in the new context. In other words, how to find a balance between intervention fidelity and adjusting the intervention to fit its context best" (Site A and B, reflexive notes)*

I arrived at this conclusion by listening to the experiences of the team members. In Site A, for example, the clinical lead expressed frustrations about integrating the lessons that had been learnt on implementation barriers.

> *"sometimes it feels like, that the lessons learned from [Itchy Sneezy Wheezy] didn't, it looks like we have to go through a lot of these lessons here today. […] And this is the really frustrating thing, because you've got this thing, which we know was difficult in the first place. And that's why there is the resistance and the hesitance, because you see the stumbling*

blocks which occur, and we haven't mastered them" (Clinical lead Site A, meeting transcription)

Alternatively, in Site B, the clinical lead expressed concerns about integrating specific Itchy Sneezy Wheezy intervention components into their local health services.

"There are pros and cons for going out as well, it's not, you know, all benefits. So, you know, one of the nice things about the clinic that's run here is that we can go and talk to each other about patients. It is actually nice working in a multidisciplinary format and patients benefit from that. […] I do have reservations about one person going out doing an allergy clinic, a bit, […] but those are just my thoughts, I mean." (Clinical lead Site B, meeting transcription)

And even the team members of the Itchy Sneezy Wheezy project echoed these frustrations when they discussed their efforts and experiences trying to spread and disseminate the project to other local areas.

"[Itchy Sneezy Wheezy project lead:] "it is frustrating to re-invent the wheel for a program that has already proved successful" (Event, fieldnotes)

After the process of inductive and deductive coding, I learnt more about Critical Realism and MELD dialectic. Based on this new understanding, I was able to frame some of the integration issues I observed as dialectical contradictions that are difficult to resolve in practice. One such dialectical contradiction can be expressed as 'what works there, does or might not work here'. A next dialectical contradiction observed is between 'intention and action'. Both contradictions were expressed through feelings of frustration, hesitance or uncertainty. And both contradictions were reflected in negotiations around the need to adapt the Itchy Sneezy Wheezy intervention and/or implementation approach to better fit local circumstances. As such, 'integration issues' were found to reflect the efforts teams embarked on trying to integrate or unite these contradictory opposites – trying to resolve dialectical contradictions in practice (Bhaskar, 2008b; Norrie, 2010). However, this dialectical turn only happened towards the end of my research.

Case descriptions

In the second phase of my analysis, I played with my data and developed time-ordered charts to help me develop individual case descriptions. As discussed, the theme 'integration' was predominantly reflected in discussions and negotiations around intervention adaptations. As such, I decided to track and explore the adaptation decisions that were agreed throughout the project course. With this new research focus in mind, I went back to re-read and re-familiarise myself with the data.

Simultaneously, I went back to the methodological literature to find analysis techniques that could help me in my investigation.

In the literature, I identified time-ordered displays as a means for drawing descriptive conclusions within single cases (Miles & Huberman, 1994). Description helps to understand the 'what' and 'how' of situations and their unfolding by uncomplicating things, removing irrelevant details and reducing information to the key elements inherent to the situation. Moreover, time-ordered descriptions preserve the chronological flow of events. This allows for the investigation of the processual nature of phenomena that is currently lacking in implementation and improvement studies (Etheridge, Couturier, Denis, Tremblay, & Tannenbaum, 2014). It also helps subsequent theory building by enabling the differentiation between preceding (causative) events and consecutive effects. Case narratives had been highlighted earlier as a powerful device for capturing chronology and causality (Porpora, 2015). However, using time-ordered displays as an intermediary step between data collection and writing case narratives helps to reduce the risk of bias and improve accuracy (Miles & Huberman, 1994).

For case study project A and B, I developed a chronological narrative and an event timeline that guided further coding focused on the causal mechanisms underpinning intervention adaptations and the use of quality improvement methods. At first, I went through my data looking for events associated to intervention decisions. Data that signified such decisions included the formal agreement of intervention components captured in contractual documents, the consolidation of team negotiations in meeting minutes or quality improvement charts, or the actual implementation of intervention components in practice. While going through this process, the projects in site A and B were nearing their official end date after 18 months of work, whereby my fieldwork covered the last 10 project months. At this point, the project manager asked me to sit down together to consolidate the learning that had developed in each project.

We decided to capture the learning of projects A and B by extending the Plan Do Study Act (PDSA) cycles the teams had developed into a PDSA project narrative. PDSA cycles support the implementation of intervention ideas by designing and implementing small tests of change that progress iteratively based on the learning that is done and captured as part of each cycle (Reed & Card, 2016). A PDSA sequence describes how consecutive actions and learning lead to the implementation of a particular change or intervention component. Multiple PDSA sequences, then, describe how an intervention is implemented in full. As such, we concluded that PDSA cycles could be used to create a narrative that captures the progressive development of the projects and the learning that was accompanied. Based on the Action Effect Diagrams (AEDs) developed by the teams

we identified the different intervention components and associated workstreams that were implemented. For each workstream, we retrospectively developed a PDSA sequence by extending the PDSA cycles that had been developed during the project based on the information captured in project documents. This resulted in a 50-page document created collaboratively, that I subsequently used to develop a timeline for each project.

I then reduced each timeline to the intervention adaptations and their causal events. One of the things I noticed in this process was the significant role that quality improvement methods played in facilitating, influencing and consolidating intervention decisions. This process helped me to further specify my research focus by redefining my second and third research questions as: *'How are allergy pathway interventions adapted when implemented locally?'* and *'How are quality improvement methods used to support local allergy pathway implementation?'*. To answer these questions more accurately, I then went back to my data to code for other causal mechanisms involved in intervention adaptation and the use of quality improvement methods. This whole process helped me to understand the dynamic unfolding of causality during the implementation of child allergy care pathways in case study A and B.

To validate, refine and elaborate this understanding, I went back to the case study participants roughly 18 months after the projects officially ended to interview them about their experiences in the project and their activities since the project had ended. Moreover, this process helped me to be more focused in my fieldwork, data collection and data analysis in case study C and D, which started six months after the official end date of case study projects A and B. So, in this second phase of my analysis I focused on developing case descriptions that allowed me to answer the second and third research questions of this thesis. These case descriptions are presented in Chapter 4.

Cross-case analysis

In the third phase of my analysis, I moved beyond individual case descriptions towards cross-case theory development. At this stage I had asked and answered some interesting research questions and I was able to present my study with a beginning, middle and end to others. However, I had selected a multiple-case ethnographic study design to address the notion that studies so far had been predominantly reductionist and therefore unable to sufficiently explain improvement outcomes (Bate et al., 2008). As such, I aimed to move beyond descriptive insights by answering the fourth research question of this thesis *'How can the local experiences of allergy pathway implementation be explained and synthesised?'.* When I presented my descriptive findings to the External Advisory Group of my research centre in April 2018, I received the feedback they were positively surprised that a descriptive implementation study had gained novel and interesting findings and they

recommended me to write up. Moreover, when I presented my study in the same month during a Child Health Steering Group meeting, attended by three study participants, I received the feedback that the results overall were reflective of their experiences. Even so, I felt unsatisfied at this stage.

My study design allowed me to collect longitudinal, context-specific and causal information to address the research gaps discussed in Chapter 2. Indeed, my case narratives had accounted for the processual nature of implementation and improvement and they highlighted how process-, intervention- and contextual mechanisms interact. However, clear and crisp theoretical contributions and cross-case insights were only yet developing. At the Steering Group meeting, for example, I presented how the varying interventions implemented across sites could be captured collectively in an abstracted intervention model that outlined intervention functions rather than intervention components. Moreover, I presented how intervention adaptations were underpinned by strategic decisions to manage contextual issues and how these decisions were supported through the use of quality improvement methods. These insights, however, were not yet fully formed. I felt like I needed to go back to the data to abstract all relevant concepts related to these ideas and more importantly I felt like the internal links and associations between these concepts were not well developed. As such, my findings did not yet have the clear structure that characterises 'theory' (Miles & Huberman, 1994). Moreover, these findings also seemed disconnected from the theories that underpinned my literature review and my deductive analytical approach. These theories had inspired my study, which subsequently developed in its own direction. As such, I felt generally unsatisfied with the lack of theoretical grounding that my findings demonstrated so far.

The Critical Realist framework MELD, however, allowed me to structure my findings and to further develop my theoretical connections and insights based on its underpinning philosophical understanding of reality. From October 2017 until April 2018, I attended a series of weekly reading seminars on Critical Realism organised by Prof Priscilla Alderson at the University College London (UCL) Institute of Education (IoE). During these seminars we were encouraged to apply Critical Realist concepts and ideas to our own research subject to gain a deeper level of understanding. I found MELD particularly helpful to create a deeper understanding of my implementation and improvement case studies due to its focus on transformational change (Alderson, 2016). Since starting the reading seminars, I have used MELD to critically review my initial analysis and to further structure and strengthen my findings (Alderson, 2021). Not only did the concepts of MELD help me deepen my analysis as described in the book example *'MELD and improving care for children with allergies'* (Alderson, 2021). It also helped me to ground my findings in a meta-theoretical understanding of real-world transformational change. In the next two Chapters, I present the refined and developed case descriptions and cross-case analysis as grounded in MELD.

Chapter 4. Single Case Study Results

Describing how change unfolds in children's allergy improvement initiatives

4.1. Introduction

This Chapter presents four individual case studies of children's allergy health service improvement initiatives. It addressed the Second Edge (2E) of MELD dialectic, which aims to understand not how things are, but how they become. The purpose of this Chapter is to demonstrate the dynamic and processual development of each improvement initiative without reducing their experiences to a static list of themes. Accordingly, each case study is presented as a narrative. The narratives support the investigation of the theoretical propositions described in Chapter 2.

> *Proposition I: Care pathways improve children's allergy services as part of a complex integrated & chronic care intervention.*
>
> *Proposition II: Improvements in the quality of children's allergy services emerge from the interactions between care pathways interventions, implementation processes, and contextual influences.*

They do so, by situating these propositions within the real-life experiences of children's allergy health service improvement initiatives. Accordingly, the narratives describe for each improvement initiative how the content of their intervention developed throughout the process of implementation in line with the geo-historical developments in their local context. Doing so, these narratives also highlight how the Chapter 2 contradictions are resolved in practice. That is, they describe how interventions were adapted and how QI methods were used throughout the unfolding of four different improvement initiatives. As such, this Chapter contributes to answering the second and third research questions.

> *2. How are allergy care pathway interventions adapted during implementation?*
>
> *3. How are quality improvement methods used to support the implementation of allergy care pathway interventions?*

This Chapter is structured as four consecutive case study narratives or improvement journeys. Prior the narratives, however, I present a theoretical overview of 2E of MELD that highlights the analytical benefits of a narrative case study structure. In short, a narrative structure can capture the geo-historical unfolding of an improvement journey in a particular space and time, while simultaneously highlighting differences across improvement journeys that evolved in a different space or time.

4.2. Second Edge (2E): negativity

The *Second Edge (2E)* of MELD dialectics focuses on the principle of negativity to understand change. Negativity as the absence of positive elements was discussed at 1M to describe phenomena in terms

of their identity and non-identity (Bhaskar, 2008b). That is, phenomena were described in terms of parts that are present and parts that are absent – parts that are and parts that are not (not here, not yet, not so, etc.). As such, 1M focused on understanding the world and its phenomena in terms of being and being different. At 2E, however, the world is understood dynamically focused not on how phenomena *are* different but rather on how they *become* different. So, 1M represents being while 2E represents becoming, which are dialectically bound together through change (Norrie, 2010).

Accordingly, 2E reflects the process of change which enriches the structural 1M understanding of change as difference. More specifically, 2E reflects the process of change as transformative negation whereby something that is, is negated to become something that is different. In this statement, 2E represents the point of becoming that occurs between 'something that is' and 'something that is different'. Hence, 2E stands for Second Edge, the edge of transformation, and it focuses on understanding the process of change as it unfolds in reality (Bhaskar, 2008b; Norrie, 2010). By engaging in the process of change or observing how this process unfolds, situations might unveil at 2E that contradict our 1M understanding of a phenomenon. More importantly, though, the unfolding process of change might also unveil how contradictory situations change and develop in real-life practice – how contradictory situations are negated. As such, 2E aims to understand how change unfolds, how dialectical contradictions manifest, and how dialectical contradictions are negated in the real world.

The structural representation of reality and change at 1M already holds a lot of complexity. Phenomena are generated by causal mechanisms that can be many in number and might interact in various ways. These qualities alone already make it hard to predict the effects of causal mechanisms operating as a collective whole (Laszlo & Krippner, 1998; Mingers, 2011; Von Bertalanffy, 1950). Absence adds to the complexity and unpredictability of events by giving way to non-determination. Causal mechanisms might be present or absent, exercised or unexercised depending on where they are situated in space and time. As such, phenomena have the potential to express rather differently depending on the expression of their generative mechanisms at specific points in time or space. This 1M understanding of difference in terms of causal mechanisms, time and space operating collectively as a *tri-unity* is taken as a foundational building block for understanding change at 2E (Bhaskar, 2008b).

At 2E, however, this structural theory is extended to account for the dynamic nature of change. Here, a dynamic element is added to the tri-unity of causality, time and space, to conceptualise how they unfold collectively as a causal process. Causality at 2E goes beyond identifying how causal mechanisms manifest to make up a particular entity or situation. Instead, 2E examines how causal

mechanisms unfold and exercise their causal powers dynamically over time and space, in order to understand how things or situations develop and have come to be so. So, the tri-unity of causality, time and space is used at 1M to explain being – how things exist. At 2E, its use is extended to explain becoming – how things develop or unfold. As such, both 1M-being and 2E-becoming are grounded in this causality, time, and space tri-unity.

This mutual grounding is the foundation to understanding 2E in terms of *rhythmic* change. 1M-being and 2E-becoming have a dialectical relationship. They are bound together in the process of transformative negation as 'being becoming non-being'. That is, 'something becoming something it is not' or 'something becoming something different' or 'something becoming to be no more'. As such, 2E transformative negation represents the process of change in terms of rhythmics of (non-)being and becoming as shown in Figure 17. The mutual grounding of 1M-being and 2E-becoming allows them to be bound together as sequential elements forming a rhythmic. Rhythmics as such are ontological entities that explain change at 2E, defined as the alternate manifesting and unfolding of causality in time and space.

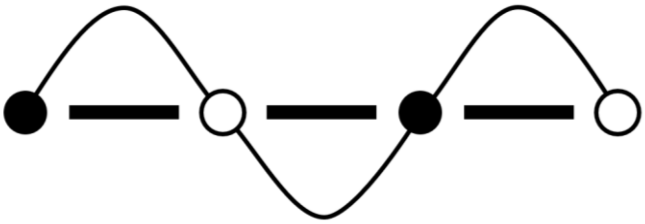


Figure 17. Rhythmic of being becoming non-being. A schematic representation of change as a rhythmic (symbolised as a wave) of (non-)being (symbolised as circles) and becoming (symbolised as lines).

Rhythmics, defined as the alternate manifesting and unfolding of causality in time and space, are emergent. In a rhythmic, causality, time and space are tightly connected and operate as a tri-unity. This connectedness gives rhythmics emergent properties. For instance, rhythmics have their own causal powers that cannot be reduced to our understanding of its parts (causality, time and space). By avoiding milk, for example, a teenager with cow's milk protein allergy might notice they're eating a lot of vegan-labelled food products and subsequently decide to commit to a fully vegan diet. To achieve this dietary commitment, they learn more about food and start creating healthier dietary habits, which positively effects their physical health. So, their allergy-influenced dietary developments – their dietary rhythmic – is having positive health effects. Nevertheless, these health effects cannot simply be explained by reducing their dietary rhythmic into its causal components: cow's milk allergy, milk avoidance, self-study, and a vegan diet. Instead, they emerge from their holistic unfolding.

Emergence also underpins why rhythmics can only unfold in one direction. In a 'being becoming non-being' rhythmic, the manifestation of causality, time and space at the first moment of being unfolds to become a different manifestation at a later moment. That is, the latter moment causally follows the first moment via the process of becoming. Since this process is emergent, the latter moment cannot be reduced back into the separate elements of causality, time and space and hence it cannot be reduced back into the first moment it developed from. As such, the process of change unfolds in one direction only and cannot be reversed. The present has emerged from the past, but the past cannot be recreated from the present. And while it is possible to learn from the past to influence the future, it is impossible to go back and change it. To illustrate this based on our earlier example: our teenager is currently eating a vegan diet with improved dietary habits. These present dietary developments were influenced by and emerged from their past dietary habits which involved the exclusion of milk to manage their cow's milk allergy. Since committing to a vegan diet, our teenager has learnt more about food which has contributed to their healthier dietary habits. This knowledge, however, can only be used moving forward and can't be used retrospectively to change their dietary habits before they were vegan. As such, it's not possible for them to go back and try different dietary changes that don't involve excluding all animal-products from their diet. They can only do so moving forwards experimenting with the re-introduction of different foods if they wish. As such, the child's past experiences influence their current actions, while their current actions cannot influence their past experiences. Their past experiences are fixed and referred to as their *geo-history*, which has emergent effects on their future development.

Change is contingent both on its geo-history and its position in time and space. The importance of where a change process or rhythmic is situated in time and space is the same as for any ontological entity. For example, the development of a child's allergy management strategies might have been different if they lived in an area without access to an allergy testing service, either due to long waiting lists or due the absence of such a service in their local area. Likewise, their allergy management strategies might have developed differently if they had visited their GP before 2004. In 2004, the Quality Outcomes Framework (QOF) was introduced in primary care as part of GP practice contracts. Seeing that the QOF was introduced to incentivise the delivery of high-quality asthma care, the care provided by the child's GP prior to 2004 might have been of lower quality. As such, causal processes have the potential not to unfold or to unfold differently depending on where the process is in time and space – equivalent to the potential of 1M phenomena to not manifest or manifest differently depending on time and space. Change is contingent in nature and has the potential to develop in many different ways. However, from all the potential change trajectories that could be, only one trajectory manifests or actualises in reality.

The potentiality or contingent nature of change allows for its course to be influenced by intentional and strategic actions. However, actions are also contingent on geo-history and their position in time and space. That is, an action is bounded in space and time – both in terms of its spatio-temporal context and in terms of the geo-historical path of the person or entity performing the action. That is, the geo-historical past of a person has brought them the skills and insights they have now and the spatio-temporal position they are in now bounds the range of possible and appropriate actions. Within this space of potential actions, strategic decisions can be made to influence a situation. Due to the nature of change, however, strategic actions might have unexpected effects and strategies might change over time or space. For instance, the allergic teenager from our example might decide to further improve their physical health by increasing their exercise level. However, increased exercise can unexpectedly trigger their asthma and make them feel unwell. Moving forward, they will have to take into consideration their exercise-induced asthma symptoms and the potential side effects of asthma medication to alleviate their exercise-induced breathlessness. Like any change, strategic change also emerges from its geo-historical past and depends on its location in time and space.

So, 2E of MELD dialectics is about understanding change as it presents itself in the real world. Negativity is the key principle underpinning 2E as it creates the potential for change and explains how change unfolds. Negativity as absence allows for the world to be incomplete, where entities do not exist, qualities did not manifest, powers are not exercised, and change has not occurred. The relationship between negativity as absence and positivity as presence brings about the potential for things to be or become different. It allows for a world where entities do not exist *here* (but do there), where qualities did not manifest *then* (but have manifested now), where powers are not exercised *in these conditions* (but were in those conditions) and where change has not occurred *yet* (but might in the future). The point of 2E in MELD dialectics is to take note of such changes and describe how it unfolds over time and space.

In Chapter 1, I discussed how causal mechanisms at the physical, inner-subjective, interpersonal and structural dimensions of reality create different expressions of children's allergy through their absence vis-à-vis presence. For example, when children with hay fever can access high-quality interpersonal care and medications that interact with their physiology appropriately, they might not experience any allergy symptoms when exposed to pollen. In Chapter 2, I discussed how the RCPCH care pathways address the chronic and multi-morbid nature of allergy and I demonstrated how the Itchy Sneezy Wheezy intervention aligned accordingly to the theoretical mechanisms of the Chronic Care Model. I also discussed how the NIHR CLAHRC NWL systematic approach, used to implement the Itchy Sneezy Wheezy intervention, consisted of a range of tools designed in accordance with

several quality improvement principles of action. In this Chapter, I will describe four case study narratives that ground the mechanisms and actions from Chapter 1 and 2 into empirical reality. In Chapter 5, I will unpack the case study narratives of this Chapter and demonstrate what mechanisms are present, which are absent, which additional mechanisms are present, and how these mechanisms unfold into four individual trajectories of children's allergy health service improvement.

4.3. Improvement journey A

4.3.1. Developing an integrated allergy improvement team

The improvement project studied in case study A officially started in October 2014. Nevertheless, the paediatricians working in the project's lead hospital had already started pre-existing plans to improve and integrate their local paediatric allergy services prior to the project starting. In 1999, the lead hospital merged with a nearby hospital to form an NHS Trust. As part of this merger, the delivery of paediatric inpatient care became concentrated in one hospital site – in lead hospital A. Consequently, the paediatricians formed an integrated team based at hospital A, while still delivering their outpatient services across sites (Merger business case). When asking what these outpatient services were like for children suffering from allergies, one of the paediatricians says:

> *"I think it was a service led by individuals with quite some expertise in the field. The weaker points, probably, it was little bit disjointed. Although saying that, it was the nature, these were different hospitals at the time, only bringing them together [with the merger]. It stayed separate for some time until we, we networked more within our department." (Clinical lead Site A, interview)*

The paediatricians delivering these allergy outpatient clinics all had a special clinical interest in allergy. Within allergy, however, they had complementary sub-specialties that aligned with their additional clinical interests – respiratory medicine, eczema, and gastroenterology respectively. The clinics they delivered had nurse support and were supported by the dietetics Department delivering separate allergy clinics for children who needed nutritional advice. As quoted above, the hospital-based allergy team slowly started to work more closely together after the hospital merger had led to the development of an integrated paediatric Department. This joint working generated several plans and ideas regarding the improvement of the health services they delivered to children with allergies.

Two of those health service improvement ideas had already been implemented prior to the 2014 improvement project (Clinical lead Site A, interview). The first improvement was the appointment of an asthma specialist nurse as part of the community nursing team in 2013. The community nursing team was based at the hospital as part of the hospital Trust, which allowed the nurse to

simultaneously join and support the hospital-based allergy team. In December 2013, the asthma specialist nurse started her own service delivering asthma clinics at the hospital and doing home visits in the community to support children who needed more intense asthma self-management support and a personal asthma action plan (Patient information leaflet, 2013). However, as part of the hospital Trust, she also did asthma reviews for children admitted to hospital. Moreover, the asthma specialist nurse joined forces with the respiratory consultant in a new multidisciplinary clinic. By collaborating, they were able to deliver a more comprehensive service with enhanced diagnostic testing, including skin prick testing, performed during clinic appointments. Moreover, by reviewing patients together, the nurse specialist was able to further develop her respiratory and allergy expertise. The second health service improvement was an asthma care pathway developed to improve and standardise the care for children presenting to the A&E Department with acute asthma or wheeze. While the need for an asthma care pathway in A&E had been identified many years ago, it was first implemented shortly after the appointment of the asthma specialist nurse in 2013. The main focus of the pathway was to standardise the urgent medical treatment delivered by different health professionals, and to increase the number and quality of comprehensive asthma reviews in line with the clinical guidance on managing asthma (BTS/SIGN guideline, 2012).

> *"We always felt that we had to streamline our approach locally, in A&E. It was very disjointed how we managed our wheezers. […] They came to A&E, were wheezy, were given a brand new inhaler and were sent out. And [then] they bounced back [to A&E]. So, there wasn't a comprehensive assessment and review [of] what went wrong and what brought them to A&E in the first place. And the second was that, when [wheezy children] came to A&E, their approach of treatment was very different from team member to team member. The nurses often said they didn't really know how to treat them, because everyone had their own idea. One was giving five puffs, the other one ten puffs, the other one nebulisers, the next one back to back, the other one stretched over four hours, and this and that. So, everyone had their own protocol in their head. […] Someone senior amongst the nursing staff mentioned it first and it was very helpful, because these, they see it every day. If I go to A&E, I only see it at the time I'm there, and then you, you leave again." (Clinical lead Site A, interview)*

During this time of health service improvement, the hospital team took a holistic approach recognising the importance of collaborating with community-based services to optimise the care for children with asthma and allergies. Accordingly, ideas to deliver consultant-led outreach clinics in GP practices had been on the agenda for years.

"So, I think the overall idea… It has always been done with some community registrars, where they did general clinics in GP land. And we had proposed that I would do it the same way, just for wheezers and respiratory [patients]. It must have been going back, I think, at least six or seven years" (Clinical lead Site A, interview)

To implement these and other ideas to improve asthma care delivered in GP practices, the hospital team started collaborating with the clinical lead of their local CCG, who also had a special clinical interest in asthma and respiratory medicine. Together, the CCG clinical lead, the respiratory consultant, and the asthma nurse specialist formed a strong clinical team. Nevertheless, they struggled to engage and motivate local decision makers.

"It was probably a year or two [before the 2014 improvement project, when we started working together]. We'd been meeting and getting nowhere, because we couldn't get cooperation from the CCG, asthma just wasn't on the agenda." (CCG clinical lead Site A, interview)

4.3.2. Adopting the Itchy Sneezy Wheezy intervention and implementation approach

At this point, the team became engaged with the Itchy Sneezy Wheezy project. As discussed, a team had developed at site A, who were improving local asthma and allergy services and who were working towards integrating primary and secondary care. As such, the Itchy Sneezy Wheezy project was introduced to a team working towards similar goals and motivated to implement similar health service structures. Moreover, the CCG clinical lead had already heard about the project at the 2013 British Society for Allergy & Clinical Immunology (BSACI) conference. However, it was a general paediatrician working at site A, who connected the Itchy Sneezy Wheezy team with the site A asthma and allergy team. More specifically, when asking both team leads how site A became committed to the Itchy Sneezy Wheezy project, they answered:

"This was really about my interaction with [one of the general paediatricians], because [he] was a member of the department as an academic himself. And so, talking to him about it, and him becoming engaged overall with [the quality improvement team], and seeing it as fitting with his agenda […]. He was able to convince his colleagues at [site A] that this is something worthwhile focusing on." (Clinical lead Itchy Sneezy Wheezy, interview)

"I think via [one of the general paediatricians], who felt it may be a route [for] trying to get these outreach clinics developed." (Clinical lead site A, interview)

This collaboration between the Itchy Sneezy Wheezy team and the asthma and allergy team at site A consequently resulted in the launch of improvement project A. In August 2014, both teams met and reached the agreement *"that [site A] would take the Itchy Sneezy Wheezy project on with [quality improvement] support"* (project meeting, minutes). Consequently, a launch event took place in October 2014, where quality improvement methods were used to empathise with the health service experiences of allergic children and to create a shared vision for the project (project meeting, workshop outcomes). Then, a stakeholder map was developed in November followed by a period of stakeholder engagement (project meeting, workshop outcomes). However, a project sustainability questionnaire filled out in January 2015, highlighted the team's concerns around the engagement of particular stakeholders and stakeholder groups. More specifically, they noted a lack of engagement from clinical commissioners and senior managers of provider organisations, and a need for recruitment due to a shortage of specialist nurses to deliver the intervention locally (project meeting, workshop outcomes).

> *"I think the issue that you had for [project A], at the beginning, was that there was lots of local, so there was lots of ground floor impetus [from clinicians]. But where it was lacking, was the links between the more, the operational team, so the actual operational team, and the executive team and then the external commissioning teams" (Hospital manager Site A, interview)*

4.3.3. Establishing financial incentives

What helped to engage these stakeholders was using the 2015 CQUIN scheme to legitimise the project. The CQUIN scheme is used by NHS England as a mechanism to achieve national quality standards in healthcare delivery. The scheme *"is to be offered by NHS commissioners to providers of healthcare services commissioned under an NHS Standard Contract"* (CQUIN guidance, 2015). As such, CQUINs are used in the contractual negotiations between commissioners and healthcare providers. Consequently, linking the Itchy Sneezy Wheezy intervention to CQUIN goals helped to gain interest from local commissioners and hospital management, and to motivate the project team.

> *"We had a very good quality lead here [who] had already been negotiating with the CCG's to improve the income of the hospital using a device called CQUIN. So, this was a quality measure which was quite rigorously constructed and was based on a reduction or a potential reduction in emergency admissions for children with asthma. And that device was used to support and incentivise the team going forward on the basis that this was worth nearly a million pounds in income […]. [T]he discussions had predated [project A], and Itchy Sneezy was seen as a mechanism to help to do that. […] Itchy Sneezy Wheezy was seen as a potential*

intervention that would be successful in reducing asthma admissions" (Paediatrician Site A, interview)

The scope of the 2015 CQUIN at site A was confirmed by May 2015 (project meeting, notes). Moreover, the plan to achieve the CQUIN comprised an interrelated web of intervention elements that contained – but wasn't limited to – the Itchy Sneezy Wheezy intervention. The implementation plan discussed during the team meeting in June, for example, comprised an extensive list of additional intervention elements and actions, including: the education of hospital and community staff; the development of a discharge care bundle; the delivery of asthma reviews after discharge; and the improvement of the referral pathways (project meeting, minutes). Over the next few months, these ideas started to become actualised. Clinic assessment forms were developed, the Itchy Sneezy Wheezy referral form was adapted, allergy education sessions targeting community healthcare professionals had started, and the asthma and wheeze care pathway for A&E was updated with a discharge checklist added (project meeting, notes; attached documents).

4.3.4. Improving the A&E asthma and wheeze care pathway

Besides the discharge checklist, a key revision to the A&E asthma and wheeze care pathway included a referral process for children at high risk of readmission. This involved a referral guideline, outlining key criteria to identify children who need a more specialist medical follow-up, accompanied by a referral form to the respiratory nurse. This process solved several interrelated issues. Firstly, the process identified and directed a patient group to be reviewed in the specialist community clinics that were being set-up as part of the Itchy Sneezy Wheezy intervention. Secondly, the process identified high-risk children and organised specialist care for them to reduce their risk of readmission, thereby directly contributing to a reduction of asthma admissions as part of the CQUIN. Thirdly, the process helped mitigate the issue that patients attending hospital for acute asthma were often not getting a GP review within 48 hours as prescribed in asthma management guidelines (BTS/SIGN guideline, 2014). The revised asthma and wheeze care pathway for A&E was approved by the relevant hospital committee in October 2015. However, its implementation already started during its development. In September, the asthma specialist nurse and respiratory consultant met up with the A&E team to discuss implementation strategies. Subsequently, the specialist nurse went to A&E to actively engage with the staff promoting the pathway and collecting feedback on its use. This was followed by an educational session to the A&E team on asthma management, inhaler technique and use of the updated care pathway, which then continued on a weekly basis. By the end of September, use of the care pathway had increased and referrals were coming in.

"With the clinical A&E pathway in use by the majority of staff, asthma referrals are coming in. At this point the team was expecting the ISW community clinics to be in place. Since, they are not, other strategies need to be considered for reviewing these children." (Specialist nurse site A, Project manager site A, and myself; project documents; PDSA cycle)

So, even though the team had made great progress in certain areas, the central idea of running asthma and allergy outreach clinics in community settings had not yet been realised.

"Talking about delivering education sessions, or team core engagement, A&E pathway development, establishing education within that… I would go for a very high [progress] score, because I think we're doing fantastically there. If we go for setting up a clinic then I'd go minus, minus 80." (Project manager site A, meeting transcript)

4.3.5. Resolving improvement obstacles

To understand the hold-up, the project manager resorted to quality improvement methods. Within the scope of one month, she organised three quality improvement sessions to progressively understand and resolve any issues and blockages. The first session involved process mapping and stakeholder mapping to understand the current situation and define a course of action. More specifically, the stakeholder map was made to clarify which stakeholders were already engaged in the project and in what capacity, and to identify which stakeholders were missing from the team and had to be engaged. The process mapping helped to create a:

"[b]etter understanding of the things that had to be done and by whom (everything seemed almost in place to get started with clinics, but there was an impasse. After using the method there was new energy). Also it became clear that different members of the team had different views on the aim and how to reach it (CQUIN focus on asthma and admissions vs allergy in general and community training). Based on the process map a compromise was reached. What next: See if agreed actions can now be put in place and [if] the proposed changes in the [current care] process (starting ISW clinics) [can be] made" (Project manager site A and myself; project documents; comments on QI use)

However, the understanding that resulted from the process mapping sessions didn't help to resolve key blockages. One of the key blockages was uncertainty around funding to deliver the project.

"Well, it's been the lack of clarity. I mean, from dietetics, we know what we want to do, which is provide a dietetic allergy clinic, to be up and running. But it's about how much money is going to be available, whether the money is going to be available. And even if it is available,

how we're going to get it. It's just all those types of things which, and it's been going on for so long that you get to a point of… Actually, we've got such a short period of time. How are we going to recruit the dietitian in such a short period of time? So it's those types of things." (Dietitian site A; meeting transcript)

Another major organisational issue was the access of administrative support to deliver the clinics.

"So, this was one of our biggest, biggest challenges and one of our biggest push backs in terms of the project. Because every single time we talked about the possibility of having or needing admin support, we were just told that it was not existent, and he wasn't there, and he wasn't available. And I think people kept giving us different messages as well. […] we kept being asked constantly 'what time it is, what day is the clinic going to be held, who's doing what, who's this, who's that, I don't understand the process, I don't understand when, who is going to see what, and' – Who was asking that? – The lead, so […] the admin manager. And again, as I said previously, I just think process maps are quite a visual easy way […] [to] reflect back and say 'this is what we need'." (Project manager site A, interview)

As such, the project manager organised a second process mapping session to map out the administrative processes and requirements for the project. She invited both the core project team and the service manager responsible for supporting the project. Process mapping was used as a tool to facilitate and structure the conversation and to have a clear visual output representing their shared understanding of the administrative support needed for hospital-based specialists to deliver asthma and allergy clinics in community settings. After this session the team received clearer answers as to what resources were available for administrative support, which led to a third process mapping session to update the clinic structure accordingly.

4.3.6. Increasing and innovating asthma and allergy clinics

While these organisational issues were being tackled, the team continued the project within their operational capacity. The team had to address the referrals coming in from the A&E asthma and wheeze pathway that were starting to build-up. Consequently, two clinics were set-up in October to ensure that these high-risk asthma patients were receiving the care they needed. Since the arrangement for the community-based allergy outreach clinics had not yet been completed, these clinics took shape as asthma review clinics delivered by two specialist nurses. One clinic was delivered by the asthma specialist nurse within the hospital. The other clinic was delivered in a community health centre by a newly appointed asthma nurse who was based there previously as part of her role in the school nursing team. To deliver these new clinics, however, the nurses had to

do their own administration. In November, the team again had to compromise on the idea of community-based allergy outreach clinics since administrative support had not yet been actualised. As such, the team decided to focus on increasing allergy expertise and capacity within the hospital rather than the community. Consequently, several clinic innovations were implemented. The first was a new allergy MDT clinic run by a paediatric registrar interested in developing his clinical interest in allergy, together with an allergy nurse and a paediatric dietitian who increased her work hours to deliver this clinic. This clinic was eventually taken over from the registrar by one of the paediatric consultants running allergy clinics. The second clinic innovation was a respiratory MDT clinic ran by the respiratory consultant together with the newly appointed asthma nurse. In this clinic, the nurse learnt how to perform and interpret skin prick tests, and she was further mentored to develop her respiratory and allergy expertise. Moreover, GPs and practice nurses were invited to join this hospital-based clinic to learn more about asthma and allergy management as an alternative to the outreach clinics. However, uptake of this offer was minimal.

Eventually, the team managed to attain administrative support, which allowed them to deliver a final clinic innovation. The process of attaining administrative support had required a lot of facilitation to overcome many types of blockages. Firstly, the project was made a management priority via the CQUIN and had to be communicated as such.

> *"what it also enabled us to do is, although there was a project manager […], it enabled me as the overseer of the CQUINs to help drive some of the processes that needed to be done, some of the engagement elements of the project that needed to be done internally, where some of the clinical team were not able to have those conversations. It's very difficult for a specialist nurse to have a conversation at a DGM [Divisional General Manager] level. […] whereas for me, as the leader for the CQUIN, I'm having those conversations all the time with different divisional general managers, different general managers. So, I was able to engage them and say 'this is funding that's coming to your division, a million pounds, and if you don't engage with it then you will not get that million pounds, and the executive team will be saying, well we lost a million pounds, what did you do about it?'" (Hospital manager Site A, interview)*

This process was especially difficult due to a lack of managerial capacity at the time. In 2010, plans for a new merger developed as a strategy to improve financial viability of the hospital and to improve the quality of care delivered to the local population. These plans resulted in the merger with another local NHS Trust in October 2014 – right during the implementation of improvement project A (Merger business plan; Merger public brochure). As such, management was preoccupied and very

busy. Moreover, there had been a lot of staff turnover within management with currently an interim service manager in place.

> *"at the time that the hospital was merging […], which was a really difficult time in terms of transition and organisational chaos with other priorities. This was a project to enhance quality that was perhaps not a major priority despite the facilitation, despite the incentivising of a CQUIN. It was almost insufficient, in its own right, to get enough management and service management capacity to actually prosecute what was needed to actually execute what was needed to get the project off the ground. […] So we had a lot of service manager gaps and turnover when, and discontinuity. […] It wasn't just at one level, it was at several levels that the turnover was taking place. So, decision making became extremely slow and budgetary issues and financial disagreements dominated the project considerably despite actually, really quite aggressive at times, project management. But it was insufficient. To get the issue high enough on the agenda and to get the actual operational issues in place was much harder than I think any of us expected." (Paediatrician site A, interview)*

Consequently, to get the administrative support in place required both engagement strategies and operational facilitation.

> *"[The service manager] was saying it's not a priority, I was saying it was a, is a priority. I was then escalating it to [the divisional general manager] who was saying 'just do it'. [The service manager] said it's not my priority and we went round in circles for a while. And then I said, 'OK, I will get the admin person'. […] Yeah, so, I had to get involved in that and put them there. They had to send their bank shifts to me and I had to put them on the [system]. […] The facilitation of it was overwhelming at times, it was very frustrating." (Hospital manager Site A, interview)*

The administrative support was in place by December with the improvement project coming to an end in March. As such, there were now time constraints that influenced the team's project decisions. Since there was not much time to re-engage primary care to co-deliver the Itchy Sneezy Wheezy community-based allergy outreach clinics, the team instead set-up an additional allergy MDT clinic in the hospital. This clinic ran from December until March by an external tertiary allergist, a dietitian and a nurse, and was designed to upskill the dietitian and nurse and increase their allergy expertise. Consequently, when the project finished in March, the dietitian was able to extend the respiratory MDT clinic by running an allergy clinic in parallel, leaving clinic slots open to give dietetic advice to food allergy patients from the respiratory clinic. By this time, the respiratory nurse had also developed her allergy expertise, which meant the respiratory MDT clinic was now operating as a one-

stop shop where children's asthma and any allergic comorbidities were managed holistically. The project developments and adaptations were consolidated when the final allergy MDT clinic was set-up in December. The consolidation was done using process mapping and the action effect method. In a process mapping session, the project manager and I updated the last process map made by the team to reflect the process and clinic innovations that had now been implemented. As such, we used process mapping to compare how the team had initially outlined and envisioned the project with how the team had actually changed the healthcare processes and clinic structure. Moreover, we updated the team's Action Effect Diagram based on a team meeting discussion focused on:

> *"Reframing expectations: What do we want from this project? […] Team revisited Action Effect Diagram to re-define project aim and required interventions to attain this until the end of March 2016." (Project documents; meeting minutes)*

4.3.7. Continuing the improvement initiative

After the improvement project officially ended in March 2016, the team continued to innovate their local asthma and allergy health services. Despite project delays and necessary adaptations, the reductions in asthma admissions outlined as part of the CQUIN were achieved. Within the existing local financial landscape, however, this unfortunately wasn't sufficient to achieve further investments in the project.

> *"So, as part of the project, if you remember, we put, we used some money from the [external quality improvement] funding to do a proof of concept. And that worked really well in terms of giving them proof of concept. However, the [CCG] didn't invest. Although we gave them the evidence they didn't invest." (Hospital manager Site A, interview)*

> *"Both organisations were in deficit, our own hospital [and the CCG] […]. So, this gave a macro environment which was extremely difficult to try and innovate. Despite potential savings, people were not willing to invest to save, and that's what you need for a… Any innovation like this needs investment in the team, the transformation, and investment in order to save longer term, and nobody was thinking longer term." (Paediatrician Site A, interview)*

When funding requests weren't reciprocated with enthusiasm, the team quickly decided to continue innovating their local asthma and allergy health services within their own capacity – as they had done during the improvement project.

> *"It's not strictly as a business case, because we just went ahead and changed things. Because going through a business case is, and all the other things… We usually find, as you know,*

nothing is moving forward. And we just adapted our, the way we are working." (Clinical lead site A, interview)

So, the team decided to continue improving their local allergy health services. The first innovation was an extension of the newly implemented allergy MDT clinic by scheduling two additional allergy clinics and one additional dietetic allergy clinic all at the same time in the same hospital Department. Aligning all clinics involved some changes in clinic scheduling. For one paediatrician, it also involved some changes in the composition of the clinical activities that make-up his job plan. The full MDT clinic model was implemented by April 2017.

"So, we have three people. There's [paediatrician 1], allergy and gut related; [paediatrician 2], allergy and eczema and skin related; and me, allergy and respiratory related. [We run the MDT model] together with one or two dieticians, which were already allocated to the Monday afternoon at [paediatrician 1's] allergy clinic, and [with] a skin prick testing nurse, who was already allocated. That's why we chose the Monday afternoon in the end. And [the respiratory nurse] is now coming on board [as well]" (Clinical lead site A, interview)

The second innovation that was implemented, was a lunchtime MDT meeting, taking place before the big allergy MDT clinic. During this meeting, the allergy team comes together to discuss difficult clinical cases, to standardise their clinical approach, and to discuss operational issues related to clinical governance and the implementation of health service improvements.

"Any cases can be brought to the MDT, so individual cases or general questions. So, I think one of them was about EpiPens, and should every child have an EpiPen that has a nut allergy, for instance. […] So, [on of the paediatricians] actually went and said, 'I've researched into this a lot now and I've got a presentation that I'm going to give'. And he then presented it to us, not as a presentation, but we discussed it. And it, it then made [us change our allergy] management [approach]." (Specialist nurse site A, interview)

Besides these health service innovations, the team continued to create learning opportunities for different healthcare professionals. For example, they delivered asthma and allergy sessions on GP training days or the hospital grand round. Furthermore, when the asthma and wheeze care pathway for A&E was updated again in October 2017, this was again followed by asthma and allergy training in A&E.

"Yeah, we are reviewing it. This [asthma and wheeze care pathways] is now version four. And I'm about to relaunch version four, and with that we will roll out the teaching and training again." (Clinical lead site A, interview)

Finally, the team participated in the establishment of a regional allergy network which aimed to bring together regional healthcare professionals interested in paediatric allergy working across community, primary, secondary and tertiary healthcare settings. The first network meeting took place in May 2016 after which is was organised every three months.

> *"I think these network meetings are very helpful, a) to see the other paediatricians and their experience – what they do and how they tackle the problem. And again, streamlining. Then we do these similar things, [the] same things, across the sector. And that's where we would benefit from the tertiary input. […] [So] that, when patients come to us as well, they also have the confidence it's something in alignment with the big centres" (Clinical lead site A, interview)*

4.3.8. Summary

Team A had been working to develop their paediatric team and their local asthma services prior to the children's allergy improvement project. As a next step, they had wanted to implement asthma outreach clinics, but struggled to get the financial support from local commissioners. The Itchy Sneezy Wheezy intervention provided an opportunity to re-engage with these plans. Members of the Itchy Sneezy Wheezy team offered advisory support and a partnership opportunity with an external QI organisation who provided a small budget and a project manager.

Implementation of the Itchy Sneezy Wheezy intervention was agreed as part of local funding negotiations as a means to achieve a reduction in asthma admissions. However, the team struggled to get the appropriate operational sign-offs to realise the intervention. To be able to achieve the reduction in asthma admissions, team A continued developing the work they started prior to the improvement project. Moreover, they explored what elements of the Itch Sneezy Wheezy intervention could be delivered within their personal sphere of influence and which elements had to be abandoned.

Throughout the project, quality improvement methods were used to facilitate team discussions. As such, they were used by team A to investigate project barriers and to agree team decisions on intervention adaptations.

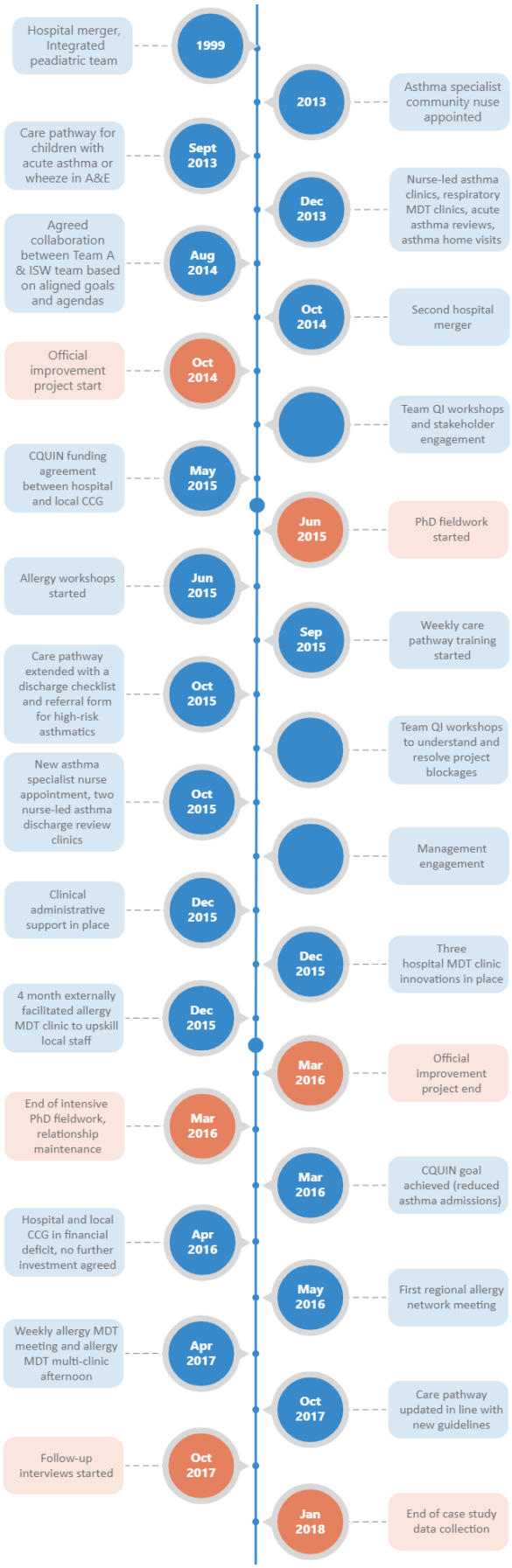


Figure 18. Timeline case study A.

4.4. Improvement journey B

4.4.1. The coming together of a team and a project

The improvement project studied in case study B started in February 2015. As part of their dissemination strategy, the Itchy Sneezy Wheezy team invited a respiratory paediatrician and a commissioner working in site B to attend a meeting of another improvement project team they were working with in their attempts to spread the Itchy Sneezy Wheezy intervention. Both the paediatrician and the commissioner had working relationships with the Itchy Sneezy Wheezy team, which supported their engagement. Their introduction at this meeting formed the start of improvement project B.

> *"I was invited, I think by [the Itchy Sneezy Wheezy clinical lead], and attended a meeting in January […]. And also at that meeting was a commissioner for [our site B] services […]. So, the two of us met at that meeting and that was the very first start of it. […] [Then] we had a number of meetings and exchanged ideas and thought about how we could implement it at [site B]. […] I guess we saw it as an opportunity to develop the services at [site B]." (Clinical lead site B, interview)*

> *"I had heard of Itchy Sneezy Wheezy before. I had an idea of what they were doing through [the QI organisation], through the, basically, so through their collaborative events, because I'd attended quite a few of those. So, I had an idea of what the process was like and what, what the improvements would be like. From a, I wasn't really thinking about it from a CCG perspective, I have to say. So, when I said, when I first spoke to [the respiratory paediatrician] I was thinking 'yes, this is a really good thing to do for the patients'. Obviously, then what came later in a way is, trying to think how does [this align with CCG priorities]." (Commissioner site B, interview)*

What followed was a launch meeting and the development of project plans. The launch meeting involved a presentation from an external quality improvement organisation about running improvement projects. They also facilitated a workshop, where the team agreed a shared aim and developed an initial intervention plan to achieve that aim. The workshop discussions were consolidated by the quality improvement organisation and fed back to the team in an Action Effect Diagram (project meeting, presentation). What followed were discussions on setting up financial and governance structures for the project. The commissioner attending these meetings and discussions was project manager within the CCG for the QIPP (Quality, Innovation, Productivity and Prevention) programme. The QIPP programme was developed by the Department of Health to encourage the NHS to meet the challenge of improving healthcare quality while also making efficiency savings by

implementing transformational changes in the healthcare system (Royal College of Nursing, 2012). At the time these project discussions were taking place, the commissioner was already working on improving adult respiratory services within the QIPP long-term conditions work stream. Consequently, she could readily identify how the Itchy Sneezy Wheezy intervention could also be financially supported as part of the QIPP scheme.

> *"So, basically the idea [of QIPP] is to redesign services, improve quality, but also to reduce the spend from a CCG perspective. So, looking at things like reducing admissions […]. [I]t's an investment to improve quality, but also to save money in the long run. […] So, [for Itchy Sneezy Wheezy,] when you're moving patient activity out into the community, there's always a benefit of obviously reducing the outpatient costs for the CCG. And also, you're always improving quality in terms of moving patients closer to home. And obviously, […] if you're upskilling the GP, even if you're spending more money in the short term, in the long term […] patients can be seen in the right setting, basically. Ideally within the GP practices rather than all going into secondary care." (Commissioner site B, interview)*

4.4.2. Developing the business case

After having identified the alignments between the Itchy Sneezy Wheezy intervention and the CCG structures and priorities, the commissioner took the lead on developing a business case to get the improvement project funded as a pilot project to improve paediatric asthma services. The first important element of the business case was to make the case for efficiency and cost savings, which was done by modelling patient activity.

> *"So, the specialists there actually went through the patient list. And they identified patients that they felt could be seen within the community, because they weren't complex. […] And obviously from my perspective, it was quite easy to calculate in terms of how much money you would save. In secondary care we pay for each outpatient's point, whereas the [pilot project's] service was actually funded on a sessional basis. So, we just funded the nurse's time and the doctor's time." (Commissioner site B, interview)*

Moving patients with easy to manage asthma from secondary care clinics to community clinics, however, meant the hospital would see a reduction in patient activity. Since hospital income is activity-based, this would mean the hospital would lose income by participating in the improvement project. Fortunately, the commissioner was able to effectively collaborate with the hospital managers. Because the hospital at site B was working towards expanding some of their specialist services, they were willing and able to participate in the project despite expecting a financial loss.

"So, even though they lost income from some of the asthma patients, they actually were looking at repatriating some cystic fibrosis patients, I believe. But so, they were looking to increase their NHS England income, their specialist service income. So, it made sense for them as well [to participate]" (Commissioner site B, interview)

The second element of the business case involved making the case for quality and healthcare improvements, which was done based on the publication of the London Asthma Standards. While team B was developing a business case for their improvement project, Healthy London Partnership (HLP) was developing the London Asthma Standards. HLP, as a partnership of health and government organisations in London, was established in 2015 to respond to the 'NHS Five Year Forward View' and the 'Better Health for London' reports (NHS England & partners, 2014; London Health Commission, 2014). Its aim was to improve the health of people living in London, with one specific work stream focusing on improving children and young people's asthma (HLP, 2020). As part of this work stream the London Asthma Standards were developed, which outlined standards for the quality of care that asthmatic children living in London should expect. These standards described ambitions for asthma care in London as a means to facilitate the implementation of clinical guidelines (Children and Young People's Strategic Clinical Network, 2015). While developing their business case, a draft of the London Asthma Standards was shared with members of team B with the announcement that a final version would be published soon. Consequently, team B acted proactively, embedding the London Asthma Standards in their improvement project, and using implementation of the standards to support their case for quality improvement.

"[The] London Asthma Standards came out, and I think that was really good timing for us. The two things happened at just the right time, [HLP] and clear standards for London. And that was very helpful. So, I think they're, in terms of the standard setting, it gave us a real… That was our real opportunity to push through getting two nurses in place. […] [B]ecause it meant that we could make a case based on meeting quality standards, not just on health economics." (Clinical lead site B, interview)

4.4.3. Starting asthma clinics in the community

The business case for improvement project B was accepted by their local CCG in June 2015, with the London Asthma Standards published in July. The project started with the relocation of two hospital-based asthma clinics to primary care practices and the appointment of a new nurse. The two practices were selected based on the geographical analysis of paediatric asthma hospital admissions and A&E attendances, with the clinics eventually being delivered by the new nurse. Initially, though, the nurse had to go through a phase of specialist asthma training, studying for her asthma diploma

and being mentored by the two senior specialist nurses learning the practical skills of reviewing and managing children's asthma.

> *"A lot of it was just observing, so sitting in clinics with the other nurses or consultant-led clinics. They also, quite quickly I was put on the asthma diploma course. So, that really helped understand it a bit more in-depth, and then more for the pathophysiology side and the medications. And then going into clinics watching, observing and seeing the common problems that arise in clinics and how to deal with them and, yeah. So basically, most of it has been through the support of the team in training me up really. (Specialist nurse site B, interview)*

4.4.4. Adopting an external project management approach

From August, when the clinics were up and running, the team started to focus more on project management to sustain and expand the improvement project. For this, the team was supported by an external quality improvement organisation. As part of the support, the organisation appointed an external project manager to support the new respiratory nurse in developing her skills on managing quality improvement projects. Moreover, the external quality improvement organisation introduced the team to several quality improvement tools, set-up a project governance structure, and facilitated peer collaboration.

> *"[The external quality improvement manager] and Sophie S [me] attended the [site B] project team meeting in August when process measures, patient experience data, stakeholder events and forthcoming advanced asthma training sessions were discussed. The [site B] project team were informed of recruitment of [an external] project manager who would coordinate scale up and rollout. [The external data analyst] confirmed his communication with [the clinical lead of team B] re: measures in terms of suitability, practicality of recording in clinics and transfer of data" (Project meeting, minutes)*

In the following months, these tools and processes were implemented. Developments in clinic attendance, referrals, and other clinic data were recorded in a project spreadsheet, which was used both for internal team discussions and to get input and ideas from external stakeholders (Project documents, meeting minutes). Plan Do Study Act (PDSA) cycles were used to discuss and record the strategies subsequently used by the respiratory nurse project manager to increase clinic referrals, to reduce the number of patients not attending their clinic appointment, and to advertise their community clinics and other opportunities for asthma training to GPs, practice nurses, school nurses and health visitors. A focus group was organised in October to get input from a group of teenagers

on their experiences with the community clinics and their ideas about the local asthma services more generally. Subsequently, in November, the team organised a process mapping workshop with local stakeholders, including school nurses and hospital staff, to *"understand exactly what was going on in terms of flow of patients through the system" (Clinical lead site B, interview)*. The pathway that was developed during the workshop and subsequently refined helped the team understand patient referral pathways and to identify where there were opportunities to increase referrals to the community clinics. For example, the team identified a lack of referrals from UCC which was followed-up by pro-active engagement of the UCC team. Moreover, the team identified the possibility for school welfare assistants and school nurses to refer directly into the community clinic rather than having to suggest pupils get a GP referral. This possibility was then picked-up in discussions with school nurses.

4.4.5. Identifying children with poorly controlled asthma in schools

These different project management strategies supported the development of a new intervention component in schools. Already from the beginning of improvement project B, schools were identified as an important opportunity for intervention.

> *"So [initially], I spent some time picking the brains of the [senior] nurse specialist over there to understand what she felt the gaps were [in their local service]. And one of the things she mentioned was actually the link between the two, […] between the school and the clinic. So, I am getting, making sure […] they could improve that part, that side of things. […] [Because] yes exactly, [that's] covered in the asthma standards." (Commissioner site B, interview)*

Other stakeholder groups confirmed that schools formed an important opportunity to further improve the care for children with asthma in site B. For example, findings from the patient focus group confirmed that schools were perceived as a priority area for intervention by teenagers (Project documents, Focus group report). Moreover, the school nurses and welfare assistants invited to the November process mapping session also highlighted there was room for improvement in the current processes in place in schools to support children with asthma.

Subsequent engagement with the school staff and school nurses led to the development and implementation of a monthly school audit to identify children with uncontrolled asthma. This intervention was the amalgamation of several ideas and developments. For example, the hospital-based specialist nurses in site B had already been involved in the development of asthma management strategies in schools for many years.

"Historically it goes back to a very long time ago. A very long time ago, probably, oh dear, 15 plus years. Because we had a girl who had really severe asthma, who used to suddenly become symptomatic and you needed to treat her very swiftly. And that really kick-started the school asthma programme. And it's changed over time, just in terms of who's doing the supporting and delivering. Because we used to do it all from here, from the acute Trust. We had three nurses who worked four hours, term-time only, and we managed to cover 101 schools. But we've now moved that out into the school nursing teams, and they're commissioned to provide that service. And within each school nursing team, there is one nurse who has got the diploma in asthma care." (Specialist nurse site B, interview)

Moreover, when the hospital team and the school team discussed the school processes in place to support children with asthma, they identified the potential to make the process more systematic and streamlined. The identification of children with poorly controlled asthma was done currently by welfare assistant based on their personal risk assessment. The welfare assistants, who assist teachers attend to the welfare needs of children at school, would then liaise with the school nurses to support the child with their asthma management. However, when the school nurses identified the child needed some more specialist support, the child had to enter the health system via their GP.

"We do a lot of work in schools with welfares, supporting them. Saying to them: if a child comes in looking for his inhaler, has his inhaler, [and] then within four hours he's back – that's telling us that he's not very well controlled. Let us know. That's what, then we would see the child. We might liaise with parents to get him seen. We might check [inhaler] technique. We might do the basic things. And then we would, if it didn't, if they weren't going to go to their GP, or if we didn't feel the GP was managing the asthma well, we would refer to the hospital." (School nurse site B, interview)

To improve this system, team B developed a monthly audit form supporting welfare assistants to identify students with poorly controlled asthma more systematically.

"There's a monthly form that the welfares fill out. That looks at who came in looking for their inhaler. If they've been looking for their inhaler two or three times a week, longer than two weeks, then they put it on the form. If they've had time off school they put it on the form. Now, the welfares should tell us anyway, but what happens is, that doesn't always happen. We've been encouraging them, tell us, put it on the form. That goes back then to [the specialist respiratory nurse]. Then what they can look, which has really been great, is that they look then over time. Because the welfare might think: oh yes, you know, he comes in now and again, he's not too bad. But when you look over time, you say yes, hold on, for three

months he's been coming in, or for two months he's been coming in. It's been really, yes. So, it helps us to see a bigger picture. Then what happens is, the hospital staff, like [the specialist respiratory nurse], would highlight this to the school nurse. Then we would go in and see the child, or we might just talk to the parents, or depending on what the issues are." (School nurse site B, interview)

Moreover, the team made some changes to make it easier for children with problematic asthma to access specialist support. Firstly, the respiratory nurse had become more accessible to the school nurses and welfare assistants for informal support and advice on managing a particular student. Although the relationship between the hospital-based nursing team and the school nurses had always been good, engagement in improvement project B had brought them even closer. Moreover, the monthly asthma audit form was reviewed by the respiratory nurse who would reach out pro-actively to the school nurses to discuss children she had identified through the form as likely having uncontrolled asthma. This again, was an opportunity for the school nurses to discuss these and other cases and get some specialist input. Moreover, team B had made their community asthma clinics accessible by agreeing with their CCG GP lead that school nurses and welfare assistants could refer directly into the clinic by-passing the child's GP if they saw fit.

"Once they've got the outreach clinic, once that was opened, we, it just, we can refer into that clinic all the time. We could always refer into the hospital anyway, but I think it's just made it a lot easier, because they don't have to wait long for an appointment. Everything, communication, is much, is really good." (School nurse site B, interview)

The development and implementation of the monthly asthma audit form was led by the respiratory nurse managing the project. After deciding with the hospital team which risk factors to capture in the asthma audit form, the specialist nurse developed and posted the form and a cover letter in January to 22 schools. She then followed-up by phone to answer any questions and resolve any issues. By the end of February 2016, 13 schools had submitted the audits with the remaining schools verbally agreeing they will submit their forms in the next month (Project documents, PDSA).

4.4.6. Developing care pathways for better regional asthma services

By March 2016 improvement project B had officially ended. Based on its success, however, the CCG decided to continue the project for another year. Improvement project B had delivered its goals as outlined in the QIPP business case. Children were receiving the same high-quality asthma care in the community as they were in the hospital, but at a lower cost. This was measured by collecting the healthcare activities delivered during each patient consultation. Training was delivered to different

types of healthcare professionals to improve asthma care across the board. And patients were exceedingly positive about the community asthma clinics.

> *"[L]ooking at how many patients went through, there was actually quite a saving. So, we would have paid a lot more if they had gone to secondary care. But financially it was quite successful. From a quality perspective, I believe we used the guidelines. So, I think one of the key things was that we were delivering the RCPCH guidelines. Although, frankly, we're doing that in the hospital as well. I think the other thing we used was the patient satisfaction [questionnaires]. So, it was quite simply just asking the patients whether they felt the clinic was the same, better, or worse in terms of their patient experience. And I believe about 70 something percent said it was better. And some of them obviously said it was the same or worse. And I think those, there were only a couple that said it was worse." (Commissioner site B, interview)*

Consequently, the CCG supported the project to continue. They both supported the team to continue the community clinics and the asthma training, and they supported the development of an asthma pathway as a means to further implement the London Asthma Standards in their local area.

> *"Commissioning Intentions for Respiratory Diseases aim to […] upscale[e] the model developed for paediatrics (asthma). […] Paediatric Asthma: The London Strategic Clinical Network for Children and Young People has recently developed a number of Asthma Standards for Children and Young People. The Standards set out 37 Quality statements that specify how RCPCH, BTS/SIGN and NICE Asthma Guidelines should be implemented into tangible services on the ground. Asthma and allergy frequently coexist, so an asthma and allergy pathway reinforces the concept of a whole airway approach for effective patient diagnosis, management and education, e.g. shared allergic triggers, inter-related symptoms and treatments. This model is deemed particularly relevant to [site B] where there is a large number of paediatric A&E attendances for respiratory disease in children aged 0-5." (Project documents, commissioning intentions)*

The development of the asthma pathway built on the process mapping workshop done during the pilot project in November 2015. These maps were taken as a representation of the local asthma services as they existed for children in site B at the time. Team B then added the community asthma clinics and its multiple referral pathways into the process maps, with all referral pathways having a box of referral criteria linked to them. The team also integrated the London Asthma Standards into these pathways, thereby designing a future ambition for their local asthma services.

"So, that started with the process map, looking at what the service was at the time. Then [we were] able to look at areas for improvement, and we based it around the London Asthma Standards. So, pretty much the, what they expect for a gold service in London, what the ambition would be. And [we] put that all together basically, and then put it, divide it, into each department. So, your inpatients, the community, primary care, school and, but [we] had agreement, so we also involved -- Yeah, so, the school nurse one, that would be… We all agreed that with the school nurses, what they thought would work best, or come to an agreement. And [that] then was agreed by the CCG." (Specialist nurse site B, interview)

After the pathways were agreed, the team set up a clinical network for local partners to work towards asthma friendly services across the borough. The network was set-up and structured as part of the ongoing collaboration between team B and their local CCG. Initially, they worked to develop a new business case to *"rollout [the] paediatric asthma programme"* (Project documents, Commissioning intentions). In May 2017, the business case for a children's asthma service was accepted. The business case outlined a set of Key Performance Indicators (KPIs) that were derived from the asthma pathways and agreed by the local network to assess progress on achieving asthma friendly services. Accordingly, the network organised quarterly meetings as a governance structure to ensure progress towards implementation of the asthma was being made.

"Technically, it's a business meeting which, because we have to report quarterly to the CCG for our key performance indicators. And so, there's a governance structure in place, and that's the purpose of that meeting. And it's to share good practice amongst the borough." (Clinical lead site B, interview)

The meetings brought together people from several health service providers to discuss implementation of the asthma pathways and any other business relevant to children's asthma care.

"So, [attending the network meeting] is the team here. There is the GP lead, although that post at the moment is vacant. Then, we've got two parents who are part of that group, the school nursing team, health visitor. There's a paediatric nurse within the community who runs a clinic within a GP surgery. She's part of that meeting, plus our two consultants here. So, at those quarterly meetings we discuss and report back on the KPIs; discussions about what things are happening; what new things will be, are in the planning stages; and about some of the focus group work that's gone on, because that actually influences, quite significantly, a lot of what we do – what families want rather than what we want, or we think's best." (Specialist nurse site B, interview)

4.4.7. Implementing asthma friendly services

The work done to achieve asthma friendly services covered several different work streams. The first work stream involved team B working on their own hospital services by improving the asthma reviews that children attending the hospital with asthma or wheeze should receive before being discharged. Doing a structured asthma review before discharge was one of the London Asthma Standards integrated into the site B asthma pathways. The new respiratory nurse had created additional clinical capacity in team B, so they had more availability to assess and review children being admitted to the inpatients Department. As such, they managed to increase the number of structured reviews given before discharge by 31% between September 2015 and March 2017 (Project documents, presentation). To further improve the asthma reviews done before discharge, the team shifted their focus to A&E, where they themselves could often not be present. The existing A&E process in site B involved a paediatrics booklet that doctors had to fill-out for each child attending A&E. The booklet sign-posted to an asthma review pro-forma, which had to be grabbed from a drawer and filled-out separately when children presented with asthma or wheeze. To streamline this process and improve the asthma reviews done in A&E, the team integrated the pro-forma into booklet. The new version of the paediatrics A&E booklet was introduced in September 2017.

> *"Now we've got a pro-forma that's been incorporated in the paediatric booklets. So, any child that comes through the hospital in A&E, PAU or the ward, there's a, we've made a pro-forma that should be now filled in by everyone. So, it gives them a structured review, and also recognises, helps recognise whether this child should be flagged up to us and referred to us. So, it's not so bad if it's PAU or [the inpatient ward], because we'll pick it up anyway, but the ones in A&E can be an issue. But this way, they're able to identify 'oh actually, this patient's had a, quite a few admissions or life threatening episode [and] needs to be seen'. So, there's ways that we've worked around it to help that yeah." (Specialist nurse site B, interview)*

To encourage its use, training was delivered to all A&E staff, they also received a presentation on its use, new doctors were trained as part of their induction, and clinicians were reminded informally to fill-out the pro-forma. In November 2017, however, the process was again updated. The respiratory consultant wanted to streamline the process as much as possible, so the A&E staff were encouraged to fill-in the right paperwork by design rather than through constant reminders. Accordingly, a peer respiratory consultant had shared an integrated asthma pro-forma that was used in his hospital. Consequently, team B conformed to a fully integrated pro-forma writing a second A&E booklet, one to be used for general paediatrics and one for children with asthma or wheeze.

> *"Well, I think it's part of my role to train, but I don't think it's part of my, I'd rather not spend my time just going on and on and on about you need to fill in this box. Because I think people just look at you and think you're a pedant. And I can see that really, I'd much rather be talking about asthma and what it means and what's the right way to approach children with asthma, than saying look, you haven't filled in box six. Because then people just get a bit like, it's just a tick box. And so, I'd rather, I want to have just a streamlined pro-forma. (Clinical lead site B, interview)*

The second work stream involved further developing the community asthma service. As part of the business case the number of community asthma clinics was increased from two to four to cover all geographical areas in the borough. These clinics were funded by the CCG and accessible to the children living in their borough. However, not all children attending the hospital at site B were living in this CCG area. Consequently, one additional asthma clinic remained based at the hospital to ensure all children attending the hospital had access to a high-quality asthma follow-up if needed. To deliver the additional community clinics, a new nurse and a secretary were appointed. The secretary, who started in August 2017, was able to relieve the nurses from the administrative work they had been taking on to deliver the community clinics. The new nurse went through a similar training programme the respiratory nurse had been through, thereby increasing the local clinical respiratory capacity. By August 2017, the newly appointed nurse just started her asthma diploma course, while the previously appointed nurse had by then finished her prescribing and her allergy course. Moreover, the new nurse was able to share the workload in team B, which allowed the team to invest more time in other tasks, including the structured inpatient asthma reviews, training of healthcare professionals, and data collection.

Data collection had been an integral part of improvement project B. In 2017, team B further expanded their information system to identify hospital patients at high risk of being re-admitted, who needed a referral to the community asthma clinics. The detection and follow-up of high-risk patients was a strategy to prevent future admissions in line with the business case goals. The system to identify children at high-risk of readmission was put in place by the respiratory nurse.

> *"So, [at the inpatient ward it] was a lot easier to review them and decide whether they needed to come into clinic or not, whereas as [the short-stay Paediatric Assessment Unit] PAU is a bit trickier. Because they might come out of hours, [and] by the time we come in the next day [to review them], they're gone. But now we've got a system in place where we've got, we'd go up there every day [and] check their book. So, we will have a log book of every child that's been admitted up there. We've got a new data spreadsheet where every child that*

attends, that is admitted, so in PAU or [the inpatient ward], it goes onto our spreadsheet, and we look at their previous admissions. We look at how many times they've come in in the last twelve months, and then overall since day of birth [how often] they've come in with wheeze. And then it's helping us flag patients up. So, if they've come in a couple of times, then we'll probably have a, have them into our clinic, see them, and then hopefully discharge them back to their GP. So, it's quite a good service." (Specialist nurse site B, interview)

A third work stream to achieve asthma friendly services across the borough was the collaboration with schools and GP practices to achieve asthma friendly status. In collaboration with school nurses, welfare assistants and GPs, and based on the London Asthma Standards, team B had defined a set of standards that described an 'asthma friendly school' and an 'asthma friendly practice'. These standards were included in the asthma pathways and used to define the KPIs of the commissioned asthma service. The work to achieve these standards started with the schools. Collaboration between the school and the hospital team had already been established many years ago and intensified during the improvement project that started in 2015. Moreover, the school nursing team had already done a lot of work over the years to put structures in place to support asthmatic children in schools.

"This academic year we have been working on [the asthma friendly school programme]. It's through the hospital. They spoke to us and said that this is what would be really good. To be honest, I truly feel that work was already going on. For us, it hasn't been very difficult. Because we already done an annual audit of the management of asthma in schools, so we've only had to put two more questions in there. […] Over the last couple of years, we have been pushing for the schools to get the emergency packs, with the inhalers in. A lot of schools, it just, when you're implementing a change it does take time. I think the first year it was a few, then gradually, gradually it's not something you could just sweep in. I think with the asthma friendly school system, they have to have that, as part of that. I think that has been something that, because it means money, it can be a challenge. But we are definitely getting there. […] [And] we had already got to a point where 99% of schools had training. We'd already, so that's why it's kind of made it quite easy." (School nurse site B, interview)

The work to achieve asthma friendly schools was led by the school nursing team. However, as part of the clinical network they collaborated with the hospital team to help all schools make further improvements to achieve asthma friendly status. For example, they identified that the school nursing team was only commissioned by the local authority to deliver asthma and allergy training to public schools. Consequently, the hospital-team stepped in to deliver training for private schools to ensure

equity. By 2018, the work to support GP practices achieve asthma friendly status was next on the agenda. This work had been slow to get off the ground due to difficulties the hospital team experienced engaging local GPs. However, with support from the CCG the team had started to gain more access to GPs and practice nurses for training, which hopefully will lead to closer relationships and more collaboration on improving local asthma services.

> *"Hopefully, [the asthma friendly practice] will encourage them a bit more, and give them more of an incentive to come and join. The other day I'd done a workshops for parents within a GP practice, which was really good. And I think that's with the help of the CCG. So, I think we're going to definitely be pushing that more as well. I think the main thing for us that worked probably better was going to the GPs themselves and doing a session for, I don't know 45 minutes, or however long they had. Where they, I could get them all together, me and [the respiratory consultant] went to quite a few of those, with the practice nurses and the GPs and we'd do training, that way, rather than them coming to sit in our clinics. I think that probably worked better, and then just having access to their forums, so [the respiratory consultant] and [the specialist allergy nurse] are going to a forum, a practice nurse and GP forum. There's quite a few which the CCG are helping them come to and present." (Specialist nurse site B, interview)*

4.4.8. Integrating allergy into children's asthma services

Moreover, now that the asthma services had reached a level of maturity, the team also started work explicitly focused on improving allergy care. The team had always considered allergies when looking after children with asthma. However, they took an incremental approach to improving their local services, starting with asthma before moving explicitly to allergies. A key reason was that the improvement project was led by the respiratory consultant who didn't want to step into the territory of his colleague allergy consultants without their involvement and agreement. Moreover, he wanted to take a developmental approach, slowly growing the team to increase the capacity to deliver high-quality allergy care. This approach involved training up nurses to manage asthma before they were further trained to manage the whole spectrum of allergic conditions. Accordingly, the respiratory nurse finished her allergy course in August 2017, with a similar training trajectory planned for the other nurse.

> *"The unit of person who's delivering the service is a nurse right? So, to get someone come in and work as an allergy and asthma nurse, where are you going to find them? They don't, they're all, those people are like band eights. […] OK, so the fact that I can name them, there's not many of them. Whereas, if you say OK actually, you're going to start with someone who is*

going to come in and [be] trained on asthma. And then in the long-term, they're going to acquire those skills, which [the respiratory nurse] already is. She's now doing her allergy [course]. So, [the respiratory nurse] will reach that point and when [she] reaches that point, our service will be able to cover that. And she's already, she already does loads of allergy in her allergy history. So, she's very good at spotting the kid who's got an undiagnosed allergy and bring them up to our clinic. So right at the beginning I thought, you've got to start with an asthma service, because that is, that's doable. And then if you, if you then give, allow those people to have confidence and give them the right training, then the allergy service will come. And we are now doing some, we're doing some, it is [a] consultant GP [based] allergy [clinic]. But I'm sure that we will build allergy into this as it evolves further." (Clinical lead site B, interview)

In November 2017, the team also started an integrated allergy clinic in primary care. The clinic was delivered by an allergy consultant and a specialist allergy nurse as a one-stop shop. This meant that testing, diagnosis, treatment and management advise were all part of the same clinic appointment. The clinic was part of a wider programme to integrate secondary and primary care by delivering specialist outreach clinics that GPs would attend to learn about a particular specialty and to build relationships. As such, the programme aligned well with the aims of team B to manage children with simple asthma and allergies in the community. The integrated allergy clinics for GP training were scheduled to continue on a semi-regular basis in 2018. Plans to deliver these clinics as a nurse-led service, however, were not yet considered.

4.4.9. Summary

Local commissioners and paediatricians in site B were brought together via their pre-existing relationships with the Itchy Sneezy Wheezy team. Their introduction initiated a collaboration that resulted in the start of an improvement project and an agreed business case for an asthma outreach service. This agreement was made locally against advice from the Itchy Sneeze Wheezy team to focus on integrated allergy care rather than asthma alone.

Despite pushback, team B felt confident about their approach. The commissioner highlighted asthma as a priority based on local data and local policy documents. The hospital consultant recognised asthma as a stepping-stone opportunity to appoint more junior staff who could be supported by the clinical team in developing the clinical expertise to recognise allergy and manage allergic comorbidities.

Team B used quality improvement to engage with external stakeholders through facilitated workshops. The ideas and insights that were gained and the relationships that were formed guided project developments. This resulted in team B developing an initiative to implement asthma-friendly services across primary care, secondary care and schools – before exploring integrated allergy clinics.

However, when a local paediatric outreach service was piloted, team B took the opportunity to collaborate and support the initiative by delivering a paediatric allergy outreach clinic.

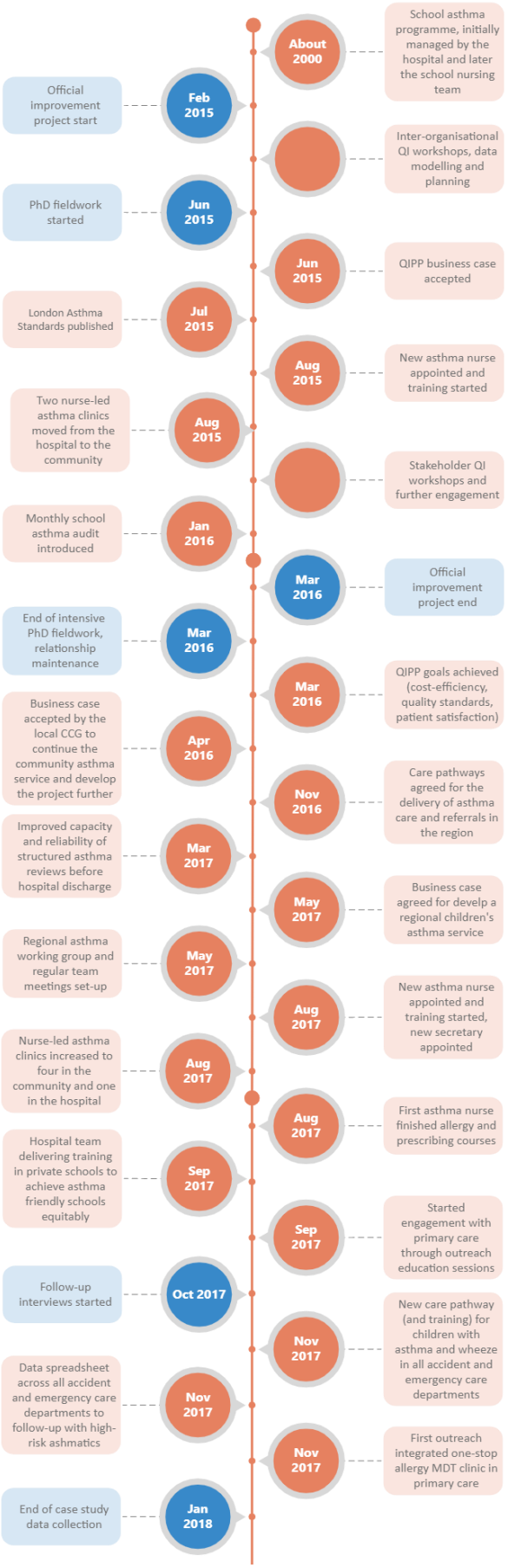


Figure 19. Timeline case study B.

4.5. Improvement journey C

4.5.1. Establishing local health service improvement priorities

The improvement project studied in site C officially started in August 2016. By this time, the team had already started work to improve their local children's health services, and the intervention they had in mind to continue that work was similar to the Itchy Sneezy Wheezy intervention. Hence, team C decided to reach out to the Itchy Sneezy Wheezy team for them to share their learning.

> *"[Y]ou would come with [the Itchy Sneezy Wheezy clinical lead] to present on what you'd done. This is the, I think at that point we'd already had the asthma and we were thinking of extending to asthma and eczema. And I was thinking: 'OK, what's your work?' So, this is really to help us decide: 'OK, what can we do in [site C], and what's possible, what's been done elsewhere? Let's take learning from that. Do we want the same model? What can we steal?'" (Project manager site C, interview)*

The work leading up to improvement project C started in 2014. The CCG had identified children's health as a local focus point, which led them to appoint a clinical lead specifically for children.

> *"The children's lead role, they hadn't really put a label on it. They just realised that they wanted to do something about children's health, children's services. And to me it felt like a population-based, that a population-based approach was perfect for it. That's what was interesting. That's what my interest was from [my clinical leadership training]." (Clinical lead site C, interview)*

The clinical lead's leadership training and his interest in population-based health encouraged him to invest time and resource into an investigation of the local health system before taking any action. He wanted to understand what health problems were particularly important in their children's population and what health services were already provided to meet children's needs. As such, he aimed to identify gaps in health service delivery and to understand system interdependencies and to prevent the implementation of improvement ideas that might not work well within the system as a whole. This type of elaborate investigation was, however, not common in CCGs.

> *"I spent the first six months in post just meeting people. I was going around and seeing what was, seeing what was available. And it was from that, that I began to develop the idea about, well actually, a good, a whole systems review would be a good place to start. […] defending that position was a little challenging at first, because people wanted services, they wanted new services. […] [B]ecause it was a, that is the standard commissioning approach. It's like you find a problem and you create a new service to fix that problem. It's a fairly standard,*

and in some cases it's entirely an appropriate way of doing it, but not necessarily always. So yeah, that's when the whole system review process started." (Clinical lead site C, interview)

The whole systems review started in July 2014 and involved a one-year project with a structured methodology.

"So, my first task was to go away and think let me do a, we call it a PID, which is a Project Initiation Document, like a scoping document, just to get agreement on that. This is the scope of the review, this is who's going to be involved, this is our governance process, these are our timelines, do you agree? This is going to be our methodology, do you agree yes or no? And that was a really good starting point to get to a discussion. […] So then, [the whole systems review] happened. We did that, we had a huge methodology in terms of doing surveys, talking to parents, consultant input, doing a literature review, looking at the data, what had happened before, what would happen now, phew. And we came up with a report and 33 recommendations." (Project manager site C, interview)

The clinical lead and the project manager ensured that the review process was very inclusive, which allowed them to build relationships with key stakeholders involved in local children's services.

"So, running that [whole systems review] process was a big part for me. It's not specifically commissioning anything, but it was a really valuable piece of work. It was very inclusive, establishing a working group where we had lots of different representation across services and across commissioning partners. Shaping the work, finding the direction of travel together, looking at the information and working out between us what we needed to know more about, running the report by them at the end, coming up with our recommendations. It was all a very inclusive approach." (Clinical lead site C, interview)

The inclusive approach to the review helped the team to create meaningful data interpretations and to develop recommendations that were supported by healthcare professionals and other stakeholders in the system.

"I think I upset the provider […], I upset them a little bit. Anyway, went back to the commissioner, had a chat: 'what if you look at this data, because you've commissioned [it], what do you think it means?' And she said to me: 'yes it's true, there were issues'. [But] because the data that [we were] looking at was from public health, covering a ten year span, she said: 'in the last two years they've made this and this improvement and if you look at that period you'll see a huge and marked difference'. Fine, resolved that." (Project manager site C, interview)

"By the time we came up with these 33 recommendations all our providers were in on it. We had a good working group, good consultant buy-in, sometimes – I wouldn't say clashes, [but] we collated constructive dialogue, constructive disagreement. [It was] a really good process." (Project manager site C, interview)

4.5.2. Exploiting an environment conducive to innovate asthma services

Three key areas for improvement were identified in the whole systems review: improved access, better prevention, and greater integration across the system (Project documents, Review report). To address these areas of improvement and to implement some key recommendations four pilot projects were proposed to test three new models of care. In 2014, the Five Year Forward View report was published outlining a long-term strategy to improve the NHS (NHS England, 2014). The report highlighted the need for new models of care to be implemented to be able to meet the changing healthcare needs of the population and to better integrate the healthcare system. The pilot projects that were proposed to implement the recommendations of the whole systems review aligned with the new models of care that were encouraged nationally. One project aimed to integrate primary and secondary care and to encourage out of hospital care by piloting outreach clinics for general paediatrics. This model allowed GPs could learn more about paediatrics and build relationships with consultants by observing specialist clinics followed by an MDT discussion. A second project aimed to reduce pressure on emergency departments by piloting a health education programme for parents of young children who frequently access emergency care. This model allows parents to gain the skills and confidence to manage minor illnesses at home. The remaining two projects aimed also aimed to reduce pressure on emergency departments by improving the preventative care for children with asthma (Project documents, Project report; Bulletin). To deliver these pilot projects a business case was developed to attain financial and organisational support from the CCG.

"That's the context, exactly, the contexts of the new models of care. Also, at the time, the CCG had a bit of money. We're not, we weren't in a financial deficit. So, there was an appetite for trying new things. And as we saw it, children's hadn't really had that funding at the time. The other thing that was new for the children's commissioning team was up to that point we'd only been commissioning community services. They hadn't done that much work with GPs. So, going into, now thinking about 'we want to do this service improvement, which is going to include practices and acute Trusts'. That was new for the team. […] Yeah, we had an appetite." (Project manager site C, interview)

As such, the financial and policy context were favourable to innovate. Moreover, at the time of the review, several key policy initiatives had also identified asthma as a specific priority area for intervention.

> *"It was called Strategic Clinical Networks, the SCNs. Then [the] London [SCNs] was like 'right we're going to make asthma a priority'." (Project manager site C, interview)*

Strategic Clinical Networks (SCNs) were established as part of the NHS reforms following the 2012 Health and Social Care Act. They were NHS funded regional networks, bringing together healthcare providers, commissioners and patients to deliver strategic advice *"in areas of major healthcare challenge where a whole system, integrated approach is needed to achieve a real change in quality and outcomes of care for patients"* (p. 3) (NHS Commissioning Board, 2012). Regional SCNs were mandated to address a number of key clinical areas. They were free, however, to establish additional networks to address additional important local challenges. As such, the London SCNs established the Respiratory Clinical Network in 2013.

> *"While we were doing the review, someone, a child had passed away from asthma actually. […] I don't think [we] had huge amounts of deaths [in site C], but a death is a death, and a death is quite serious. We'd already had the NRAD report saying 'look, these deaths are avoidable'." (Project manager site C, interview)*

A year after the London Respiratory Clinical Network was developed, the National Review of Asthma Deaths (NRAD) was published in October 2014. The NRAD was commissioned by the Healthcare Quality Improvement Partnership (HQIP) to *"understand the circumstances surrounding asthma deaths in the UK in order to identify avoidable factors and make recommendations to improve care and reduce the number of deaths"* (p. ix) (Levy et al., 2014). It was the largest study on asthma deaths worldwide and it highlighted how the NHS was accountable for preventing asthma deaths by delivering evidence-based asthma care.

These policy initiatives reinforced the findings from the whole systems review which had also identified asthma as a local priority (Project Documents, Project report). Consequently, by demonstrating how local, regional and national priorities aligned, team C was able to make a strong case for the CCG to support the asthma pilot projects. Accordingly, their business case was approved by August 2015.

> *"It became necessary to make a case. To say to them – 'Well, this is great, [but] are you aware we don't look at anything for children? This is important. Asthma is a life limiting illness, potentially, in children, and adults as well, but it's important for children.' You're*

raising the profile of it. […] So [we made our case] from [the whole systems review], [but] also the work that was being done pan-London and nationally. So it was, it became a bit easier." (Clinical lead site C, interview)

4.5.3. Piloting asthma service improvements in primary care

The first asthma pilot project focused on asthma being underdiagnosed, which prevents children from accessing appropriate care. The whole systems review had highlighted that over half of children accessing emergency hospital care due to asthma were not on the asthma register, which indicates they were not diagnosed with asthma by their GP. Accordingly, the number of children in site C on the asthma register was lower than expected based on national asthma prevalence estimates (Project Documents, Project presentation). Consequently, GPs were recruited and paid to identify all asthmatic children in their practice as part of the first asthma pilot project. In September 2015, GPs received training to search their electronic records to find all patients with asthma symptoms. They then reviewed the notes of these patients and invited all children who were not yet on the asthma register to come in for an appointment to assess whether or not they required an asthma diagnosis. This process updated the asthma registers, which could then be used to improve asthma reviews.

Regular asthma reviews are an important element of asthma care. They are associated with better outcomes for patients and hence, they are included in clinical guidelines (British Thoracic Society & Scottish Intercollegiate Guidelines Network, 2016). However, team C was aware that the structures currently in place to encourage GPs to perform annual asthma reviews was flawed, especially for children.

"So, you know QOF, Quality Outcomes Framework? So, children are basically ignored in terms of QOF. There's no, nothing significant for children in Quality Outcomes Framework for general practice. […] [The] asthma QOF is pretty much it. But asthma QOF is like, have you had an annual review tick box, and then there's three questions about asthma control. So, they're on there, but that's it." (Clinical lead site C, interview)

"A lot of [times,] the three [QOF] questions were used for children as well. Well, they are mostly used as part of maybe an existing complaint. They were already, [for] another reason they came in [to see their GP]. And [then at the practice,] they'd add that asthma review separately. Yeah, so, you'd come in for chicken pox. And they see you've been coded as asthmatic, and it will say, it will flag up. [Then GPs will ask:] 'Can we just ask the QOF questions?' – tick, tick, tick. [And] according to EMIS, then you've had an asthma review." (Specialist nurse site C, interview)

The Quality and Outcomes Framework (QOF) was introduced in 2004 to promote healthcare quality in primary care (NHS Digital Primary Care Domain, 2017). It's a financial rewards system used to incentivise GP practices to perform certain clinical activities and achieve certain clinical standards defined in QOF indicators. And while there are no QOF indicators specifically for paediatrics and allergy, the 2016/17 QOF indicators for asthma did encourage GPs to perform annual asthma reviews by measuring:

> *"The percentage of patients with asthma, on the register, who have had an asthma review in the preceding 12 months that includes an assessment of asthma control using the 3 RCP questions" (NHS Digital, 2017)*

However, team C recognised the limitations of this QOF indicator to encourage high-quality asthma reviews for children. The indicator states little about the quality of asthma reviews. Moreover, the validity of using the three Royal College of Physicians (RCP) asthma control questions with children has been rebutted (Andrews, Richardson, Wilson, & Gaillard, 2018). The NRAD report echoed these concerns, highlighting how high-quality care in accordance with clinical guidelines delivered by clinicians with asthma expertise could have prevented approximately half of audited asthma deaths (Levy et al., 2014). Accordingly, a second asthma pilot project followed to improve the quality of asthma reviews.

The second asthma pilot project was launched in April 2016. To encourage better asthma reviews, an evidence-based asthma consultation template was developed. This aligned with the NRAD recommendation that a *"standard national asthma template should be developed to facilitate a structured, thorough asthma review. This should improve the documentation of reviews in medical records and form the basis of local audit of asthma care"* (p. 41) (Levy et al., 2014). The asthma template prompted primary care clinicians to discuss and report important consultation activities.

> *"[The asthma pilot] seeks to promote best practice reviews and management plans for asthma, including a personal asthma action plan (PAAP), through provision of a locally developed EMIS Web template that emphasises the critical aspects of clinical review for asthma." (Project documents site C, Asthma pilot service specifications)*

> *"The requirements of having an asthma review before and now is a lot [different]. Now they've got the EMIS template. There's a lot more that they have to do before they can say 'yeah, we've done an asthma review', which is encouraging." (Specialist nurse site C, interview)*

The asthma template was integrated into the primary care IT system EMIS to facilitate an uninterrupted work flow for primary care clinicians. Moreover, it allowed for the integration with other EMIS functions, and it operated as an automated data collection system to support the evaluation of the asthma pilot project.

> *"[T]hat template would collect, would give us some information about whether these children were getting decent reviews done. So, that was part of it, and it would be collecting data from, pulling data from GP practices. Looking at whether they've completed this template, would give us a proxy measure of whether these children had had a good review or not." (Clinical lead site C, interview)*

The pilot project evaluated three different organisational structures to understand how the quality of asthma reviews could be improved most effectively within a system of limited resource. The first structure involved business as usual, incentivising GPs to do asthma reviews as part of the QOF. The second structure involved incentivising GPs to deliver extended asthma reviews based on the asthma consultation template. In this structure, practices were trained to use the template and paid for delivering longer asthma review appointments where the template was used and filled out. The third structure involved the appointment of a specialist asthma nurse to deliver extended asthma review consultations in specialist clinics hosted GP practice hubs (Project documents; Asthma pilot service specifications). The data from these clinics demonstrated that the asthma reviews performed by the specialist asthma nurse were of a very high standard (Project documents; Project presentation). However, the quality of asthma reviews performed by primary care clinicians was inconclusive, because many GPs and practice nurses failed to fill-out the asthma template. Moreover, small numbers of hospital admissions and poor quality A&E data made it difficult to draw reliable conclusions about the impact of the different asthma review structures on emergency care utilisation. Nevertheless, the asthma pilot achieved its aim of learning how to use clinical expertise most appropriately to improve asthma reviews for children in primary care.

> *"It was an incredibly valuable experience, because we got lots of useful information from it. We were blessed with [our specialist nurse]. She's such a motivated, independent – I mean independent in the sense that she will just look at other things that she could be doing. So, her time wasn't, she was very motivated to get out into practices, make the links. She was doing education with the practices, because she realised that was a good way in, the practices wanted it. She was reaching out to health visiting, school nurses, arranging training with them. All just off her own back […]. And she was feeding back to us a lot of the time. And it was from that, that we were beginning to see, using her just to do annual reviews for*

children was a waste of time. It wasn't a valuable use of a really highly skilled resource. It was pointless, and we'd be better off improving, for the annual reviews, trying to improve the quality of those, leaving that with general practice. And having, making it possible for practice nurses to do it with the right training. But then using [our specialist nurse] for the more challenging cases, doing the outreach, doing the education, making the links between primary and secondary care. And that's, so we learned an awful lot. And the pilot helped us to create, to understand where a resource like this would be most valuable." (Clinical lead site C, interview)

The learning of the asthma pilot projects and the whole systems review led to the development of improvement project C. One of the recommendations from the whole systems review had been to develop a system-wide atopy strategy for managing asthma, eczema and allergies (Project documents, Review report). Moreover, the specialist nurse from the asthma pilot project had identified that 86% of children attending her review clinic had atopic comorbidities. And while many of them benefitted from extra input and education on managing their allergic conditions, only 4% of children needed a secondary care referral for more specialist input.

"Not only did they have the extended asthma review, but there was a need for eczema education, there was a need for an EpiPen teaching as well. Because you'll find that there were few that had food allergies, and I was like 'oh, do you have an EpiPen, yes?' and then I was 'do you know how to use it?' – 'No, never had to use it'." (Specialist nurse site C, interview)

Furthermore, the asthma pilot had highlighted that GPs and practice nurses were best positioned to deliver asthma reviews. By using the asthma template as a clinical support tool and by accessing the specialist asthma nurse if educational support was needed, they could adequately support most children during their asthma review and identify those who needed additional support managing their asthma and atopic comorbidities. Moreover, the pilot had identified that most children needing more support could be seen be a specialist nurse in the community rather than needing a secondary care referral. As such, the specialist nurse community clinics created an opportunity to move care out of hospital and into the community. This idea was further developed in improvement project C that aimed to improve the health services for children with atopic conditions.

"From the data from [the asthma pilot project], and the experience I got from doing those clinics, [it was] highlighted that there was a need for the next stage, which is to introduce more of an atopy clinic." (Specialist nurse site C, interview)

4.5.4. Building the case for atopy clinics in the community

As a sequel to the asthma pilot project, improvement project C was supported within the CCG by the children's implementation group. This group consisted of the clinical lead for children, the commissioning lead, and the three project managers who had each been leading one of the three new care models pilot projects. They would come together to discuss challenges, extend operational support if needed, and coordinate project reporting. The implementation of improvement project C was primarily supported, however, by a working group that brought together a range of external stakeholders with relevant expertise. The development of the working group was facilitated by the stakeholder engagement that was done during the whole systems review.

> *"So, there's basically the [whole systems] project working group that came to an end when the review ended. [Then] we looked at what we wanted to achieve really, atopy. [So,] some new people joined and other people left. But by then, we'd already established the group. [It] was active, responsive and we were getting things done." (Project manager site C, interview)*

Initially, the working group concentrated on developing a business case to extend the specialist nurse role project to deliver community atopy clinics for children with asthma and eczema post the asthma pilot. The working group started in September 2016 by brainstorming what services and resources were already accessible to children with allergies. All suggestions were noted on flip chart paper and grouped as being part of community, secondary or tertiary care services. Then, connections were added between the services and resources to demonstrate who could directly access them (Project documents; Meeting minutes, Provider map). Moreover, to get ideas and insights about running a nurse-led atopy service, the team invited the Itchy Sneezy Wheezy clinical lead to present on the Itchy Sneezy Wheezy project. In October, the team made a more detailed map of their local allergy services by brainstorming the specific service elements being provided in primary and secondary care, and what types of patients are managed in each setting. This exercise was also used to brainstorm the role and remit of the specialist atopy nurse within this system.

> *"[Clinical lead]: 'for today, I wanted to focus on the service element and just brainstorm some ideas'. The team then moved on to deciding the remits of primary care, the community nurse and secondary care – see diagram. [Clinical lead]: 'can you get that, because that will be useful for our business case', referring to the thresholds for referral between primary care, community nurses and secondary care" (Meeting team C, field notes)*

In addition to designing how the role of the specialist atopy nurse would fit with other local allergy services, team C also reviewed local data to understand what needs could be addressed by this new

service (Project documents; Meeting minutes). The clinical lead specified the importance of collecting data to develop a strong business case for the new nurse-led atopy service.

> *"[The clinical lead] highlighted 3 purposes for collecting data: 1) to find out the scale of the issue looking across the two trusts [in site C], primary and community care; 2) to find out the financial and social costs of running the atopy service compared to how much it is going to cost if nothing is done (for example with the increasing prevalence of allergy); 3) to measure the quality of care and how we would be improving that" (Meeting team C, field notes)*

He particularly emphasised the importance of making a financial case. When the asthma pilot projects were proposed in August 2015, the CCG was in a good position to innovate and invest. However, this position had since changed, which meant it was important to argue clearly how a financial investment in a new atopy service would save costs in the long run.

> *"[Clinical lead]: 'We can only deliver a service if we can make a financial case for it. The quality case is quite easy to make, but the CCG is running into a financial deficit. So, we need to make a financial case as well'" (Meeting team C, field notes)*

The financial case was made by collating the research and findings from the asthma pilot project, emergency admissions data, audit data from one site C hospital Trust on asthma A&E attendances, and audit data from the other Trust on outpatient dermatology appointments. This data was used to estimate the scale and costs of allergy care in site C. The team was aware, however, that the data wasn't perfect.

> *"Notably, it has not been possible to quantify the full costs of atopic care in Camden nor the (QIPP) gains possible due to the way prescribing and activity data across primary and secondary care is collected and coded" (Project documents site C, Business case)*

Nevertheless, team C was able to develop a strong business case for their nurse-led atopy service. In addition to outlining the local care need, the financial case, and the integration with existing services, team C also explicitly highlighted how the atopy service would support the implementation of local and national strategies as laid out in their Local Care Strategy and their regional Sustainability Transformation Plan (STP). STPs were developed in 2016 to support the local implementation of the Five Year Forward View, which has been discussed earlier (NHS England, 2014). Each STP laid out a multi-year plan for one of 44 geographical areas. The Local Care Strategy on the other hand, is developed specifically for site C, and aims to complement and contribute to the regional STP (Project documents; Local Care Strategy 2016 presentation). The nurse-led atopy service addressed the strategic aims set out in these documents by delivering a new care model focused on prevention, on

improved coordination between health services, and on the delivery of out of hospital care when possible (Project documents; Business case). The business case was further supported by patient feedback from the asthma pilot project, as well as by the feedback from three parents with allergic children of the ten parents who took part in a CCG focus group organised in October 2016 (Project documents; Business case). In November 2016, the business case was approved, with the nurse-led atopy service scheduled to go live in April 2017 after the asthma pilot project officially ended (Project documents; Committee papers).

The nurse-led atopy service was implemented as part of a wider strategy to improve the health services for children with atopic conditions and allergies.

> *"What are we trying to achieve: To have a system wide atopic service – I.e. the service is everything across all elements. – Best to think of the nurse as the community element rather than as a new service." (Project documents site C, Meeting minutes)*

4.5.5. Developing asthma and eczema care pathways

What followed in this pursuit to improve services for children with atopic conditions and allergies was the development of patient pathways. However, after clearly expressing the aim of system-wide improvements during the working group meeting in November, I was surprised that the first drafts of an asthma and eczema pathway excluded many important stakeholders.

> *"I thought the process map that [the consultant] developed was really good. However, I found it interesting that she developed it on her own. It was not surprising to me that the first few questions immediately evolved around the role of health visitors and school nurses, because they were largely left out. […] When [the consultant] asked if someone would be able to help her with drawing the process map on the computer, I immediately volunteered. […] I intend to ask how other stakeholders and their processes fit into this map. I expect that after these probes, we will either have to contact the different stakeholders individually to find out more or that we come to the conclusion we need a separate session making the process map all together." (Project meeting team C, Reflective notes)*

Accordingly, after meeting the consultant, I went back to develop a second digitised draft of the pathways based on our discussion. Moreover, I went back to talk to the school nurses and community nurses so their work processes could be included in the map as well. After a few more iterations the pathways were presented to the working group in February 2017. The project manager had printed them on big A0 papers and stuck on the wall. The working group was then split in two and asked to discuss each pathway, to write their comments on the pathways, and to feed back their

thoughts to the other group at the end of the session. The feedback that came through initially was quite negative.

> *"[The consultant] kept mentioning it was too complex and that she couldn't easily see the process. [The clinical lead] also said that initially he thought it looked quite complicated and that this wasn't what he was expecting. And before the session [the project manager] told me that [another consultant] had emailed her that he couldn't see the process map well on his computer and that it was difficult to print – which was why she decided to print them on big sheets" (Project meeting team C, Reflective notes)*

By the end of the session, however, people were predominantly positive. Having the pathways in a big format on the wall rather than on the computer, and having people there who could elaborate on their part of the process, made it easier for the consultant, for example, to navigate the pathways and see their value.

> *"So, this was very informative. For the first time, we got a variety of stakeholders who had worries, concerns or skills on offer or a point of access or [who] were willing to engage more or less. And it meant that in some ways, a whole-system pathway would actually cut down unnecessary cost in a massive way. Because if you are aware of what a school can do, what a community nurse can do, what a health visitor can do, you're much more confident at telling the family to go home. Whereas if you are not sure what can be done, then you do not have a choice. […] We were holding them back, because we were fearful the child would not get care. […] So these pathways have a tremendous value in clarifying what will happen when the child is not in your care." (Consultant site C, interview)*

Moreover, even though my understanding of patient pathways misaligned with the idea the clinical lead had in mind initially, he recognised the benefit of both types of patient pathways for the project.

> *"[The clinical lead] mentioned this is not what he is used to seeing from a primary care perspective. However, he said: 'what is important about this, is that it covers the whole system… Looking across all parties, school, community, the whole system, and trying to improve that'" (Project meeting team C, Field notes)*

He identified that visualising the whole-systems pathway helped to identify and appreciate improvement ideas that support better coordination between services.

> *"So, I think that what we had done was an incredibly important piece of work. Because I think it was important for the work, for the group, to understand what is happening where –*

where's the flow of information? How are school nurses involved for example? And just things like that. And that was really important to understand. We were looking at our services [holistically]. So, with our, with the template for asthma, [for example,] we wanted to make sure we saw how valuable having school nurses involved is. So, in order to get your points for having completed the template, you've got to have made an effort to pass the information to the school nurses. And [for that reason] we've put their contact details on." (Clinical lead site C, interview)

However, he explained that normally he refers to patient pathways as primary care decision support tools developed by the CCG to help GPs with clinical management and referrals for particular patient groups. And while this information was included in the primary care section of the whole-systems pathways, the section had to be disconnected and reformatted to fit this specific purpose and to align with the style and structure of the other pathways that were published by the CCG in site C.

"So, having the whole system mapped out has been really important and useful. And then what we've, what's ended up now being created for primary care, is really just taking out the essential stuff that we had, that was relevant to primary care. This is how you make a diagnosis; these are your signs which will make you think of a differential diagnosis; these are your, these are the patients that you need to refer; and here's a hyperlink through to the webpage which tells you how to go about doing it. So, there's just, it was distilling it down." (Clinical lead site C, interview)

"[Site C] had gotten into the habit, has deliberately worked towards making sure all of their guidelines looked roughly the same – with the same colour schemes and the same size arrows and all of that. So, there was [also] an aesthetic thing when it didn't look like what they were expecting." (Clinical lead site C, interview)

The whole-system pathways were presented in June 2017 at a CCG governance meeting to demonstrate how the primary care pathways and the nurse-led atopy service were integrated within the patient journey as a new model of care (Project documents; Committee papers). As a result of this meeting, the primary care pathways were reformatted in line with CCG conventions. They were approved and published shortly after.

4.5.6. Improving evidence-based and cost-effective prescribing

Medication recommendations were included as part of the pathways in an effort to encourage GPs to prescribe according to the local formulary. Integrating and standardising local prescribing practices through an agreed formulary was another work stream of improvement project C intended to

improve atopy services. The need to standardise prescribing was already identified in the 2014 whole systems review.

> *"When we did the review, parents were saying that consultants in the hospital were telling them one thing and then a GP would then decide not to. […] The GP was just saying 'oh no, we can't prescribe that'." (Project manager site C, interview)*

This frustration was echoed by a dermatology consultant during a project meeting in April 2017.

> *"[The consultant] said: 'the formulary worries me actually. […] It's immensely frustrating when you have a child under control and then it gets all mixed up'. She was referring to GPs changing medications, because the ones prescribed in secondary care are not on their primary care formulary" (External meeting site C, field notes)*

Team C was also motivated to review and implement an agreed formulary for financial reasons. One of the dimensions being assessed when developing a formulary is cost-effectiveness, whereby the use of cheaper medications is promoted if their clinical effectiveness is equally good. As such, a formulary could prevent clinicians from prescribing expensive medications that have no added patient benefit. However, a formulary might inadvertently disregard patient preference or clinical expertise, especially when evidence is limited.

> *"[The consultant] looked at the primary care formulary and said 'this is purely cost, I'm sorry'. The CCG prescribing advisor explained how formularies are developed based on the available evidence. That they are aware that the emollients that should be prescribed are the ones that a patient will use, which is why the formulary includes several product options. However, when there is no evidence that one product is better than another, the cheapest does get selected. She says 'I think with dermatology specifically, it's the lack of evidence [that is a problem]'." (External meeting site C, field notes)*

Moreover, after analysing their local prescribing costs, team C realised that updating their local formulary might not be worth the financial earnings.

> *"[W]hen we looked at the cost of our emollient budget in [site C], looking at formulary versus non-formulary, and there is a significant amount of non-formulary prescribing. But actually, it's not a huge cost difference. And the amount of time that would be taken to really address that, and have [a regional] emollient formulary, is just like, it just doesn't seem worth it." (Clinical lead site C, interview)*

As such, team C decided to stop investing in the development of a formulary agreed across healthcare providers. Moreover, they identified their regional Medicines Optimisation Network was in a better position to take on this type of work. The network had a committee dedicated to developing joint formularies and their geographical reach aligned better with the hospital catchment areas.

> *"We were just going to do it for ourselves. And then, I don't have a lot of capacity, [the clinical lead] doesn't have a lot of capacity, and it's a lot of work. […] [I]f we do it for [our regional STP footprint], then it gets, they have more resource. Because the other thing you have to think as well, or we have to realise, is that if [site C] CCG does a formulary and we want the Trust to adopt it, the Trust doesn't just look at [site C] patients. […] So, if we do it at [a regional] level, then that's, it's a better thing to do." (Project manager site C, interview)*

The members of the CCG medicines committee were also active members of the regional medicines network and their formulary committee. As such, they were able to inform team C that the network had already been doing work on asthma inhalers in alignment with the team's priorities, and that they would take on board their expressed need to agree eczema and allergy formularies across healthcare providers as well (Project documents; Meeting minutes, Committee minutes).

4.5.7. Making practical and financial arrangements for atopy clinics in the community

With the formulary work handed over to the medicines team, team C could focus on finalising the arrangements for the nurse-led atopy service. The service went live in July 2017 three month after the asthma pilot project had finished. Its development was based on the experiences of the asthma pilot project and the structures that had been put in place. For example, the specialist nurse, who had been running the extended asthma review clinics, was now going to deliver specialist atopy clinics for children who needed more in-depth support to manage their asthma, eczema and atopic comorbidities. Moreover, to support her clinic and its evaluation, a digital atopy clinic template was created by adapting the digital asthma review clinic template. To improve the management of referrals and the booking patients, this process was digitally streamlined as well. To ensure all GPs used this digital process, many had to be referred to a quick online user guide and email referrals had to be consistently declined. Finally, the first atopy clinics were delivered in the practices that had been hosting the asthma review clinics. These practices were situated in one locality. However, to ensure the atopy service covered all three localities, the clinical lead would recruit more practices to provide clinic space – going out to CCG locality meetings, followed-up by an email to collect expressions of interest. Practices who were interested in hosting an atopy clinic were subsequently contacted by the specialist nurse to agree arrangements (Project documents; Meeting minutes).

While many of the practical elements of the nurse-led atopy service could be developed based on the asthma pilot project, the funding and governance arrangements had to change. The asthma pilot project was funded as an investment to explore new models of care that could deliver cost savings in the long-run. This meant that the service models resulting from the project were expected to be delivered at no extra cost as part of the existing commissioning structures. Since the atopy service was delivered by a nurse in the community, team C tried to incorporate the service within the community nursing contract.

> *"It was trying to strike a deal. So, the community nursing in [site C] is contracted from the [hospital] by [our] CCG. So, we pay them 'X' amount to deliver community nursing services, and that's got a certain, that contract has like 'we will provide these services'. So, we wanted to include the community nurse, the community atopy nurse as part of that, and say 'as well as delivering these other things, we also want you to deliver our community atopy nurse as well, within that same contract'. So, then we [had] discussions about: 'is there any uplift in the value of the contract to accommodate this?' or 'what do you want to lose instead, because?' It was those sorts of discussions." (Clinical lead site C, interview)*

During the negotiations, the hospital team was willing and able to see how this new model of care with different financial arrangements could benefit children, as long as they retained able to run a financially healthy service.

> *"There are certainly financial advantages [on a systems level]. Because each child who comes to A&E, there's a charge. And often that results in an outpatient request via either a GP or other stakeholders, and that's extremely expensive. […] [The atopy service,] it's expensive for the hospital, we lose a lot of revenue with it. But we feel on the whole, money goes in the right place. That is, if the CCG does not have to waste money for a preventable condition, it will be reinvested for something, which is better anyway. So on the whole, financially, quality of care wise, ease of access, lifting the training standards and education for primary care – this is a positive step forward. [And the] hospital has always told us that if something is right for the delivery of children's care, they will be happy to deliver it. And that has always been our principle rather than worrying that we will lose money. Fortunately, fortunately, the rise in standards for asthma has actually resulted in very high referrals anyway. And that has meant that our incomes aren't affected. Mostly because the volume of the work is just too high for the service and provisions we had. And we do not want to over-expand for a condition which is largely preventable." (Consultant site C, interview)*

Now that the specialist atopy nurse was funded from the community nursing budget, the governance structure for the atopy service changed accordingly. The specialist nurse runs clinics in GP practices for children who struggle to manage their atopic conditions. To ensure these clinics can be delivered consistently as part of a reliable service, the specialist nurse trained her colleagues in the community nursing team, so they could provide cover. And since the community nursing team is part of the hospital trust, the hospital consultants can mentor and support the specialist nurse.

> *"So, her appraisal, her supervision, her training, her performance sits with us. So, she would have a meeting with us, she will update [us], and because she sends a copy of the letter for the child who is being seen back to us […], we have assurance that it's going OK." (Consultant site C, interview)*

4.5.8. Improving and standardising asthma care in the hospital

Being based in the hospital as part of the hospital Trust, also resulted in the role of the specialist nurse being extended to support hospital-based care for children with asthma. As a specialist respiratory nurse she was asked to review all children who have been admitted to the hospital with an asthma diagnosis. Moreover, when she would realise a child has had multiple emergency attendances, the nurse would contact the GP and ask them to schedule an asthma review.

Besides directly supporting the clinical work, the specialist nurse also focused on improving the asthma care processes by training hospital staff. This work was initially triggered by a serious incident that happened, whereby a child with asthma had died.

> *"So, when coming into this role [in July 2017], coming into [the hospital], they had recently had an incident, a serious incident, where a child had died following being discharged with asthma within, I think it was within the first week of discharge from here. They died in the community. Now one of the things that were highlighted were issues around documentation and care planning. And we saw, well, I, coming in from the outside, saw there was a bit of a dip in education. […] So, I developed a generalised asthma presentation that covered the key points of what we wanted to get across in going with the London standards. And [I] delivered, so this presentation was formulated to be delivered across to medical staff and nursing staff, but we focussed mostly first on nursing staff, ED [nurses], general [nurses], community [nurses], yeah I said general, inpatient [nurses]. So, after I'd done the presentation, I trained the practice development nurses […] who work alongside the nursing staff to ensure that their education [and] development is up to scratch. […] So, I trained their senior nurse and then the whole team, and they rolled it out." (Specialist nurse site C, interview)*

The specialist nurse had finished training the practice development nurses by December 2017. From this point onwards, they took ownership of the training programme aiming to continue educating nurses across the Trust's three hospital sites with regular asthma competency assessments. They also aimed to extend the training programme to medical staff, and integrate the education programme with the new care models initiative that was running in the hospital.

The hospital in site C was selected as one of the national case studies of the new care models programme initiated by the government to test new ways of collaborative working (NHS England, 2016). This meant that together with its two sister hospitals, it was selected as a vanguard site to improve acute care collaborations, standardising care for high-volume conditions across all hospital sites and delegating the treatment of complex cases one hospital harbouring the relevant expertise (NHS England, 2018). Several conditions were selected as a clinical focus, whereby the paediatrics team decided to focus on improving the services for children with respiratory issues.

> *"In paediatrics, we felt the wheezy child was important. Because obviously there's big volume in paediatrics that come through the door in A&E, and there's, we know there's a lot variability in care at the moment." (Consultant site C, interview)*

The Trust-wide initiative was launched in July 2017. The paediatrics team decided to focus on the development of a pro-forma to improve and standardise the care delivered to children with asthma or wheeze attending A&E. They had collated and adapted pathways from different hospitals, which they had started testing by April 2018. Next steps involved rolling out the pro-forma to the two sister hospitals and incorporating the pro-forma into the digital work flow as part of the Trust's strategy to go paper-free in the next few years.

> *"So, the development of the pro-forma. So, for asthma there's no real standard national guideline of how to go about it. There's lots of different protocols. So, in the HLP [Healthy London Partnership] there's lots of different protocols from around the sector, such as [hospital X], and there's some protocols from [there] as well. So we amalgamated those, and it was consensus-based actually between the clinicians [across hospital sites]. And what we're doing is, we're using it, testing it, and then seeing what users think, and then adapting it. So, we've done a few changes already and we've done that in small testing sessions so far. And we're planning to do a few more small testing sessions and then try and implement it. And then keep on top of it and keep improving it." (Consultant site C, interview)*

4.5.9. Summary

Team C had been working on a strategy to improve local children's services. Based on a whole systems review, they identified priority areas for improvement, and started a program of pilot projects to test and evaluate solutions. Based on this work, team C recognised the potential benefits of a nurse-led community service for children with asthma and eczema.

After starting an initiative to improve children's asthma and eczema services, team C identified and contacted the Itchy Sneezy Wheezy team to share their experiences implementing a similar nurse-led service in the community. However, rather than implementing an allergy service, team C was focused on progressively implementing the lessons from their review and pilot program.

Accordingly, team C had recognised the benefit of a specialist nurse in the community to support children in managing their asthma and any allergic comorbidities. Moreover, eczema services had been identified as area for improvement.

Team C used quality improvement methods within their team to design a nurse-led service that was well-integrated with other local asthma and eczema services. Team members were also asked to collect data for a business case. And the new service design was used to develop care pathways for primary care that included the latest clinical guidance and referral criteria for the new service.

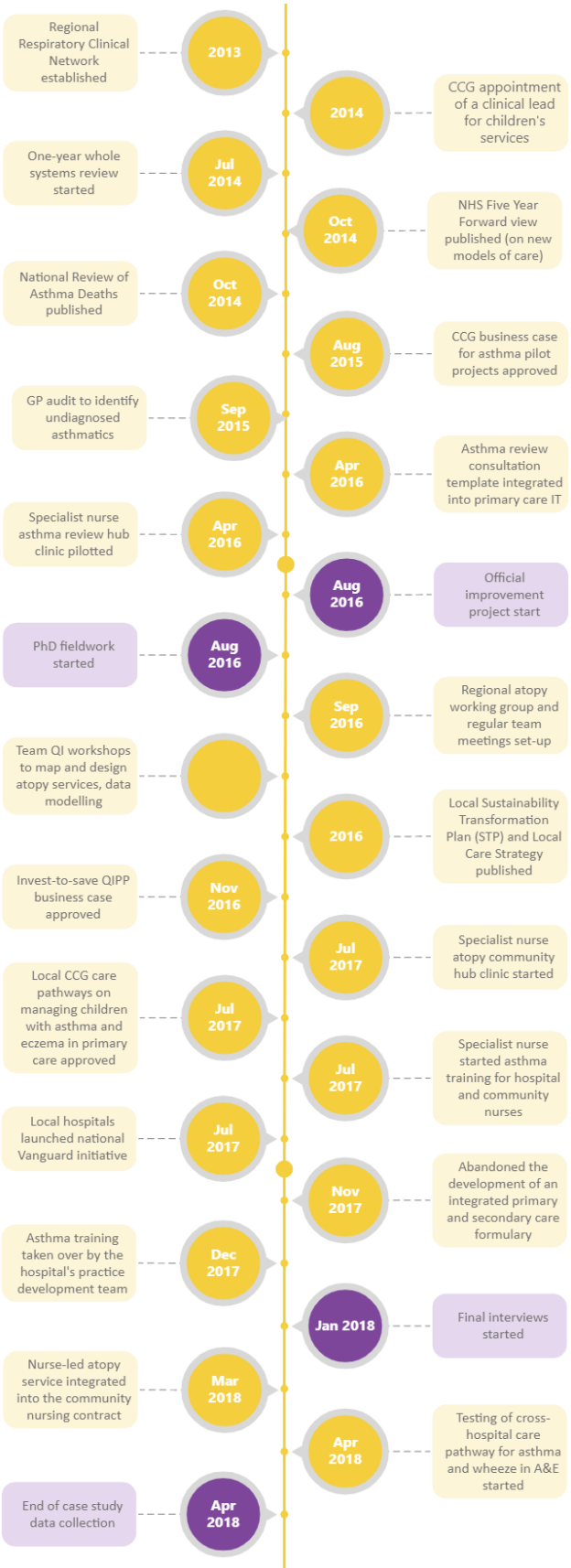


Figure 20. Timeline case study C.

4.6. Improvement journey D

4.6.1. Implementing children's services in the community to improve patient pathways

The improvement project studied in site D officially started in September 2016. The project focused on *"improving pathways for paediatric allergy"* (Project documents; Meeting presentation) as a continuation of changes to the local children's services that had been developing since the establishment of the CCG in 2013. In April 2013, a 6 month community-based acute response pilot service was commissioned to support children to manage minor illnesses at home, which has continued since. Then, in April 2015, a 12 month community-based respiratory pilot service was commissioned to support children to self-manage their respiratory conditions, which has also continued. And finally, in December 2016, a community-based dermatology service was commissioned specifically for children, which supported the existing general community-based dermatology service with additional capacity and paediatric expertise. The development and evolution of this portfolio of community-based health services was pushed forwards and supported by consistent leadership of the clinical lead for children and young people.

> *"There's definitely been pockets of things that have been quite innovative at the time. It was a number of years ago actually that the [acute response] element was developed. So, it's pre my time. […] I think having a consistent clinical lead that could see an alternative to sending every child to hospital. So, I'll probably give, I think there was a commissioner pre [our current head of commissioning] that was involved in it. Which, she may have been quite instrumental as well. But I think give [our clinical lead] her due really as a really consistent, passionate, driven clinical lead. She's been very, a big part to driving that agenda forward I think."*
> *(Project manager site D, interview)*

The ambition to care for children in the community where appropriate was both promoted by government policies and derived from the clinical lead's professional background. In 2004, the NHS Improvement Plan was published to accelerate and push forwards the improvements that had resulted from the major NHS investments and reforms outlined in the 2000 NHS Plan (Department of Health, 2000, 2004). Creating a better experience for patients by delivering care closer to home was a central topic in this plan.

> *"[The NHS] will also improve people's care closer to home – through specialist nurses and GPs with a special expertise in their condition – which will lead to fewer emergency admissions to hospitals which cause anxiety for patients and their families and are a poor use of hospital resources."* (p. 10) (Department of Health, 2004)

The 2008 NHS Next Stage Review reinforced that the ambition to deliver care closer to home was shared by local leaders and patient populations, with some local innovations already being implemented to make this a reality (Department of Health, 2008). The above policy ambition was also clearly echoed in the vision of team D as expressed by the clinical lead.

> *"[S]eeing more children closer at home, less hospital attendances, and use skill mix appropriately and properly. So, that was the aim [of improvement project D], and that was behind all the work that I've done around paediatrics." (Clinical lead site D, interview)*

To implement this policy ambition and translate it into health service improvements, the clinical lead could draw on a range of professional experiences. This involved her experience as a GP practitioner, medical educator and appraiser, focused on the direct delivery of safe and high-quality care by clinicians. However, her professional experience reached beyond direct healthcare delivery. Initially, she focused on supporting clinical practice through the development and implementation of clinical pathways, which was later extended to health service improvement more broadly.

> *"I've always been quite passionate about doing pathway work, clinical pathways. And, you know, so, I've worked shortly with Map of Medicine. And then after that what happened was, I generally said 'right, let's get clinical pathways become a norm rather than an exception'. So, but what I've found was just working on pathways, you can take years. But implementing it is the hardest, so, making it the norm. And so, before the CCG we had the PCT [Primary Care Trust]. So, at that time, I started off working with the teams for gynae pathways, and then obviously paediatric pathways. And then the clinical lead for children and young people job came up [at the CCG] and I applied for that. And I got that post, and then I did a business leadership programme with the King's Fund […]. And then I started looking at projects. So, my interest is basically service redesign and development, really." (Clinical lead site D, interview)*

Accordingly, the clinical lead and her CCG colleagues initiated the development of several community services. The first community service involved a community-based acute response service, which was piloted between April and October 2013. It was developed as a potential solution to reduce unnecessary hospital admissions and emergency attendances, which included a relatively high number of children with minor illnesses who could be better managed in primary care (Project documents; Project report).

> *"The CCG gets figures on a quarterly basis I think, if not monthly, of all the referrals into the children's ward at [the] hospital with the length of stay and the practices that were sending the children in. And they identified that there were a very high number of patient who were in*

and out of our paediatric assessment unit, and certainly didn't stay overnight. So, they were interested in reducing those figures, because of course that was at a cost implication to themselves, and it's a poor experience for the children. If they can be cared for out of hospital, it is actually a lot better for them" (Nurse team lead site D, interview)

The acute response service is delivered by a mixed team of community and hospital nurses taking referrals both from primary care and the hospital. Taking referrals from primary care, the service aims to prevent children from attending hospital by reviewing and supporting children who are acutely unwell with a minor illness. Taking referrals from the hospital, the service aims to facilitate early discharge, prevent hospital admissions and re-direct hospital follow-ups by offering follow-up appointments in the community or by telephone.

"We find a lot of families in [site D] are seen by the GP, are given an appropriate care plan in the mornings, for example. But because they're not better at tea time, the parents think 'oh, it's wrong, I'll take them to A&E', but unnecessarily. It's just a case of, the child's got a viral illness that's going to take two or three days to get better. So, if we can see the children and we can give that information, we can give them the reassurance that the child, though unwell, is not seriously unwell. And it also educates the parents, where if they get the same, similar illness in the future, they know how to care for them. That's predominantly what we do with [the acute response service]. But we also see children who have attended A&E with injuries, and then we, we'll follow them up. We'll do the dressing changes and we'll keep an eye on the child until the wound has healed. […] And we also do some children who need a course of intravenous antibiotics. Again, rather than going into the hospital and hanging round for a while to get that done, they can come to the [acute response] service. There's fairly strict guidelines for the patients that we can deliver that service to, but we are doing that where possible." (Nurse team lead site D, interview)

Based on the evaluation of the pilot it was decided to continue the service in 2014/15. The evaluation demonstrated that both staff and patients were very positive about the service (Project documents; Project report). Moreover, the service was able to deliver care that was both timely and easy to access. However, the anticipated cost savings that were expected from a reduction in hospital admissions were not achieved. It was assumed this was associated to the service not yet running at full capacity, which resulted in efforts to increase awareness of the service amongst local GPs.

Following the successful implementation of the acute response service, the agenda to move care closer to home was taken forward. A business case was developed at the CCG, which translated the

ambition to move care closer to home into a vision statement, accompanied by a health service model and a financial plan to realise the vision (Project documents; Business case). The intention was to incrementally develop and deliver *"a 0-19 Children & Young Peoples integrated pathway of community-focused healthcare"* (Project documents site D, Business case). Implementation of the community-based acute response service had been the first step towards delivering such a pathway. The next steps that were proposed in the business case were extending the acute response service, improving the asthma pathway, followed by the review and improvement of the dermatology pathway.

The community-based acute response service was extended in December 2015 to include jaundice screening. Initially, the intention was to extend the service to include nurse prescribing, so that suggested courses of treatment no longer had to first be reviewed by the child's GP. Consequently, children attending an acute response clinic appointment would be able to get their prescription straight away and start their treatment as soon as possible. Moreover, having a nurse prescriber would allow the acute response service to reduce workload in primary care. The idea was for the hospital to support this development by financing a prescribing course for one of their nurses working at the acute response service. However, this idea was put on hold and focus shifted towards the development of a jaundice screening service to extend the community-based acute response service. In 2017, the acute response service was recognised by the UK Care Quality Commission (CQC) as an example of outstanding practice (Project Documents; CQC Quality Report).

> *"[I]n the past, any baby who was noticed to be jaundiced by the midwife would be referred into the hospital. They actually now come to [the acute response service]. And we can monitor them there, and we can do blood tests, and make sure that they don't need to go into hospital. Because there's only about 10% of the babies who look jaundiced that actually need to go into hospital. Whereas up to us developing this service, 100% went into hospital." (Nurse team lead site D, interview)*

While the business case proposal to develop nurse prescribers was taken over by the jaundice screening service, the proposal to improve the asthma pathway was translated into a 12-month pilot project as planned. Initiative to improve the asthma pathway came from the hospital respiratory team who wanted to support community-based professionals caring for children with asthma.

> *"They had come to the CCG asking for funds for training, and that was training for school head teachers and also training for primary care. And we said, rather than giving you money, why don't we look at a comprehensive service [review], how the service is run. So, we looked, we delved into the service that was already existent and it opened up a whole lot of things*

that we needed to look at. And then we said, why don't we then commission a children's community respiratory team service?" (Clinical lead site D, interview)

Consequently, a pilot for a community-based respiratory service ran from April 2015 until April 2016. The service was part of the wider strategy of the CCG children's team to commission community services to improve patient pathways. The community-based respiratory service was run jointly by a respiratory nurse from the hospital and a physiotherapist from the local community healthcare provider. The purpose of the service was to direct children away from the hospital and care for them in the community (Project documents; Pilot evaluation). As such, the service accepted children referred from primary care or triaged from secondary care, who needed some additional support to control and manage their condition, but who did not have any complex needs requiring specialist input.

"There were two nurses that were based in the hospital. They were actually just supporting consultants to see children. Whereas, what you really, and a lot of those children didn't really need to go to a hospital setting to be seen. But what we did was, we commissioned a service where we have the nurse specialist based in the community, seeing a cohort of children that they could see within their skill mix, with appropriate criteria. And then when needed, the children would be escalated and moved on, to be seen in secondary care." (Clinical lead site D, interview)

The service also liaised with the acute response team to support children who have had acute asthma exacerbations. The acute response service was used to implement the asthma best practice guidelines to review all children attending hospital with an acute exacerbation within 48 hours of discharge. During these reviews, the acute response team would assess whether the child needed more support to manage their asthma, and refer them to their colleagues of the respiratory service if this was the case. As such, the community-based acute response and respiratory service worked together to support children with acute asthma to better control and manage their condition, thereby reducing the likelihood of them returning to the emergency services.

"[C]hildren who've been admitted into hospital with a wheezy episode, on discharge from the hospital, they are referred to the [acute response] service for their 48 [hour] review. The national review into asthma deaths in 2014 stated that all children who have been admitted into hospital should be reviewed within 48 hours in primary care. That, to get them to be seen by the GP often doesn't work, but we can see them in the [acute response] service. And because it's classed as a community service and primary care, then that meets those guidelines. So, we see a lot of children in [the acute response service] who have been in the

hospital. When we review them, if, when we're taking their history it turns out they've been in hospital quite a lot or attended their GP frequently with wheeze, then we can refer them directly to the [community respiratory] service from there. And then, the other way that we will do it, is the children who the GP send in with an acute wheezy episode, again, when we take the history, if this has been a recurrent feature, then we can direct them to [the community respiratory service] as well." (Nurse team lead site D, interview)

Evaluation of the 12-month pilot of the community respiratory service resulted in its continuation as a commissioned service (Project documents; Pilot evaluation). It was demonstrated that the service was likely to be cost-effective by diverting expensive secondary care appointments where appropriate, and by reducing unscheduled care appointments through supporting children to better self-manage their condition. Moreover, children and parents had overwhelmingly positive feedback about the service and especially highlighted how useful the educational support had been. The importance of educational support was also reinforced by healthcare professionals who had been interviewed as part of the evaluation. They highlighted how longer clinic appointment slots and seeing children when they're not acutely unwell, is likely to be conducive of parents being better able to absorb any information given. Moreover, specific advantages of the community respiratory service that were highlighted were better access, both due to the physical clinic location and shorter waiting times, and the service accepting children as young as 6 months. The age criteria for the community respiratory service had been changed from 2 years to 6 months during the pilot, because it was highlighted that GPs felt less confident managing young babies, and parents needed longer appointments to feel confident and reassured about the condition and medications of their wheezy babies. The changed age criterion resulted in an increased number of referrals from primary care.

After the successful pilot of the community respiratory service, the last item in the business case for a children's integrated pathway of community-focused healthcare could be addressed – a review of the dermatology service. The proposal to review the children's dermatology pathway arose from the observation that different dermatology services were provided for children, each with advantages and disadvantages.

"The hospital were running a paediatric eczema clinic, which was run by one of the nurses. But it was charged at standard outpatient tariff, like seeing a consultant, but they were just seeing a nurse. So, then we went through a period of time, where… Then we were told that we're not allowed to refer to that service, because it's not actually commissioned [appropriately]. And then all of the children were being referred to the [community]

dermatology service, which wasn't actually specifically a children's service." (GP site D, interview)

The benefits of these dermatology services were complementary. The eczema service delivered in the hospital was specialised towards children, whereas the community-based dermatology service was more cost-effective. This was taken as an opportunity to integrate both services and improve the dermatology pathway for children. The dermatology service review was also taken as an opportunity to align the service improvements with the acute response and respiratory service as part of the CCGs strategy to deliver care closer to home when appropriate. This resulted in the implementation of a new children's dermatology service delivered in the same community location as the acute response and respiratory service.

"[T]he children with eczema or adults with eczema, or any skin condition, are seen by a community provider anyway, under a block contract. And what we did was, the waiting times were very long, exceptionally long. But what we did is, we then liaised with that provider to say: 'why don't we have a service where we can just have children seen, with common skin conditions, in a clinic that would be based at the same place where we had the respiratory team based, and we have the [acute response] team based? So, it's all children being seen under one umbrella.' So, [that's regarding] the clinicians from [the community provider]. And then there was a nurse in the hospital who was actually doing the same, but they were not joined up. So, we brought those two clinicians together, to run the eczema and dermatology service in the community." (Clinical lead site D, interview)

The new children's dermatology service that was implemented in December 2016 built upon the community dermatology service that was already delivered. The existing community dermatology service was delivered by a consultant and a GP with a special interest in dermatology, supported by a nurse. They would run mixed clinics for adults and children, diagnosing and managing a range of skin problems (Project documents; Service specification). To improve this service for the paediatric patients, the consultant and GP were asked to run a separate clinic twice a month where they would only see children in a child-friendly environment. More specifically, these clinics were moved to the building where the children's respiratory service and the acute response service were delivered also. Moreover, the specialist paediatric eczema nurse from the hospital was asked to come and support the service with an eczema clinic. She had been involved in the development of a hospital-based eczema service, where she was independently delivering eczema clinics for children. To support the new service, she was asked to deliver her eczema clinic twice a month in the community alongside the consultant- and GP-led clinic. The purpose of doing so, was to integrate the hospital- and

community-led dermatology services, and to make her specialist skills available to children closer to home.

> *"Unfortunately, in the community they didn't have a paediatric nurse that deals with children all the time. So, my role was to come out of the hospital to provide that service as well. […] I feel [children] need their own environment. They need nurses that are dealing with children all the time. So, we're aware of all the education and psychological needs, as well as treating the physical conditions. So, I think it's really needed in that respect. Plus the waiting rooms were not ideal, all the time to be with adults. So, it's streamlining for children, really." (Specialist nurse site D, interview)*

The two types of clinics delivered as part of the children's dermatology service are complementary. The nurse-led clinic mainly focuses on practical and educational support for children and parents to manage their eczema, whereas the consultant/GP-led clinic focuses on diagnosis and treatment of a variety of skin conditions, like warts and blemishes. However, having both clinics run simultaneously next-door to each other facilitated clinical collaboration and support.

> *"What the dermatologist's seeing is just mainly things he can diagnose and then treat from this clinic. So, the letters are triaged by a nurse to make sure we're getting the right patients to the right clinics. […] Mine's only, mainly eczema children. So, if it's, sometimes the GP might not have explained that in the letter, and it might go to the dermatologist in his clinic. If it does, and he knows it's eczema, and it needs more practical and more support, then he'll pass that patient onto me. Sometimes I've had a patient come in on my clinic. It might say it's an eczema, the GP thought it was an eczema rash, and then when I've looked at it I think 'no, I don't think this is eczema'. I've asked the dermatologist then for his opinion, and he's come into my room and then he might say 'this treatment'. If he wants to see them again, then I'll move it over to his clinic. So, it's nice that we're both here at the same time so we can bounce off each other, really." (Specialist nurse site D, interview)*

The children's dermatology service also has a level of collaboration with the respiratory service that runs in the same building. The daily operations of all three children's community services (the acute response, respiratory and dermatology services) delivered in this building are managed by the same person. As such, she is able to plan and coordinate referrals between services to some degree. Moreover, knowing all nurses who work in the building and the remit of their expertise, facilitates clinical advice being asked and shared. This is especially relevant for the respiratory and dermatology service, with many children having asthma and eczema as comorbid conditions.

"[I]f we have children who have come to us with asthma, who we know have got eczema as well. And sometimes the eczema exacerbation can cause a flare up of their, sorry the asthma exacerbation can cause a flare up of their eczema. And if we've got any concerns about that, if the parents don't feel that they're able to cope, then we can contact [the eczema nurse] straight away and ask for advice. We try and keep one appointment free in her Thursday clinics for children like this. It doesn't always work. And that is, at times, she does have to see them in the hospital, which isn't what the CCG [prefers], but it's the best thing for the child." (Nurse team lead site D, interview)

4.6.2. Improving the pathway for children with allergies

As such, by 2017, the team had delivered the changes and improvements proposed in their business plan to support the delivery of *"a 0-19 Children & Young Peoples integrated pathway of community-focused healthcare"* (Project documents site D, Business case). To continue this agenda, improvement project D was initiated, focused on *"improving pathways for paediatric allergy"* (Project documents site D, Meeting agenda). The focus on allergy pathways was seen as a natural progression from the dermatology service. Firstly, because eczema is often caused by allergic physiological mechanisms, which are therefore best considered together.

"Some of the GPs are not aware of everything we do. And then I have to stress there's no allergy testing that will be done here. It'll have to be referred through to the [hospital] service. […] [The] consultant paediatricians, they're seeing different children in their clinics. And then they feel it might need another investigation to go the lines of skin tests. So, then they'll ask me to do that. And my, part of my role is doing that in the hospital environment. So, sometimes I feel like I'm doing part of the service here in the community and then all the service in the hospital." (Specialist nurse site D, interview)

Secondly, because many allergic children have comorbidities. As such, focusing on the children's allergy pathway could improve the integration between the community-based respiratory and dermatology service that had already been implemented.

"[The respiratory nurses] do their own clinics, I do my own [eczema] clinics. And then sometimes we get the occasional patient where they've seen both of us. […] But I think in the future we could work more together. Because we are a lot similar, what we're doing and what they're doing. And a lot of patients are atopic, so they've got the eczema, the asthma and hay fever all in one." (Specialist nurse site D, interview)

> *"[I]t was natural progression really, from the [children's dermatology] service, to the paediatric allergy service. Because they are interlinked, and they are again interlinked in terms of respiratory. So what, in an ideal world, you'd want, is a one stop shop, really." (Clinical lead site D, interview)*

As such, improvement project D started in September 2016 to improve children's allergy services. Both the clinical lead and the project manager for the CCG's children's team had developed project management expertise through practical and educational experiences in their careers that shaped the project management strategy used for improvement project D.

> *"So, we create a project management plan, you have objectives, you have outcomes, you have timescales, you have a team, you have stakeholder engagement, visioning events, looking at evidence. So, these elements are all very, very similar [across project management approaches]. And that's how we applied that to this project" (Clinical lead site D, interview)*

The project management strategy used in site D, included a literature search which resulted in their engagement with the Itchy Sneezy Wheezy intervention. It was performed to identify innovative services and interventions to learn from. Initially, the literature search identified a team who had adopted the Itchy Sneezy Wheezy intervention in their local area.

> *"[I]t was through a literature search [we found the other Itchy Sneezy Wheezy project]. And then [our project manager] happened to know one of the GPs who works there. And then [she] organised for, because I couldn't go, [one of our paediatricians] and a few others to visit the service." (Clinical lead site D, interview)*

Through this team, the idea for a community-based children's allergy service could develop further. Moreover, they facilitated an introduction with the Itchy Sneezy Wheezy team for further input. Contact with the Itchy Sneezy Wheezy team started in July 2016 during a phase of stakeholder engagement. During this phase, connections were made with national stakeholders for inspiration and advice, and with local stakeholders to develop a team with the necessary skills and motivation to improve local allergy services. By September 2016, a stakeholder map had been developed with mostly named individuals to engage, satisfy, monitor and inform (Project documents; Stakeholder map).

All stakeholders were subsequently invited to the launch event of improvement project D which took place in October 2016. Their engagement was one of the achievements of this meeting.

> *"[Consultant paediatrician]: this has been the largest group of allergy-minded people sitting in the same room in [site D] since, well, ever […] That's what we need enthusiasm." (Site D, fieldnotes)*

Different stakeholders were invited to present on their experiences of the allergy services that were delivered locally. This included presentations from a father of a child with complex food allergies, a paediatric hospital consultant, a GP with a special interest in allergies, someone from the referral management team, and the manager of the hospital-based laboratory doing allergy blood tests. The aim of these presentations was to create a shared understanding of existing services and to create a shared problem definition for the project (Project documents; Meeting agenda).

> *"The way this meeting was set-up was that we heard the experiences from all these stakeholders. So, that we really did get quite a rich picture. I thought it was interesting that the healthcare professionals were really caring and understanding towards each other's stories and perspectives." (Site D, fieldnotes)*

The next part of the meeting was focused around the development of a driver diagram to draft the team's shared problem definition and to define a purpose for the project. Doing this as a team exercise was important to the project manager, who had defined the purpose of the meeting as *"clarify[ing] collectively what we are trying to achieve" (Site D, fieldnotes).* Moreover, she explained that collaboration and sharing insights is necessary to think outside of the box of our own experience and helps to identify innovative and creative solutions. It also creates empathy, which results in the development of solutions that are appropriate and liberating for all stakeholders involved, which will subsequently motivate people to put in the effort required to make change.

> *"[Project manager]: there is a need to collectively come up with a solution that's workable. […] We are all really good at doing our own bit, but it's hard to go beyond that. And for that to happen, we need to do it together. [The project manager] emphasises repeatedly that we need to work together." (Site D, fieldnotes)*

With this intention in mind, the driver diagram exercise ended up being a collective brainstorming identifying a shared purpose and different drivers.

> *"[The project manager] asked if I wanted to write on the whiteboard, which I agreed to do. The process became quite fluid. There was a lot of shuffling, erasing and writing down new things. I wrote down everything that was being said, asking people 'where' rather than 'if' it should be placed on the board. Only when things involved measures or specific interventions I did not want to put it on the board, as to me those were next steps. Especially [our patient*

representative] was very excited about this process and contributed a lot. [The paediatric consultant] did as well. However, I felt like some other clinicians struggled more to surrender to the process, trying to see how the specific interventions and targets they had in mind aligned to the drivers being brainstormed." (Site D, fieldnotes)

The drafted driver diagram was taken by the CCG team to prepare for the next team event. Initially, they went through a process of data analysis to better understand the issues discussed at the launch event and to specify potential areas of improvement. Then, they collated a list of improvement ideas from the presentations, discussions and other stakeholder interactions. This was followed by a cost calculation for all improvement options, which were then grouped based on the level of financial investment required for their implementation. The analysis was performed at the CCG over a 3-month period by a temporary member of staff with support from the project manager and clinical lead. The work was presented at the next stakeholder event in January 2017 with the aim to share some of the reasoning behind the improvement options that were proposed, and to support the team make informed decisions on how to move forwards in the project. The data presentation was followed by a review of the driver diagram in small groups. After which the group was brought back together to switch focus from the problem definition to thinking about practical solutions. They were asked to review the improvement options prepared by the CCG, which resulted in the development of an initial action plan consisting of four clinical work streams and a team of named individuals assigned to each.

"Yeah, so in terms of progress there was, I think there was a number of work streams that we took from the driver diagrams that we said we would take forward." (Project manager site D, interview)

4.6.3. Continuing local efforts to improve allergy testing

The first work stream focused on allergy testing. In site D, skin prick testing is performed in the hospital when children with suspected allergies have been referred for a paediatric outpatient clinic appointment. Alternatively, clinicians in primary and secondary care can request blood tests that detect IgE antibodies to specific substances. When IgE antibodies are present in the blood sample, this is indicative of an allergy to the substance. Initially, allergy blood testing requests were referred by the local hospital in site D to a bigger regional hospital with a specialist immunology laboratory (Project documents; Project presentation). However, this was an expensive process for the hospital. So, when in 2014 the biochemistry Department reviewed their work processes to explore how they could make quality and cost improvements, allergy testing was one of the processes on the agenda for change.

> *"So, when you refer these allergy [tests] off to another laboratory, the other provider does, say, a panel. And a panel of allergens will be a particular mix that says, you have five constituent allergens [tested] within that mix. And if it comes back as positive, then it can be any one of those five [allergens you are allergic to]. So, they then do all the five specific [tests]. So, you can see quite quickly how it can cascade into being quite expensive. […] [W]e always had a very large spend on allergy" (Biochemistry manager site D, interview)*

During the review, other immunological tests were also identified as particularly expensive to refer to a different hospital. Subsequently, the biochemistry team investigated how these costs could be cut, and they identified a piece of equipment that allowed them to do some of these immunological tests in-house. After purchasing the new testing equipment, the team had to ensure they were adhering to all safety standards. As such, they launched their new testing service with an initial trial phase, whereby all test results were validated against the same tests being performed by a different laboratory.

> *"We had a projected rollout. Because obviously, everything that we decided to analyse on that equipment had to be validated and checked against UKAS standards. So, we couldn't just go big bang with it and do everything at once. So, we had to check the results that would come in from the reference laboratories. [Check] that they were comparable to what we were reporting, and then migrate over." (Biochemistry manager site D, interview)*

Moreover, the team appointed a clinical immunologist working for a different hospital to oversee the service and to provide a clinical review for all positive tests.

> *"So, we have a consultant, who works [at another] immunology department, [who]'s responsible and monitors all our work clinically. And certain tests that we do, that need input from them, we refer to them. So, we're more of a negative screening immunology laboratory. And all our positive tests go over to [hospital X] to be reviewed by the consultant over there." (Biochemistry manager site D, interview)*

This new testing service delivered by the local hospital in site D went live in April 2015 and started doing allergy tests in April 2016 (Project documents; Project presentation). Clinicians could request allergy blood tests either on paper or electronically. Electronic requests were supported by the Integrated Clinical Environment (ICE) software, which integrates the laboratory information system with the IT systems used in primary, secondary and community care to optimise communication between services and to share data safely. To encourage electronic requesting, the biochemistry

team had gone out to GP practices to liaise with GPs and practice managers, which is how the biochemistry manager and the clinical lead met initially.

> *"[Her] Practice is only, like, round the corner. And originally, when we were rolling out the ICE project, she was one of the clinicians that I met then, at that practice, when we was rolling it out, myself and the girl who left. So, I knew [the clinical lead] from that perspective." (Biochemistry manager site D, interview)*

Subsequently, when improvement project D started, the clinical lead reached out to the biochemistry manager to see if they could collaborate to improve allergy testing for children.

> *"[The clinical lead] emailed me out of the blue. And I said to her 'oh well, this is, I could see the project that you're doing, as in, it runs quite nicely alongside what we're currently trying to do', which was to review how we did allergy testing in the community. So, that's how I got involved." (Biochemistry manager site D, interview)*

When the allergy testing sub-team got together, they identified a number of possible improvements. For example, many children testing for allergies don't require expensive blood tests and could be diagnosed using skin prick tests that are cheaper and quicker. As such, the team explored whether the supply of skin prick testing could be increased. The development of a community allergy service was seen as an opportunity to make skin prick testing available in the community, where it wasn't yet provided as a service. Considering it takes about 30 minutes to perform a skin prick test and get the results, this is not a feasible procedure to integrate into primary care consultations that take about 15 minutes on average. Moreover, offering skin prick testing requires the practice to invest in the procurement and storage of materials, and the test results require a level of clinical interpretation, which might not be within the clinical competences of the practice physicians. As such, skin prick testing tends to be a secondary care service delivered at the hospital. In site D, skin prick testing was a standard procedure offered during their paediatric allergy clinics. Moreover, in their general paediatric clinics, consultants sometimes identified patients suitable for skin prick testing, which they then asked the nurse to perform there and then if she was available. However, the demand for skin prick testing was very high and the workload for skin prick testing at the hospital could not be further increased within existing resources.

> *"We do a couple of allergy clinics a month with [paediatrician A]. So, I'll be there on Wednesday morning when he's doing his allergy clinic. He does two of them a month with me, but he's started doing clinics every week on his own. So, it reduces the amount of patients, because he does his own skin prick testing as well, because there's only me in this*

role doing it. And I can't afford to give another day's clinic for him when I've got other patients on the ward that I've got to deal with as well. So, it will be [paediatrician A], but my skin tests for the hospital, there's quite a lot I can do. And that's [also] from all the other consultants, and all the paediatricians, we've got nine paediatricians, but also the ears, nose and throat consultants at the hospital." (Specialist nurse site D, interview)

As such, the focus was shifted from skin prick testing to improving the requests that were made to the laboratory for allergy blood tests. The data presented at the stakeholder meeting in January 2017 had highlighted a steady increase in the number of allergy tests requested in primary and secondary care in the three years prior to the hospital's re-configuration of their allergy testing service (Project documents; Presentation). Moreover, data collected at the laboratory demonstrated this trend had continued after the re-configuration also (Project documents; Presentation). Consequently, the allergy test requests received by the laboratory were investigated further for opportunities to improve the quality and efficiency of allergy testing in site D. This work aligned with the work of the biochemistry team, who were improving and streamlining their new testing service. As such, the work could be incorporated within their improvement project without additional financial resources. When reviewing the laboratory's allergy test requests, it was identified that the requests from primary care often lacked a clear clinical grounding. For example, many requests were received for rare and unlikely allergies. Moreover, requests often involved large panels of allergens unlikely to all be relevant. To improve this issue, the ICE lab request system was seen as an opportunity by operating as a decision support tool to support physicians to make more relevant test requests.

When the lab-based allergy testing service was first implemented in April 2016, the ICE requesting process was very basic. However, the ICE system had a range of functionalities that could be implemented to optimise this process. Initially, the team decided to use this functionality to restrict the tests that could be requested in primary care. This involved restricting the particular allergens that could be tested.

"So, I think at the last meeting that we had with [the consultant], we populated all the specific allergies onto the ICE system so that they're available. We've put some restrictions specifically on children. So, any kids under one could not have any daft allergies requested, because they just weren't exposed to those. So, there was no need for those to be requested." (Biochemistry manager site D, interview)

This also involved restricting the particular tests that could be requested. Specifically, the possibility to request stool tests for diagnosing lactose intolerance in infants had been removed for primary care practitioners. The reason is that in infants, lactose intolerance is very rare and consequently

these cases could be diagnosed in secondary care where the test is still available to request (Interview transcript; Consultant site D).

> *"We have managed now, to stop GPs from requesting faecal reducing substances [tests] for lactose intolerance. Because what was happening was, in primary care, GPs were getting confused between lactose intolerance and cow's milk protein allergy. And they were unnecessarily requesting the lactose intolerance test. So, what we again did was, myself and [our consultant], we put briefs in the bulletin [as] good education. We've got a GP bulletin that goes out to practices, and it's again, around education, to educate practices. But then we decided, the condition lactose intolerance is so rare that we might as well take it off EMIS and ICE, for primary care to request. So, primary care cannot actually request that test, and it's not needed in fact." (Clinical lead site D, interview)*

After implementing the testing restrictions, the team wanted to implement a clinical decision tree as part of the ICE request process to provide physicians with a set of suggested allergens to test for. The suggestions would be based on information on the child's clinical history, provided by physicians. A machine learning algorithm would then predict what allergens to test for based on the clinical information provided, improving its predictions by testing them against the actual test outcomes.

> *"And we were then also going to look at trying to take some clinical information via a set of questions. So, when you requested, sort of like, an allergy reaction test, it would ask questions like: 'Have you been experiencing any symptoms? What are they? Blah, blah, blah. Are they seasonal? Does it affect your sleep pattern?' All these types of things. And then from those questions, we'd hopefully then present the user with the list of the allergens that would be the most likely, that are causing them the problems. There are less likely suspects, because you can actually see that from the requesting patters and the results that you actually get." (Biochemistry manager site D, interview)*

Unfortunately, this work was delayed when a key member of staff supporting the technical implementation left her job due to workload issues. Nevertheless, when I left the field in 2018, this work stream was still on the agenda and being progressed by the biochemistry team.

> *"[W]e had one person in the trust who was a specialist with ICE. […] [S]he was the ICE administrator, but she was also doing a lot of other things for the IT department with the rollout of other projects. And I think the work got a bit too much for her, and in the end she just said 'I'm leaving'. And she left to go and work for ICE. So, she works for the software company […] and took all the experience with her. So, that left us in a bit of a situation where*

we had to try and learn how to do it ourselves, with no resource, and manage our own job. So, we haven't actually fully deployed anything yet. […] [But] I've been trying to train one of my staff, as part of her role, to do some ICE work, to get this up and running. We've sort of like, we've looked at one pathway for airborne allergens, for respiratory type allergens. And we're just sort of like working through those, and trying to get ICE to do what we think it can do. But, we may as well, because we've lost that experience in the trust, we may not, it may not actually be possible to do it with that system. So, we're just feeling our way around that at the moment." (Biochemistry manager site D, interview)

4.6.4. Adopting regional strategies to improve CMPA management in primary care

The removal of the option to request stool tests for diagnosing lactose intolerance in infants aligned with the second work stream of improvement project D, which focused on allergy prescribing. More specifically, the team decided to improve their local prescribing of milk-replacement formulas in alignment with regional improvement work happening at the time. In 2013, practical guidelines were first developed in the UK to support primary care physicians to diagnose and manage Cow's Milk Protein Allergy (CMPA) in infants (Venter, Brown, Shah, Walsh, & Fox, 2013). Following publication of these guidelines, the regional medicines network for site D developed specific recommendations for prescribing milk-replacement formulas for children with CMPA and lactose intolerance. These recommendations were first published as regional guidelines in November 2014 with an updated version published in April 2017 (Project documents; Prescribing guidelines). These regional guidelines were developed with support from the regional allergy network, who were also doing other work to optimise prescribing of milk-replacement formulas in practice. In January 2016, the network started an improvement initiative to better support children with CMPA (Project documents; External project report). The initiative was part of the RCP Future Hospital Programme and officially finished in September 2017 after 1.5 years. They developed and ran a survey between May and September 2016 to establish the level of confidence and knowledge in primary care regarding the management of children's allergies (Project documents; External project report). They also analysed data from multiple CCGs on the prescription of milk-replacement formulas to assess the quality of CMPA treatment. As solutions to improve the management of CMPA, the regional allergy network did a pilot with a local CCG to test a consultation template developed for primary care and to test group dietetic sessions as a way to support families more efficiently and effectively.

The CCG in site D had been collaborating with the regional CMPA initiative as a means to support local improvements. For example, the preliminary research of the CMPA initiative had highlighted that also in site D there was room to improve the management of children with CMPA in primary

care. Site D had contributed to the data collection of the regional CMPA project, which allowed for its local data to be analysed separately as part of improvement project D. This highlighted that from the 22% of GPs responding in site D, only 52% felt confident to advice the parents of children with CMPA on milk-replacement formulas (Project documents; Presentation). Moreover, about 65% of children were prescribed an extensively hydrolysed formula and 35% an amino acid-based formula, in contrast to expert opinion estimating that roughly 90% of children can successfully manage their CMPA with the cheaper extensively hydrolysed formula (Project documents; Presentation; External project report).

Moreover, collaboration with the regional CMPA initiative aimed to attract external resources for local improvements. The pilot for the group dietetic sessions performed as part of the CMPA initiative had good results, which were presented an allergy network meeting at the end of 2016. During this meeting, the group was also asked about their interest to be included as a test site in a research funding application to roll-out and study the concept of group dietetic sessions on a larger scale. Site D joined the application as an opportunity to support their highly stretched dietetic service with a funded position for a dietitian to deliver the group sessions on CMPA. The research funding application was submitted in March 2017. Unfortunately, though, news came in June 2017 that the application had been unsuccessful (Project documents; Project report). Moreover, in December 2017 the CCG in site D went into a voluntary financial turnaround, which meant that no new business cases were going to be financially supported that could have increased capacity of the dietetic service through CCG financing.

As such, site D was in a situation with local data highlighting a need to improve the management of CMPA in primary care; with updated regional CMPA prescribing guidelines; without external research funding to improve local CMPA services; and without CCG funding for local service improvements. Consequently, the team focussed on possibilities to improve the management of CMPA in primary within existing resources.

> *"Since we were in the position that we were in, and no extra money could be invested, let us then concentrate on primary care. To see, and also, let us concentrate on the primary care prescribing for cow's milk protein allergy, diagnosis of cow's milk protein allergy, and also start looking at the test request. You know the blood tests requests that go through for milk allergy? And see if we can improve patient care, quality of those investigations, quality of coding, diagnosis, prescribing. And in other words, improve and concentrate on primary care." (Clinical lead site D, interview)*

First, team D took the opportunity to collaborate with their CCG medicines management team to encourage implementation of the regional CMPA prescribing guidelines in primary care. The medicines management team had been working on the implementation of Optimise Rx as a way to improve the quality of GP prescribing and to reduce the cost of inappropriate prescribing. Optimise Rx is a clinical decision support system that is integrated with the IT systems used in primary care. It flags to GPs any prescribing decisions that are not in agreement with local policies, and it prompts them with the relevant evidence so they can re-assess their decision (Project documents; User manual). Consequently, publication of the new CMPA prescribing guidelines in April 2017 aligned the interests of team D and the medicines management team to implement new Optimise Rx prompts for milk-replacement formula prescribing in accordance with the new guidance. The prompts were embedded in the GP systems by June 2017.

After the CMPA Optimise Rx prompts were embedded, team D continued their efforts to implement the new CMPA prescribing guidelines using clinical audits. Towards the end of 2017, the clinical lead and her trainee did an audit at their own GP surgery to understand and improve the practices of their GPs on diagnosing and managing CMPA in young children. The audit was designed based on the updated regional guidelines, and the results were fed back to the clinicians to make them aware of particular issues that were found and to encourage them to change their practice.

> *"[W]e did, conducted an audit of all patients up to the age of four who've been diagnosed with cow's milk protein allergy. [Collecting data on] what they are being prescribed and what's going on with them, [so] are they being put on the Milk Ladder, are they on the right milk, are they being prescribed the adequate amounts? So, my GP trainee did the first cycle audit. […] [T]hen we presented the audit in our practice. We've got a list size of 10,000 with six, eight GPs and four trainees. [So,] presented the findings of the audit, which basically showed that, A) there were problems with coding, B) there were problems with prescribing amounts, C) the right milk was not being prescribed. As a result of which, it had cost implications. And the other important thing is, there were a few children aged three or four, who weren't actually on the Milk Ladder and were still being prescribed the milk, which needed to be addressed." (Clinical lead site D, interview)*

A paediatric hospital consultant and a dietitian were invited to attend the audit feedback session to answer any questions and to provide some additional educational input. As such, the audit provided a useful educational opportunity for GPs to improve their prescribing of milk-replacement formulas and to gain more confidence in diagnosing and managing CMPA.

"I remember being in one of the committees and one of the GPs literally launched at me with 'these terrible parents are coming in and demanding these milks, it's terrible, we need to stop this from happening'. Which shows, well, there probably was an issue with that. But probably because the quality of care and the knowledge was not good enough in primary care around it. So, they, basically they were just, it felt like GPs were saying, 'we're just prescribing them to get them out of the surgery', without really understanding. They were just responding to that parental need. Whereas now, the conversation seems to have shifted to being 'well, we still have a bit of that, parents coming in demanding, but we have a better understanding now of what we're meant to be, what we're meant to be saying and doing. We understand the kind of evidence-base behind it'." (Project manager site D, interview)

The success of the CMPA audit at the GP practice of the clinical lead was followed by the decision to roll-out the audit in 2018 across the other 29 local practices. The roll-out of the audit was mandated and registered at the CCG as an improvement project to achieve their Quality, Innovation, Productivity and Prevention (QIPP) goals for 2018/19. The hospital paediatrician and dietitian had offered to continue their educational support for the practices that were interested.

"[T]his audit is going to be repeated by my registrar and we've got a medicines coordinator in each and every practice, who [will support]. And it has become a, now, a mandate for all practices to be conducting this audit." (Clinical lead site D, interview)

In a greater effort to improve the management of CMPA in primary care and achieve the 2018/19 QIPP goals, team D also implemented a consultation template to support GPs. The template was an adaptation of the consultation templates developed by the regional allergy network. As part of their CMPA improvement initiative, they had developed two CMPA consultation templates to support GPs to deliver evidence-based care in agreement with current guidelines. Both templates were made for EMIS, a widely used primary care IT system. One template was tailored towards GPs with an interest in allergy, supporting them with the diagnosis and management of new patients suffering from CMPA. The other template was less detailed, focusing mainly on prescribing milk-replacement formulas. After the templates had been piloted successfully, they were taken by the clinical lead of site D and adapted in collaboration with the CCG's medicines management team and their IT Department to ensure alignment with local processes and work flows. The adapted CMPA consultation template was tested in the practice of the clinical lead in February 2018, after which it was rolled-out to the other practices in the area.

"[T]hey had the template, but it needed tweaking. So, we have now got a cow's milk protein [consultation template]. And I worked with [the] IT department in clinical commissioning and

another unit to have a template for cow's milk protein allergy in EMIS Web. In our, which, and this, we are testing it out next Tuesday, and then it will be rolled out to all the 29 practices. So, when they can see, or, when they see a kid with cow's milk protein allergy, they are going to be using that template to help them diagnose, prescribe. So, it's basically, a template is a prompt" (Clinical lead site D, interview)

4.6.5. Allergy education for professionals in the community and primary care

The CMPA consultation template and clinical audit both contributed to the education of healthcare professionals working in primary care, which was the specific focus of the third work stream of improvement project D. As part of this work stream, several opportunities were found to educate health professionals within existing structures. Two hospital consultants and the dietitian had offered to deliver training sessions on childhood allergies to primary and community healthcare professionals who were interested. The clinical lead facilitated the organisation for their offer to reach the intended audience. She invited them to present at a couple of Practice Learning Time (PLT) meetings from June 2017 onwards, which were organised by the CCG every other month to update and educate all primary care professionals in the area. She also invited them to present at the paediatric symposium in September 2017, which targets healthcare professionals with an interest in children and young people. Finally, she had put them in touch with sponsor organisations that were part of the CCG relational network. This resulted in a collaboration with Nutricia, facilitating the delivery of training on CMPA, lactose intolerance, and formula prescribing at regional events for primary care. Moreover, the healthcare professionals were also contacted directly with requests to deliver allergy training. For example, the dietitian was invited in the summer of 2017 to deliver training on CMPA to the local health visiting team at one of their monthly meetings. And she had supported the development of a community-based dietetic colleague.

"[W]e do have dieticians that are based in GPs surgeries and those dieticians are adult trained dieticians. They haven't done any paediatric training. But one of the girls, she's left now, she's moved back to Ireland. But she did have an interest in, I did some training with her, for her to be able to, again, manage those simple cow's milk allergy patients. So, they were seen a lot quicker, they were seen in their own GP surgeries, and they were managed by a dietician there. And then only referred into myself if it turned out to be complex and she didn't feel competent with the management. So that worked really well for helping with my caseload and waiting list, helping the patient satisfaction. […] So, going forward, that's something that I would be quite keen to do, but it depends on the dietician feeling competent and confident and wanting to have that training." (Dietitian site D, interview)

The consultant on the other hand, had been requested by schools and by parents of his patients to deliver allergy training in schools and nurseries. These training sessions would focus primarily on general allergy information, EpiPen training, and the management needs of specific pupils. Moreover, he would discuss allergy during hospital-based lunchtime teaching sessions for GP trainees. However, the consultant acknowledged that allergy training is lacking for this particular group.

> *"[W]e have potentially seven GP trainees going through our department every four or six months, and it would be unlikely that all of them would get to come and sit in an allergy clinic. So, I think sadly, as we probably most of us know, that it is an area that's deficient in their training. […] [B]ecause when you think about what problems occur on the ward, it is babies coming in with vomiting and things. So, on a ward round and everything, most of them will be aware of milk intolerance and reflux and what we do about it. But the other allergies, you don't get children coming onto the ward with egg allergy, or particularly peanut allergy, or any of the other ones. So, that sort of thing is not something they're going to meet on the ward part of their training." (Consultant site D, interview)*

4.6.6. Finding a feasible solution to improve the integration of allergy care

The final work stream of improvement project D focused on improving patient pathways with the Itchy Sneezy Wheezy intervention in mind as a potential solution. Previously described project elements had all been delivered within existing resources, which was necessary due to financial resources being unavailable at the CCG at the time. Accordingly, any new health services to improve the patient pathway for children with allergies had to be delivered within the same financial constraints.

> *"The CCG had moved from a position of being open to investing in the development of community services to – we're open to invest in the children's, in the community service, but you have to demonstrate a return on investment. So, the climate had changed from when we started the children's community team with [the acute response] and [the respiratory service]. […] To come, just before Christmas [2017], we were in financial turnaround, and you wouldn't get a penny for anything, and actually we were taking money back from things. So, at the time [in the first half of 2017], it was about trying to make that return on investment case." (Project manager site D, interview)*

Financial modelling done by the CCG had highlighted that the implementation of a community-based allergy service, like the Itchy Sneezy Wheezy model, was no option in site D under the current

circumstances. For example, a key mechanism underpinning the financial case for the Itchy Sneezy Wheezy model was a reduction in unscheduled care by improving allergy management in the community. However, in site D, the costs for allergy- and asthma-related unscheduled care was already low with relatively few children attending the A&E department or being admitted because of allergies. These low of unscheduled care were likely influenced by the community-based acute response, respiratory and dermatology services that had already been implemented in site D. Moreover, these community services had also already shifted significant allergy-related outpatient activity away from the hospital by setting-up specialist nurses in the community to support children with asthma and eczema, who don't require specialised consultant input.

> *"[O]ur numbers going through [our] hospital A&E have gone down. Some of those will have gone through the [acute response] team instead. And equally, we've got another team in the children's community team, […], who deal with respiratory healthcare. So, there will be some activity that we have diverted away from the hospital, but that will have gone into the children's community team, which is pretty cost effective. Mainly, for the most part, nurse-led. So, if you see what I'm getting at in terms of saying that it's not as straight forward for us in [site D], as I understand it, to make an economic case for similar work." (Project intern site D, interview)*

Without an expected return on investment, the CCG was not able to financially support the delivery of a new community-based allergy service. Likewise, the local hospital was also not able to deliver a community-based allergy service within their existing resources. The hospital service involved one allergy clinic a week, run by a paediatric consultant, and another two clinics a month, where the consultant had support from a nurse doing skin prick testing. If children needed additional dietetic advice, they were referred to the highly stretched dietetic service.

> *[The other Itchy Sneezy Wheezy site] just moved one [clinic] to the community. So, that was 10% of their service, and they moved it to a practice. […] They went out there with two consultants and a nurse and the dietitian. So, they sent out to their peripheral clinic more than the total assets of my department. So, the model is not particularly good [for us]. So, it worked ideally so, in a sense that each consultant could spend half an hour with a patient, the dietitian could spend 15 minutes, and the nurse could spend 15 minutes. And so, that added up to an hour's contact for every patient. Right, and so, that's what I try and emulate [in the hospital]. So, I probably spend three quarters of an hour with everyone, because you don't have the other backup. And that's about the amount of time I think that many children with allergies need to spend with clinical people in order to resolve the issue, but yeah. So, I don't*

think unfortunately their model is something that's appropriate for a G[eneral] D[istrict] H[ospital], because you don't have the manpower." (Consultant site D, interview)

"[T]he majority of children I see, there isn't the capacity [for in-depth dietetic advice]. And unfortunately, sometimes you send a dietician referral, and it maybe four or five months before they get seen, which or a four month old with milk allergy, is a bit of a waste of time. So, that's our problem. I don't have, unlike the diabetic clinic, you don't have someone in the clinic with you. [And] I don't have anyone who will pick-up a quick referral, and that's a big flaw in our system." (Consultant site D, interview)

Consequently, the lack of dietetic support for children with allergies was seen as a key area for improvement.

"What we've identified is that we've got a real gap in our dietetics provision. But actually, we're spending quite a lot of money through a consultant's tariff, having consultants do the, some of the roles that perhaps a nurse could take on, or a dietician could take on, in terms of ongoing support and care. And I think that the consultants would agree with that." (Project manager site D, interview)

"The clinical lead and project manager were discussing that they see a dietitian as quite a cheap solution that can make a big difference. [Clinical lead:] 'we don't want her to get sucked into the general dietetics pool'. [Consultant:] 'we don't just need a dietitian, but paediatric and with expertise in allergy'" (Site D, Fieldnotes)

Neither the CCG nor the hospital had funds available to appoint another dietitian to support the dietetic team. Instead, the retirement of the dietetic service manager in November 2017 was used as an opportunity to explore increasing the dietetic capacity for managing children with CMPA. Her retirement freed-up clinical hours that could be re-distributed strategically in the dietetic team. Moreover, the team had one dietitian with a special interest in paediatrics and the skills to manage children with simple CMPA independently. She was interested in increasing her clinical hours to support the paediatric allergy service at a greater capacity. As such, it was decided to use this opportunity to implement a pilot.

"We need to demonstrate its benefit. If we are looking for, if there was no resources required to deliver this, we could actually say: 'well we'll do it anyway, because it's best-practice'. But actually, the person concerned is having to increase their hours, that's [our dietitian]. We need an admin person to increase their hours, and we need the consultant to change their practice. So, we actually need to have something documented. We need to formalise, so that

other people then looking in, and seeing the outcome of the pilot, can question and agree/ disagree whether in fact it's something worth investing in long-term." (Service manager site D, interview)

4.6.7. Piloting CMPA dietetic clinics

The pilot started in March 2018 over a 3-month period to trial a weekly dietitian-led CMPA clinic. The aims of the pilot were to test whether a dietitian-led CMPA service could safely reduce the consultant workload, while simultaneously reducing waiting times.

"[T]his pilot would be a single point of access for all the referrals from the GPs. And they would be screened by the team that look at all the referrals coming into the paediatricians and into the hospital as well. And then, the appropriate ones would come to me. That was how it was decided that it would work. […] That's a process that is still trying to be arranged on that end basically. So, in order to get the pilot up and running, what we've been doing, is looking at the referrals that come in through the, straight to the dietetic department. […] I am auditing whether the ones that haven't [been reviewed by a consultant already], whether they need a consultant referral [after my appointment]." (Dietitian site D, interview)

Whenever a patient attending the dietitian-led CMPA clinic presents with issues that fall outside of the dietitian's competency-level, she refers the patient to the paediatric consultant. Initially, however, the dietetic pilot was meant to reduce the need for consultant referrals by improving multi-disciplinary working between the dietitian and the consultant.

"[We want] the dietician to run a clinic, running alongside a consultant. The consultant seeing their own patients, but then if there were queries or questions in relation to the patients that they see as a new patient, at least there's a consultant in close vicinity within the same locality to ask or answer any questions" (Service manager site D, interview)

"[Consultant:] 'The other thing with diagnosis is, the dietitian has to go on history alone, and won't do any skin prick testing'" (Site D, Fieldnotes)

Moreover, the ultimate goal of team D had been to deliver a multi-disciplinary allergy clinic with a consultant, a nurse, and a dietitian working collaboratively to support children with more complex food allergies. However, the development of such a service short-term was not considered to be feasible within the local circumstances. Nevertheless, in an effort to prepare for the development of this model of care, the dietitian took the initiative to improve her allergy expertise. She identified professional development opportunities to learn more about managing food allergies in children

through the regional allergy network, where she networked with other dietitians and arranged to shadow one of the specialist dietitians in her allergy MDT clinics.

> *"I think it's a good pilot to, because there's quite a lot of proportion of patients are milk allergy patients. So, it's good in that sense. And it's providing a better service in that sense, but it's not really solving the allergy patients as a whole, that problem. […] It's been a milk allergy focused conversation and I think that's probably where my expertise is at the minute. So, I suppose that a learning point for me is really, I want to improve my knowledge and experience with general allergy. And that's why I'm going to shadow [a dietitian] in a more specialist allergy clinic, in a bigger hospital, where a lot of our patients, if they were complex, would get referred to that kind of service. So, that will be really useful to see how things are managed there." (Dietitian site D, interview)*

So, while the development of a community-based allergy service had been put on hold, a lot of other efforts had been made by team D to improve their local children's allergy services within existing resources.

> *"[W]e really have to think about, when you're looking at other models around the country, how similar is that situation to yours, and what's the likelihood of you being able to replicate that. Is it something you'd have to do on a bigger footprint? But some of that was driven by I think some people's view about wanting to develop the children's community team model in that way. Whereas if you look at your driver diagram, and the outcomes you're trying to achieve, and the primary drivers that we had around training, testing, prescribing, various other things. It's very possible that we might have achieved the same aims that we were aiming for, without actually investing in this all singing all dancing service. Now we'll have to keep monitoring that over time." (Project manager site D, interview)*

4.6.8. Summary

Team D had already developed children's services in the community, bringing care from the hospital closer to home to improve care pathways for specific groups of children. They ran respiratory and dermatology clinics and recognised an opportunity to improve the pathway for allergic children who often experience asthma and eczema as allergic comorbidities.

Subsequently, team D brought different stakeholders together to review local allergy services and identify areas for improvement. They also identified the Itchy Sneezy Wheezy intervention and invited the team and other presenters to share relevant insights and experiences during a project launch event.

The review of local services, however, identified that the added benefit on an integrated allergy service to the already existing respiratory and dermatology services could not be justified financially. However, team D identified a financial and quality opportunity for better collaboration and coordination in the hospital between the allergy and the dietetic teams.

Moreover, the review highlighted other opportunities to improve children's allergy services that were within the collective scope of influence of the team D stakeholders. Accordingly, the hospital team collaborated with the laboratory team to improve the allergy testing service, and they worked with commissioners to deliver training in the community.

As such, quality improvement methods were used to identify and evaluate improvement options, and collaborative alliances were sought to develop and implement interventions.

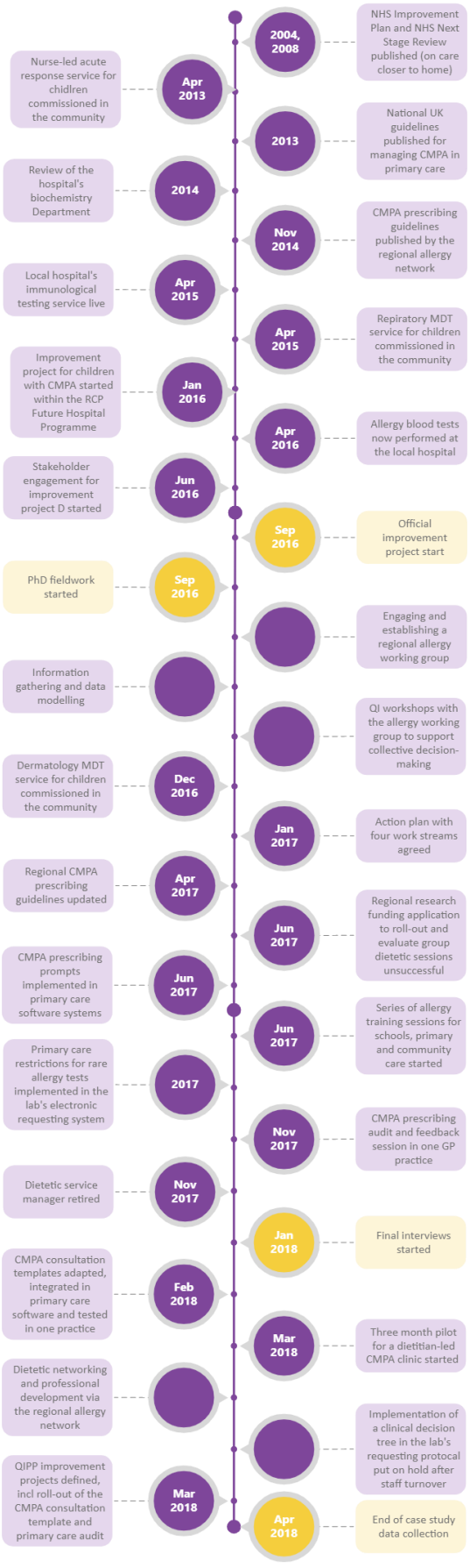


Figure 21. Timeline case study D.

4.7. Conclusion

This Chapter has presented narratives that describe the initiatives of four healthcare teams improving their local children's allergy services. More specifically, they describe the chronological developments of children's allergy services across four regional health systems. To best represent the unique dynamic and processual developments within each improvement initiative, a similarly unique narrative structure was used. Each narrative describes how the team engaged with the Itchy Sneezy Wheezy intervention, which is the connecting event across all improvement initiatives. As discussed in Chapter 3, cases were selected based on their intention to implement the Itchy Sneezy Wheezy intervention as a means to compare improvement initiatives. Accordingly, the narratives describe how teams got to involve the Itchy Sneezy Wheezy intervention in their improvement plans, what prior health service developments led to this involvement, and what improvement interventions were implemented thereafter. As such, the narratives describe how health service improvement interventions developed and evolved over time in each of four regions.

4.7.1. Spatio-temporal and geo-historical contingencies

Each case study narrative demonstrates how the improvement of children's allergy services reflects a contingent process of change. The contingent nature of change can be understood by positioning the start of each improvement initiative – positioning them in space, in time, and along their geo-historical path. In space, all improvement initiatives were located in the UK. As such, all improvement initiatives were part of the NHS and exposed to English policy initiatives. However, one initiative was located in the north-west of England and three in different London boroughs. The case studies reflected the geographical differences between London and more rural English areas that were also identified in Chapter 1. That is, allergy specialists are often less prevalent in more rural areas, which impacts the local capability to rapidly expand or re-design their allergy services.

In time, all improvement initiatives started between 2014 and 2016. Around that time several important policy documents were published that encouraged interventions like the Itchy Sneezy Wheezy intervention. For example, the NHS Five Year Forward View (Department of Health, 2014) encouraged the implementation of seven new models of care. One was the multispecialty community provider model that encouraged GPs to collaborate in networks or hubs and host specialist services outside of the hospital. The Itchy Sneezy Wheezy intervention and its nurse-led allergy outreach clinics are an example of this type of healthcare model. Moreover, the report set-out a goal to reduce hospital admissions and emergency attendances. As discussed in Chapter 1, asthma is one of the main causes for children to attend hospital (Blair et al, 2017), which meant commissioners were more motivated to improve children's asthma services. Moreover, reports like

the NRAD (Levy et al, 2014) or the London Asthma Standards (HLP, 2014) described clear strategies and guidelines to support the improvement asthma services. These developments align with the case study experiences. For example, team A shared how before 2014 they struggled to engage local commissioners. Team B shared how their successful collaboration with local commissioners relied heavily on the alignment of their goals through the London Asthma Standards (HLP, 2015). Team C and D, on the other hand, were both led by local commissioners. Both teams proactively aligned national policy goals with local data analysis to prioritise improvement initiatives, with the consequence that in 2018 commissioners from team D shared that they had put the allergy project largely on hold to focus on other policy priorities.

Finally, each improvement initiative is positioned at a specific point in the geo-historical development of their local allergy services for children. The services that have been developed so far, the life experiences that people bring to the team, and the relationships that have been established impact how the improvement initiatives unfold – both in terms of intervention adaptations and quality improvement methodology. For example, the leadership training of the clinical lead in team C had prepared and motivated him to take a population-based approach to improving local children's services. This shaped the improvement methodology that was used by team C that evolved systematically and progressively over several years. Alternatively, team D had already developed multiple community-based services by the time they engaged with the Itchy Sneezy Wheezy intervention. On the one hand, this meant they had already developed the expertise and relationships to deliver a similar project. However, the positive impact of their community services on asthma admissions in combination with low numbers of admissions for other allergic conditions made it difficult to make the case for further investment to develop an integrated allergy community service.

The positioning of the case studies in space, time and geo-historically explains why the four improvement initiatives are different, why they implemented different interventions and why they used different quality improvement methodologies. The mechanisms, like allergy expertise, that support the clinical delivery children's allergy services might not be present in certain areas. The mechanisms that motivate local decision-makers, like NHS policies, might not be present at a certain time. Or the relationships, the mechanisms that support interdisciplinary collaboration, might not yet have been developed in a particular region. As such, the spatio-temporal and geo-historical positioning influences which causal mechanisms are absent or present at the start of an allergy improvement initiative. Moreover, the way that improvement initiatives develop will depend on what mechanisms are activated over the course of the project. For example, team A had secured the finances needed to deliver an integrated allergy clinic in the community with dietetic and

administrative support. However, due to operational issues, finances could not be released and the dietetic and administrative support needed to deliver an integrated allergy clinic could not be activated in a community setting. Instead, the team focused on re-organising their existing services to deliver better integrated allergy care. Another example where causal mechanisms might be present, but not actualised, is demonstrated in site C and D. Both teams referred to the publication of policy documents as motivator to support the implementation of community-based allergy clinics. However, the lack of finances at both CCGs at the time meant these projects were still not supported despite their alignment with policy goals. Instead, team C negotiated a change in the nursing contract to include the delivery of the intervention and team D decided to focus on other interventions. As such, the contingent nature of the allergy improvement initiatives explains how initiatives unfold in different ways and why they each implement different intervention adaptations.

4.7.2. General improvement strategies

The case study narratives describe the causal flow of children's allergy improvement initiatives. They demonstrate which causal mechanisms were present, which were activated, which had a positive effect on health service developments, which were experienced as barriers. The narratives also demonstrate how teams approached different situations, what motivated them to adapt their intervention and how they used quality improvement methods to negotiate intervention adaptations and navigate contextual influences. The specific actions taken by the teams were reactive to the causal mechanisms they were faced with. However, at a more abstract level, the actions teams took tended to align with a more general strategic approach towards the improvement of local children's allergy services. These general improvement strategies reflect an internal consistency in the way teams managed contextual influences and intervention developments, which was supported by their use of quality improvement methods. The improvement strategies that were identified in each case are as follows:

Making it work – Team A demonstrated a clear commitment to implement the Itchy Sneezy Wheezy intervention. Accordingly, they worked hard to overcome contextual challenges that prevented them from achieving this goal. For example, when team A struggled to convince local commissioners to support the project financially, they went and identified the CQUIN as an alternative funding structure. Moreover, whenever their efforts to implement the Itchy Sneezy Wheezy intervention stalled, team A would resort to QI methods to explore the causes of stagnation and to identify how these issues could be addressed. For instance, process mapping was used to try and understand the hold-up in implementing community-based allergy clinics. Subsequently, process

mapping was used again to visualise and communicate the administrative support that was needed to start the clinics.

Cultivating flowers – Despite push-back, team B was clear about starting their improvement initiative small and progressively increasing its scope and capacity. Accordingly, they started by moving two hospital-based asthma clinics into the community and recruiting a nurse who was new to asthma and allergy. Over time, this effort developed into a community service with four asthma clinics delivered by two nurses who had developed the skills to manage allergic comorbidities. Moreover, team B also slowly expanded the scope of their effort. Their use of QI methods encouraged them to engage with stakeholders from other services. These engagements developed into new working relationships, whereby team B first supported improvements in school asthma services, which subsequently evolved into a collaborative effort to improve asthma services across the regional health system.

Building on solid ground – The improvement initiative in site C evolved from a systematic effort to improve local children's services. This effort started with a review of the local health system. The review offered a rich understanding of children's healthcare needs and the mechanisms currently in place to address those needs. This formed the foundation for subsequent improvement efforts. Subsequently, team C developed pilot projects that were designed to address key areas for improvement. Moreover, the evaluation of these projects gave further insights into what types of interventions would be most useful to improve local children's services. From these developments improvement project C evolved. This meant team C had a solid understanding of local healthcare quality deficiencies, they had built stakeholders relationships across the healthcare system, and they had practical experience with setting-up new clinics in community settings.

Finding opportunities and synergies – Team D explored the implementation of the Itchy Sneezy Wheezy intervention as a natural progression from prior efforts to improve local children services. They had implemented respiratory and eczema services in the community and recognised the opportunity to integrate these services to deliver more effective allergy care. However, when they had brought a team together to explore this opportunity further, they identified that the delivery of a community-based allergy service would not be cost-efficient locally. Instead, they identified other opportunities to improve local children's services. For example, they adopted a CMPA consultation template that was shared by their regional allergy network and they collaborated with the hospital laboratory team who were developing their allergy testing service.

Chapter 5. Cross-Case Analysis

Elaborating the theoretical explanation of children's allergy improvement initiatives

5.1. Introduction

This Chapter presents a cross-case analysis. It addresses the Third Level (3L) of MELD dialectic, which is focused on totality. Totalities represent a coherent relational understanding able to explain diverse and contradictory manifestations of phenomena. The cross-case analysis presents such a theoretical explanation of children's allergy improvement initiatives. As such, the first purpose of this Chapter is to elaborate the theoretical explanation presented in Chapter 2 based on the empirical case study data. The second purpose is to integrate the insights from the four individual case studies. Accordingly, this Chapter elaborates the theoretical propositions described in Chapter 2.

> *Proposition I: Care pathways improve children's allergy services as part of a complex integrated & chronic care intervention.*
>
> *Proposition II: Improvements in the quality of children's allergy services emerge from the interactions between care pathways interventions, implementation processes, and contextual influences.*

In the previous Chapter 4, these propositions were situated within the practical experience of children's allergy health service improvement. This Chapter draws on that situated understanding to specify and elaborate the theoretical propositions. More specifically, this is achieved by finding common ground across the individual case studies. In the previous Chapter, the case studies were presented as a chronological causal unfolding. In this Chapter, the narratives will first be broken-down into its causal mechanisms, before all parts are re-integrated into a representation of a children's allergy improvement initiative that generalises across all four case studies. Breaking-down the case study narratives into their component parts gives the opportunity to understand the connections between the case studies. Then, these insights are consolidated again to represent children's allergy improvement initiatives as an integrated whole – a totality (Bhaskar, 2008b). In this Chapter, the case experiences are consolidated into three sub-totalities. As such, this Chapter contributes to answering the fourth research questions.

> *4. How are local children's allergy health service improvement experiences integrated?*

This Chapter starts by presenting a theoretical overview of 3L of MELD explaining the concept of totalities. Then, I will present the three different sub-totalities developed in this thesis. First, I describe the *child allergy intervention content* sub-totality. Second, I describe *the allergy improvement context* sub-totality. And third, I describe the *improvement process* sub-totality. Then, in the latter section of this Chapter, I discuss the relationships between these sub-totalities based on several case-study examples.

5.2. Third Level (3L): totality

The *Third Level (3L)* of MELD dialectics focuses on the principle of totality to understand and make sense of contradictory, conflicting and differential experiences faced in real life. More specifically, dialectical reasoning is used at 3L to critically evaluate dialectical contradictions identified at 1M and observed at 2E, to identify how these contradictions are situated in reality, and to speculate how they are bound together in a totality. By situating the dialectical contradictions in the real material world, it is possible to explore their common ground and shared foundations which allow them to be bound together in real-world totalities. Finding common ground and shared foundations requires a deeper-level investigation of the component parts of dialectical contradictions rather than sublating them into a higher-level conceptual understanding. This process of situating helps to understand how dialectical contradictions exist within the world, what their underlying causes are and how they are connected. These insights are subsequently consolidated in a 3L totality, which now represent a more considerate reflection of the real world than previously held.

As such, 3L aims to improve our understanding of dialectical contradictions without resolving them which can only be done through action. This understanding can, however, support the planning of actions that are likely to facilitate change and resolve contradictory situations in practice. 3L dialectical reasoning also facilitates scientific progress. That is, it supports scientific critique by situating theoretical and analytical claims within the real world to assess their correspondence with reality. Understanding how such claims are reflected in different real-world situations allows for their refinement rather than their mere rejection or verification. So, instead of assessing their universal truth, 3L reasoning helps assess the boundaries and limitations of their truth in different contextual situations. That is, to assess what exactly these theoretical and analytical claims represent, mis-represent or not represent in different real-life situations.

3L reasoning also helps to unpick contradictions between different theoretical and analytical positions. Such logical contradictions could indicate some mistakes or gaps in our thinking or be a sign of contradictions that exist in the real world. For example, through my 2E observations and experiences I aim to identify whether the logical contradictions between implementation and quality improvement also express as such in reality. Dialectical reasoning at 3L subsequently aims to unpick and uncover how potential contradictory implementation and improvement experiences are connected at a deeper level. So, at 3L, real-world contradictions are situated within their structural and geo-historical contexts, where their component parts and interconnectedness are explored –

resulting in their reconstruction as parts of a totality. This reconstruction requires a creative leap of thinking while remaining grounded in the critical realist understanding of reality.

Dialectical reasoning at 3L involves a process of diffraction and totalising that results in 3L totality. Dialects as practiced in MELD has started with 1M non-identity consolidating our understanding of the world as it is. This stage was followed by 2E negativity, aimed at understanding how the world unfolds and changes. By exploring at 2E how the world unfolds, how phenomena change over space and develop over time, it is possible to identify contradictory situations and phenomena in practice. This empirical information is subsequently used to ground 3L dialectical reasoning, which is a two-part process. The first stage involves diffracting and contextualising of the dialectical situations observed at 2E. This means that the empirical information collected at 2E is used to break-up the dialectical situations into its parts and/or multiple forms. For example, different care pathway interventions that are implemented with contradictory results, can be broken-up into interventions components. The second stage, then, involves constellating and totalising the dialectical components by exploring their interdependencies that make them part of a whole.

A 3L totality, or constellation as it's often referred to in MELD, operates as a system. A system of interdependent components has three properties: 1) each component affects the functioning of the whole, 2) no component has an independent effect on the whole and is instead always influenced by at least one other system-component and 3) all possible sub-systems also have these properties, so that no independent sub-systems exist within a system (Ackoff, 1974). As such, systems rely on the organisation and interactions between system-components, which makes that many systems are better understood as patterns or structures rather than 'things' (Macy, 1991). Accordingly, the term constellation tends to be preferred in DCR over the term system to describe 3L totalities.

The constellationality of 3L totalities explains why the second totalising stage of the 3L reasoning process is so critical. That is, the dialectical elements that have been identified at the stage of diffraction are interdependent and can therefore only be understood fully in relation to the dialectical situation as a whole. So, at the totalising stage of 3L reasoning the dialectical pieces are metaphorically glued back together by describing their relationships. As such, 3L totalities can be understood as a re-description of dialectical situations that captures them as a collection of dialectical elements that are analytically distinct, but through their interdependency form a constellational whole.

The relationship between dialectical elements and the constellational totality can take different forms. For example, elements of a totality might reflect real opposites that co-occur in the world, such as being and becoming, structure and agency, fidelity and adaptation or implementation and

continuous improvement. Such contradictory components constellated in a totality are referred to as dualities. However, elements of a totality can also reflect other constellational relationships, such as identity-in-difference or unity-in-diversity. These types of constellations refer to contradictory expressions of phenomena in the world. For example, a care pathway intervention might manifest differently across different time-points during implementation. The enduring identity of the intervention, though, holds all different intervention manifestations and expresses how they relate across time. Alternatively, the diversity of care pathway interventions implemented across geographical settings can be expressed as a unified whole that reflects how their similarities and differences relate to each other. A schematic representation of this principle is demonstrated in Figure 22.

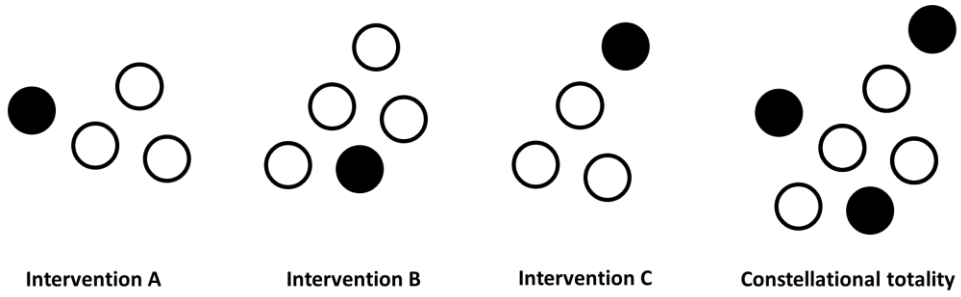


Figure 22. Unity-in-diversity. Schematic example of three diverse interventions unified in a constellational totality by exploring how their differences and similarities are interrelated.

The constellational relationship between a totality and its components brings about emergent properties and patterns through holistic causality. As explained above, the structure of a totality affects its components, while the components through their interdependencies affect the whole. This mutual causal relationship between a totality and its components is referred to as holistic causality in DCR and is closely associated to the system's theory concept of emergence (Mingers, 2011). Through holistic causality, totalities and its components might express emergent properties or patterns that are absent when the totality is broken-down into its individual components rather than taken as a whole (Laszlo & Krippner, 1998).

The capability to produce an allergic reaction can for example be understood as an emergent property of an allergic person. This property arises from the interaction between their immune system and an allergen operating as a physiological totality within the person. However, when the allergen and the immune system are taken independently, the person loses its capability to produce an allergic reaction in addition to the allergen losing its capability to trigger the reaction. As such, an allergic reaction is explained through holistic causality of an allergen and the immune system operating within the totality of a person. Emergence is synchronic in this example, reflecting holistic

causality at a specific point in time. Synchronic emergence reflects a 1M understanding of phenomena emerging from their generative mechanisms. Emergence can also be diachronic however, reflecting holistic causality as it evolves over time. Diachronic emergence reflects a 2E dynamic understanding of phenomena unfolding and changing in rhythmics over time. For example, 'I' can be understood as the diachronic totality of my past.

Besides emergence, holistic causality also explains how phenomena in the world become stratified. Phenomena can be understood as totalities of interdependent generative mechanisms (Hartwig, 2007). The relationships among generative mechanisms determine the internal structure of phenomena (Porpora, 1989). Through holistic causality, these structures might develop emergent causal capabilities as a whole. Like in the example above, where holistic causality resulted in a person's capability to produce an allergic reaction, which itself has causal consequences. As such, structures themselves also operate as mechanisms with causal powers and tendencies (Hartwig, 2007). Consequently, structures can co-generate bigger structures thereby creating layered phenomena and a stratified reality (Bhaskar, 2008a).

Even though structures might operate as causal mechanisms, they are still distinct. That is, a particular mechanism can co-generate multiple different structures, while a particular structure can be generated through multiple different mechanism-combinations (Hartwig, 2007). For instance, cow's milk protein can operate as a causal mechanism in multiple structures, such as digestion or inflammation. As such, inflammation can be caused by cow's milk protein when generated by allergic mechanisms. However, inflammation can also be generated by non-allergic mechanisms. To resolve an inflammatory reaction, it is therefore important to understand the particular structure of mechanisms that is underpinning the reaction (Porpora, 1989). So, the analytical totalities developed at 3L express holistic causality, which enables them to hold emergent properties and be stratified. As such, the structure of 3L totalities mimics the structure of real-world phenomena.

It is important for analytical 3L totalities to reflect reality, because in MELD they are used to inform action aimed to resolve dialectical contradictions as encountered in the world. This means that 3L totalities should also be depth-open, which makes them contingent and undetermined in nature. This contradicts Hegel's totalities which are closed by definition to achieve analytical dialectical resolution. Being depth-open means that totalities have both a horizontal and a vertical dimension of being. Their vertical dimension or depth refers to their stratification as described above. Their horizontal dimension or openness on the other refers to their permeability, allowing them to interact with contextual mechanisms. As mentioned earlier, no element of a totality independently effects the whole (Ackoff, 1974). Instead, the relationship between elements and the whole totality is

always mediated by the interactions with other elements in the totality. This type of mediation is called internal mediation and refers to the interactions between elements internal to the totality. In stratified totalities, these interactions can exist both within and between levels. The consequence being that element-totality relationships can be mediated by unpredictable emergent effects. Mediation can also be contingent, however, which refers to the interactions between (elements of) a totality and contextual mechanism. By accounting for contingent mediation, the analytical totalities developed at 3L embrace the open nature of reality. They themselves are not closed and hence are contingent in nature.

This means that the description of a totality depends on its context of use, either being described as concrete universals or as concrete singulars. Totalities as concrete singulars are the focus of applied health research and describe totalities in particular spatio-temporal settings. As concrete singular the elements of a totality are described exactly as they manifest in reality, mediated by the particular contextual mechanisms that are present or absent respectively. An allergic child can, for example, be described as a concrete singular totality, whereby the described elements together explain the contradictory symptomatic experiences the child has. The understanding this totality brings, is especially helpful to achieve the aim of improving the experiences of this specific child, as is the case for the healthcare professionals treating this child as their patient. Totalities as concrete universals on the other hand, are usually the focus of more theoretical research that generalises across empirical cases. They remove the effects of specific contextual influences, the contingent mediation, and instead describe the universal structure that situations have in common. As such, concrete universal totalities can explain and bind together contradictory phenomena and situations. For example, a concrete universal totality could describe allergies as a constellation of elements that influence the experiences of an allergic child. Each element might be irrelevant, however, to the experiences of any specific child. Furthermore, the way these elements express will be contingent on the contextual situation of each child.

Concrete universal totalities and concrete singular totalities are both contingent on contextual situations. As discussed, concrete universal totalities represent a useful understanding of phenomena in general. However, they are not able to describe or predict any specific occurrences, which are determined by the conjuncture of all mechanisms present in their specific context. Concrete singular totalities are similarly undetermined. Even though they only represent our understanding of a particular situation, the local phenomenon being explained is dynamic in nature and might become different than it was when described and explained in the totality. Accordingly, no totality can predict the exact causal path of a particular local phenomenon, which is determined by the unfolding emergence of causal mechanisms over time.

So, 3L totalities are depth-open and undetermined, in line with our ontological and meta-theoretical understanding of reality. Consequently, when a 3L totality does not properly reflect a real-world situation, it could either mean that its content is analytically wrong or that it is simply incomplete and needs adjusting to account for temporal developments or more diverse experiences. This open and unfinished nature of 3L totalities makes them both adaptive to the developing scientific discourse and to different real-life situations.

5.3. Totalities in children's allergy improvement

5.3.1. Unifying children's allergy interventions in a totality

The child allergy intervention content sub-totality contains the intervention components that were implemented across improvement initiatives. The case studies presented in Chapter 4 describe how local children's allergy services were developed over time across four different improvement initiatives. At some point, these developments were influenced by the Itchy Sneezy Wheezy intervention. However, as discussed, the extent to which teams adopted the Itchy Sneezy Wheezy intervention depended on prior health service developments, contextual differences, and reflective insights facilitated by QI methods. Besides, some teams already had elements of the Itchy Sneezy Wheezy intervention embedded in their local services prior to the improvement initiative. For example, team D had already implemented community-based respiratory and asthma services. Moreover, all teams implemented additional elements that were not part of the Itchy Sneezy Wheezy intervention, like the school audit in site B. As such, intervention adaptations are in this case better understood as intervention developments that started prior to and continued after engagement with the Itchy Sneezy Wheezy intervention. In this Chapter's analysis, all intervention elements implemented across the case studies to improve children's allergy services are included.

To develop an integrated intervention totality across all four case studies, I abstracted all intervention components from the case study narratives before re-integrating them based on their internal relationships. This 3L process of diffraction and totalising aims to bring together several differentiated interventions into a single intervention totality. The intervention totality I developed reflects a 'unity-in-diversity' constellation by expressing the similarities and differences between the four case study interventions within a unified intervention totality. Across all four case studies, I inductively abstracted a total of 26 intervention components (or health service developments). All intervention components and their local expressions are presented in the last two columns of Table 11. Some of the intervention components were implemented across all case study sites. For example, each site implemented *'Clinics for children with allergic conditions delivered by specialist nurses in the community'*. Team A and B had implemented nurse-led clinics for children with asthma, and team C

and D had implemented clinics for children with asthma and eczema. Some intervention components, however, were only implemented by a single case study site. For example, only team D had implemented a *'Dietetic allergy clinic'* to manage children with simple milk allergies. And some intervention components were only partially implemented in certain case study sites. For example, team A, B and C all implemented a '*Clinical care pathway for urgent and emergency care'.* However, the care pathways implemented by team B and C did not include a referral form to support the integration of emergency treatment with follow-up services. Alternatively, all teams worked to increase their local allergy capacity through *'Specialist allergy competence development (for nurses, dietitians, or consultants)'.* In team A and B, nurses had first been trained to develop their asthma expertise before completing their allergy diploma. Team B and D also supported the development of their clinical staff. However, the nurse in team B and dietitian in team C had not yet completed any allergy-specific training. Instead, the nurse in team had developed her asthma and eczema clinical expertise, while the dietitian in team C had organised to start her allergy training at the time when I left the field. The four case narratives in Chapter 4 describe in more detail how all 26 intervention components were expressed and integrated in local practice.

Table 11. Child allergy intervention totality and its expression across the four improvement initiatives studied.

Healthcare delivery system		A	B	C	D
Organisation of local allergy services	Health system care pathway that organises and defines allergy services across settings		●	●	
Community-based specialist allergy services	Clinics for children with allergic conditions delivered by specialist nurses in the community	●	●	●	●
Integrated allergy care	Dietetic allergy clinics				●
	Condition-specific clinics (e.g. asthma) providing integrated care for allergic comorbidities	●	●	●	
	Fully integrated allergy clinic: paediatric allergy consultant advice, skin-prick-testing, specialist nurse self-management support, dietetic advice	●	●	◗	◗

Integrated clinical governance	Support structures for the community specialist nurse, including specialist clinical mentoring and appropriate nursing cover	
Integrated health service administration	Specialist community service contracting	
	Access to patient information in community clinics	
	Equal access to the community clinics for patients from hospital and CCG catchment area	
Clinical information systems		A B C D
Data access to support clinical decisions	Clinical database to identify children for review based on signals of poor disease control	
Clinical decision support		A B C D
Guideline implementation	Clinical care pathway for primary care	
	Clinical care pathway for urgent and emergency care	
	Electronic consultation template	
	Prescribing prompts in line with the local formulary (digital or paper-based)	
	Clinical audit and discussion of findings	
Clinical support structures	Independent allergy education/training sessions for healthcare professionals across care settings	
	Outreach allergy training clinics and/or case discussions in the community	

	Specialist allergy competence development (for nurses, dietitians, or consultants)	
	Allergy MDT meetings and support	
	Regional allergy network to share clinical and organisational learning	
Self-management support		A B C D
Allergy-focused consultations	Allergy focused history to support integrated allergy advice and prescribing for allergic comorbidities	
	Longer clinic appointments for in-depth self-management support	
	Assessment of disease control and the organisation of appropriate follow-up	
	Shared care plan across health settings	
Community resources		A B C D
Allergy support in schools	Implementation of asthma and allergy policies in schools	
	Asthma/allergy training in schools	

Moreover, the allergy intervention totality has a stratified internal structure, with the 26 intervention components representing the lowest level of stratification. The second stratum is formed by 10 intervention categories that organise the 26 intervention components. The 10 intervention categories are presented in the first column of Table 11. The third stratum is formed by the 5 components of the Chronic Care Model (CCM): '*Healthcare delivery system'*, '*Clinical information systems', 'Clinical decision support', 'Self-management support', and 'Community resources'* (Wagner et al., 1996). The 5 CCM components are presented as headings in Table 11.

Using the CCM components to structure the allergy intervention totality aligns with MELD principles. In MELD, totalities operate as systems in which each component must affect the functioning of the system as a whole and in which all components are always influenced by at least one other system component (Ackoff, 1974; Bhaskar, 2008b). This aligns with the research on the CCM presented in Chapter 2, which highlights that integrated care interventions were found to be more effective when they implemented multiple CCM elements (Coleman et al., 2009). Moreover, the CCM highlights that its elements are interrelated (Wagner et al., 1996). These inter-relational characteristics of the CCM are echoed in the allergy intervention totality. A simpler overview of the allergy intervention totality, with only its top two strata, is presented in Table 12. Here you can see that the intervention categories *within* CCM components are related. For example, within the CCM component *'Healthcare delivery system'*, it can be shown that '*Community-based specialist allergy services'* are more effective when they also *'deliver integrated allergy care'*. Moreover, the intervention categories are also related *across* CCM components. For example, *'Data access to support clinical decisions'* can support the implementation of a specific *'Organisation of local health services'* by proactively identifying children that fulfil the referral criteria for a particular service.

Table 12. Intervention component categories implemented across improvement initiatives.

Healthcare delivery system	**Clinical decision support**
Organisation of local allergy services	Guideline implementation
Community-based specialist allergy services	Clinical support structures
Integrated allergy care	
Integrated clinical governance	**Self-management support**
Integrated health service administration	Allergy-focused consultations
Clinical information systems	**Community resources**
Data access to support clinical decisions	Allergy support in schools

The structure of the child allergy intervention totality helps resolve the dialectical contradiction observed across the four case studies, where different interventions were implemented despite the Itchy Sneezy Wheezy intervention as a common anchor. It reflects the diffraction of all contradictory case study interventions into intervention components, which are subsequently re-integrated or constellated based on the CCM (Wagner et al., 1996). As such, the child allergy intervention uses the CCM structure to integrate the diversity of interventions implemented across initiatives into a unified representation, reflecting a unity-in-diversity constellated totality. This totality reflects a *concrete universal*. As discussed earlier in this Chapter, concrete universals describe a universal structure that situations have in common by removing contextual contingencies. As such, they can bind together the contradictory expressions of phenomena (Bhaskar, 2008b, 2010; Hartwig, 2007; Norrie, 2010). As a concrete universal, the child allergy intervention totality binds together the contradictory intervention developments that were observed across improvement initiatives. They describe all intervention components that could be implemented locally. However, not all components will be implemented in any specific improvement initiative, and which components are implemented will be contingent on its contextual situation. As such, each unique improvement initiative reflects a

different expression of the child allergy intervention totality. A schematic representation of this relationship between the improvement initiatives and the child allergy intervention totality is depicted in Figure 23. It demonstrates the CCM structure that represents the first stratum of the child allergy intervention totality. How the CCM components are expressed within each case study site varies depending on what intervention components were implemented locally. These variations in local interventions are demonstrated through the heuristic use of a radar chart, in which the five CCM components represent five intervention dimensions that express differently across the case study sites.

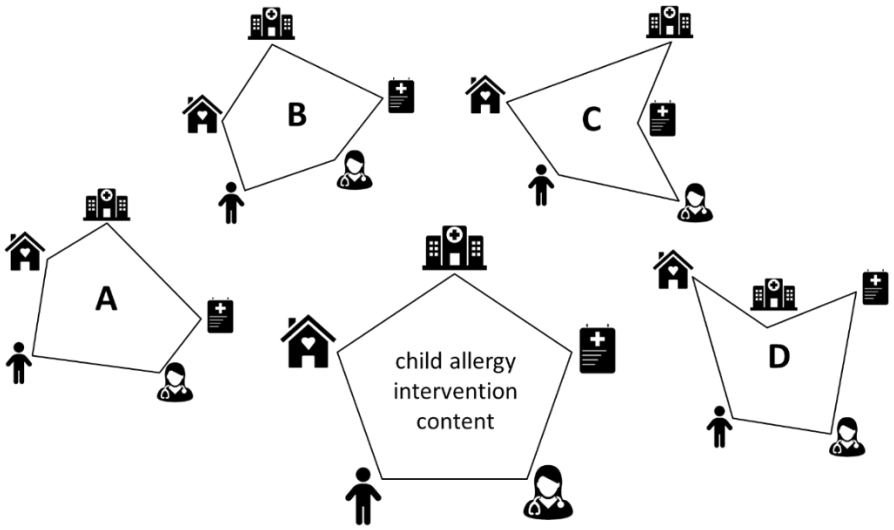


Figure 23. Unity-in-diversity. Schematic representation of the dialectical relationship between local interventions and the child allergy intervention totality.

5.3.2. Representing the context of improvement as totality

The allergy interventions that were implemented across case study sites form an important part to understanding the improvement of children's allergy services. However, the case study narratives in Chapter 4 and the theoretical developments in Chapter 2 both emphasise the additional importance of a quality improvement process and the local context. In the previous section, I discussed how the different case study interventions could be understood in terms of a universal intervention structure, a child allergy intervention totality. In this section, I demonstrate how the context of the improvement initiatives can also be understood as a totality. The context totality represents a universal structure that unifies the diversity of contextual influences that impacted the development of children's allergy services across the four case study improvement initiatives. The contextual influences were structured under five components. *'Clinical services and capacity', 'Improvement structure', 'Relationships and project engagement', 'Accountability, priorities, alignments', 'Resources and opportunities'.*

'Clinical services and capacity' reflect the local children's allergy services that were implemented at the start of an improvement initiative (or at any future point in the development of the initiative) and the allergy expertise available across local clinical staff. For example, site B had a hospital-based allergy team delivering fully integrated allergy clinics, in addition to having a hospital-based respiratory team who delivered asthma and respiratory clinics, but were all trained in allergy also.

'Improvement structure' reflects the methodological approaches that teams applied in their improvement initiative, the learning and governance structures that teams used to share information and make decisions, and the distribution of job roles and responsibilities to manage and support the process of improvement. For example, an external project manager was appointed in site A, who set-up regular team meetings (as a governance structure) and who applied the quality improvement methodology taught in their organisation.

'Relationships and project engagement' reflect the existing relationships between professionals who look after children with allergies or who make decisions about their care, and their personal interests to contribute to the improvement of children's allergy services. For example, team C had established good relationships with relevant stakeholders during their whole systems review. They also collaborated with a specialist asthma nurse during their pilot projects who was keen to develop her allergy expertise and continue working locally.

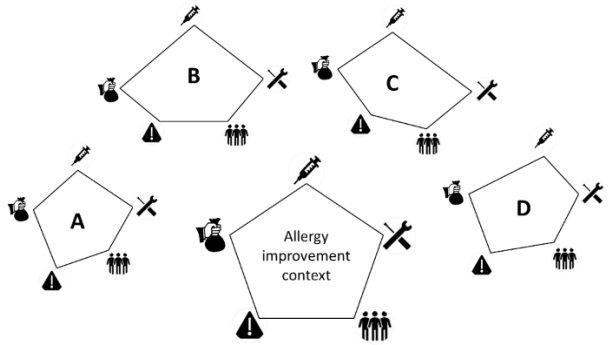
Accountability, priorities, alignments' reflect external motivators that align with the improvement of children's allergy services, which can be used to generate resources and to bring stakeholders

together to work collectively on the improvement initiative. For example, the Itchy Sneezy Wheezy team had demonstrated the possibility of children's allergy interventions to reduce the number of hospital admissions, which aligned with the financial and policy priorities of commissioners at that time. Consequently, this alignment was used by team A to collaborate with local commissioners to secure financial resources for their improvement project.

'Resources and opportunities' reflect structural conditions that can be exploited to support the improvement of children's allergy services. For example, the retirement of a senior dietitian in case study site D presented the opportunity to increase the hours of a more junior dietitian to deliver a dietetic allergy clinic. Alternatively, when the CCG in case study site D was no longer in the financial position to invest in service developments, team D identified an opportunity in the community nursing contract that could be changed to include the delivery of a community-based atopy clinic.

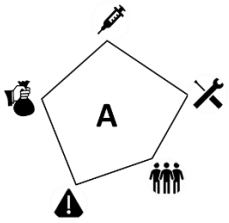
The context totality represents a unity-in-diversity constellated totality that is a concrete universal, similar to the intervention totality presented in the previous section. As such, the context totality integrates the contextual mechanisms that influenced the intervention developments across the four case studies into a universal structure. All case studies are uniquely positioned in space and time. As such, they reflect unique contextual conditions to the local improvement of children's allergy services, whereby certain conditions can facilitate improvement initiatives while other conditions can be experienced as barriers. However, the contradictory contextual conditions are bound together in the structure of the context totality (Bhaskar, 2008b, 2010; Hartwig, 2007; Norrie, 2010). The five components of the context totality contain a variety of contextual mechanisms that can be either present or absent in the context of a specific improvement initiative at a specific time. These local variations can be expressed schematically through another radar chart, whereby the five components represent five context dimensions that express differently across case study sites and at different times along the improvement initiative. This schematic overview of the context totality, its components, and its local expressions is presented in Table 13. A more detailed description for each case study that demonstrates how the five context components expressed locally are presented in Table 14, Table 15, Table 16, and Table 17.

Table 13. Allergy improvement context totality and its expression across the four improvement initiatives.



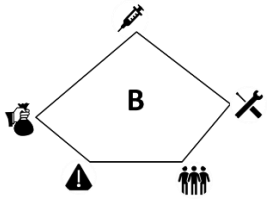
Clinical services and capacity	**Accountability, priorities, alignments**
Improvement structure	**Resources and opportunities**
Relationships and project engagement	

Table 14. Local manifestation of the context totality in case study A.



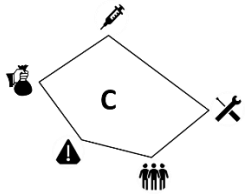
Clinical services and capacity	**Accountability, priorities, alignments**
Integrated team of paediatric consultants with an interest in allergy working across hospital sites	Itchy Sneezy Wheezy intervention success
Improvement structure	**Resources and opportunities**
External QI approach and project manager; QI process in clinical meetings and co-learning collaborative meetings to tackle challenges	Alignment with the 2015 CQUIN scheme
Relationships and project engagement	
Hospital management pre-occupied with a merger; high staff turnover in the CCG	

Table 15. Local manifestation of the context totality in case study B.



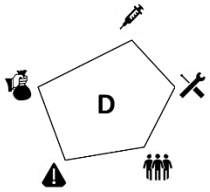
Clinical services and capacity	**Accountability, priorities, alignments**
Longstanding allergy and respiratory MDT working at the local hospital	London Asthma Standards; Itchy Sneezy Wheezy intervention success
Improvement structure	**Resources and opportunities**
External QI approach/support; nurse project manager; QI process in clinical meetings, stakeholder workshops, and co-learning collaborative meetings	Alignment with QIPP; hospital aspiration to extend specialist services with NHS England funding
Relationships and project engagement	
Historic relationship with the school nursing team; commissioner support	

Table 16. Local manifestation of the context totality in case study C.



Clinical services and capacity	**Accountability, priorities, alignments**
Allergy services provided across two local hospitals; identified need to improve children's atopy services	Local needs assessment; asthma pilot evaluation; NRAD report; FYFV report; Sustainability Transformation Plan (STP); Local Care Strategy
Improvement structure	**Resources and opportunities**
CCG QI approach and project manager; integrated in CCG management and governance structures; team meetings for stakeholder input on QI process	Financial case for a community atopy service; increased/high demand on hospital respiratory services
Relationships and project engagement	
Stakeholder relationships established during a review of children's services; GP relationships developed during the asthma pilot project	

Table 17. Local manifestation of the context totality in case study D.



Clinical services and capacity	**Accountability, priorities, alignments**
Allergy services provided across two local hospitals; identified need to improve children's atopy services	Regional CMPA improvement project; updated regional CMPA guidelines; development of a local allergy testing service
Improvement structure	**Resources and opportunities**
CCG QI approach and project manager; integrated in CCG management and governance structures; team meetings for stakeholder input on QI process	No financial case for further community developments; dietetic FTE available after a retirement
Relationships and project engagement	
Stakeholder relationships established during a review of children's services; GP relationships developed during the asthma pilot project	

The internal structure of the context totality is consistent with the system characteristics that are inherent to MELD totalities. More specifically, the totality demonstrates that its components are internally related. For example, the availability of financial resources (*'Resources and* opportunities') is often aligned with policy initiatives boosting certain areas of work (*'Accountability, priorities, alignments'*). Another example is that well-integrated clinical services (*'Clinical services and capacity'*) rely on good professional relationships (*'Relationships and project engagement'*).

5.3.3. Representing the process of improvement as a totality

In the previous two sections, I discussed how the case study interventions and contexts could be understood in terms of a universal structure, a child allergy intervention totality and a context totality. In this section, I demonstrate how the improvement process can also be understood as a totality. The improvement process totality represents a universal structure that unifies the diversity of quality improvement approaches that were used across the four case study sites to support the improvement of children's allergy services. To develop the totality, the case studies were first analysed separately to identify the different quality improvement methods, actions and strategies that were used across the case study sites. These were subsequently abstracted to eight fundamental principles, which form the internal structure of the improvement process totality. The eight principles that structure the improvement process totality are: '*Team development', 'Learning from and with others', 'Process mapping and design', 'Developing aims and plans', 'Developmental improvement', 'Patient and public involvement', 'Using data', 'Long term planning'.*

'*Team development'* reflect the actions and strategies that were used to enrol people in an allergy improvement team. This involves strategies like recruitment, stakeholder mapping, relationship building, and stakeholder engagement. For example, team A experienced an ongoing struggle to get clinical administrative support in place. At some point, they considered whether they needed to enrol a member from the administrative team to help them understand and resolve the issue and to support the team moving forward. Accordingly, they developed a stakeholder map to identify which people needed to be involved and they made an effort to engage a few strategically selected individuals. Team C, on the other hand, had developed relationships with local stakeholders during their whole systems review, which they utilised to develop an allergy improvement team. They were strategic in the way they enrolled local stakeholders. Knowing how busy clinical staff are, they communicated specific and bounded requests for individuals to input and add value to the project.

'Learning from and with others' reflect the actions and strategies that were used to brainstorm, develop and share ideas for improvement. This involves strategies like literature searches, collaborative and/or advisory governance structures, collaborative events, interdisciplinary collaborations, and participation in clinical networks. For example, members of the Itchy Sneezy Wheezy team participated in the advisory board of team A. They shared insights during regular board meetings. Board meetings were shared with a second allergy improvement project to cross-pollinate ideas and strategies. Team A also participated in a regional allergy network where they shared their care pathway for urgent and emergency care services, which was picked-up by other hospital clinicians in the network. Alternatively, team D had done a literature search to identify teams,

projects and ideas that were relevant to their improvement initiative. That's how they identified the Itchy Sneezy Wheezy team, who they invited to present at their launch meeting together with other internal and external stakeholders. Moreover, team D also participated in their regional allergy network, where the CMPA audit and CMPA consultation template were shared that team D adapted and then implemented locally.

'Process mapping and design' reflect the actions and strategies that were used to understand and change the organisation of local health services, of clinical processes, and of administrative processes. This involved the mapping of existing processes, identifying opportunities to change processes, and designing new processes. For example, team C mapped local health services to understand how the new community-based atopy clinic could be integrated. This helped them to understand what the new referral pathways for children with asthma and eczema would look like locally. This information was subsequently used to develop referral criteria that were integrated into the clinical process they designed for managing children with asthma and eczema in primary care. Team A, on the other hand, used process mapping to understand and resolve project barriers. For example, team A had added a referral form to their asthma care pathway that referred children with high-risk asthma to a community-based asthma clinic they were implementing as part of the improvement initiative. However, there were issues with setting-up the clinic. Team A subsequently mapped the local asthma services that were delivered by the hospital team and their colleagues to understand what solutions they could implement immediately to review the high-risk children who were being referred into a clinic that did not yet exist.

'Developing aims and plans' reflect the actions and strategies that teams used to formalise project goals and plans to deliver the project. These included strategies to brainstorm and generate ideas, to make project decisions, and to formalise plans. For example, team A, B and D created Action Effect Diagrams (AEDs) and driver diagrams to develop a shared aim and directive for the improvement initiative. Team A subsequently used the AED to iteratively record team decisions on planning interventions and progress on implementing them. Team B used the AED primarily at the start of the project to develop a team vision that they referred to a couple of times throughout the project as a reminder. Team C used the AED to collectively brainstorm an improvement goal and intervention ideas that could achieve that goal. For the main ideas, team D did a cost-efficiency analysis which was presented back to the team to help them decide which ideas to take forward and deliver in smaller working groups. Team C relied even more than team D on data to define project goals and plans. Their project aims had developed from their whole systems review and the pilot project evaluation that followed.

'Developmental improvement' reflect the actions and strategies used to incorporate work and learning done previously into the development of the improvement initiative. This can include strategies to build on historical work that has been done locally, to create opportunities for adaptive development within an improvement initiative, or to create opportunities to integrate and develop learning from peers into the improvement initiative. For example, team B and D developed a process with their local CCG to grow and scale-up their intervention over time. Team B started by signing off a business case to move two asthma clinics from the hospital into the community as a pilot project. When this project was successful, they agreed a new business case to scale-up to four asthma clinics in the community to cover the whole region and to develop asthma care pathways. When this project was successful also, team B agreed a third business case to implement the asthma care pathways aimed to deliver asthma-friendly services in the hospital, in schools, and in primary care. Similarly, team D piloted and implemented a series of children's services in the community. These services were implemented sequentially, whereby the success of one service was a motivation to continue the general trajectory of moving care from the hospital into the community. Accordingly, team D was motivated to deliver an allergy service for children in the community. However, the business case for allergy service was rejected based on their local cost modelling. Alternatively, team A created flexibility and opportunities to change the project plans whenever they experienced severe obstacles. When this happened, they got together as a team to assess the obstacles, decide how they could be managed, and explore alternative interventions that were within the control of the team to deliver.

'Patient and public involvement' reflect the actions and strategies used to learn from patients and the public to support the improvement initiative. This includes involvement strategies to develop intervention ideas, to deliver the improvement initiative, and to evaluate health service developments. For example, team B performed focus groups with young people and parents to identify priority areas for improvement in their local asthma services. Team A and B used questionnaires to collect feedback from patients on the new service developments that were implemented. And team D invited a parent on their team to support the delivery of the improvement initiative as a team member.

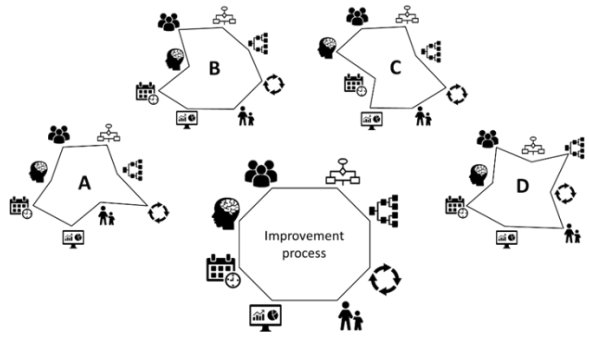
'Using data' reflects all the data analytics teams used to support the improvement initiative. This included the use of data to identify priority areas for intervention, to compare and contrast improvement ideas, to make the case for investment, and to evaluate the impact of interventions. For example, team C performed a whole systems review that highlighted children's asthma and eczema as priority areas for health service improvements. Team D used financial modelling to compare the costs and benefits of several improvement options. And team A analysed their data on

hospital admissions to evaluate the impact of their intervention and assess their CQUIN goals achievement.

Finally, *'Long term planning'* reflects the actions and strategies that were used to support continuous improvement and to move the improvement work forward beyond the timelines of the initiative. This includes strategies like embedding governance structures for improvement, developing an improvement-focused team culture, ongoing relationship management and stakeholder engagement, and ongoing development of an improvement agenda. For example, team B and C used a project-based governance structure, whereby they used project evaluations to decide how to develop and scale the work further in a follow-up initiative. Alternatively, team A and B continued to run regular team meetings to discuss and progress ongoing improvement efforts within the team.

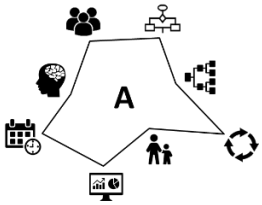
The improvement process totality represents another unity-in-diversity constellated totality. As such, the improvement process totality sets a structure that captures the variety of actions and strategies that were used by the different case study teams to support their improvement initiatives. Each case study team had a unique methodological approach to support local improvement. The uniqueness of the approach is a consequence of the geo-historical development of organisational improvement practices and improvement expertise locally in each case study site. For example, the whole systems improvement approach in team C developed from the expertise and experiences of their clinical lead. Alternatively, team A and B were encouraged to use the improvement approach that was developed by the QI organisations that supported the teams to run their improvement initiative. The uniqueness of the approach is also a consequence of the specific contextual influences experienced in a specific case study site at a specific time in their improvement initiative. That is, each improvement approach was adaptive to the specific contextual challenges and opportunities teams were faced with. However, the contradictory improvement approaches are bound together in the structure of the improvement process totality (Bhaskar, 2008b, 2010; Hartwig, 2007; Norrie, 2010). The eight principles of the improvement process totality contain a variety of actions and strategies that can be either present or absent in the process of a specific improvement initiative. These local variations can be expressed schematically through another radar chart, whereby the eight principles represent eight process dimensions that express differently across case study sites. This schematic overview of the improvement process totality, its components, and its local expressions is presented in Table 18Table 13. A more detailed description for each case study that demonstrates how the eight improvement principles expressed locally are presented in Table 19, Table 20, Table 21, and Table 22.

Table 18. Improvement process totality and its expression across the four improvement initiatives.



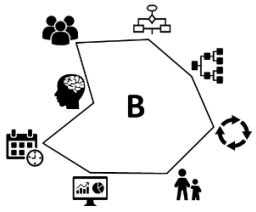
Team development	**Developmental improvement**
Learning from and with others	**Patient and public involvement**
Process mapping and design	**Using data**
Developing aims and plans	**Long term planning**

Table 19. Local manifestation of the improvement process totality in case study A.



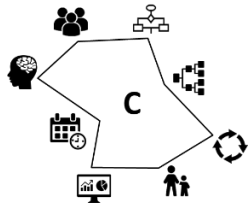
Team development	**Developmental improvement**
Core hospital-based project team established; external project manager recruited; presenting to local CCGs; mapping named individuals to clarify roles and involvement needs; strategic push for key individuals	Initiative aligned with prior improvement intentions; PDSA cycles used to optimise/improve intervention elements (education sessions and MDT allergy clinics); incremental development of MDT collaboration
Learning from and with others	**Patient and public involvement**
Collaboration with the Itchy Sneezy Wheezy team; shared learning with peer improvement project; dissemination via regional networks	PREM collection started after new MDT clinic formats were implemented
Process mapping and design	**Using data**
To understand and resolve administration challenges re: community clinics; patient journey drafted during team meeting; process issues fed-back and discussed; admin process/requirements mapped with manager	Analysis of asthma (re-)admissions to evaluate CQUIN goals; allergy education feedback used to improve subsequent sessions; started PREM collection
Developing aims and plans	**Long term planning**
Facilitated launch event to develop a shared aim and AED; AED updated to reflect project progress; team AED discussion to prioritise/agree final actions and encourage data collection	Increasingly mobilise and organise the clinical MDT to improve services within own control; continue engagement with external stakeholders to try and recruit financial or community resources

Table 20. Local manifestation of the improvement process totality in case study B.



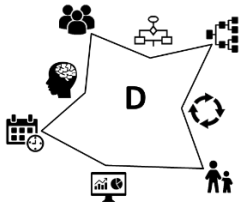
Team development	**Developmental improvement**
Core clinical team involved; facilitated CCG introduction; project nurse/manager recruited; stakeholder invitations to QI workshops; integrated improvement team formation	Development from one nurse new to asthma delivering two community asthma clinics to two nurses with asthma/allergy expertise and four clinics; and from community care to asthma friendly services
Learning from and with others	**Patient and public involvement**
Collaboration with the Itchy Sneezy Wheezy team; shared learning with peer improvement project; dissemination/learning via regional networks	Focus groups done to direct project developments; patient feedback collected to evaluate the new community clinics (compared to the hospital clinics)
Process mapping and design	**Using data**
To integrate asthma aspirations into existing services; drafted during QI workshop; improved with specific stakeholder follow-up; developed to reflect LAS aspirations; agreed with stakeholders; CCG approved	Cost-modelling to develop a QIPP case; clinic activities and patient feedback to make a case for continuation; cross-service patient data to identify children for review; service process measures to monitor KPIs
Developing aims and plans	**Long term planning**
Facilitated launch event to develop a shared aim and AED; AED to reflect long-term vision; used by external QI team to discuss project progress; interim plans consolidated in CCG business cases and KPI goals	Ongoing data collection and CCG collaboration to keep demonstrating the case for project continuation; increasingly bringing in stakeholders to integrate and improve more services

Table 21. Local manifestation of the improvement process totality in case study C.



Team development	**Developmental improvement**
Recruitment CCG children's lead and project manager; whole systems review stakeholder engagement; integrated improvement team formation; thoughtful, specific, efficient participation requests	Starting with a needs assessment based on a whole systems review; informing an asthma pilot project; that informed the development of a new atopy service
Learning from and with others	**Patient and public involvement**
Input from Itchy Sneezy Wheezy team; collaboration with fellowship project; dissemination via regional networks	Patient experiences captured in whole systems review; parent representatives invited to integrated improvement team
Process mapping and design	**Using data**
To understand local services, define new atopy service remit, develop GP clinical care pathway; drafted during team meeting; developed based on guidelines; improved with team feedback; CCG approved	Mixed-method assessment of local services and population need; mixed-method pilot evaluation; health service cost-modelling; electronic consultation templates for data extraction
Developing aims and plans	**Long term planning**
Improvement areas defined based on whole systems review and asthma pilot; improvement goals and plans developed/discussed during team meetings, and formalised in a CCG business case	Based on a systematic population-based approach; using the whole systems review, improvement evaluations and continuous stakeholder input to ensure initiatives strategically address core local issues

Table 22. Local manifestation of the improvement process totality in case study D.



Team development	**Developmental improvement**
Core CCG children's team; clinical community children's team development; local and wider stakeholder mapping; stakeholder engagement phase; integrated improvement team formation	Iterative development of children's community services; supporting/continuing the implementation of a local allergy testing service; adopting and embedding tools and strategies from the regional allergy network
Learning from and with others	**Patient and public involvement**
Input from Itchy Sneezy Wheezy team; collaboration with ongoing improvement initiatives; learning via regional networks	Parent representative invited to the integrated improvement team
Process mapping and design	**Using data**
	Mixed-method community service evaluations; using data to define the local problem and make the case for intervention; financial modelling to decide feasibility of improvement ideas; clinical audit in primary care
Developing aims and plans	**Long term planning**
Driver diagram development in team meetings; improvement ideas and financial estimates presented and discussed; work streams and groups developed	Based on a systematic review of local services for children with allergies; identifying strategic alliances with published policies; by building multi-disciplinary collaborations based on mutual goals

The internal structure of the improvement process totality is also consistent with the system characteristics that are inherent to MELD totalities in that its components are internally related. For example, stakeholder workshops to map local processes (*'Process mapping and design'*) or to develop a shared project aim (*'Developing aims and plans'*) supported the enrolment of stakeholders in the improvement teams (*'Team development'*). Also, the development of interventions (*'Developmental improvement'*) is usually supported by learning from data analysis (*'Using data'*).

5.3.4. Interdependencies between sub-totalities

In the previous three sections, I explained children's allergy improvement initiatives in terms of three independent totalities – a child allergy intervention totality, improvement context totality, and improvement process totality. And I discussed how each totality reflects the improvement experiences across the four different case study sites. In this section, I discuss how these three totalities act as sub-totalities of a larger integrated child allergy improvement totality by focusing on their interactions and interdependencies. In Chapter 2, I discussed that quality improvement is understood as the interaction between interventions (content), context and the improvement process. However, how these components interact exactly is insufficiently explored due to a lack of process-oriented studies of healthcare improvement (Etheridge et al., 2014; Pettigrew et al., 2001). The narrative case studies presented in Chapter 4 address this gap. They were developed to understand 'becoming' as part of 2E of MELD dialectic and accordingly they describe the causal unfolding of mechanisms involved in the development of the case study improvement initiatives over time. As such, the case studies exemplify how the interdependencies between intervention, context and improvement process manifest in the real world. In this section, I discuss what interdependencies have been observed across the case study interventions, contexts, and improvement processes, and I present how these observed dynamics are embedded in a more advanced theoretical understanding of children's allergy improvement initiatives as an integrated totality. A schematic overview the children's allergy improvement initiative totality and its internal dynamics is presented in Figure 24.

The children's allergy improvement initiative totality demonstrates a structural representation of the children's allergy improvement initiative as a real-world phenomenon. The structure of totalities in 3L of MELD are meant to reflect the structure of reality, which facilitates the translation of the theoretical understanding (in the mind) at 3L of MELD into practical action (in the world) at 4D of MELD dialectic (Bhaskar, 2008b, 2010; Hartwig, 2007; Norrie, 2010). Accordingly, totalities are depth-open, which means they are both vertically and horizontally open. Vertically open means that totalities can be re-constructed within a more refined or larger stratified structure. Horizontally open

means that totalities are permeable and able to interact with mechanism outside of the system. These structural characteristics make totalities contingent and undetermined in nature. This means that the expression of a totality depends on the influencing and emergent effects of the environment in which it is situated. This reflects the reality we have observed, whereby the children's allergy improvement initiatives manifested very differently across the four case studies. Accordingly, the totality in Figure 24 describes the general structure of a children's allergy improvement initiative (its components and their relationships) based on the case study observations without defining or predicting how a future improvement initiative will develop. Instead, the observation of future initiatives can be used to extend and refine the children's allergy improvement initiative totality developed in this study.

The structure of the children's allergy improvement initiative totality in Figure 24 presents the amalgamation of the diverse and contradictory case study experiences into a single integrated theoretical representation in line with the principles of 3L of MELD dialectic (Bhaskar, 2008b; Norrie, 2010). For example, the observation that the involvement of allergy specialist doctors was instrumental to support the delivery of integrated allergy care in the children's allergy improvement initiatives in case study A, C and D contradicts the experiences observed in case study B where only respiratory specialist doctors were involved. The structure of the children's allergy improvement initiative totality holds space for the existence of both experiences by presenting a collection of interdependent sub-totalities and sub-totality components that can manifest, manifest differently or not manifest depending on the causal interactions that unfold in a specific real-world situation.

The nature of the causal interactions between sub-totalities and between sub-totality components in the children's allergy improvement initiative totality is also presented in Figure 24. Firstly, the sub-totalities were found to inhibit and reinforce expressions in the other sub-totalities. Secondly, the components within a sub-totality were found to inhibit and reinforce one another. These causal interactions between the sub-totalities and sub-totality components are again situational, contingent on the place and time in which they unfold. For example, the team in case study A struggled to engage local commissioners, which caused them to identify other funding opportunities resulting in a funding agreement between the hospital and commissioners under the CQUIN framework in May 2015. In June 2015, however, a draft of the London Asthma Standards was shared with the commissioners in case study B, which caused them to be motivated and engaged when they were approached to support and fund local asthma and allergy service improvements, resulting in the approval of a local CCG QIPP business case.

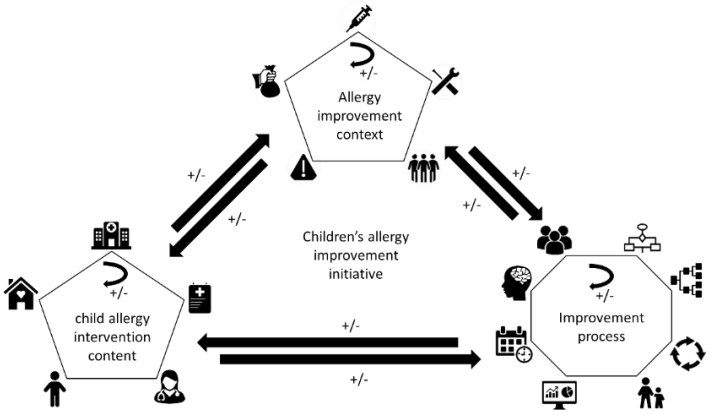


Figure 24. Schematic overview of the children's allergy improvement initiative totality.

The case study narratives presented in Chapter 4 demonstrate the actual unfolding of causal paths. They demonstrate the observed interactions and interdependencies between intervention, context, and process within four unique improvement initiatives. Accordingly, the case studies exemplify the types of interactions contained within the relationships between intervention-, context-, and process sub-totalities. They provide the empirical evidence for the theorised interactions that has been lacking so far. Examples of these observed interdependencies across case study sites are described in Figure 25, Figure 26, Figure 27, and Figure 28.

Case study A is used to demonstrate how the diagrams can be understood. Figure 25 depicts two examples that show how the dynamic unfolding of events in case study A can be described through the intervention-, context-, and improvement process totalities and their interdependencies.

> Example A1: Team A had expressed an interest to implement the Itchy Sneezy Wheezy intervention. However, they had no resources available to support its implementation *('Resources and opportunities', context totality, 1).* To get financial support for their initiative, team A subsequently approached local commissioners *('Team development', improvement process totality, 1,2)*. The commissioners demonstrated a lack of interest and support *('Relationships and project engagement', context totality, 2,3)*, which moved the team to identify finances elsewhere. They then identified the CQUIN funding scheme *('Resources and opportunities', context totality, 3,4)*. As part of the CQUIN scheme, team A agreed to deliver a reduction in asthma admissions. Due to ongoing implementation issues, they found themselves at risk of failing the CQUIN. To mitigate this risk, they came together to brainstorm alternative intervention ideas and to redefine their project priorities and plans, which was captured in an AED *('Developing aims and plans', improvement process totality, 4,5).* Team A subsequently improved the integration of hospital-based services for children

with allergies, in line with the new plans, rather than implementing a community-based allergy clinic *('Healthcare delivery system: Integrated allergy care', intervention totality, 5,6)*.

Example A2: Team A experienced operational difficulties preventing them from implementing clinics in the community *('Healthcare delivery system: Community-based specialist allergy services', intervention, 1)*. To understand what barriers were preventing them, the team organised a process mapping workshop *('Process mapping and design', improvement process totality, 1,2).* They identified issues in organising the appropriate administrative that weren't easily resolved *('Healthcare delivery system: Integrated health service administration', intervention totality, 2,3).* Consequently, team A developed a stakeholder map to identify which people needed to be engaged to resolve the issue *('Team development', improvement process totality, 3,4)* and they developed a process map that outlined the administrative process that needed to be put in place *('Process mapping and design', improvement process totality, 3,4).* However, they struggled to engage the right stakeholders, as they were in the management team who were pre-occupied with an organisational merger *('Relationships and project engagement', context totality, 4,5).* Fortunately, the hospital manager overseeing all the CQUIN programmes was motivated to make the project a success *('Relationships and project engagement', context totality, 5,6).* They subsequently took action personally to recruit a person to provide the administrative support that team A needed *('Team development', improvement process totality, 6).*

Each example uses a short narrative to describe a causal chain of mechanisms and events. Each causal narrative is summarised in Figure 25 in two separate diagrams. To map the narrative onto the diagrams, the causal mechanisms and events in each narrative are coded in brackets. The codes all follow the same format: 'description of causal mechanism or event' *('belongs to component x', in totality y, as part of causal chain(s) a,b)*. The bottom schematics in Figure 25 are a causal path that depicts the narratives as a linear chain of events. Each link in the chain is numbered and consists of three elements: two mechanisms or events and their causal connection (A_1 $causes_1$ B_1). Some causal links have more elements (A_1 and B_1 $cause_1$ C_1) and most elements belong to more than one link (A_1 $causes_1$ $B_{1,2}$ $causes_2$ C_2). The top schematic is the child allergy improvement totality that depicts the narrative as a system of causal relationships. The symbols represent the totality components to indicate the type of causal mechanism or event. The link numbers illustrate the causal flow of mechanisms and events. And the arrows illustrate the causal connections between mechanisms and events. The arrows demonstrate whether a causal connection is internal to one sub-totality or between two sub-totalities. They also demonstrate the direction of the causal flow between sub-totalities. Accordingly, the diagrams demonstrate that the child allergy improvement totality diagram

can be used to depict a causal case study narrative. That is, its structure captures both the narrative components and their interrelations, which has been a gap currently in improvement science research. Figure 26, Figure 27, and Figure 28 present similar diagrams that represent the causal unfolding of events in case study B, C and D respectively. Accordingly, they demonstrate that the child allergy improvement totality captures the narrative structure of all four case studies and not just one.

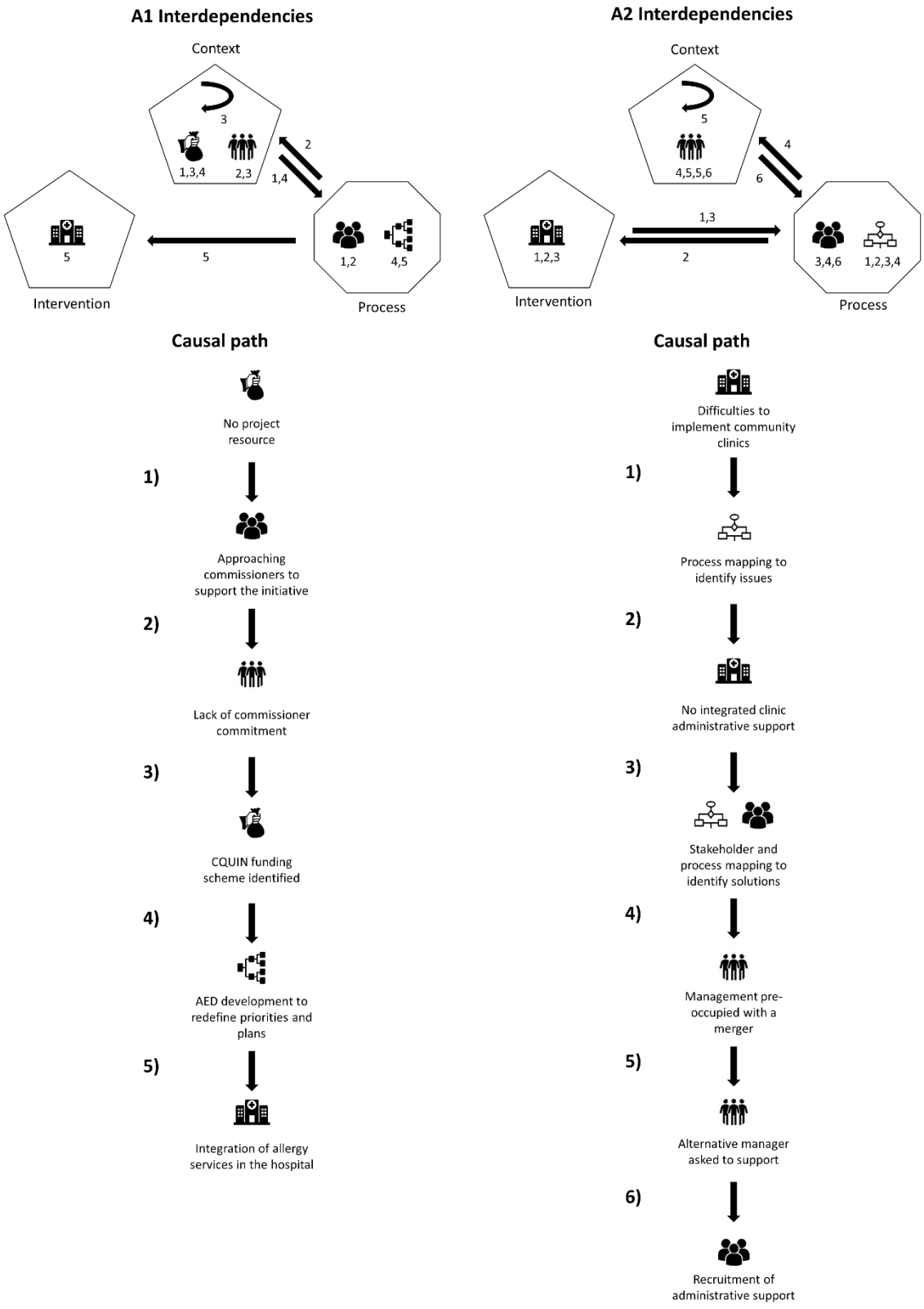


Figure 25. Case study A expressions of sub-totality interdependencies based on two causal path examples.

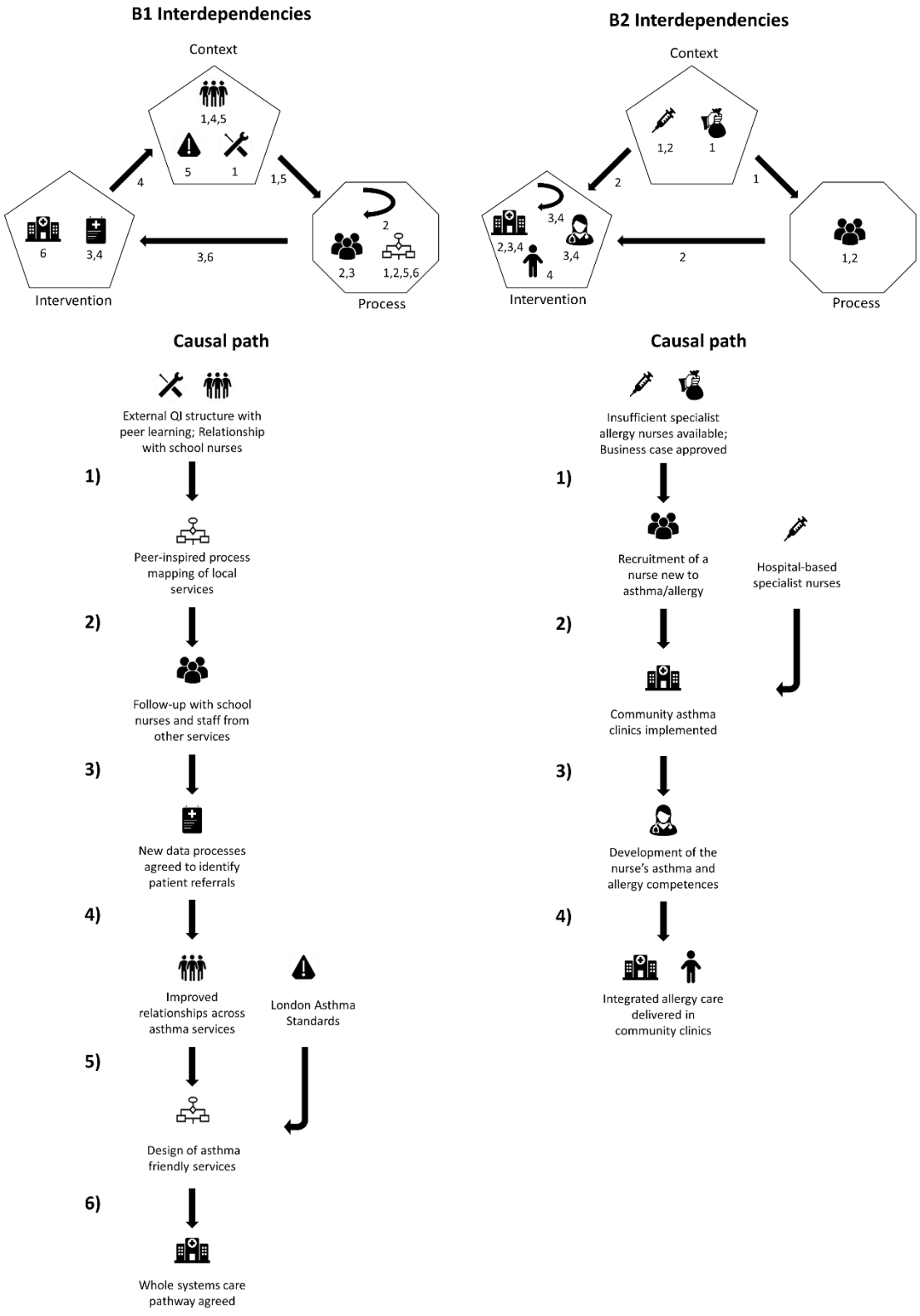


Figure 26. Case study B expressions of sub-totality interdependencies based on two causal path examples.

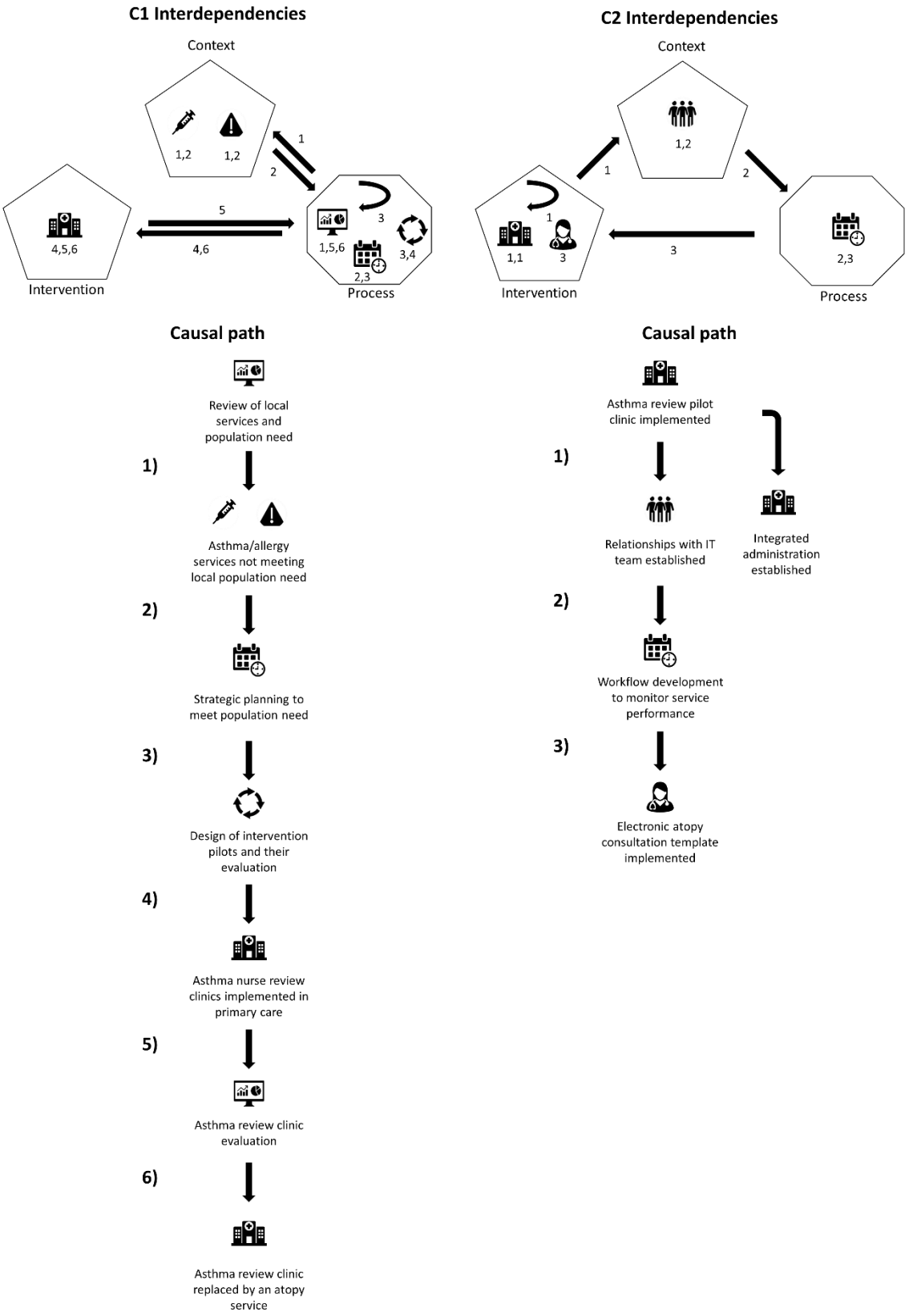


Figure 27. Case study C expressions of sub-totality interdependencies based on two causal path examples.

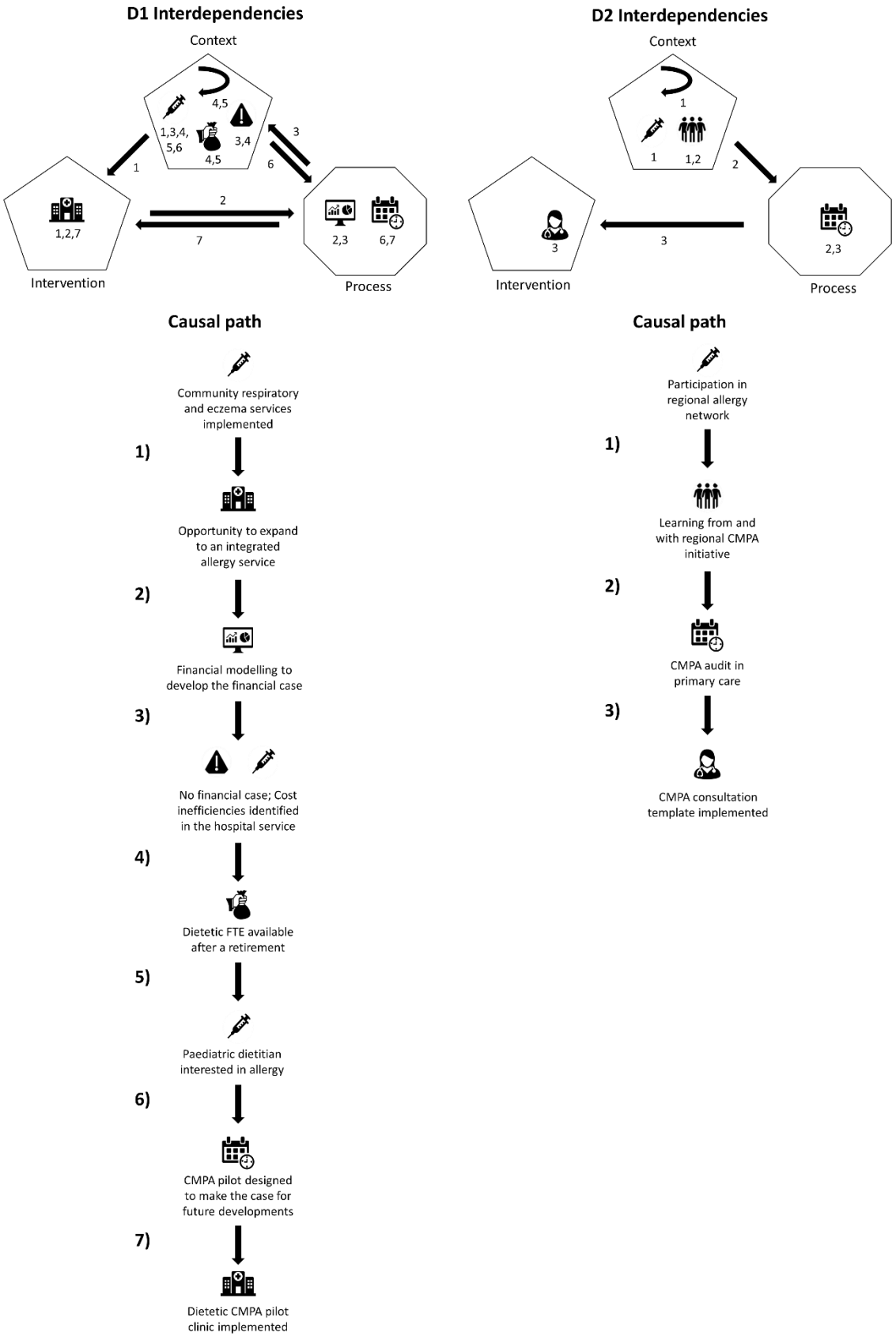


Figure 28. Case study D expressions of sub-totality interdependencies based on two causal path examples.

The diagrams in Figure 25, Figure 26, Figure 27, and Figure 28 describe the interdependencies between sub-totalities and within sub-totalities that were observed in eight examples of causal chains unfolding across the case studies (two examples from each case study). The structure of the children's allergy improvement initiative totality was used to visualise the local manifestation of each causal chain example in reality. The relationships that were observed in these examples highlight what type of relationships exist in reality. Accordingly, the sum of all observed relationships gives us information about what types of relationships really exist between the different components of health service improvement. When all component relationships between and within sub-totalities are analysed across Figure 25, Figure 26, Figure 27, and Figure 28, the following dynamics are found.

There are two-way relationships between the intervention content-, the improvement context-, and the improvement process sub-totalities

There are internal relationships between components within each sub-totality

The unfolding of a specific causal path can be triggered by activation in either sub-totality

The manifestation of causal relationships sometimes depends on the activation or presence of multiple components within or across sub-totalities

The manifestation of causal relationships can be triggered by non-events or the absence of certain sub-totality components

Active components can facilitate or inhibit the manifestation of certain developments

Accordingly, these dynamics within and between the child allergy intervention-, context-, and improvement process sub-totalities have been integrated in the children's allergy improvement initiative totality presented in Figure 24.

5.4. Conclusion

This Chapter has elaborated the theoretical understanding of children's allergy improvement initiatives by integrating the diverse improvement experiences observed across the four case studies into a children's allergy improvement initiative totality presented in Figure 24. The totality has the same structure as the health policy triangle, discussed in Chapter 2, which explains improvement initiatives based on the content, the process, and the context of the initiative (Walt & Gilson, 1994). However, the totality presented in this Chapter has extended this structural representation. Firstly, the internal structure of each health policy triangle component was elaborated, representing them as three separate sub-totalities consisting of multiple interacting components that were found to influence child allergy improvement initiatives across the four case studies. The sub-totalities represent a unifying structure with unique expressions across the four local case study improvement

initiatives. Secondly, the health policy triangle was elaborated by defining the relationships between components based on empirical case study evidence. Accordingly, I discussed the nature of the interdependencies between and within sub-totalities based on a set of causal chains that had unfolded in the real-life development of the case study improvement initiatives. The sub-totalities and their interdependencies were integrated into a theoretical representation of children's allergy improvement initiatives, which explains how they can develop differently over time and across situations. In line with a DCR understanding of totalities, the children's allergy improvement initiative totality can be adapted or extended when it fails to adequately represent future improvement initiatives. For example, other children's allergy improvement initiatives are likely to implement different intervention components, which could be included in the children's allergy intervention totality.

Chapter 6. Practical Recommendations

Interpreting the study findings to support improvement of children's allergy services in practice

6.1. Introduction

This Chapter presents practical recommendations to support the improvement of children's allergy services based on further analysis of the findings from the previous Chapters. It addresses the Fourth Dimension (4D) of MELD dialectic focused on agency. As discussed, MELD dialectic sets out to resolve dialectical contradictions in practice rather than analytically. Accordingly, the purpose of this Chapter is to develop practical recommendations that follow from this study. The first purpose of the Chapter is to resolve the theoretical contradictions that were identified in Chapters 1 and 2, by grounding them in the empirical case studies presented in Chapters 4 and 5. The second purpose of the Chapter is to translate the theoretical findings into recommendations to support agency or action intended to improve children's allergy service in practice. This Chapter contributes to the final research question of this study.

5. *What recommendations can support the local improvement of children's allergy services?*

This Chapter starts with a theoretical overview of 4D of MELD to demonstrate how the relationship between theory and practice is understood in MELD dialectic. The remainder of this Chapter is structured by research question. Under each research question, I discuss the relevant research findings. Specifically, I focus on the propositions and contradictions relevant to each question and argue how they are grounded in the empirical case study data. The empirical grounding of the research propositions and contradictions demonstrates how its parts are dialectically related. Based on this dialectical understanding, I then derive practical recommendations to support the dialectical resolution in practice and to answer the final research question posed in this thesis.

6.2. Fourth Dimension (4D): transformative praxis

The *Fourth Dimension (4D)* of MELD dialectics focuses on the principle of transformative practice or agency to resolve dialectical contradictions within the real world, striving for emancipation and freedom. As discussed earlier, MELD dialectics is materialist in contrast to Hegel's rationalist dialectical method. This means that MELD assumes that dialectical contradictions exist in the real world and hence need to be resolved in the real world. Hegel's dialectics on the other hand uses a three-stage method to improve our understanding of dialectical contradictions, framing them as rational contradictions to be resolved epistemologically in our minds. Like Hegel's dialectic, MELD uses the principle of totality at 3L to improve our understanding of dialectical contradictions. In MELD, however, a fourth dimension (4D) or fourth stage was added to transform this understanding into action.

As such, MELD can resolve the dialectical contradiction between theory and practice that underpins the third research gap of this thesis. In Chapter 2, I defined the aim of improvement science as developing knowledge that is practically relevant and able to support healthcare professionals to make local healthcare improvements (Marshall et al., 2013). Accordingly, I discussed studies demonstrating the benefits of applying theoretical knowledge and understanding, including EBM, into the practice of healthcare and healthcare improvement. As such, the need and desire for scientific theories to be embedded into practice is clear. In reality, though, healthcare science and healthcare delivery are often considered as completely separate practices without much consideration for their interdependencies and interactions. Science is supposed to be value-free focusing on factual knowledge only, while healthcare delivery has too many contingencies for scientific knowledge to be directly applicable, and healthcare professionals are preoccupied saving lives. MELD, however, has been developed to address this issue – to resolve the dialectical contradiction between theory (science) and practice (healthcare delivery) that exists in the real world (Bhaskar, 2008b). It does so, by highlighting how theory and practice are both independent and interdependent elements of practice as a more general totality.

MELD also provides a methodological approach to integrate theory and practice in reality. In MELD, theory is studied at 1M and practice is studied at 2E. What follows at 3L is theory development. Here, the theoretical insights gathered at 1M are tested, refined and elaborated based on the practical experiences captured at 2E. As such theory development at 3L is a practice in itself. Finally, at 4D, the theoretical insights developed at 3L are used to guide practice. The integration of theoretical insights into practice follows the DCR understanding that science has an emancipatory axiology, where scientific (i.e. theoretical) insights have ethical (i.e. practical) implications (Bhaskar, 2008b). That is, scientific theories contribute to our ability to create a better world – by pointing out false beliefs that should no longer influence our actions; by describing what the world is like and thereby how it could be different; and by explaining situations and phenomena in terms of causal mechanisms that could be strategically manipulated to create change (Bhaskar, 2008b, 2009; Norrie, 2010). It is through these mechanisms that the theoretical insights captured in 3L totalities support the practical resolution of dialectical contradictions at 4D. That is, 3L insights support the planning of strategic actions at 4D that could transform care pathway implementation, improve the care delivered to children with allergies and free them from their allergy symptoms.

To understand how strategic actions can cause transformation, it is important to understand the dynamics between structure and agency. At 2E, I defined the nature of change as the alternate unfolding and manifesting of causality over time and space. At 3L, I described how causal mechanisms can interact and collectively form systems or structures with their own causal

properties. Based on this understanding, humans exist and behave within a network of structures and mechanisms that causally influence their experiences, thoughts and actions. That is, actions are influenced by the spatio-temporal and social position someone is in and the causal conditions relative to that position. Accordingly, contextual conditions might limit the actions someone is able to perform and make the performance of certain actions more likely than others. These principles describe how a person is influenced by their contextual conditions – how structure influences agency. However, based on the same principles, actions also have causal consequences that influence contextual conditions, which means that agency conversely also influences structure (Archer, 2003).

In its most generic form agency can be defined as consequential action or the causal power to make something happen (Latour, 2005). Human agency in the context of social change is more specific, however. It is intentional, which involves conscious behaviour directed towards a purpose (Porpora, 2015). Mediated by consciousness, humans have the capacity to have subjective experiences, to reflect, to make moral judgements and to communicate socially (C. Smith, 2010). These cognitive capabilities influence what actions people take and mediate the influence of structure by granting people the *"power to deliberate internally upon what to do in situations that were not of our own making"* (p. 342) (Archer, 2003). Internal deliberation, or reflexivity, has been proposed as a mediating mechanism underpinning the interplay between structure and agency (Archer, 2003). It reflects the subjective individual interpretation of objective contextual conditions, which explains why people often respond differently when positioned in similar circumstances. More specifically, reflexivity is defined as the *"personal capacity to reflect upon ourselves and our concerns in relation to our social circumstances"* (p.342) (Archer, 2003).

Concerns are the things that subjectively matter to people, motivating them to take action (Archer, 2003). They connect the external objective world people live in to their internal subjective experiences (Manyukhina, 2018). That is, concerns are personal, subjectively developed and prioritised based on personal experiences, emotions and reflections. Nevertheless, they represent real-world issues that exist objectively. For example, personal concerns that motivated me in this study are child wellbeing, staff wellbeing and healthcare quality. These concerns are priorities to me, because they relate to personal experiences that are important to me. For example, based on both academic and personal experiences, I know the importance of positive childhood experiences, which motivates me to help create such experiences to support the flourishing of children as adults. Based on personal concerns, people use their cognitive capabilities to develop *projects*, strategising what actions can be taken to achieve goals aligned to these concerns (Archer, 2003). When such agential

projects are subsequently enacted, they have the power to influence structure and change contextual conditions.

So, 4D represents the last stage of MELD dialectics where the lessons learnt throughout the other MELD stages are translated into practice recommendations that are most likely to improve a situation. However, ethical practice recommendations are fallible in the same way scientific theories are. Accordingly, they also require testing, refinement and elaboration, making transformative practice or improvement a developmental process just like scientific discovery. MELD, as such, is an iterative process of acting and learning. That is, the 4D theory-based practice recommendations are developed to change actual practice, which can initiate a new cycle of practice-based theory-development to inform and improve the recommendations made so far. This study can be interpreted, as such, designed as a new MELD iteration aiming to improve and refine practice recommendations made so far regarding care pathway implementation and regarding the improvement of allergy care for children.

6.3. Mechanisms of children's allergy care and of care pathway interventions

This section discusses and interprets the study findings that answer the first research question.

1. *What are the quality deficiencies in children's allergy services?*

The national allergy reviews that motivated this study have described several deficiencies in children's allergy services. However, by discussing the health service deficiencies within the broader context of childhood allergies and children's allergy care, I also explained their causal mechanisms. More specifically, I discussed how quality deficiencies in children's allergy services are explained through the interactions between physical, interpersonal, and structural mechanisms. I explained that allergy involves physical immune reactions, which often cause allergy symptoms across multiple organ systems. However, healthcare structures have evolved historically around organ-based specialties, whereby allergy as an integrated specialty is less established, since it developed more recently. Consequently, in the absence of allergy specialists, many children are referred to several organ-based specialists to manage persistent allergy symptoms without any coordination of treatments. Moreover, as a newer specialty, allergy is also still underrepresented in the medical curriculum and there are less (training) positions for allergy specialists. Consequently, non-specialist professionals, like GPs, will generally have had little exposure to clinical information on children's allergy despite the publication of allergy-related clinical guidelines over the years. Moreover, the lack of allergy specialists and the lack of allergy knowledge in non-specialist settings is especially problematic in light of the high prevalence of allergic disease in children that was discussed. As such,

deficiencies in the quality of children's allergy care reflect a lack of allergy capacity within the NHS, the fragmentation of care across system-based specialists, and limited opportunities for support with the management of allergy symptoms over time. These particular issues, however, are not specific to children's allergy care. Instead, they are generalizable to most patients with chronic conditions and multi-morbidity.

To improve children's allergy services, it is important to understand children's allergy care in terms of this complex of interdependent causal mechanisms. This is important, because simple interventions often don't resolve complex problems. Instead, multi-faceted interventions tend to be more effective (Shojania & Grimshaw, 2005). Moreover, an understanding of the causal mechanisms of children's allergy care helps to understand why and how an intervention might be (in)effective, which is useful both in the development and evaluation of targeted interventions (Astbury & Leeuw, 2010; Westhorp, 2013). In this study, I have used the mechanistic explanation of children's allergy care accordingly. I used it to interpret the evaluation studies of care pathway interventions; I used it to situate and assess the RCPCH care pathways and the Itchy Sneezy Wheezy intervention; and I used it frame the interpretation of my case study data. As such, I used the mechanistic understanding of children's allergy care to develop and investigate the first theoretical proposition of this thesis.

> *Proposition I: Care pathways improve children's allergy services as part of a complex integrated & chronic care intervention.*

This proposition was developed in Chapter 2, where I used the mechanistic understanding of children's allergy care to situate and assess the RCPCH care pathways and the Itchy Sneezy Wheezy intervention. I identified that the RCPCH care pathways seemed to address all key allergy mechanisms. Moreover, I argued that the success of the Itchy Sneezy Wheezy intervention was likely due to its multi-faceted nature. More specifically, the Itchy Sneezy Wheezy intervention contained many components that were important to impact the causal mechanisms of poor-quality allergy services, but that were also unusual for care pathway interventions. Instead, the Itchy Sneezy Wheezy intervention was found to better reflect integrated and chronic care interventions and the intervention could be organised based on the validated Chronic Care Model (CCM) (Wagner et al., 1996).

Consequently, I used the CCM to frame my cross-case analysis. That is, all improvement initiatives aimed at some point to implement the Itchy Sneezy Wheezy intervention. And since I had demonstrated that the components of the Itchy Sneezy Wheezy intervention could be organised within the CCM, I investigated whether the components of the case study interventions could similarly be organised within the CCM. However, the Chapter 4 case studies identified that

implementation of the Itchy Sneezy Wheezy intervention was only an element of the health service developments that were implemented across the improvement initiatives. Nevertheless, the intervention components could still all be organised within the CCM. More specifically, the CCM was able to act as the unifying structure that consolidated the diverse child allergy interventions implemented across cases. Accordingly, the CCM was used to structure the child allergy intervention sub-totality discussed in Chapter 5. The CCM was particularly appropriate, because research evidence had already demonstrated that the CCM components are interdependent and that all components influence intervention outcomes (Coleman et al., 2009; Glasgow et al., 2001; Wagner et al., 1996), which are also two key characteristics of DCR totalities (Ackoff, 1974; Bhaskar, 2008b).

The structure of the child allergy intervention sub-totality supports elaboration of the first theoretical proposition. Across improvement initiatives, 26 intervention components were abstracted, which were clustered into 10 intervention segments, across the 5 CCM components, which collectively comprise the structure of the child allergy intervention sub-totality. Accordingly, the child allergy intervention sub-totality reflects a stratified structure of three levels. Moreover, three types of care pathway intervention components were identified across improvement initiatives. The organisation of these components within the child allergy intervention sub-totality structure confirms and elaborates *Proposition I.* A schematic representation is demonstrated in Table 23. This Table, first of all, demonstrates that the care pathway intervention components operate within the CCM structure, which confirms that care pathways operate as part of a complex integrated and chronic care intervention. The Table also demonstrate that the two clinical care pathway components are organised within the same intervention segment, which highlights that these are similar care pathways used to implement guidelines. However, the health system care pathway component is organised within a different intervention segment, which highlights that it's a different type of care pathway used to organise local allergy services. Accordingly, the child allergy intervention sub-totality also confirms the theoretical notion in Chapter 2 that care pathways are hierarchically organised. Finally, it should be noted that DCR totalities are depth-open in line with reality. Accordingly, the child allergy intervention sub-totality can be elaborated based on new empirical cases. This might lead to the inclusion of patient-level care pathways, which were not implemented in the four cases studied.

Table 23. Theoretical elaboration of Proposition I: care pathway intervention component interdependencies.

	**Healthcare delivery system**	
	Organisation of local allergy services	Health system care pathway that organises and defines allergy services across settings
	**Clinical decision support**	
	Guideline implementation	Clinical care pathway for primary care Clinical care pathway for urgent and emergency care
	**Clinical information systems**	
	**Self-management support**	
	**Community resources**	

Proposition I: Care pathways improve children's allergy services as part of a complex integrated & chronic care intervention.

Based on the elaboration of Proposition I, the following practice recommendations can be derived:

Recommendation I: The RCPCH care pathways can be used in combination with the CCM to design integrated care interventions that impact the underpinning mechanisms of high-quality allergy care (discussed in Chapter 1) to improve children's allergy services locally.

Recommendation II: Different types of care pathways can be embedded as part of a single children's allergy integrated care intervention. Health system care pathways can be implemented to organise local allergy services in a region. Clinical care pathways can support the implementation of clinical guidelines in one or multiple healthcare settings.

6.4. Intervention adaptations

This section discusses and interprets the study findings related to the second research question.

2. *How are allergy care pathway interventions adapted during implementation?*

In Chapter 4, I presented four case studies of children's allergy improvement initiatives. Each case study reflected a narrative which described how allergy interventions developed progressively over time. Based on the case studies, I also concluded that each improvement team seemed to operate in line with a general improvement strategy. Accordingly, the case studies demonstrated how adaptation decisions tended to be negotiated in line with these improvement strategies.

That is, team A generally operated by the strategic principle '*making it work'.* They were most motivated to implement the Itchy Sneezy Wheezy intervention with fidelity. As such, adaptations were only considered when severe implementation difficulties were experienced. For example, team A had implemented a new referral process, which referred patients with uncontrolled asthma to a new community-based allergy clinic. However, the team struggled with the implementation of administrative support in the community. Accordingly, only when referrals were coming in, did the team decide to start the allergy clinic in the hospital instead.

Team B generally operated by the principle *'cultivating flowers'.* They had bought into the design and the underlying principles of the Itchy Sneezy Wheezy intervention to improve care for their local child population. Moreover, team B recognised that the high-quality asthma and allergy services in the hospital were unable to support children with uncontrolled asthma and unrecognised allergies in the community. As such, the team understood they had to support community-based services if they wanted to improve care for local children, and the Itchy Sneezy Wheezy intervention had proven to be an effective mechanism. Accordingly, team B developed the vision to implement a specialist nurse service in the community and to improve other community-based services. The Itchy Sneezy Wheezy intervention was adapted initially to develop more appropriate intermediary goals, while working towards this long-term vision. Over time, Team B became more practiced with the use of QI methods and implemented a more systematic QI approach. This resulted in further adaptations to the Itchy Sneezy Wheezy intervention over time based on the data and insights accumulating from their QI methodology.

Team C operated by the strategic principle '*building on solid ground'.* They had taken a highly systematic approach to improve local children's services. At a certain stage in their approach, they recognised the potential to gain inspiration and insights from the Itchy Sneezy Wheezy intervention, which seemed similar to the intervention they had planned based on local data. As such, fidelity to the Itchy Sneezy Wheezy intervention played no explicit role. Nevertheless, the systematic approach still resulted in the implementation of an intervention that was very similar to the Itchy Sneezy Wheezy intervention.

Team D generally operated by the principle *'finding opportunities and synergies'.* In line with this strategy, they had identified the Itchy Sneezy Wheezy intervention in a literature search as an opportunity to expand and integrate their community asthma and eczema services. However, a financial modelling exercise demonstrated that the Itchy Sneezy Wheezy intervention didn't align with their current priorities after all. Accordingly, they moved on to identify other interventions and opportunities to improve their local children's allergy services, while putting the idea to implement the Itchy Sneezy Wheezy intervention on hold for a more appropriate time.

In Chapter 2, I discussed the need to investigate the adaptation of allergy care pathway interventions, since the improvement science literature provided contradictory advice on this issue. On the one hand, intervention adaptations were recognised to enhance implementation by improving the fit between interventions and their local contexts. This approach is generally encouraged in the study of QI methods, which emphasises an adaptive improvement process in which interventions can be selected flexibly and improved over time based on local data monitoring. On the other hand, intervention fidelity was recognised to enhance improvements by replicating intervention structures that had already achieved positive outcomes elsewhere. This approach is generally encouraged in implementation science, which emphasises the importance of high-fidelity implementation so that the local implementation of evidence-based practices will be more likely to achieve the positive outcomes that were also achieved in scientific studies.

> *Contradiction IV: Intervention adaptations generally enhance implementation, while intervention fidelity generally enhances healthcare improvements*

The case studies, presented in Chapter 4, demonstrate how this contradictory dynamic plays out in reality. Accordingly, they support the resolution of this contradiction. They do so, by exemplifying the relationship between implementation and improvement in practice. The case studies demonstrate that implementation of the Itchy Sneezy Wheezy intervention was part of an ongoing effort and commitment to improve local children's allergy services. As such, the Itchy Sneezy Wheezy intervention was implemented to achieve pre-existing aspirations, plans, ideas and/or efforts to improve children's allergy services, rather than the improvement initiative being solely focused on replicating the Itchy Sneezy Wheezy intervention. This demonstrates the relationship between implementation and improvement, whereby improvement contains implementation. This relationship still holds based on the theoretical assumptions that underpin implementation and improvement. That is, the adaptive process of improvement, in which interventions develop over time, can contain the high-fidelity implementation of evidence-based practices. As such, the case studies demonstrated how the dialectical relationship between high-fidelity implementation and

adaptive improvement manifested in reality, which subsequently helped to define the relationship and resolve the contradiction. This resolution is visualised in Figure 29.

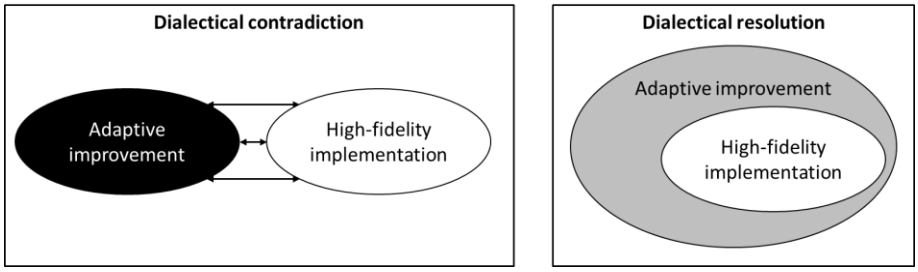


Figure 29. Resolution of the dialectical contradiction between implementation and improvement.

Moreover, the case studies also exemplify how the adaptation decision process can be navigated in line with this dialectical understanding of implementation and improvement. The case studies demonstrated that intervention adaptation was generally considered a normal practice to integrate the Itchy Sneezy Wheezy intervention within the larger adaptive process of improving children's allergy services locally. However, the extent in which adaptations were accepted depended on the general improvement strategies that were implicit within the case studies – *'making it work', 'cultivating flowers', 'building on solid ground'* and *'finding opportunities and synergies'*. That is, teams that operated based on a general improvement strategies that aligned with implementation principles, tended to appropriately emphasise fidelity. However, teams that operated based on a general improvement strategies that aligned with improvement principles, tended to appropriately emphasise adaptation.

For example, team A operated based on the strategy *'making it work'*, which aligns with implementation principles. Accordingly, they tended to work hard to achieve fidelity, while lacking a rigorous data infrastructure that would help them evaluate the appropriateness of adaptations. On the other hand, team C operated based on the strategy *'building on solid ground'*, which aligned heavily on improvement principles. Their initiative had a thorough QI approach that emphasised the collection of different types of data to evaluate intervention developments with the aim to inform future developments. Accordingly, they used the Itchy Sneezy Wheezy intervention for inspiration with no intention to implement it with fidelity. The other two teams operated from a more middle ground. That is, team B operated based on the strategy *'cultivating flowers'* with a long-term vision to implement the Itchy Sneezy Wheezy intervention. Accordingly, they operated based on implementation principles aiming for high-fidelity implementation at some point. However, they accepted intermediary adaptations to facilitate the progressive development of the initiative. Moreover, when they progressively developed and systematised their QI approach, they also started to implement additional intervention components that they developed progressively based on local

information. Finally, team D operated based on the strategy *'finding opportunities and synergies'*. Accordingly, they were operating based on parallel processes. They adopted evidence-based interventions from peer projects when they aligned with local priorities and capabilities. However, the adoption of evidence-based interventions was part of an overarching systematic QI approach, which included the identification and evaluation of known interventions against local goals and priorities. The QI process was subsequently used to inform adaptations to the evidence-based intervention components, as well as to develop distinct intervention components.

These observations demonstrate how the contradictory stances towards intervention adaptation across implementation and improvement science is resolved by improvement teams in practice. As discussed in Chapter 2, implementation science recommends fidelity to evidence-based interventions. This recommendation is based on the notion that scientific studies (or local evaluations) have demonstrated positive intervention outcomes, and intervention fidelity increases the likelihood of achieving similar outcomes while the impact of adaptations is uncertain (Elliott & Mihalic, 2004; Durlak & DuPre, 2008). Improvement science, on the other hand, recommends interventions to be adapted to their local context. This recommendation is based on the notion that a systematic quality improvement approach aims to develop a deep understanding of the local context and local processes, which is used to inform the intervention design, monitor the intervention outcomes, and adapt the intervention accordingly (Langley at al, 2009). As such, the contradictory stances towards intervention adaptation are based on different principles, whereby implementation principles emphasise external evidence to manage local uncertainty, while improvement principles emphasise the creation of local evidence to support an ongoing adaptive process. Figure 29 demonstrates the dialectical relationship between high-fidelity implementation versus adaptive improvement and the case studies demonstrate how different adaptation principles have been applied in practice. Consequently, the following recommendations are derived to support the adaptation of interventions in practice.

> *Recommendation III: Intervention adaptation is encouraged when improvement initiatives operate based on improvement principles. In this case, a systematic QI approach is used to inform and evaluate intervention developments as part of an ongoing adaptive process based on local data and insights.*
>
> *Recommendation IV: Intervention adaptation should be minimised when improvement initiatives operate based on implementation principles alone. In this case, interventions are based on external rather than local evidence. Evidence-based interventions are implemented*

with the aim to replicate the outcomes achieved elsewhere. This effort is compromised when interventions are adapted in ways not supported by external nor local evidence.

Recommendation V: When improvement initiatives operate based on a hybrid of implementation and improvement principles, adaptations can be made for the intervention developments that are (equally) underpinned by improvement principles, since they are locally informed and evaluated as part of a systematic QI approach.

6.5. Quality improvement methods

This section discusses and interprets the study findings that answer the third research question.

3. *How are quality improvement methods used to support the implementation of allergy care pathway interventions?*

In Chapter 4, I presented four case studies of children's allergy improvement initiatives. These case studies describe how the different improvement initiatives used QI methods over the course of the initiative to support the development of local children's allergy services. The case studies also indicated that each improvement team seemed to operate in line with a general improvement strategy.

Team A operated by the strategic principle '*making it work'.* Accordingly, they predominantly used QI methods to identify and resolve implementation challenges. For example, stakeholder- and process mapping were used when team A struggled to establish administrative support in the community. As such, QI methods were often used in response to implementation stagnation and contextual challenges. However, they were not used spontaneously. Instead, the project manager decided strategically when to apply which methods based on ongoing developments. Nevertheless, team A did not have a strong data infrastructure in place to evaluate and inform intervention developments over time.

Team B generally operated by the principle *'cultivating flowers'.* During their improvement initiative, an external organisation introduced them to their QI approach, which included a structure to learn with another allergy improvement initiative. After some initial demonstrations and independent experiences, team B bought into the principles of QI methods. Accordingly, their use of QI methods became increasingly intensive and sophisticated. For example, their use of data evolved from the collection and review of clinic data to the collection and review of integrated data across hospital and community services. Alternatively, their stakeholder engagement developed from engagement with

the school nurses to the development of an integrated improvement team with stakeholder representatives across asthma services.

Team C operated by the strategic principle '*building on solid ground'.* Team C decided to use a population-based approach to improve their local children's services, which relies on an in-depth understanding of population needs and supply of local services to inform health service improvements. To obtain this information, team C followed a systematic project plan that included QI methods, such as stakeholder and patient involvement and data analysis. This process consequently provided team C with a solid contextual understanding to develop health service improvements. Moreover, team C maintained a systematic approach throughout their improvement initiative. For example, they consistently implemented evaluation strategies to promote iterative health service developments.

Team D operated by the principle *'finding opportunities and synergies'.* Accordingly, they tended to use QI methods to identify, evaluate, and select opportunities for health service improvements. These functions were integrated in a systematic approach that team D used in their improvement initiative. For example, they identified the Itchy Sneezy Wheezy intervention through a literature search. Moreover, they identified ongoing allergy initiatives in the hospital laboratory and the regional allergy network through stakeholder engagement. Subsequently, they used data modelling to explore the costs and benefits of different improvement opportunities. Finally, team D integrated stakeholder activities into their meeting structure to support the selection of improvement options. This process resulted in the development of multiple working groups to implement the agreed health service improvements and subsequent developments. Several working groups continued the systematic use of data to evaluate project developments. For example, one working group conducted an audit to evaluate the implementation of clinical guidelines, while another group designed a process to evaluate the CMPA pilot. However, I left the field before I could observe whether such strategies were used consistently and continuously across groups.

In Chapter 2, I discussed the need to investigate the use of QI methods for the purpose of implementation, since both are based on contradictory principles and assumptions. QI methods are derived from improvement science, which promotes the systematic use of QI methods to inform adaptive intervention developments. Implementation science on the other hand encourages a systematic process to support high-fidelity implementation of evidence-based practices.

> *Contradiction V: QI methods are used for implementation even though implementation and improvement are based on contradictory underlying principles and assumptions.*

The case studies, presented in Chapter 4, demonstrate how this contradictory dynamic plays out in reality. Accordingly, they support the resolution of this contradiction. They do so, by exemplifying the relationship between implementation and improvement principles. The relationship between implementation and improvement principles is understood based on two variables: the systematic use of QI methods and intervention adaptations. Accordingly, improvement principles emphasise the systematic use of QI methods to inform and evaluate the development of interventions based on local data and insights. Intervention adaptations are likely to follow from this process, but not necessarily. Contrarily, implementation principles emphasise fidelity to increase the likelihood of achieving positive intervention outcomes that have been demonstrated elsewhere. The way in which high-fidelity implementation is achieved is less important. QI methods could be useful, for example to support stakeholder engagement or to overcome operational issues. If QI methods are used systematically, they might inform adaptations.

The relationship between implementation and improvement principles, understood in terms of intervention adaptations and the use of a systematic QI approach, is visually depicted in Figure 30. The dialectical understanding of improvement initiatives in Figure 30 is supported by the empirical case study findings. In the previous section, I discussed how improvement initiatives adapted the Itchy Sneezy Wheezy intervention in line with a general improvement strategy. In this section, I discussed how the improvement initiatives used QI methods in line with their general improvement strategy. Each case study initiative is positioned within the implementation/improvement framework in Figure 30 accordingly.

Case study A demonstrated how improvement initiative A operated based on the general improvement strategy *'making it work'*. In line with their strategy, they were motivated to implement the Itchy Sneezy Wheezy intervention with fidelity, and they used QI methods mostly in reaction to implementation challenges with the aim to remove any barriers to high-fidelity implementation. Their use of QI methods, as such, was unsystematic and not organised to proactively inform the development and evaluation of intervention adaptations. Accordingly, case study A is positioned as 'low adaptation' and 'low systematic use of QI approach' in Figure 30.

Case study B demonstrated how improvement initiative B operated based on the general improvement strategy *'cultivating flowers'*. In line with their strategy, they were motivated to implement the Itchy Sneezy Wheezy intervention as part of a long-term vision to improve local services for children with asthma and allergies. However, over time their QI approach became more systematic and informed additional intervention developments. Accordingly, case study B is positioned as 'low adaptation' and 'high systematic use of QI approach' in Figure 30.

Case study C demonstrated how improvement initiative C operated based on the general improvement strategy *'building on solid ground'*. In line with their strategy, they were found to use the Itchy Sneezy Wheezy intervention for inspiration only. Instead their intervention development was based on a highly systematic QI approach that started with a local population health review followed by the iterative development and evaluation of pilot interventions. Accordingly, case study C is positioned as 'high adaptation' and 'high systematic use of QI approach' in Figure 30.

Case study D demonstrated how improvement initiative D operated based on the general improvement strategy *'finding opportunities and synergies'*. In line with their strategy, they explored the Itchy Sneezy Wheezy intervention as an opportunity to further develop their local children's services. However, the systematic QI approach that was used by team D to identify, assess, implement, and evaluate external interventions resulted in the Itchy Sneezy Wheezy intervention being abandoned in favour of other intervention developments. Accordingly, case study C is also positioned as 'high adaptation' and 'high systematic use of QI approach' in Figure 30.

Accordingly, the framework in Figure 30 demonstrates how the general improvement strategies identified across the four case studies relate to the use of implementation and improvement principles respectively. As discussed previously, implementation principles refer to high-fidelity implementation of evidence-based intervention with minimal adaptations to increase the likelihood of replicating the intervention outcomes achieved elsewhere. Improvement principles refer to the use of a systematic QI approach to inform the development of interventions as part of an ongoing adaptive process based on local data and insights. Accordingly, implementation science emphasises external evidence, whereas improvement science emphasises local evidence. Consequently, it is hypothesised (see Figure 30) that for general improvement strategies that are neither based on implementation nor improvement principles their initiative's outcome will be uncertain due to an absence of underpinning evidence. In addition to the three recommendations about intervention adaptations presented in the previous section, a fourth recommendation can be abstracted from the dialectical understanding of improvement and implementation as presented in Figure 30.

> *Recommendation VI: Develop an initial awareness of 1) the general improvement strategy that is applied explicitly or implicitly in your improvement initiative, 2) whether this strategy is based on implementation principles, improvement principles, a combination of both or neither, and 3) whether QI methods and intervention adaptations are applied accordingly. It is recommended to subsequently evaluate whether the strategy, principles and methodological approach are theoretically consistent and consistent with the ultimate improvement goal. Changes can be then made with intention.*

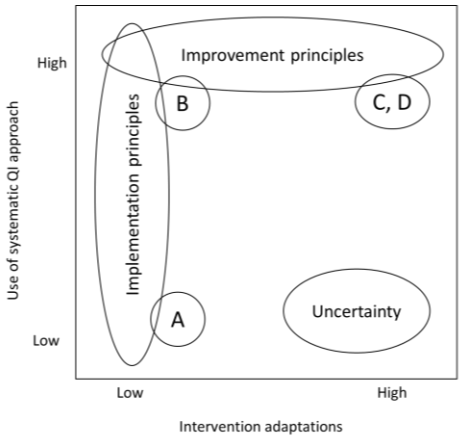


Figure 30. Dialectical relationship between improvement and implementation principles.

6.6. Children's allergy improvement initiative totality

This section discusses and interprets the study findings that answer the fourth research question.

4. How are local children's allergy health service improvement experiences integrated?

In Chapter 5, I discussed how the case studies could be integrated to reflect a general understanding of children's allergy improvement initiatives. This theoretical understanding was achieved through the development of a children's allergy improvement initiative totality, which is presented schematically in Figure 24. The children's allergy improvement initiative totality elaborates the theoretical understanding of improvement initiatives that was presented in Chapter 2. This understanding was based on the health policy triangle (Walt & Gilson, 1994) and summarised in the second theoretical proposition.

> *Proposition II: Improvements in the quality of children's allergy services emerge from the interactions between care pathways interventions, implementation processes, and contextual influences.*

The children's allergy improvement initiative totality elaborated Proposition II in several ways. Firstly, it elaborated the content, context, and process of improvement as three interdependent sub-totalities: the child allergy intervention content sub-totality, the allergy improvement context sub-totality, and the improvement process sub-totality. Each sub-totality reflects a unified structure of components that were observed to impact improvement initiatives across case studies. These components are represented symbolically in Figure 24. As discussed in Chapter 5, the sub-totalities adhere to the DCR characteristics of being depth-open. That is, they can be hierarchically organised, like the child allergy intervention sub-totality is, and the way the totality manifests depends on its unique geo-historical position. Accordingly, in Chapter 5, I discussed how the sub-totalities were expressed within the geo-historical settings of the four improvement initiative case studies.

More specifically, the structure of the child allergy intervention sub-totality consists of 26 intervention components organised within 10 intervention segments, which were structured based on the CCM. A more in-depth discussion of this sub-totality has been discussed earlier in this Chapter. Furthermore, the structure of the improvement process sub-totality was derived from the NIHR CLAHRC NWL systematic approach (Howe et al., 2013). Two of four cases were specifically encouraged to use this approach. The other two cases had developed their own systematic QI approach. However, when compared across cases, the improvement methods and strategies that were used were similar. More specifically, the use of QI methods could be integrated when I adapted the components of the NIHR CLAHRC NWL systematic approach to be more expansive. For example, 'the model for improvement' was abstracted to 'developmental improvement', so it could include consecutive pilot project based on their evaluations. A comparison of the NIHR CLAHRC NWL systematic approach and the improvement process sub-totality is presented in Table 24.

Table 24. Origins of the improvement process sub-totality component

NIHR CLAHRC NWL systematic approach methods		**Allergy improvement context sub-totality components**
Process mapping		Process mapping and design
NHS III Sustainability Model		Long term planning
Action-Effect-Method (based on driver diagrams)		Developing aims and plans
Model for Improvement including Plan-Do- Study-Act (PDSA) rapid cycle testing of change ideas		Developmental improvement
Measurement for improvement		Using data
Stakeholder engagement		Team development
Patient and public involvement		Patient and public involvement
Dissemination of learning		Learning from and with others

In contrast, the structure of the allergy improvement context sub-totality was developed inductively from the case study data. However, when these components were compared with other theoretical frameworks, they demonstrated a high-correlation with the factors of the MUSIQ (Kaplan et al., 2012; Reed, Kaplan, et al., 2018a). This comparison is demonstrated in Table 25.

Table 25. Comparison of the allergy improvement context sub-totality components to the MUSIQ

MUSIQ factors	**Improvement process sub-totality components**
Type 1 context	Clinical services and capacity
Data infrastructure; Infrastructure QI&I Portfolio management; Capability for improvement; Infrastructure Specialist QI&I Staff; Workforce focus on QI	Improvement structure
Team diversity; Physician involvement; Subject matter expert; Team tenure; Team leadership; QI leadership; Patient engagement & involvement	Relationships and project engagement
External motivators; External knowledge project specific; Motivation to change; Task strategic importance to the organisation	Accountability, priorities, alignments
Resource availability; Project sponsorship;	Resources and opportunities

Moreover, Proposition II is also elaborated by the interdependencies that the children's allergy improvement initiative totality describes between and within sub-totalities. The interdependencies between the content-, context-, and process sub-totalities were abstracted from eight causal path examples that were presented in Chapter 5, derived from the case study narratives in Chapter 4. Accordingly, the case studies demonstrated that all sub-totalities have two-way causal relationships. Moreover, these relationships can reinforce or inhibit the expression of certain sub-totality

components. The causal path examples that were presented in Chapter 5 also confirmed the presence of internal relationships within each sub-totality. Finally, the children's allergy improvement initiative totality demonstrated that causal interactions can be triggered by the presence and activation of components or clusters of components or by the absence of components. For example, the absence of project resource caused team A to pro-actively engage with local commissioners.

As such, the children's allergy improvement initiative totality also adheres to the DCR characteristics of being depth-open. That is, the totality is both hierarchically structured and contingent on geo-historical developments and positioning. The local manifestation of the children's allergy improvement initiative totality is exemplified in the causal unfolding observed across the four case study improvement initiatives. That is, when I entered the field, each of the four case study initiatives demonstrated a unique manifestation of the children's allergy intervention totality, the improvement process totality, and the allergy improvement context totality – depending on the initiative's geo-historical positioning and prior developments. While in the field, I observed how the improvement initiatives changed and developed following a unique causal trajectory that resulted in four equally diverse totality manifestations when I left the field.

Moreover, the interdependencies between the child allergy intervention sub-totality, the allergy improvement context sub-totality, and the improvement process sub-totality seemed to express emergent effects. That is, in each of the four case study initiatives a general improvement strategy was identified that described a general approach towards intervention development (and adaptation), the improvement process (and use of QI methods), and the contextual challenges and opportunities. The four general improvement strategies were implicit in the interactive development of the child allergy intervention, improvement process and context. However, when teams become aware of their improvement strategies, they are empowered to be intentional. That is, they become empowered to critically evaluate their strategy in the context of their improvement goals, to change their strategy if needed, and to take action to support strategy implementation. Accordingly, the following practice recommendations can be developed.

> *Recommendation VII: The child allergy improvement initiative totality can be used to develop an understanding of the improvement initiative at different points in time, which can be used subsequently to identify opportunities for further development and next steps.*
>
> *The child allergy intervention totality (presented in Table 11) can be used to assess what interventions have been developed already and where there are opportunities for further development. More specifically, improvement teams can assess their 'healthcare delivery*

system' by exploring the organisation of local allergy services, the implementation of community-based specialist allergy services, the delivery of integrated allergy care, the implementation of integrated clinical governance, and the implementation of integrated health service administration. They can assess their 'clinical information systems' by exploring that data systems and access used to support clinical decisions. They can assess 'clinical decision support' by exploring guideline implementation and other clinical support structures. They can assess 'self-management support' by evaluating the allergy-focused nature of consultations. And they can assess their 'community resources' by exploring the allergy support in schools. Specific intervention examples are presented in Table 11, which might be extended by teams based on their local evaluations and developments.

The improvement process totality (presented in Table 18) can be used to assess what QI methods have been applied so for and how the different methods could be used more effectively. The eight methods that were identified are 'team development', 'learning from and with others', 'process mapping and design', 'developing aims and plans', 'developmental improvement', 'patient and public involvement', 'using data', and 'long term planning'.

The allergy improvement context totality (presented in Table 13) can be used to assess what challenges and opportunities are present in the local context and how these could be mitigated or exploited. The five contextual influences that were identified are 'clinical services and capacity', 'improvement structure', 'relationships and project engagement', 'accountability, priorities, alignments', 'resources and opportunities'.

Recommendation VIII: the understanding of a local child allergy improvement initiative can be used to critically evaluate their approach towards the improvement process, intervention development, and contextual challenges and opportunities. When teams have a general improvement strategy in place to achieve their ultimate improvement goals, they can assess whether their improvement approach supports the improvement strategy or whether they should change their approach accordingly. Alternatively, teams can evaluate what general improvement strategy is implied in their improvement approach, and critically evaluate whether this strategy aligns with their ultimate improvement goals or if they want to change it.

Recommendation IX: the dynamic interdependencies captured in the child allergy improvement totality can be used to plan tactical moves in line with the general improvement strategy and the ultimate improvement goals. The causal path examples (presented in Figure 25, Figure 26, Figure 27 and Figure 28) demonstrate how the development of improvement

initiatives can be described as a causal chain of component interaction across the child allergy intervention sub-totality, the improvement process sub-totality, and the allergy improvement context sub-totality. The sub-totality components can be used in a similar fashion to plan (rather than describe) a sequence of tactical moves with the aim to cause a chain of developments in the improvement initiative.

6.7. Conclusion

In this Chapter, I discussed the findings from the previous Chapters with the aim to develop recommendations for practice. More specifically, I developed nine recommendations based on the analytical interpretation of the study findings. In Chapter 2, I identified multiple theoretical contradictions in the care pathway literature and the improvement science literature. In this Chapter, I analysed the case study narratives to understand how the theoretical propositions and contradictions are situated in real-world practice. This process supported me to develop a structural understanding of care pathways and of the relationship between implementation, improvement, intervention adaptations and the use of quality improvement methods. Such a structural understanding of propositions and their relationships, highlights the boundary conditions of propositions rather than simply rejecting or verifying their position. For example, the structural representation of care pathways describes that clinical care pathways are used to support guideline implementation, while health system care pathway are used to organise local services. If you use them differently, the outcomes are likely not as expected.

Situating theoretical contradictions in a structural representation of the empirical case study reality facilitates the 4D of MELD framing of agency being influenced and bounded by structure. Accordingly, a structural awareness of phenomena and situations supports people to reflect on their own position and plan what actions will most likely move them towards the achievement of their goals under these specific structural circumstances. For example, if emergency department staff aren't well educated in the management of asthma and allergies, a clinical pathway might be implemented to support the staff deliver evidence-based care in accordance with clinical guidelines. A health system care pathway would be less useful in this situation. The recommendations that were developed in this Chapter aimed to encourage people reflect on their structural conditions and aims, and act accordingly.

The child allergy improvement initiative totality developed in Chapter 5 and the improvement strategies developed in Chapter 4 are also drawn upon in the development of practice recommendations in the Chapter. The improvement initiative totality is a structurally stratified, consisting of the allergy intervention, improvement process, and context sub-totalities. Moreover,

the improvement strategies developed in Chapter 4 describe a general plan of action or agency at the level of the improvement initiative totality that emerged from the actions at the sub-totalities. At 4D of MELD, an awareness of your improvement strategy and an understanding of the structural conditions in your improvement initiatives (as expressed conceptually the improvement initiatives totality) can be used to plan actions at the sub-totality level to support the implementation of the larger agential vision expressed in the improvement strategy.

As such, 4D of MELD is able to bring together the agential improvement strategies developed in Chapter 4, and the representation of improvement initiatives in a structured totality, as developed in Chapter 5. Improvement strategies can be used to influence the course of the improvement initiatives development. Moreover, the structure of the improvement initiative can influence which actions are possible, which are impossible, and which will most likely achieve the desired consequences. Reflecting on the situation and the potential actions can support the development of improvement initiatives both strategically and tactically at the sub-totality level.

Chapter 7. Discussion

Discussion of the main findings

7.1. Summary of the study findings

This study has been performed to support the improvement of children's allergy services. The study is set in the context of the United Kingdom (UK), where national reviews consistently identified that the health services and care delivered in the NHS were unable to meet the needs of children suffering from allergies. Successive reports demonstrated few improvements in the delivery of children's allergy services, especially in primary care and other non-specialist settings (Department of Health, 2006a; House of Lords, 2007; Royal College of Physicians, 2003, 2010). In response to these findings, the RCPCH published a set of integrated care pathways that describe best-practice care for children who suffer from any of the eight most common allergic conditions (Warner & Lloyd, 2011). These care pathways were developed as tools for healthcare professionals nationally to improve the organisation of their local allergy services and to improve the quality of care provided to allergic children. In 2011, the RCPCH care pathways were implemented locally as part of the Itchy Sneezy Wheezy project. The Itchy Sneezy Wheezy intervention was commissioned as a community-based children's allergy service in a local London area in 2013. In 2014, the service was decommissioned again (Warner & Spitters, 2017). This study evolved in response to these developments in clinical practice. They highlight the issue that even when deficiencies in healthcare quality are recognised, they might not generally get resolved. Moreover, even when health services are changed, these changes might not be sustained. Accordingly, this study aimed to investigate the practice of children's allergy health service improvements to understand how it can be better supported.

Study purpose: To support the improvement of children's allergy services in practice.

This purpose was achieved by designing a study to answer the following research questions.

7.1.1. Achieving quality in children's allergy services

1. *What are the quality deficiencies in children's allergy services?*

The national reviews of children's allergy services have described several quality deficiencies in children's allergy services. In Chapter 1, I explained the causal structure of these quality deficiencies through a broader discussion of childhood allergies and children's allergy care. I discussed how quality deficiencies in children's allergy services can be explained through interdependencies between physiological, environmental, and treatment mechanisms at the physical dimension; clinical mechanisms at the interpersonal dimension; and organisational mechanisms at the structural dimension. More specifically, quality deficiencies will manifest when the treatment, clinical and organisational mechanisms do not effectively address the physiological and subjective experiences of allergic children.

In Chapter 2, I discussed how care pathway interventions could address quality deficiencies in children's allergy care. I demonstrated how the structure of the RCPCH care pathways (Warner & Lloyd, 2011) aligns to the mechanisms of allergic disease. It describes care along multiple stages of allergic disease to support ongoing care to manage the long-term nature of allergies. It comprises multiple documents to support the management of different allergic conditions with internal references to support the management of allergic comorbidities. And it is structured based on allergy competences rather than professional roles, so that the clinical expertise that is available locally can be maximised to support the large number of children suffering from allergies in a health system where allergy expertise is limited. I then discussed that to implement the RCPCH care pathways or to otherwise address the mechanisms that foster high-quality allergy care, a complex intervention is required. More specifically, I discussed the need for allergy interventions to integrate care across allergic comorbidities and to support a seamless experience of care and support over time. The Chronic Care Model (Wagner et al., 1996) discusses five key intervention mechanisms that support the design and delivery of such interventions.

7.1.2. Intervention adaptations

2. How are allergy care pathway interventions adapted during implementation?

In Chapter 2, I discussed how different improvement science disciplines present different views on intervention adaptation. That is, implementation science tends to encourage intervention fidelity, while improvement science encourages process-driven adaptive intervention development. In Chapter 4, I subsequently presented four case study narratives to understand how these different perspectives are reconciled in practice. The case study narratives describe the chronological unfolding of four children's allergy improvement initiatives. All case study teams had explored the Itchy Sneezy Wheezy intervention and considered how it might inform their initiative. In the case study narratives, I describe how teams developed their local allergy services and negotiated intervention decisions that either aligned their efforts with the Itchy Sneezy Wheezy intervention or diverted them to explore adaptations and alternatives. The case study teams managed these negotiations and intervention decisions in different ways. Yet, there seemed to be a general pattern to the way that individual teams approached intervention decisions and improvement more generally.

At the end of Chapter 4, I presented four case-specific improvement strategies that were implicit in the actions, negotiations and decisions of the case study teams during their improvement initiatives. These improvement strategies shaped the negotiations and intervention decisions in each case study initiative. The strategy *'making it work'* motivated team A to implement the Itchy Sneezy Wheezy

intervention with fidelity if possible. The strategy *'cultivating flowers'* motivated team B to adopt the Itchy Sneezy Wheezy intervention as a long-term vision. The strategy *'building on solid ground'* motivated team C to use the Itchy Sneezy Wheezy intervention to strengthen ongoing local developments. The strategy *'finding opportunities and synergies'* motivated team D to evaluate the Itchy Sneezy Wheezy intervention as a potential opportunity to improve children's allergy services alongside other opportunities.

In Chapter 6, I returned to the case study findings to examine how the relationship between intervention fidelity and adaptation manifests in practice. The case study narratives demonstrated how in practice most teams considered implementation of the Itchy Sneezy Wheezy intervention to achieve pre-existing aspirations or to develop ongoing work. Implementation of the Itchy Sneezy Wheezy intervention was seen as a potential means to improve local allergy services. The dialectical relationship between implementation and improvement was defined accordingly, as implementation being contained in improvement. Moreover, within the improvement initiatives, some teams worked to implement the Itchy Sneezy Wheezy intervention with fidelity, while all teams implemented interventions that were different from the Itchy Sneezy Wheezy intervention. As such, the case studies demonstrated how teams engaged in an adaptive process of improvement where the development of interventions sometimes includes the implementation of an intervention with fidelity. The dialectical relationship between fidelity and adaptation was defined accordingly as high-fidelity implementation being part of ongoing adaptive improvement. Consequently, I recommend in Chapter 6 that interventions should be adapted according to the strategies of the improvement initiative as a whole.

7.1.3. Using quality improvement methods

3. *How are quality improvement methods used to support the implementation of allergy care pathway interventions?*

In Chapter 2, I also discussed that improvement science disciplines hold different positions regarding the role of quality improvement methods in improvement initiatives. Implementation science recommends the use of quality improvement methods to facilitate the implementation of interventions, while improvement science encourages the use of quality improvement methods to systematically guide the process of improvement and inform intervention development. To understand how these contradictory positions could be reconciled, I explored how quality improvement methods were used in practice. In the narratives presented in Chapter 4, I described the role of quality improvement methods in the unfolding of the four case study improvement initiatives.

At the end of Chapter 4, I discussed how the use of quality improvement methods in the case study improvement initiatives was shaped by a general improvement strategy. The four case-specific improvement strategies were implicit in the actions, reflections and decisions of the case study teams during their improvement initiatives. The strategy *'making it work'* motivated team A to use QI methods to overcome implementation challenges. The strategy *'cultivating flowers'* motivated team B to develop and apply an increasingly comprehensive QI approach. The strategy *'building on solid ground'* motivated team C to use QI methods as part of a data-informed approach for progressive improvement developments. The strategy *'finding opportunities and synergies'* motivated team D to use QI methods to identify, evaluate and select improvement opportunities.

In Chapter 6, I returned to the case study findings to examine the role of quality improvement methods in practice. The case study narratives demonstrated how some teams used quality improvement methods to guide and inform the development of their improvement initiatives, according to improvement principles. Whereas other teams used quality improvement methods predominantly to control and manage how the improvement initiative developed, according to implementation principles. In Chapter 6, I argued how the relationship between the use of quality improvement methods and intervention adaptations is mediated by the epistemological principles a team operates under. I argued how improvement principles emphasise the systematic use of quality improvement methods. Intervention adaptations are likely to follow from this process, but not necessarily. Contrarily, implementation principles emphasise intervention fidelity with minimal adaptations. Quality improvement methods could be used to support implementation, but not necessarily. In Chapter 6, I visualised these relationships and how they were expressed in the four case study improvement initiatives. These dynamics showed how the contradictions between improvement principles and implementation principles are resolved in practice. Consequently, I recommend in Chapter 6 that teams become aware of the principles that underpin their improvement strategy (improvement vis-à-vis implementation), so they can use quality improvement methods and adapt interventions accordingly.

7.1.4. Integrating improvement experiences

4. How are local children's allergy health service improvement experiences integrated?

In Chapter 5, I presented a theoretical totality of a child allergy improvement initiative, which unifies the local experiences of four diverse improvement initiatives. This totality consists of three interdependent sub-totalities: the child allergy intervention totality, the context totality, and the improvement process totality. Each sub-totality consists of a set of interdependent components that were identified across the four improvement initiatives. Moreover, the child allergy improvement

initiative totality describes the interdependencies between and within sub-totalities. At the end of Chapter 5, I present a visual representation of the children's allergy improvement initiative totality.

In Chapter 6, I discussed how the structure of the totality aligns with many of the theoretical concepts identified in Chapter 2. The structure of the three sub-totalities reflects the health policy triangle, which conceptualised implementation as the interaction between (intervention) content, (improvement) process, and context (Walt & Gilson, 1994). Moreover, the components of the improvement process totality and of the context totality align with the components of the NIHR CLAHRC systematic approach for improvement (Howe et al., 2013) and the Model for Understanding and Success in Quality (MUSIQ) (Reed, Kaplan, et al., 2018a) respectively. However, the child allergy improvement initiative totality adds two important insights. First, it presents a novel structural representation of a complex allergy intervention that aligns with the mechanisms of allergic disease. The depth-open structure of the intervention totality allows it to be elaborated based on the experiences of other improvement teams. Second, the child allergy improvement initiative totality describes its internal interdependencies, its system dynamics, which were described in the case study narratives in Chapter 4 and abstracted in Chapter 5. This creates the opportunity for future research to identify patterns of interactions that might unfold within or across different improvement initiatives. In Chapter 6, I recommend teams to use the dynamic structure of the child allergy intervention totality to reflect on the current position of their improvement initiative and to plan tactical actions that could support them navigate their improvement initiative and implement their improvement strategy.

7.1.5. Practical recommendations

5. *What recommendations can support the local improvement of children's allergy services?*

In Chapter 6, I developed a set of nine practice recommendations based on the analytical interpretation of the empirical study findings. The practice recommendations address the contradictions in the improvement science literature, which were highlighted in Chapter 2. In Chapter 6, I evaluated how these contradictions were situated in the case study findings to understand their dialectical interdependencies. This integrated understanding clarified the recommendations from the improvement science literature by specifying their boundary conditions and by re-interpreting them within the context of the empirical case study data. The recommendations align to the prior four research questions and have been summarised in the previous four sections.

7.2. The use of MELD dialectic

In the previous section, I re-introduced the problem definition and summarised the main findings of this study in response to the research questions. In this section, I will discuss how the stages of MELD facilitated my analysis. In Chapter 3, I discussed that MELD has been developed as a framework to identify, understand and resolve dialectical contradictions (Alderson, 2021; Bhaskar, 2008b; Norrie, 2010). MELD dialectic is materialist and aims to resolve dialectical contradictions in practice. The theoretical work in MELD aims to inform practice by developing an understanding of the causal structure of phenomena, which can subsequently be utilised to inform agency and change. MELD can be understood as an iterative process, where a structural understanding can inform agency in practice, which can reveal new contradictions that spark the development of a revised structural understanding to inform subsequent practice.

7.2.1. 1M of MELD: transforming confusion into contradictions

In Chapter 1 and 2, I discussed how phenomena are understood at 1M of MELD in terms of causal mechanisms that can be present or absent, activated or non-activated, and manifest or not manifested (Archer et al., 1998; Bhaskar, 2010; Hartwig, 2007). Phenomena, as such, can manifest different characteristics depending on which mechanisms are activated and how mechanisms interact. Contextual conditions can influence the activation and manifestation of mechanisms, which explains why phenomena often express differently in different circumstances. This theoretical explanation of difference, as mediated by absence, invites researchers to be curious about seemingly contradictory situations and to explore what underlying structure they might have in common.

This 1M understanding facilitated my reframing of issues that were confusing to me during the early stages of the research as dialectical contradictions. So, rather than backgrounding issues that didn't seem to make sense, I brought them to the fore as questions, propositions and contradictions that needed to be explored in more depth. This reframing started in Chapter 1, when faced with multiple national policy reports that repeatedly demonstrated important quality issues in children's allergy services in the UK that weren't being addressed (Department of Health, 2006a; House of Lords, 2007; Royal College of Physicians, 2003, 2010). The reports highlighted a contradictory (and confusing) situation. In the national allergy reports many quality solutions were *present*, while in practice these solutions were *absent*. When learning about the trajectory of the Itchy Sneezy Wheezy project, I was faced with a similarly confusing and contradictory situation. In 2013, the Itchy Sneezy Wheezy intervention was *present* as a commissioned service, while in 2014, the same intervention was decommissioned and *no longer present*. These situations made me question why potential solutions

to improve children's allergy services might be present in theory, yet not in practice. And even when a potential solution is implemented one moment, it can be discontinued the next moment.

In Chapter 1, I first explored these questions by unpacking the structural underpinnings of quality in children's allergy services as suggested at 1M of MELD. I revisited and extended my literature review to focus on the causal mechanism of allergy in children and their care. This process resulted in some important insights into the nature of allergy in children and its implications for the organisation of care, which misaligned with certain structural elements of the NHS as they had evolved historically. For example, medical specialisation evolved predominantly by organ system. Consequently, system-based specialists are now often presented with allergic children who experience system-based symptoms (e.g. a dermatologist managing a child with allergic eczema). However, they might not have sufficient allergy expertise to manage the allergic underpinnings of the symptoms nor to manage the manifestation of allergy symptoms as comorbidities in other organ systems.

In Chapter 2, I used this structural understanding to unpack why it might be difficult to translate theoretical allergy solutions from reports into clinical practice. I specifically focused on the RCPCH allergy care pathways published in response to the national allergy review reports. The academic literature on care pathways was difficult to make sense of. Evaluation studies demonstrated that care pathways were successful sometimes, other times they were not (Allen et al., 2009; Rotter et al., 2008). Conceptual studies demonstrated that care pathways were different in different situations (De Luc, 2000; Panella & Vanhaecht, 2010). And how a care pathway is understood by one professional can be different from how a care pathway is understood by another professional (Allen, 2009). Moreover, in the context of children's allergy, research on care pathways was mostly absent (Diwakar et al., 2017). The mechanistic perspective at 1M of MELD helped me move forward in a meaningful way. In Chapter 2, I first discussed how the literature-based care pathways mechanisms aligned with the structure of the RCPCH care pathways. I also discussed how the structure of the RCPCH care pathways addresses the allergy mechanisms presented in Chapter 1. The structure of the RCPCH care pathways appropriately accounted for the chronic and multi-morbid nature of allergic disease, and I argued that an intervention to implement the RCPCH care pathways must do also. I subsequently identified the Chronic Care Model, which identified five structural mechanisms that need to be implemented to support chronic and integrated care. This structural framework, together with the mechanistic understanding of allergy from Chapter 1, allowed me to unpack the Itchy Sneezy Wheezy intervention and understand through which mechanisms the interventions was operating. However, a mechanistic understanding of the Itchy Sneezy Wheezy intervention does not help clarify why the intervention was present in 2013 and absent in 2014, nor why it was present in a local London area and absent in other areas.

In Chapter 2, I explored the improvement science literature to investigate why allergy solutions might be implemented in some areas (and not others) at some moments in time (and not others). As a starting point, I explored the implementation of Itchy Sneezy Wheezy intervention (Warner & Spitters, 2017). The Itchy Sneezy Wheezy team had used '*a systematic approach for quality improvement*' to develop and implement an integrated allergy intervention in a local London area. The intervention was subsequently discontinued in that London area. However, '*dissemination*' efforts had been followed-up by teams in other areas, who were now considering '*implementation*'. Accordingly, the study of quality improvement approaches, diffusion of innovations (which includes dissemination) and implementation science seemed relevant to understand the presence vis-à-vis absence of interventions. In Chapter 2, I discussed contributions from each field in understanding the structure of improvement in terms of the intervention content, the improvement/implementation process, and the context. However, this discussion highlighted multiple contradictions in the way that these three constructs were understood across disciplines, which makes it difficult to apply the theoretical insights into practice. Accordingly, to support the improvement of children's allergy services in practice, an effort was needed to integrate the contradictory insights across disciplines. A dialectical process like MELD, designed to resolve contradictions, can facilitate such an effort.

So, 1M of MELD supported me to identify and unpack contradictory situations in the improvement of children's allergy services. At the next stage of MELD it is explored how such theoretical ideas express in the dynamics of reality – how contradictory ideas play-out in practice, and how allergy and improvement mechanisms develop over the course of real-world improvement.

7.2.2. 2E of MELD: finding humility in process

In Chapter 4, I discussed how 2E of MELD emphasises a dynamic understanding of phenomena that explains how they change and develop. This perspective shifts the focus from *being* different at 1M to *becoming* different at 2E. Change, at 2E, is described in terms of '*rhythmics*' of '*being – becoming – non-being*' that unfold over time or space (Bhaskar, 2008b; Norrie, 2010). These rhythmics describe the flow of causal mechanisms interacting and phenomenon manifestations changing accordingly. As such, rhythmics develop over time or space. However, they are also still contextualised within time and space, which explains why phenomena can develop in different ways, depending on their spatio-temporal position. Researchers are encouraged at 2E of MELD to explore how phenomena change and develop and transform in reality. Such a focus on process gives insights into the dynamics of change and it invites researchers to examine how the contradictory situations of 1M of MELD are either created or negated. Moreover, studying change empirically supports the evaluation of theoretical ideas about improvement against practical experiences of improvement in the real world.

The integration of theoretical and empirical insights is performed at 3L of MELD. Instead, 2E of MELD is about observing transformation and change, and noting how dialectical contradictions come and cease to be.

In Chapter 4, I presented four case study narratives that describe how children's allergy services changed and developed in four different sites according to 2E objectives. The 2E understanding of change as rhythmics encouraged me to look beyond the four allergy improvement projects, which all had a specific start and end point. Instead, I described some of the prior experiences of teams and individuals that influenced their approach during the improvement projects. I also described some of the health service developments and ideas that had been established prior and which impacted the improvement projects. Moreover, in two of the four case studies, I was able to follow-up with the teams to understand how their improvement initiatives developed beyond the project phase. These efforts helped me make better sense of the improvement projects, how they evolved from prior developments, how they were part of ongoing improvement efforts, and why they developed differently across case studies.

The geo-historical positioning of the improvement projects within a larger process of health service development facilitated me to make sense of certain contradictions that emerged. The four case study sites were selected based on the criteria that they all considered the implementation of the Itchy Sneezy Wheezy intervention as part of their improvement initiative. However, the interventions that were implemented across all four case studies were very different. Being able to observe how interventions developed over time across the four case studies facilitated me to understand how these differences came about in reality – rather than in theory. It supported an inductive sense-making that seemed more appropriate than an inductive approach based on the principles of improvement science disciplines.

Making sense of this contradiction through the lens of implementation science didn't seem appropriate as most teams didn't feel strongly committed to implementing the Itchy Sneezy Wheezy intervention. Each team did operate based on a more or less explicit vision of an intervention they were aiming to implement though. These visions aligned with the Itchy Sneezy Wheezy intervention in many ways, but were also highly influenced by geo-historical experiences and developments. Moreover, how strongly committed teams were to implementing their vision with fidelity varied across case study sites.

Making sense of the contradiction through the lens of an adaptive methodological quality improvement approach didn't seem appropriate either. Quality improvement methods did play an important role in intervention development. Some teams relied on such methods to inform

intervention developments 'bottom-up', which could have explained why interventions developed differently across different case study sites. However, other teams used quality improvement methods in different ways, for example to manage contextual influences. Moreover, in some teams, contextual influences didn't seem to be something to be managed or navigated, but something to be exploited explicitly to inform the development of the intervention.

As such, the differences between the interventions that were implemented seemed to rely on the way teams approached their intervention vision, the use of quality improvement methods, and their contextual conditions – rather than those elements in themselves. This insight facilitated the inductive development of the four improvement strategies: *'making it work', 'cultivating flowers', 'building on solid ground'* and *'finding opportunities and synergies'*. Each strategy describes a general approach that was used by teams to navigate their improvement initiative and to achieve improved care for children with allergies. The name of the strategies emphasises the dominant strategic principles. For example *'making it work'* foregrounds implementation of an intervention vision, whereby quality improvement methods are used predominantly to manage contextual influences. Alternatively, *'finding opportunities and synergies'* foregrounds alignment with contextual conditions with little commitment to a single intervention vision. The improvement strategies were seen as a useful way to describe the process of the four case study initiatives as a whole. They were able to explain why the interventions developed so differently across case study sites. And they aligned with the theoretical notion that improvement is influenced by intervention content, improvement process, and context as outlined in the health policy triangle (Walt & Gilson, 1994).

7.2.3. 3L of MELD: the beauty of structured wholeness

In Chapter 5, I discussed totalities, which are developed at 3L of MELD to re-define our theoretical understanding of phenomena in a way that explains how contradictory manifestations develop in practice. The development of totalities involves the process of diffraction followed by integration (Bhaskar, 2008b; Norrie, 2010). Phenomena are broken down into multiple components during diffraction. The components are subsequently re-integrated by defining their relationships. Totalities reflect a structural representation of phenomena that is depth-open, just like phenomena are in reality. Having depth means that totalities can be part of bigger totalities, while its components can be broken down into lower-level mechanisms, which reflects how phenomena exist in a stratified world. Being open means that totalities are contextually contingent. Accordingly, they will present in different ways depending on what situation they are explaining. The process of developing totalities supports researchers to develop theoretical descriptions of phenomena that are firmly grounded in empirical reality and that are able to reflect multiple contradictory situations.

In Chapter 5, I present a totality of children's allergy improvement initiatives, consisting of three sub-totalities, which was developed based on the 3L dialectical process. This process facilitated me to engage with the theoretical developments described in Chapter 1 and 2. When developing the child allergy intervention totality, I used the CCM components (Wagner et al., 1996) and my mechanistic understanding of childhood allergies to support the abstraction of intervention components. Moreover, I described in Chapter 6 how the component breakdown in the improvement process totality and in the context totality aligned with publications in the improvement science literature (Howe et al., 2013; Reed, Kaplan, & Ismail, 2018b). A criticism of the improvement science disciplines I discussed in Chapter 2 was its pre-occupation with reducing quality improvement down into intervention components, quality improvement methods, contextual barriers and facilitators, which doesn't reflect the dynamic nature of improvement (Braithwaite et al., 2018; Greenhalgh & Papoutsi, 2018; Moore et al., 2015). However, the 3L analytical process highlights this as an important first step.

The second step of the 3L analytical process facilitated me to make a next step towards the development of a dynamic understanding of improvement. By bringing the components of interventions, improvement processes and initiative contexts together into one child allergy improvement initiative totality, I was able to describe the interactions between components across different sub-totalities. For example, I could describe how components of context were influenced by components of a quality improvement approach. Instead, studying each area separately only allows the investigation of relationships between contextual components or between the various methods in a quality improvement approach. While this understanding is useful, it's not sufficient to understand how improvement initiatives develop. This notion had been grasped in the second iteration of the MUSIQ, which included a two-way causal connection between context and the use of quality improvement approaches (Reed, Kaplan, et al., 2018b). In Chapter 5, I explored what types of relationships between components of the child allergy improvement initiative totality existed in reality. This exercise demonstrated two-way relationships between all three sub-totalities and within each sub-totality. Moreover, it demonstrated that the child allergy improvement initiative totality was able to represent the unique causal development of different case study improvement initiatives.

7.2.4. 4D of MELD: something to work with

In Chapter 4, I discussed how the materialist nature of MELD dialectic is realised at 4D of MELD through action. The structural understanding of phenomena that is developed at 3L of MELD is utilised at 4D of MELD to change real-world situations through action. Accordingly, I discussed the

relationship between structure and agency as it is understood in critical realism. Structure influences and constrains agency, while agency can influence and change structure (Archer et al., 1998; Bhaskar, 2010; Porpora, 2015). The relationship between structure and agency is mediated by reflexivity. Reflexivity allows people to reflect on the situation they find themselves in and decide which actions could be taken within that situation to achieve the things that matter to them (Archer, 2003). Accordingly, researchers are encouraged at 4D of MELD to reflect on the understanding developed through the previous stages of MELD, and to generate recommendations and insights that could be used in practice to resolve dialectical contradictions and achieve positive change.

The emphasis on agency encouraged me to focus the interpretation of my findings, so that they addressed the research questions in a practical way. I explored how the theoretical contradictions, summarised in the Proposition and Contradiction statements in Chapter 1 and 2, were resolved in practice in the empirical case studies. The care pathway literature, for example, presented contradictory insights that obscured the way in which care pathway implementation could support the improvement of children's allergy services. In practice, however, it was clear how different types of care pathways were implemented as part of a larger allergy intervention. This relationship between the different care pathways and the intervention as a whole, was clearly structured in the child allergy intervention totality presented in Chapter 5. In Chapter 6, I brought these insights together to support healthcare professionals who might need clarification when their team decides to 'implement a care pathway', just like I needed clarification when the care pathway I developed wasn't the 'right one'.

In Chapter 2, I also discussed several contradictory insights across improvement science disciplines, especially around the adaptation of interventions and the use of quality improvement methods. However, as discussed in Chapter 4, teams seemed to adapt interventions and use quality improvement methods in specific ways based on their general improvement strategy. In Chapter 6, I analysed in which way these strategies were based on implementation or improvement principles. This analysis demonstrated that in practice, some teams operate predominantly on implementation principles, some on improvement principles, and some on both. Consequently, supporting healthcare professionals to develop an awareness of the underlying principles of their improvement strategy will help them foreground the most relevant academic insights to implement and adhere to.

In Chapter 6, I discussed how healthcare professionals could use the child allergy improvement initiative totality. One the one hand, the totality allows for a compact structural description of the unfolding of causal events in the real world. This characteristic could be utilised to summarise and share learning across different improvement initiatives. Moreover, the structural representation of

child allergy improvement initiatives can support healthcare professionals to reflect on their current circumstances and envision what the consequences of different actions might be. It also supports teams to reflect on the patterns of interactions they observe in their improvement initiative, which can help them identify what improvement strategies they are implicitly implementing. When teams are aware of their improvement strategies, the child allergy improvement initiative totality can be used more specifically to implement the strategy, by planning tactics based on the mental simulations of the causal consequences specific actions might have within the initiative.

As such, the interpretation of the research findings presented in Chapter 6 supports healthcare professionals reflect on their improvement initiative and plan action accordingly.

7.3. Research contributions

The main purpose of this study was to support the improvement of children's allergy services in practice. To achieve this purpose, I positioned myself at the intersection of clinical allergy, improvement science and critical realism. This interdisciplinary study makes three key research contributions.

7.3.1. Clinical allergy: theoretical insights to support the improvement of allergy services

This study makes a first contribution to the clinical allergy literature by developing a totality of integrated child allergy interventions. The Department of health recommended the development and implementation of allergy care pathways when national reviews of children's allergy services demonstrated important quality issues (Department of Health, 2006a). This resulted in the development of the RCPCH care pathways, which were implemented as a pilot project in a local London area (Warner & Lloyd, 2011; Warner & Spitters, 2017). However, there were very few published articles on allergy care pathways that healthcare professionals could use to support local implementation. One literature review found only three prospective studies published on integrated allergy care pathways (Diwakar et al., 2017). This study addresses this gap by integrating the allergy interventions implemented across four case study improvement initiatives into a single intervention totality that is presented in Chapter 5.

The child allergy intervention totality describes 26 intervention components that have been implemented across the four case study sites. A description of allergy intervention components has not yet been presented in the clinical allergy literature and could support operationalisation of the RCPCH care pathways (Warner & Lloyd, 2011) The 26 intervention components are clustered under the five components of the CCM (Wagner et al., 1996). This study demonstrates how the CCM can be applied within the context of clinical allergy. Moreover, Chapter 6 demonstrated how the allergy

intervention totality makes sense of the care pathway literature by describing the way that different types of care pathways can be implemented as part of an integrated child allergy intervention. The structure of the intervention totality allows for additional components and interdependencies to be integrated, and it also accounts for contextual contingencies in practice. In Chapter 4, I presented four case study narratives that can be used to contextualise the child allergy intervention totality in an effort to support implementation into local practice. Finally, the mechanistic overview of children's allergy presented in Chapter 1, supports theoretically grounded reflexivity for teams needing to make intervention decisions.

The second contribution this study makes to clinical allergy sits at the intersection with its contribution to improvement science. More specifically, within clinical allergy knowledge is also needed to understand how the integrated allergy intervention can be implemented and adapted as part of an ongoing process of children's allergy health service improvement and development. However, the contributions this study has made to the implementation and improvement literature is discussed in the next section.

7.3.2. Improvement science: introducing dynamics

Three distinct contributions are made to the improvement science literature. This study makes its first contribution to improvement science by integrating dynamics into the theoretical explanation of improvement. In Chapter 2, I discussed how implementation and improvement studies struggled to explain why interventions and quality improvement methods were sometimes implemented with great success, and sometimes they weren't (Walshe & Freeman, 2002). Rather than evaluating if they had been successful, it was necessary to understand why they were. This led to a series of studies exploring the factors to success – what were the intervention components, the quality improvement methods, and the contextual barriers and facilitators associated to improvement? Numerous frameworks were developed that described and summarised such components (Nilsen, 2015). However, the relationships between components were often not defined with the consequence that explanatory power was lacking. A call was made to investigate the dynamic nature of improvement, which this study contributes to (Braithwaite et al., 2018; Greenhalgh & Papoutsi, 2018; Moore et al., 2015).

More specifically, the child allergy improvement initiative totality presented in Chapter 5, captures the interactions across intervention, improvement and contextual components, needed to describe the dynamic nature of improvement. In Chapter 2, I presented the health policy triangle that explains implementation as interactions between intervention content, process and context (Walt & Gilson, 1994). Moreover, I presented the CCM which describes intervention components (Wagner et al.,

1996); quality improvement approaches which describe improvement methods (Chiarini, 2011; Hellsten & Klefsjö, 2000; Howe et al., 2013); and the MUSIQ which describes contextual factors. The improvement initiative totality, reflects the integration of these models into a hierarchical structure. This integrated structure allowed me to model some of the improvement dynamics that were observed within each of the case study initiatives. The longitudinal case studies afforded observation of the causal unfolding of the improvement initiatives over time. Consequently, several causal chains were taken from the observations as examples to demonstrate the dynamics in the improvement initiative totality. The dynamical structure of the improvement initiative totality opens up an opportunity for future research to explore improvement dynamics in more depth.

7.3.3. Improvement science: introducing agency

The second contribution this study makes to improvement science is the development of *'improvement strategies'* as a theoretical notion that explains why improvement initiatives develop differently in different settings. The case study narratives demonstrated how teams seemed to rely on a general approach to navigate their improvement initiative. Improvement initiatives didn't seem to develop solely from the interactions between intervention components, improvement methods and contextual influences. Instead, the four case study initiatives seemed to develop differently, because they approached these components differently. Based on the case study narratives, I abstracted four strategies to describe how team approached their improvement initiative. *'Making it work'* represented a strategic emphasis on intervention implementation, whereby quality improvement methods were used predominantly to manage contextual influences. *'Cultivating flowers'* represented a strategic emphasis on progressive development, whereby interventions and quality improvement practices and infrastructures developed progressively in scale and rigour over time. *'Building on solid ground'* represented a strategic emphasis on process-informed intervention development, whereby the learning from project informed the development of the next and so on. *'Finding opportunities and synergies'* represented a strategic emphasis on the development of interventions in alignment with contextual opportunities.

The improvement strategies introduce agency in an academic field that focuses predominantly on structural issues. They describe a general plan of action to achieve improvements in the way children's allergy services are delivered. The improvement strategies operate at the level of the improvement initiative, but they are realised through team engagement with their intervention, the improvement process and their context. This awareness together with the structural representation of allergy improvement initiative totality supports agency. That is, it gives people the opportunity to reflect on their strategy and decide whether it needs changing. Moreover, the improvement initiative

totality helps teams to reflect on the conditions of their improvement initiative and plan tactical moves that could support the implementation of their strategy accordingly.

7.3.4. Improvement science: defining disciplinary boundaries in practice

This study makes its third contribution to improvement science by resolving the dialectical contradictions between improvement and implementation science in practice. In Chapter 2, I reviewed three improvement science disciplines: the diffusion of innovations, implementation science, and the study of quality improvement approaches. The review demonstrated that the disciplines presented several contradictory perspectives, which makes it difficult for healthcare professionals to engage in theoretically-informed healthcare improvement.

The two main contradictions that were identified involved the adaptation of interventions and the use of quality improvement methods. Implementation science encourages teams to avoid intervention adaptations in support of high-fidelity implementation, in contrast to improvement science where teams are encouraged to develop interventions adaptively in response to the quality improvement approach being used. As such, improvement science encourages teams to use quality improvement methods to design and develop interventions based on analytical insights, in contrast to implementation science where teams are encouraged to use quality improvement methods to manage contextual conditions in support of high-fidelity implementation. These contradictions create uncertainty around the way interventions should be adapted and the way quality improvement methods should be used in practice.

In Chapter 6, I analysed how the four case study teams adapted interventions and used quality improvement methods in practice. The schematic representation of the analysis (presented in Figure 31) demonstrates the relationships between intervention adaptations and the use of quality improvement methods within each of the four case study initiatives. These relationships demonstrate that certain teams operate predominantly based on implementation principles, some teams operate predominantly based on improvement principles, while others operate based on a hybrid of implementation and improvement principles. Moreover, the analysis demonstrates a situation where teams operate against improvement and implementation science principles.

This representation of the relationships between implementation science principles, improvement science principles and practice demonstrates the boundaries of the disciplinary principles in practice. For example, when teams operating based on implementation principles are forced to adapt their intervention, they should use a systematic quality improvement approach to inform the adaptations if they want to avoid pseudo-scientific practice. Demonstrating the boundaries of implementation

and improvement science principles schematically, as such, supports teams to develop an awareness of their underlying principles and act accordingly if possible. Moreover, it supports improvement science research to understand where each discipline might add valuable insights and where their insights might be limited. In Chapter 6, I also argued the dialectical relationship between implementation and improvement science, as implementation being part of improvement. Accordingly, it makes sense to operate based on improvement principles generally. However, there might be specific interventions where it's very important for patient safety or clinical outcomes that they are implemented with high-fidelity. In such situations it makes sense to draw on implementation science insights specifically.

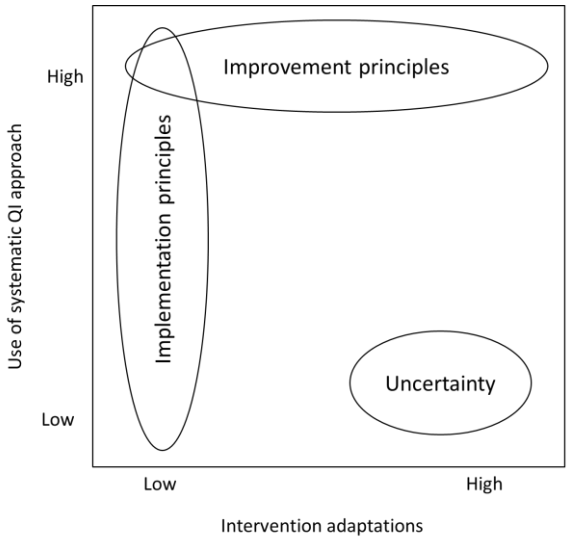


Figure 31. Dialectical relationship between improvement and implementation principles.

7.4. Limitations and future research

This study developed a theoretical understanding of children's allergy improvement initiatives based on four ethnographic case studies. This was achieved by using MELD dialectic to develop a children's allergy improvement initiative totality. This totality represents intervention, improvement and context components that influence children's allergy improvement initiatives. The contextual factors aligned with the MUSIQ, which is a well-grounded model based on a systematic literature review and qualitative analysis (Kaplan et al., 2012; Reed, Kaplan, et al., 2018a). Moreover, MUSIQ has made an initial attempt to identify interdependencies between contextual components. The improvement components were abstracted from the NIHR CLAHRC NWL systematic approach, which had been developed for local use (Howe et al., 2013). As such, these components were not intended to be expanded as a means to represent different QI approaches. In this study, the components were found to be reflective of two additional QI approaches. However, the validity of these components of the improvement process totality needs to be assessed in future research. The child allergy

intervention sub-totality was developed based on four case studies. However, the improvement initiatives demonstrated significant variation in the type of intervention components they implemented. Accordingly, additional case studies should be conducted to extend as well as validate the intervention components identified so far.

In this study, I reviewed the literature on the diffusion of innovations, implementation science and the study of quality improvement methods. These disciplines focus on the study of overlapping phenomena that were all relevant to the case that was studied. However, as separate disciplines with different focal points, the inter-disciplinary insights were often found to be incongruent. However, this is not to say that one discipline is right and another wrong. As discussed in Chapter 2, each disciplines has made valuable contributions both in practice and research. Instead, I discussed how different disciplines are grounded in different epistemologies, they use somewhat different vocabularies, and they emphasise different scientific methodologies. As such, they present a different perspective. Philosophy as a science can facilitate disciplinary integration by exploring how different epistemological perspectives are grounded in ontology. Accordingly, MELD dialectic describes how contradictory theories can be understood by grounding them in empirical reality. The philosophical grounding that persists in this thesis created the opportunity to study the intersection across disciplines, supporting their integration within the wider improvement science field. However, this research effort takes away from other theoretical developments that could have been made within a single discipline.

The dynamic structure of the improvement initiative totality that was developed also creates an opportunity to be used as a model for research in system dynamics. In this thesis, I demonstrated how the totality was able to describe causal chains that were abstracted from the case study narratives. Accordingly, future research might collect multiple improvement narratives, break them down into causal chains, and translate them in terms of causal component relationships in the improvement initiative totality. Such a data set of system interdependencies as they have evolved across many case study narratives could be used to mode system dynamics to get a deeper understanding of improvement patterns. For example, it could be investigated whether the improvement strategies presented in this thesis indeed express as independent system dynamical patterns.

Moreover, the case studies that were conducted in this research were ethnographic. For the purpose of this study, this was the most appropriate method, as it required longitudinal, empirically-grounded observations of the actions, thoughts and developments that explain how improvement initiatives unfold over time. However, this meant that there were no scientific intervention evaluations

conducted. Instead, local evaluations and analyses were performed, often to make the case for (ongoing) investment or as part of governance and reporting requirements. However, many initiatives and their evaluations were ongoing when I left the field. Accordingly, it is not certain whether the intervention components that have been implemented actually achieved patient benefits. As such, future research could focus on the evaluation of the individual and collective effects of intervention components on patient outcomes. Moreover, studies could extend quantitative research designs to evaluate which improvement initiatives develop better patient outcomes, initiatives who apply implementation principles, who apply improvement principles, or who apply hybrid principles.

Finally, this study aimed to support the improvement of children's allergy services in local practice. As such, it has developed a children's allergy improvement initiative totality, local case examples, and a set of specific recommendations for practice. However, it is yet unclear whether these efforts are helpful to improvement teams nor whether they are effective. Accordingly, to finalise MELD, this work needs to be proactively taken to healthcare professionals and integrated into local improvement initiatives. However, this was beyond the scope of this research.

7.5. Conclusion

In conclusion, this study was able to develop novel practice recommendations to support the improvement of children's allergy services in local practice. These recommendations developed from the MELD dialectical process that was applied in this study. As discussed, the four stages of MELD were specifically developed to inform actions in the real world (Bhaskar, 2008b).

Accordingly, at 1M, I developed an understanding of the causal mechanisms that explain the quality deficiencies in children's allergy services that have been identified in successive national reviews of allergy services in the UK. Moreover, I developed an understanding of the causal mechanisms that explain improvement initiatives based on the improvement science literature. However, due to its interdisciplinary nature, the improvement science literature was full on contradictory insights. As such, it makes sense that healthcare professionals might struggle to implement the advice of improvement scientists.

Consequently, at 2E, I observed the causal unfolding of four children's allergy improvement initiatives in clinical practice. In this Chapter, I described how observation of the causal unfolding of improvement initiatives in the real world supported the resolution of some of these theoretical contradictions. Across the case study initiatives, I also identified four improvement strategies that described the general approach taken by teams to navigate their improvement initiative.

At 3L, the case studies allowed me to elaborate the theoretical understanding of improvement initiatives. That is, I was able to integrate the practical experiences of four improvement initiatives into a theoretical totality of a children's allergy improvement initiative. This totality unifies the diverse improvement experiences. However, its structure represents the dynamical and depth-open nature of improvement initiatives in reality. As such, the totality holds a richness that was lacking from previous theoretical explanations of healthcare improvement initiatives.

Finally, at 4D, the resolution of dialectical contradictions and the novel theoretical developments were translated into nine practical recommendation to support the improvement of children's allergy services in local practice. The theoretical and practical insights developed in this study at the four stages of MELD dialectic are aimed to support healthcare professionals develop an awareness and understanding on the clinical and improvement context they are operating in and to reflect on what actions could best support them to improve children's allergy services under these conditions.

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Appendix A. The burden of allergic disease

Allergies form a significant physical, social and emotional burden for sufferers and caregivers. The patient impact of some of the main allergic conditions (eczema, rhinitis and asthma), as well as the economic impact of allergic disease, are explored in more detail below.

Eczema – Eczema is known to not only physically effect children, but also have a significant emotional and social adverse effects on children and their families (Carroll, Balkrishnan, Feldman, Fleischer, & Manuel, 2005; Chamlin, 2006; S. Lewis-Jones, 2006). Physically, eczema involves inflammation of the skin that leads to a variety of symptoms, such as dry and itchy skin, redness of the skin, skin swelling, and skin lesions, which can be painful, sore and bleeding easily when scratched (M. S. Lewis-Jones & Finlay, 1995). Emotionally, as the disease is often very visible, children regularly mention feeling embarrassed and upset. This influenced their engagement with certain activities, such as swimming or physical activity in school (M. S. Lewis-Jones & Finlay, 1995). The physical appearance can also affect how children with eczema are treated by others. Unaffected school-age children make derogatory comments on the eczema and bullying also occurs (M. S. Lewis-Jones & Finlay, 1995). Parents of pre-school children with eczema have mentioned other adults and children avoid their child (Chamlin, Frieden, Williams, & Chren, 2004). This significant impact, which is dependent on disease severity, is reflected in a study that compared quality of life of children suffering from a number of conditions. They found that quality of life of children with generalised eczema (eczema affecting the whole body) was found to be lower than for children with diabetes and even asthma (Beattie & Lewis-Jones, 2006).

One of the major problems related to eczema is itching and subsequent scratching. This can first of all cause sleep disturbances. In their case control study, Stores, Burrows, & Crawford (1998) found that school-age children with eczema woke up more often during the night than healthy children. They also found that the time awake after children with eczema had fallen asleep highly correlated with their time spent scratching. Eczema related sleep disturbances occur often. A survey of 300 parents of children with eczema (age 0-6) showed that in 68% of children their sleep was affected by their eczema. On top of that, the child's eczema affected parents' sleep in 61% of respondents (Chamlin et al., 2005). Secondly, itching and scratching can affect children's emotional wellbeing. Parents of children with eczema often report crying as well as showing irritability, restlessness and frustration when talking about the child's behaviour (Chamlin et al., 2004). Additionally, in a case control study, Daud, Garralda, & David (1993) found that preschool children with severe eczema showed more clingy and fearful behaviours than healthy children when put in an unfamiliar situation.

For parents, the condition also has a significant emotional burden, including feelings of guilt, worry, exhaustion, helplessness, embarrassment and resentment (Chamlin et al., 2004; Lawson, Lewis-Jones, Finlay, Reid, & Owens, 1998).

Eczema treatment also contributes significantly to the disease burden. Eczema treatment always requires topical steroids and large amounts of emollients preferably applied after bath time (National Institute for Health and Care Excellence (NICE), 2007). However, children with eczema often experience stinging when showering and the application of creams is time consuming (M. S. Lewis-Jones & Finlay, 1995). Even when the skin is clear, emollient use is recommended to maintain the condition of the skin and prevent flare ups. This time commitment is also problematic for parents. On top of applying creams on younger children or helping older children with bandaging when necessary, they often also need to do extra cleaning and washing of clothes and bed-linen (Lawson et al., 1998). This also adds to the financial cost related to eczema. So, in addition to the direct costs of medical consultations and medications, we need to not underestimate the extra so-called in-direct costs for families that include extra household costs and the significant time investment of parents and children (Su, Kemp, Varigos, & Nolan, 1997).

Rhino-conjunctivitis – Rhino-conjunctivitis is often considered to be a mere inconvenience, not recognising how seriousness the disease really is. Some of the most frequent and bothersome rhino-conjunctivitis symptoms include: nasal congestion, rhinorrhoea (runny nose), frequent sneezing, headache, red and itchy eyes, itchy nose, watery eyes, post-nasal drop, cough and interrupted sleep (Canonica, Bousquet, Mullol, Scadding, & Virchow, 2007; Meltzer et al., 2009). The burden of these symptoms can be more easily comprehended when taking into account that about 50% of rhinitis patients experience symptoms over 4 months per year, and 20% of patients experience symptoms over 9 months per year (Schoenwetter, Dupclay, Appajosyula, Botteman, & Pashos, 2004).

The impact rhino-conjunctivitis has on people's lives can be demonstrated in several ways. (Meltzer et al., 2009) found for example that parents of children with allergic rhinitis reported significantly lower general health for their children and fewer positive emotions (e.g. 'being full of energy' and 'being calm and peaceful'), compared to the parents of non-allergic children. In addition, parents reported their child's allergic rhinitis impacted on daily activities, such as sports or outdoor activities, as well as on school performance. The impact of rhinitis on school performance has also been demonstrated in a case-control study (Walker et al., 2007). This study showed that 15-17 year olds who experienced rhinitis symptoms on the day of their final exam, were 40% more likely to drop a grade from their practice to their final exam, compared to their non-symptomatic peers. When symptomatic students were also taking sedative antihistamines, the increased likelihood of dropping

a grade increased even further to 70%. Rhinitis-related sleep disturbances contribute to reduced performance and productivity. In fact, roughly 50% of people diagnosed with rhinitis experience sleep disturbances, such as difficulty falling asleep or waking up in the night, that cause tiredness during day-time (Canonica et al., 2007; Meltzer et al., 2009). The extent to which rhinitis impacts health-related quality of life depends on disease severity and frequency of symptoms (Canonica et al., 2007).

The varying severity and frequency of rhino-conjunctivitis symptoms might explain the patterns of healthcare use linked to the disease. Studies have shown that many people suffering from rhinitis don't access healthcare. For example, Bauchau & Durham (2004) found that 45% of people who were clinically diagnosed in their study as having rhinitis, did not report ever being diagnosed by a physician prior to the study. And among those who were previously diagnosed, 21% of people who would benefit from medication had not used any. On the other hand, in a survey regarding children diagnosed with allergic rhinitis, 62% of parents reported their child was seen by a healthcare professional in the past 12 months, and 17% of parents even reported 5 or more healthcare visits in the last year (Meltzer et al., 2009). This survey also highlighted the high reliance on over-the-counter (OTC) medications, with 54% of parents reporting they used OTC medications, and 25% reporting they only use OTC medications. Inappropriate use of sedating anti-histamines rather than the more modern and safer alternatives is a frequent problem encountered when patients are eventually reviewed in a specialist service.

Asthma – Asthma is linked to debilitating symptoms that can be difficult to manage. Asthma is a lung condition that is linked to symptoms like difficulty breathing, wheezing, feelings of a tight or painful chest and coughing (Gabe, Bury, & Ramsay, 2002; Liu et al., 2007; Rudell et al., 2012). When asthma symptoms suddenly worsen, this is called an exacerbation or an asthma attack. If asthma is treated appropriately, asthma can be become well controlled so that symptoms (including asthma attacks) become minimal or absent (Cockcroft & Swystun, 1996). Unfortunately, a lot of people experience poorly controlled asthma. A large scale primary care survey of 2429 American asthmatic children between 4 and 17 years old, demonstrated that 46% of these children had uncontrolled asthma (Liu et al., 2010). They used the Childhood Asthma Control Test (C-ACT) (Liu et al., 2007) to measure asthma control. These findings are highly likely to be generalisable to Europe, since Rabe et al. (2004) found very similar patterns of asthma symptoms in the United States (US) compared to Western Europe.

Asthma, especially when uncontrolled (Dean et al., 2010; Guilbert et al., 2011), has a significant impact on patients' lives. First of all, asthma can restrict children from participating in certain activities, mainly activities requiring physical exertion (Gabe et al., 2002; Rhee, Wenzel, & Steeves, 2007). This can go hand in hand with bullying, loneliness and feelings of frustration or embarrassment for not being able to keep up with peers. Embarrassment has also been used to describe the feelings related to using inhalers in schools (Rhee et al., 2007). However, there have been indications that the increased prevalence of asthma has decreased some of the stigma around asthma in schools (Gabe et al., 2002). Secondly, asthma often impacts sleep, which can contribute to daytime sleepiness, missed school days and school performance (Desager, Nelen, Weyler, & De Backer, 2005; Diette et al., 2000). It has been estimated that between 30% and 40% of children with asthma wake up during the night due to their asthma, with a greater risk of waking up when asthma is more severe (Desager et al., 2005; Diette et al., 2000; Strunk, Sternberg, Bacharier, & Szefler, 2002). Finally, asthma attacks can be very stressful. Children suffering from asthma are often anxious about having an asthma attack and when they do, this can cause panic or fear or dying (Gabe et al., 2002), which is indeed a real threat (Levy et al., 2014). These feelings are often shared by parents (Jonsson, Egmar, Hallner, & Kull, 2014).

The seriousness of asthma symptoms can lead to emergency healthcare visits and can even cause death. In the before mentioned survey by Liu et al. (2010), 17% of asthmatic children reported visiting the emergency department or urgent care centre in the last 12 months due to their asthma, and 4% had been admitted to hospital. When investigating the several causes for Emergency Department (ED) attendance amongst children, asthma was found to be amongst the top ones (Blair et al., 2017; Sands et al., 2012). In addition, looking across data from both paediatric and adult populations between 2011 to 2012 in the UK, there were an estimated 96.000 admissions to hospital due to asthma and regrettably 1160 people died due to their asthma (Mukherjee et al., 2016). A national review has been performed to investigate asthma deaths that happened in the UK between February 2012 and January 2013 (Levy et al., 2014). It highlighted, amongst other things, that of the 195 people who died from asthma in that period, only 43% of people were managed by hospital specialists, 47% had been admitted to hospital before, with 21% of people having accessed emergency care in the year prior to their death. Moreover, it was assessed that 46% of asthma deaths might have been avoided if evidence-based clinical practice guidelines had been properly implemented.

Economic impact – In addition to the burden of allergic disease on children's wellbeing is a significant economic burden. Based on data from 1991/1992, the direct costs of allergies for the NHS were estimated to exceed £1 billion a year (Gupta et al., 2004). This included £0.7 billion of GP

prescriptions, which takes up 10% of the total GP prescribing. Other factors taken into account were physician consultations and hospital admissions. Based on data from 2011/2012 the direct NHS costs for asthma alone approached £1 billion (Mukherjee et al., 2016) and reached £1.1 billion when including disability living allowance. It should be noted that these estimates do not include over-the-counter (OTC) medications, housekeeping costs and indirect costs, such as missed school/work days, decreased productivity, disability and mortality. Moreover, while hospital admissions have stabilised since the 1990s for asthma and eczema, they are still increasing significantly for anaphylaxis and food allergy (Gupta et al., 2004, 2007).

The multi-level experience of allergies – So, the experience or the burden of allergy for children is understood as multifactorial. More specifically, the multiplicity of mechanisms linked to the wellbeing of an allergic child can be said to exist on several levels of reality (Bhaskar & Danermark, 2006). Firstly, there are **physiological mechanisms** within the child that cause allergic reactions and the associated physical symptoms. Secondly, allergies are caused by allergens in our **physical environment** that interact with a child's physiology. Consequently, children and their caregivers will have to manage how they move around in their physical environment to avoid or minimise exposure to allergens to a degree that is attainable and acceptable for their health and wellbeing. Thirdly, allergies interact with children's **psychology and emotional state**. Allergy-induced sleep disturbances can cause low mood and irritability for example. And experiences of (life threatening) asthma attacks or anaphylaxis can cause fear and anxiety, which might limit how freely children move around in their physical and social environments. Accordingly, allergies interact with children's **social environment**. Allergies might make it uncomfortable or dangerous for children to partake in particular social activities that might exacerbate their symptoms or expose them to allergens. Alternatively, being excluded from social activities, allergy-related stigma, and potential bullying might influence a child's psychology. Finally, allergies also interfere in a child's **socio-economic environment**. For example, I discussed how allergies can impact school performance, or how families might have to pay for medications or household adjustments to support the child manage their allergies. However, some families might not have the resources or the knowledge to do so. As such, the experience and wellbeing of allergic children are impacted by many different factors that exist on different planes in their worlds (Bhaskar & Danermark, 2006). Consequently, a 'medicalised' approach to care that focuses solely on the physiological allergy mechanisms is necessary, but insufficient to explain the holistic experiences, considerations and behaviours of children living with allergies. Instead, there are many other factors involved that together create an individual experience for each allergic child, depending on where they live, whether they have supportive peers and families, school policies, family resources, etc.

Appendix B. Evidence on care pathway effectiveness

Evidence suggests that care pathway interventions have positive effects on the whole. One systematic literature review was specifically interested in evaluating the overall effects of care pathway interventions (Rotter et al., 2010). The review included 27 studies with a total of 11.398 participants, and evaluated care pathway effects on several different outcome. For each outcome the authors performed a meta-analysis to develop a more precise estimate of the outcome value based on the pooled data from studies that were comparable enough to combine. The results indicated that care pathways were associated with a statistically significant reduction in in-hospital complications and better documentation of care. A reduced length of stay (LOS) in hospital and a reduction in hospital costs were also reported in many of the studies, but results could not be pooled for these outcomes due to large variation between the studies. Finally, there was no evidence for an improved hospital readmission rate or for improved in-hospital mortality (Rotter et al., 2010). Limiting some of the variation between care pathway interventions, systematic reviews have also been conducted that focus on specific clinical conditions. These include reviews on the effectiveness of care pathways interventions for stroke care (Allen & Rixson, 2008; Kwan & Sandercock, 2004), hip fractures (Leigheb et al., 2012), surgery (Ronellenfitsch et al., 2008), end-of-life care (Phillips et al., 2011), and asthma (Banasiak & Meadows-Oliver, 2004; Chen et al., 2014). However, most reviews lacked sufficient comparable studies to perform meta-analyses as a consequence of their bounded study focus. So instead, they used a narrative or integrative review methodology. The E-P-A identified four key outcomes of care pathway interventions: health outcomes, patient safety, patient satisfaction and use of resources (Vanhaecht et al., 2007). In light of these outcomes, the above literature reviews can be summarised as follows. Care pathways tend to positively impact on the use of resources (e.g. LOS) and patient safety (e.g. complications); information is lacking on the impact of care pathways on patient satisfaction; and studies generally failed to demonstrate a positive impact on functional patient outcomes (e.g. independence after stroke or mobility after hip surgery).

To better understand these outcome effects, the relationship between care pathway interventions and mediating factors has also been investigated. The E-P-A care pathway definition identified mutual decision-making and organisation of care as two key mediating factors (Baron & Kenny, 1986) that explain how care pathways affect the outcomes discussed in the previous paragraph (Vanhaecht et al., 2007). This hypothesised relationship between care pathway interventions and outcomes, mediated by mutual decision-making and organisation of care, is represented schematically in Figure 32. Evidence supports the hypothesis that mutual decision-making and organisation of care influence outcomes. For example, inter-professional team work has been demonstrated to affect patients

safety (Manser, 2009), and healthcare organisation has been demonstrated to affect LOS (L. C. Price et al., 2006). Moreover, studies have also been performed that indicate that care pathway interventions influence these mediating factors.

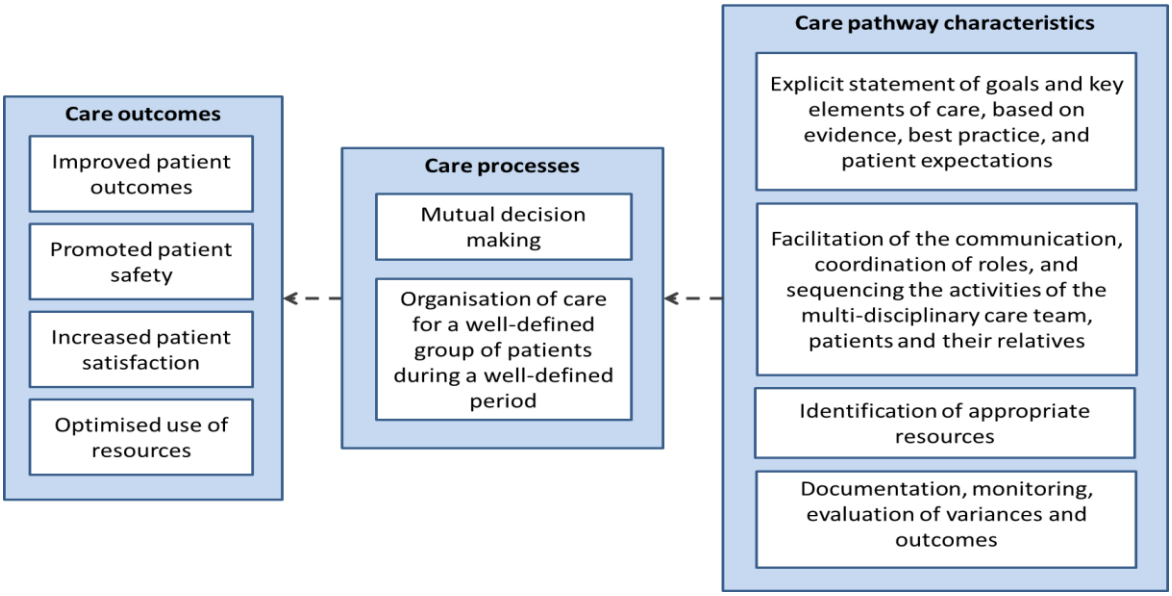

Figure 32. Schematic representation of the Vanhaecht et al. (2007) E-P-A care pathway definition

Accordingly, a literature review found evidence that care pathways positively impact mutual decision making – or more specifically team work. The review assessed 26 studies that evaluated the relationship between care pathways and teamwork either quantitatively or qualitatively (Deneckere et al., 2012). The assessment resulted in team work 20 indicators being identified, which were classified under three categories: team inputs, team processes and team outputs. When subsequently reviewing the relationships between care pathway interventions and these team work indicators, the authors concluded that care pathways positively influenced 17 of the 20 indicators. It should be noted however, that based on the application of a modified version of the Polit & Beck (2004) four-level evidence hierarchy, the authors concluded that the evidence was lacking in strength (Deneckere et al., 2012).

There is also evidence supporting the relationship between care pathway interventions and the organisation of care. A systematic literature review on the use of care pathways for patients with hip fractures identified for example that care pathways positively impact on a number of process measures that suggest improved organisation of care (Leigheb et al., 2012). One study that compared prospective data from 151 patients admitted after care pathway implementation with retrospective data of 143 patients, showed for example that significantly more patients in the care pathway group were operated within 24 hours after hospital admission *($p = .048$)* (Gholve et al., 2005). Another study in the review, comparing data from 90 patients admitted six months before care pathway

implementation to data from 88 patients admitted afterwards, showed that patients in the care pathway group were seen more quickly by the geriatric medical unit for assessment *($M_{difference}$ = 1.3 days; p < .0001)*, and the time between geriatric assessment and discharge was also shorter for patients in the care pathway group *($M_{difference}$ = 6.6 days; p = .018)* (Tallis & Balla, 1995). Vanhaecht, De Witte, Panella, & Sermeus (2009) took a different approach demonstrating a positive impact of care pathways on care organisation. They developed the Care Process Self Evaluation Tool (CPSET), a 29-item scale (scored 1 to 10) organised in five sub-scales: patient-focused organisation, coordination of the care process, communication with patients and families, collaboration with primary care, and care process follow-up (Vanhaecht, De Witte, et al., 2007). After validation of the CPSET, they administered the tool in 49 Belgian and Dutch hospitals (38 patient groups in 16 clinical areas) to analyse the organisation of 103 care processes (approximately half of them supported by a care pathway) (Vanhaecht et al., 2009). Based on CPSET scores, Vanhaecht et al. (2009) classified all studied care processes as either well-organised or weakly-organised. Of the well-organised care processes, 77% was supported by a care pathway. Whereas of the weakly-organised care processes only 44% was supported by a care pathway. Note that this also demonstrates that care processes can be well-organised without care pathways and that not all care pathways lead to well-organised care. However, on the whole, the authors found that the probability of a care process being well organised was 4.3 times higher when the care process was supported by a care pathway *(OR: 4.26; 95% CI: 1.40 to 13.61)* (Vanhaecht et al., 2009).

The studies discussed thus far have focused on care pathway effectiveness across care pathway types and implementation settings. By doing so, they focused on exploring the effectiveness of care pathways on the whole, their mean effect (Borenstein et al., 2009). While this is appropriate for certain purposes, it can also obscure differences between studies (Petticrew et al., 2013). Care pathways come in many shapes and forms (Bragato & Jacobs, 2003; Vanhaecht et al., 2010), they are used for a range of different purposes (De Luc, 2000), and they are implemented in a variety of clinical settings and countries (Currie, 1999; Vanhaecht et al., 2006). Accordingly, the studies included in the synthesising literature reviews are heterogeneous, which needs to be taken into account when interpreting the aggregated results. Knowing that in general care pathways tend to have positive outcomes is a useful rule of thumb, but does not provide the evidence needed to inform decisions in practice regarding the implementation of specific types of care pathways in specific settings. Instead, diversity across studies will have to be explored further, investigating whether there are patterns underlying the mean effect of care pathways.

Efforts investigating the dispersion of the overall care pathway effect indeed show variable effects for different types of care pathway interventions. There are different methods available for exploring

the dispersion of overall intervention effects (Borenstein et al., 2009). One such methods is narrative review, which can be used to identify themes that explain and summarise differences between study results (Petticrew et al., 2013). Allen, Gillen, & Rixson (2009) performed such a narrative systematic literature review to investigate differential effects of care pathways (Allen et al., 2009). Recognising that different interventions are likely to have variable effects in different circumstances, Allen et al. (2009) reworked their main research question to ask *"what works, for whom, in which circumstances"* (p. 61) (Allen et al., 2009) instead of only asking whether care pathways are effective on the whole. This approach is promoted in realist evaluations (Pawson & Tilley, 1997) and realist reviews (Pawson, Greenhalgh, Harvey, & Walshe, 2005). Allen et al. (2009) included seven high-quality randomised controlled trials in their review, including one focused on children's asthma care in the ED (Cunningham et al., 2008) and one on inpatient children's asthma care (Johnson, Blaisdell, Walker, & Eggleston, 2000). Their narrative analysis yielded a number of interesting results. The review highlighted that in some circumstances care pathways improved adherence to evidence-based guidelines, clinical decision-making, and documentation. Most notably, though, they found that care pathways tend to be most effective for predictable patient care trajectories, and for addressing explicit service deficiencies. Whereas for more variable care trajectories and for services that are already evidence-based with good multi-professional working, the impact of care pathways is less certain. They also found that depending on the purpose, benefits of care pathways may be greater for certain patient groups (Allen et al., 2009). So, the review was able to unpack the relationship between care pathway interventions and outcomes – identifying predictability of patient care, prior health service quality, and care pathway purpose as moderating factors (Baron & Kenny, 1986) that influence the strength of the relationship.

As such, the scientific literature clarifies the role of care pathways in establishing healthcare quality. As discussed, the quality framework describes how healthcare quality can be understood through the analysis of healthcare outcomes, care processes, structures, and their inter-relations (Donabedian, 1966). In this section, these quality components were evaluated in the context of care pathway interventions. Scientific evaluations indicated a positive combined effect of care pathway interventions on the outcomes use of resources and patient safety, while evidence of positive effects on patient satisfaction and health outcomes were lacking. To explain a rather disappointing direct effect of care pathway interventions on healthcare outcomes, the influence of healthcare processes and structures was explored. Accordingly, the processes of mutual decision-making and care organisation were recognised to mediate the relationship between care pathway interventions and healthcare outcomes. Moreover, predictability of patient care, prior health service quality, and care

pathway purpose were recognised as structural elements that moderate the relationship between care pathway interventions and healthcare outcomes.

Appendix C. Historical development of improvement science disciplines

In this thesis, different disciplines have been discussed to understand quality improvement in healthcare. That is, scientific literature was discussed that focused on care pathways, diffusion of innovations, implementation, and QI approaches and methods. To better understand the distinction between these disciplines, a short historical overview is presented.

Care pathways

Care pathways are a method inherited from management theories to improve the quality and efficiency of care. One key management theory that forms the basis for care pathways is Scientific Management introduced in 1914 by Frederick W. Taylor in his book *'Principles of scientific management theory'*. Taylor's philosophy was to *'work faster by working smarter'* aiming to reduce waste by improving processes and methods of production (Niebel, 2012). He started by breaking work assignments down into smaller tasks and assigning specific allowed completion times for each task. Based on this philosophy, the Critical Pathway Method (CPM) and Programme Evaluation and Review Technique (PERT) were developed in the 1950s (Kelley & Walker, 1959). Both are mathematical algorithms that model the duration of a project, representing different activities and their interdependencies. An example is shown in Figure 33. In 1985, these models for planning and standardizing processes were translated into healthcare in the form of case management plans (Zander, Etheredge, & Bower, 1987), later called clinical or care pathways. Care pathways were introduced to the UK in the early 1990s (Zander, 2002). At the same time, Business Process Reengineering (BPR) was introduced as another business management strategy which gained popularity quickly (Davenport & Short, 1990; Grint, 1994; Hammer, 1990). Similar to Taylor's approach, BPR focused on analysing and improving processes to achieve better performance and efficiency. However, BPR recognises that iteratively streamlining existing processes will not bring about optimal improvements if those processes themselves are ineffective. Instead, BPR encourages fundamental redesign of the system as a whole in order to achieve the greatest possible benefits. Impacted by BPR, care pathways in healthcare developed from tools to plan and standardise clinical processes to tools that could also be used for healthcare redesign (Bragato & Jacobs, 2003).

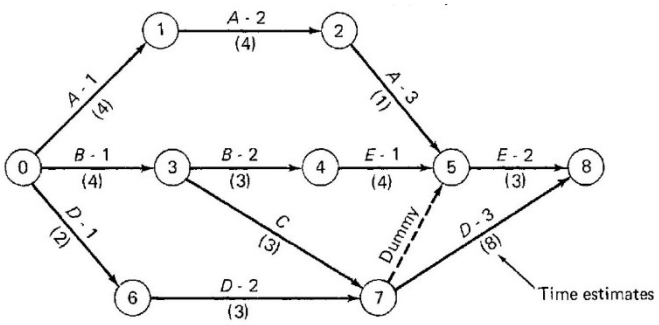

Figure 33. Example Critical Path Diagram. This Critical Path Diagrams shows how the activities of processes A, B, C, D, and E are interrelated. For example, activity E-1 depends on B-2 being completed, whereas activity D-3 depends on both C and D-2 being completed. For each activity, a completion time is estimated. The total completion time is estimated by calculating the longest path through the network (B-1, C, D-3; 15). This is called the critical path. Adopted from Moder & Phillips (1970).

The use of care pathways spread rapidly in the UK since their introduction in the 1990s. One study demonstrated that by 1998, 86% of 330 surveyed NHS trusts were using care pathways, with 72% of the 330 trusts being in the development or piloting phase. The five most common conditions for which care pathways were implemented were: hip fracture, hip replacement, stroke, asthma, and myocardial infarction (heart attack) (Currie, 1999). The rapid spread of care pathway use was facilitated by the perceived ability of care pathways to respond to policy developments towards quality, efficiency, patient centeredness, and integration such as described in *'The NHS plan: a plan for investment, a plan for reform'* (Bragato & Jacobs, 2003; Department of Health, 2000; Pinder, Petchey, Shaw, & Carter, 2005).

The popularity of care pathways resulted in adaptations and varieties being used in practice. As discussed, the introduction of BPR in healthcare resulted in the evolution of care pathways being used for standardisation initially, to them being used for the redesign of clinical processes also (Bragato & Jacobs, 2003). This distinction between the two types of care pathways was reflected in the language used by healthcare professionals. Care pathways used for standardisation were often called processes, whereas care pathways used for redesign were more often referred to as tools (Currie & Harvey, 2000). Moreover, when care pathways were identified as opportunities to implement more wide-ranging governmental policy goals, they diversified even further. A survey of healthcare organisations developing care pathways in the UK, identified they were used to improve the efficiency of clinical processes, the effectiveness of health services, the continuity of care across different teams or services, and the patient focus of healthcare design and delivery (De Luc, 2000). Accordingly, the term care pathway is often used interchangeably with a number of different terms, including critical pathways, care algorithms, care protocols, integrated care pathways, and multi-disciplinary care maps (Currie & Harvey, 2000; De Bleser et al., 2006). This diversification of terms and applications creates confusion about the meaning of care pathways.

However, the ambiguity around care pathways has also allowed it to bring different types of healthcare professionals together. Consequently, care pathways have been identified as *boundary objects* (Allen, 2009). Healthcare is dependent on the coordinated efforts of different groups, like doctors, nurses, pharmacists, managers, policy-makers, and patients. While all being part of the same healthcare system, different groups perform distinct activities, hold unique types of knowledge, and have diverse interests. Moreover, what makes these groups separate – what gives them boundaries – is having to defend and create space for their own activities, knowledge and interests. That is, *"a profession is a set of turf battles that are later yoked into a single defensible position in the system of professions"* (p. 860) (Abbott, 1995). The evolution of care pathways to be used for such varied purposes has created an interest in care pathways across many different groups in healthcare (Allen, 2009). For managers and policy-makers, care pathways can be a mechanism to improve care and save costs. For nurses, care pathways can be a mechanism to coordinate the activities between multiple healthcare professionals. For doctors, care pathways can be a mechanism agree clinical processes between colleagues. And for patients, care pathways can be a mechanism to encourage evidence-based and patient-focussed care. As such, care pathways fit the definition of boundary object, which is understood as an *"object that lives in multiple social worlds and which has different identities in each"* (p. 409) (Star & Griesemer, 1989). Boundary objects translate between groups. They are malleable enough to suit different groups, while having sufficient integrity to exist across groups. However, the ability of care pathways to attract the interest of multiple groups does not magically remove the underlying tensions that exist between groups. Accordingly, when different groups collaborate on the development and implementation of care pathways, these tensions still need to be resolved (Allen, 2010). Resolving these tensions requires a degree of creativity, which explains why care pathways have evolved and diversified over time.

Diffusion of innovations

Rooted in rural sociology, the study of diffusion of innovations has provided descriptive insights which are highly relevant for adopting new interventions (i.e. innovations) in healthcare to improve quality. Diffusion is commonly defined as *"the process by which an innovation is communicated through certain channels over time among the members of a social system"* (p. 6.) (Rogers, 1995). Often a distinction is made between diffusion and dissemination viewing them as two ends of a spectrum (Lomas, 1993). Diffusion is considered passive, with new ideas spreading spontaneously, unplanned and uncontrolled. Whereas dissemination is considered active, with new ideas being shared with a targeted audience and the communication being tailored and managed accordingly. However, in practice it can be difficult to distinguish the two (Rogers, 1995). Diffusion as such is a key mechanism for change, (potentially) leading to the incorporation of innovations (e.g. ideas, methods

or technologies) into the practices and beliefs of people and organisations (Katz et al., 1963). As such, diffusion is often referred to more generally as the process of adopting and embedding innovations into routine practice locally (Katz et al., 1963). Or put simply, diffusion is *"how things, ideas and practices – get from here to there"* (p. 145) (Katz, 1999). The first investigations of how this happens were performed by sociologists and anthropologists in the 1930s who were tracking the diffusion of cultural items, traditions and ideas in space and over time (Katz et al., 1963; Valente & Rogers, 1995). These early studies were descriptive in nature, which started to change since the Ryan & Gross (1950) landmark study *'Acceptance and Diffusion of Hybrid Corn Seed in Two Iowa Communities'*. This study was designed to integrate the sociological interest in diffusion with a more practical interest of increasing agricultural productivity. It focussed on new research areas which were more relevant to practice by analysing adoption decision-making processes, early adopter characteristics, and the impact of different types of communication on innovation adoption. Such insights could then be used to inform and influence practice. This study was extremely influential and triggered many consecutive studies on the diffusion of innovations in rural sociology (Valente & Rogers, 1995). In 1962, Rogers summarised and published this new body of diffusion research in the first edition of *'The Diffusion of Innovations'*. This easily accessible overview generated much traction in other disciplines to explore its application and to further develop the theories. In health for example, diffusion theories were elaborated by accounting for the social practices in medical communities and the innovations' developmental stage (Coleman, Katz, & Menzel, 1957; Greer, 1988). Over time these sociological studies established a significant theoretical understanding of the manifestation of diffusion in real-life. However, more practical knowledge on how to best influence this process remained largely unexplored.

To facilitate quality improvement by more speedy and widespread adoption of innovations, studies began analysing deliberate efforts to influence diffusion and to actively spread and scale-up interventions to other areas. As described above, the sociological historical roots of the diffusion of innovations literature resulted in a highly descriptive and conceptual knowledge base. This leaves a gap for more practical knowledge to actively facilitate diffusion which is urgently needed in health. Health inequalities and variations in the quality of care exist on global and national levels (Institute of Medicine, 2001; Kennedy, 2010; Marmot, 2005; Marmot et al., 2010; Royal College of Physicians, 2010; World Health Organization, 2000). To improve health for all and establish more equitable health services, local beneficial health innovations need to become more widely accessible. However, beneficial innovations rarely diffuse on their own accord and serious concerns exist regarding the pace and reach of diffusion of healthcare innovations (Barker et al., 2016; de Opacua, 2013; Simmons, Fajans, & Ghiron, 2007; Simmons et al., 2009; Simmons, Ghiron, Fajans, & Newton, 2010).

The diffusion of most beneficial health innovations requires active planning and organised actions to be successful. In healthcare, this type of active diffusion of innovations is often referred to simply as spread or scale-up. In line with their aim of improving health for all, the WHO has defined scale-up as: *"deliberate efforts to increase the impact of health service innovations successfully tested in pilot or experimental projects so as to benefit more people and to foster policy and programme development on a lasting basis"* (p.1) (Simmons et al., 2009). Distinctive features of this definition compared to more traditional definitions of diffusion are: the focus on active over passive spread, the focus on successfully tested innovations, and the focus on achieving sustainable positive outcomes (Simmons et al., 2009). Simmons et al. (2009, 2010) define four types of scale-up: horizontal scale-up, vertical scale-up, diversification and spontaneous diffusion. Horizontal scale-up refers to the expansion or replication of innovations to different geographical areas or different target populations. Vertical scale-up refers to national or sub-national institutionalisation of innovations via various policy, political, legal or institutional mechanisms. Diversification or grafting refers to the testing and adding of interventions to an existing innovation package to address differences in purpose, population or context. Whereas spontaneous scaling-up (although rare) refers to the diffusion of innovations without any active and deliberate guidance. Over time, several frameworks have been developed focused specifically on the process and practice of spread and scale-up (Barker et al., 2016; Cooley & Ved, 2012; Massoud et al., 2006; Nolan, Schall, Erb, & Nolan, 2005; Simmons et al., 2007, 2009, 2010).

Implementation science

Developed as part of the Evidence-Based Medicine (EBM) movement, implementation science focusses distinctly on the implementation of interventions that are supported by scientific research to improve healthcare quality. Implementation science is rooted in the field of medicine, stemming from the Evidence-Based Medicine (EBM) movement. Implementation has already been highlighted as one of the stages in the process of diffusion (Rogers, 2003). Within this process, implementation follows the decision to adopt an innovation locally. During the implementation phase, an innovation is put to use in practice. Implementation science focuses on the implementation of evidence-based healthcare interventions, including programs, practices, processes, policies and guidelines (Rabin & Brownson, 2012). Within this context implementation science is defined as: *"the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based [interventions] into routine practice, and hence to improve the quality (effectiveness, reliability, safety, appropriateness, equity, efficiency) of health care."* (p.2) (Eccles et al., 2009). The narrowed focus on evidence-based interventions in this definition as a sub-group of potential innovations to be implemented, signifies the grounding of implementation science in EBM. EBM emerged in the 1990s

as a modernist movement (Wieringa et al., 2017) characterised by the rejection of traditional and religious explanations, favouring positivist epistemology instead. Accordingly, during the rise of EBM, it got expressed as a new paradigm, which *"de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making [instead] stress[ing] the examination of evidence from clinical research"* (p.2420) (Evidence-Based Medicine Working Group, 1992). The shift in EBM towards research evidence as the cornerstone of clinical practice does not mean clinical experience is to be rejected. In practice though, this is often misunderstood, ignored or forgotten. EBM does distinguish between scientific research and clinical experience, whereby the EBM community by and large prioritises research evidence (Greenhalgh, Howick, & Maskrey, 2014; Wieringa et al., 2017). In addition, some types of research evidence are valued more than others (Howick, 2011). Differentiation of evidence types has been supported by the development of evidence-hierarchies, ranking certain types of evidence and certain types of studies as more credible than others. The common classification of evidence is shown in the evidence-hierarchy in Figure 34. In its pure form however, EBM calls for research evidence to be actively and conscientiously interpreted and integrated with clinical expertise and patient choice to achieve the best care for individual patients (Sackett et al., 1996). More recently, the use of healthcare resource, has been added as an element for healthcare professionals to consider and integrate into clinical practice decisions (Rogers & Hutchison, 2017).

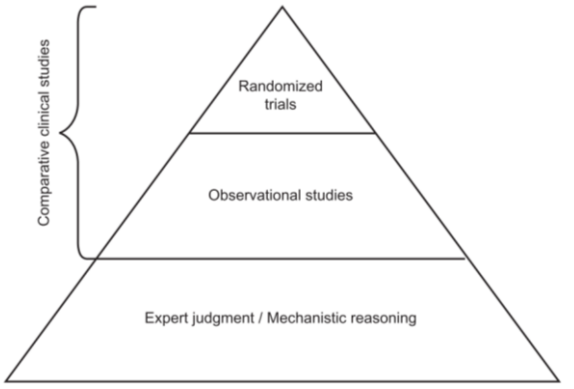

Figure 1.1 Simplified EBM hierarchy of evidence (systematic reviews of all study types is assumed to be superior to single studies).

Figure 34. Simplified EBM hierarchy of evidence. From Howick (2011). Systematic reviews of all study types is assumed to be superior to single studies.

Over time implementation studies advanced, developing theoretical and practical insights that facilitate the uptake of EBM interventions in clinical practice. Initially, the uptake and integration of research evidence into clinical practice was thought to be realised simply via publication of research findings in medical journals (Brownson et al., 2012). However, it soon became clear that such passive approaches were not effective for changing health professional behaviour (Oxman, Thomson, Davis,

& Haynes, 1995). For educational interventions targeting healthcare professionals published between 1970 and 1993 only about 14% were implemented in practice after a process of 17 years (Balas & Boren, 2000). These and other findings demonstrating that the potential benefits of health research were not realised in practice slowly initiated increased support for studies on how to close this 'translational gap' (Brownson et al., 2012; Cooksey, 2006). Various types of studies were encouraged to address different stages in what is called the 'translational pipeline'. The 'pipeline' metaphor is used to outline logically succeeding steps and stages to get discoveries from the life sciences and basic medical research via the development of novel efficacious technologies and interventions into clinical practice (Braithwaite et al., 2018; Cooksey, 2006). Implementation studies address the latter half of this process, the aforementioned 'second translational gap'. The first wave of implementation studies (drawing on experience from diffusion of innovations and related fields) established a breath of knowledge on implementation facilitators and barriers. A wave of effectiveness studies (i.e. pragmatic trials) followed, testing how specific implementation strategies for managing barriers and facilitators influence the uptake of interventions (Brownson et al., 2012). However, these studies largely failed to use theory or other means for exploring and testing their working mechanisms (Davies, Walker, & Grimshaw, 2010) and have therefore been described as *"an expensive version of trial-and-error"* (p. 108) (Eccles, Grimshaw, Walker, Johnston, & Pitts, 2005). Nonetheless, these studies did lead to a knowledge base of potential implementation strategies compiled in taxonomies (Powell et al., 2012, 2015; Waltz et al., 2015). Since, implementation studies have become more varied, numerous and sophisticated. Over the last 20 years, these studies created an abundance of implementation models, frameworks and theories (collectively termed here as 'framework') with over 60 frameworks identified in a 2012 review (Tabak et al., 2013). These frameworks have collated and developed understanding in implementation science regarding the process and stages of implementation, the factors and mechanisms that influence implementation, and the strategies to evaluate implementation (Nilsen, 2015).

QI approaches and methods

The study of quality improvement approaches and methods evolved from the industrial quality movement where they were first developed and applied as part of a practical and continuous commitment to improve product quality for competitive advantage and business survival. Quality improvement approaches and methods now used in healthcare stem from Japan where such methods were first developed after World War II to strengthen their industrial sector. The Japanese economy suffered greatly from World War II and following the war Japan strived for a competitive position in the global market. The following three decades, Japanese manufacturing industries transformed with great success by improving product quality (Anderson et al., 1994; Cole, 1998).

Specifically the transformation of the automobile manufacturer Toyota Motor Corporation has been highly influential (Magee, 2008). The Japanese economic situation prohibited implementation of a mass production system similar to that of US competitor Ford Motor Company (Womack, Jones, Roos, & Carpenter, 1990). The Ford system used material and human resources inefficiently making it too costly to be implemented as such in Japan (Dahlgaard & Mi Dahlgaard-Park, 2006). Following this observation, Eiji Toyoda (CEO) and Taiichi Ohno (head engineer) developed a vision to make improvements in the most economical way, focussed on reducing waste (Japanese: *muda*). Waste is defined as everything that increases cost without adding value for the customer (Juran, Gryna, & Bingham, 1974). To implement their vision, the Toyota Production System was developed (Abe & Fitzgerald, 1995), which later got labelled lean manufacturing (Womack et al., 1990). Lean manufacturing requires management to empower all employees to collaborate in teams, continuously improving production processes via several key principles (Dahlgaard & Mi Dahlgaard-Park, 2006; Womack et al., 1990). Toyota's approach improved product quality significantly and made them a world leader in car manufacturing (Abe & Fitzgerald, 1995). Japan's success gaining competitive advantage over Western industries by improving product quality sparked what has been called the quality movement in Western cultures in the 1980s (Cole, 1998).

Aiming to replicate its success, the Japanese quality improvement approach evolved over time to better fit Western business processes, thereby changing some of its practices. Western organisations struggled initially to implement Japanese quality systems due to misunderstandings and cultural misalignments. Their implementation required adaptations to be made. As such, the Japanese approach to managing quality evolved when integrated in Western organisations, *"losing over time its Japanese style"* (p.347) (Chiarini, 2011). A well-known approach for improving quality developed in the US during the 1980s Japan-inspired quality movement is Motorola's Six Sigma (6σ) methodology (Dahlgaard & Mi Dahlgaard-Park, 2006). The methodology aims to reduce the number of defected products by improving its manufacturing processes, specifically focused on reducing process variation (Andersson et al., 2006) by means of the DMAIC process: Define, Measure, Analyse, Improve, Control (Park, 2003). Some specific Six Sigma elements highlight its westernisation particularly well. For example, Six Sigma relies heavily on the use of specialised statistical methods to demonstrate the link between suggested process improvements and (financial) outcomes. This mechanism encourages Western managers at all levels of the organisation to actively engage with and support quality improvement efforts, something seen as key success factor to the Japanese approach (Andersson et al., 2006; Dahlgaard et al., 2002; Ishikawa, 1984). Another example is the hierarchical Six Sigma training and development programme to establish engage employees with quality improvement. The training programme serves as an external motivator engaging people by

means of career progression and certification in contrast to the Japanese approach using internal motivators for engagement based on Japanese values that people inherently want to do well (Chiarini, 2011).

Adaptation and evolution of Japanese quality management during the Western quality movement, exemplified by Six Sigma methodology, brought about several distinct approaches to quality improvement. Due to their shared origin, however, many approaches have common methods that align with shared underlying principles (Andersson et al., 2006; Chiarini, 2011; Dahlgaard & Mi Dahlgaard-Park, 2006; Klefsjö, Wiklund, & Edgeman, 2001). Five broad principles underlying several industrial quality approaches are: leadership (management's commitment), a focus on customer and employee satisfaction, a focus on facts (measurement), continuous improvement (Japanese: *kaizen*), and participation of all stakeholders (Dahlgaard et al., 2002). Although the presence of such practices and principles has been positively associated with business performance, many efforts to implement specific industrial quality improvement approaches have failed (Andersson et al., 2006; Harari, 1993; Mason et al., 2015; Shortell et al., 1998). Studies are therefore currently investigating how industrial quality improvement approaches and methods should be used to establish actual improvements. In the health sector, this involves further adapting and elaborating industrial approaches and methods for healthcare purposes and understanding exactly when and how such approaches and methods are successful (Langley et al., 2009; Marshall & Mountford, 2013; The Health Foundation, 2013; Walshe, 2007).

Appendix D. Dialectical Critical Realism

As discussed, I adhere to the philosophy of DCR rather than choosing between medical positivism and industrial pragmatism. A summary of DCR philosophy that shows how DCR connects to pragmatist and positivist epistemologies, is best based on the *'holy trinity'*. The *'holy trinity´* refers to three key pillars of critical realism: ontological realism, epistemological relativism and judgemental rationality (Bhaskar, 2008a). These three pillars touch on all four core philosophical disciplines (Benton & Craib, 2011). That is, ontological realism refers to ontological or metaphysical considerations about the nature of the 'things' being studied. Epistemological relativism refers to the epistemological considerations about the relations between the 'things' studied and our knowledge of those. Epistemology considers the potential for true knowing, the types of knowledge considered scientific, and the ability of scientific methods to attain true knowledge. Judgemental rationality refers to logical considerations about reasoning in science and the validity of scientific arguments. Finally, judgemental rationality also links to ethical considerations about the role of science in defining and defending morality in society. This is especially important in the context of improvement science, which is inherently normative. As discussed in Chapter 2, healthcare quality is often defined based on quality goals, operationalised as empirical or normative standards (Donabedian, 1966). These standards allow for specific measurements to define what is 'good' and 'bad' quality. Subsequently, actions that improve these quality measurements are considered 'right' and actions that don't improve quality measurements are considered 'wrong'.

So, critical realism firstly assumes the existence of **ontological reality**, with a clear separation of ontology and epistemology. It rejects the positivist collapse of ontology into epistemology discussed earlier. It also however, rejects the pragmatist integration of ontology and epistemology. As discussed, while pragmatists usually do assume the existence of reality separate from knowledge, they tend to find this distinction irrelevant since acting in the world always depends on both the world and experience (Misak, 2016). Critical realists however, are more concerned with how things are and how knowledge relates to reality. Some metaphysical beliefs held by many critical realists, including the ontological reality of nature, culture and morality have been discussed under ontological assumptions (Archer, 1996; Norrie, 2010). Critical realists are concerned with understanding and learning about all such elements of reality in contrast to positivists, who roughly consider subjective elements out of scope for objective science and certainty (Benton & Craib, 2011). Another critical realist metaphysical belief concerned the stratified nature of reality (Bhaskar, 2008a). Stemming from this assumption is the focus in critical realism to explain phenomena by exploring their underlying causal mechanism which are believed to be ontologically real. They are real for their

real effects even if the mechanisms themselves cannot be directly observed or otherwise known (Alderson, 2016). In critical realism, both empirical and non-empirical ontologically real causes are the subject to scientific study in contrast to positivism which exclusively focuses on empirical phenomena and in contrast to pragmatism which generally prioritises experiential subjects and epistemological issues (DeForge & Shaw, 2012).

In regard to our knowledge of reality, critical realism assumes **epistemic relativism**. Like constructivists and pragmatists, critical realists argue that knowledge is created in and shaped by socio-cultural conditions. What follows is that the knowledge someone has of reality depends on their socio-cultural position. This contradicts the positivist idea that objectively derived knowledge is a true reflection of reality independent of its situatedness. Instead, critical realists assume that even when referring to the same object of reality, the knowledge held of such might differ across individuals or across cultures and it is impossible to know with certainty which knowledge is a true reflection of reality (Bhaskar, 2008a). Since critical realists oppose the assumption that knowledge can be fully objective, they support methodological pluralism (Porpora, 2015). While some methods might inherently be more objective then others, critical realists believe that all scientific methods have their own benefits and limitations and all methods can elicit insightful information about reality if used appropriately. Despite assuming epistemic relativism and supporting methodological pluralism, critical realists maintain their belief in ontological realism and the possibility of truth unlike constructivists. The reason is that critical realists hold an alethic rather than epistemic truth account. So, rather than evaluating truth through epistemic notions like certainty, critical realists argue that knowledge claims are true when they agree with reality. And even though it is impossible to know with certainty whether knowledge claims are true in this sense, critical realists assume that some knowledge claims better represent reality than others.

To assess which knowledge claims are most in agreement with reality, critical realists call on **judgemental rationality**. Judgemental rationality refers to the possibility to argue that some claims are better grounded in reality than others. Underpinning judgemental rationality is the conception also held by pragmatists that knowledge and science are developmental (Hartwig, 2007). Knowledge develops through a continuous process of putting our theories and conceptions of reality to the test. This has been described as a dialogue between knowledge and reality, where theories and ideas are put forward to which the world responds empirically, accepting or rejecting the ideas more or less ambiguously (Porpora, 2015). Based on how the world *'talks back'* we might gain confidence in our theories or decide to change our theoretical position. Alternatively, the world talking back might bring new empirical discoveries requiring theories to change or expand. However, using empirical observations and experience to judge theories is not always straightforward. What can make it

difficult to judge theories against empirical data for example, is underdetermination of theory by data (Pietsch, 2012). Holistic underdetermination refers to the issue in theory testing that any theoretical hypothesis is inherently associated to a set of auxiliary assumptions, including methodological, theoretical or ontological assumptions. So, when scientific experiments designed to test a particular hypothesis have negative results it might be the case that one of the auxiliary assumptions is false, not the hypothesis tested. Contrastive underdetermination, on the other hand, refers to the issue that supportive evidence for one theory does not automatically rule out any alternative theories. Instead, empirical observations might support multiple contrasting theories, such as the theory of light particles and of light waves. These issues demonstrate that the dialogue between knowledge and reality is not always simply resolved by *'listening to the empirical evidence'*, which tends to be the positivist message. This approach can stifle scientific development, through endless theory rejection when experimental results are negative or when empirical anomalies are found (Lakatos, 1968). Instead, scientific progress relies empirical falsification and rational critique. Rational critique allows theories to be expanded, refined or changed in the face of empirical falsification, before they are rejected in full. As such, judgemental rationality mediates the interplay between scientific theories and empirical observations. It helps improve scientific conceptions of reality in accordance with empirical observations and judge which theories most likely represent reality.

However, **judgemental rationality** is not only used in DCR to judge the likelihood of theories to be true epistemically. It is also used to judge the moral truth of actions. DCR assumes morality to be real and plural (Bhaskar, 2008b). Moral pluralism refers to the assumption that individuals and communities can hold different moral positions that can co-exist alongside one another (Norrie, 2010). Their moral positions depend on their underlying ethical values, i.e. the principles they hold on what behaviour is morally right or wrong. Values have causal properties in that they influence beliefs and guide behaviour. Ethical values are both personal and cultural. That is, people hold personal values that are individually subjective, which might align with or diverge from cultural values held by their community. The existence of cultural values highlights how communities and society are objectively moralised, promoting certain moral viewpoints over others. Accordingly, communities and societies have cultural traditions, beliefs, laws and norms that implicitly or explicitly promote 'good' and punish 'bad' behaviour. The ethical values and moral viewpoints embedded in such cultural elements are understood through subjective interpretation (Archer, 1996; Porpora, 2016). However, culture is more than individual sense-making or cognition. It involves meaning that is socially shared across communities and society despite its subjective nature (Porpora, 2015). Despite this subjectivity, both personal and cultural moral viewpoints have the capacity to exercise

causal powers and influence people's intentions and actions (Archer, 1996; Porpora, 2016). So, moral viewpoints are real in the sense that they have actual causal consequences in the world.

Moreover, moral realism in DCR extends to the assumption of alethic moral truth. This means that the moral viewpoints held by individuals or in society might not be a true reflection of morality. This aligns with the alethic notion of epistemic truth, which indicates that the knowledge we hold might not be a true reflection of the world. So, it is not possible to know for sure whether our moral standpoints are truly moral. The moral viewpoints held by people and in society might be wrong and the actions taken consequently might therefore also be morally wrong. However, through judgemental rationality it is possible to critique our moral standpoints and develop standpoints that are more likely to be truly moral than others. This can be illustrated based on the observation that working hard not always leads to better healthcare quality. Society generally holds the moral stance that working hard is good. Based on judgemental rationality, however, it was discovered that hard work is not the only mechanism influencing healthcare quality. Likewise, simply holding onto the moral stance that 'working hard is good' might not reflect true morality in circumstances where, for example, inefficient administrative processes result in unnecessary work or where staff burnout might lead to safety issues. So, in the moral realm, judgemental rationality also helps to critique, refine and elaborate moral stances rather than simply verifying or rejecting them. Subsequently, different or more nuanced moral stances can be taken that encourage actions that are more likely 'right' and therefore able to emancipate people and improve situations. As such, judgemental rationality is used to progress the scientific and the moral discourse. It seeks to improve our understanding of and our actions in society, which makes DCR particularly suitable to study and support healthcare improvement.

Appendix E. The literature review process and the Itchy Sneezy Wheezy case study

This study involved an exploratory phase to develop a robust basic understanding of the subject area before starting the main empirical study. The exploratory phase involved a literature review that was informed by an exploratory case study. Two key purposes of the exploratory phase were to develop a more defined problem definition and several theoretical insights and hypotheses that could be investigated in-depth in the main part of this study (Yin, 2018). The results address the first moment (1M) of MELD dialectics and answer the first research question posed in this study *'What issues underly existing UK allergy health services not meeting children's needs?'.* This exploratory stage started with my familiarisation of a short 250-words PhD project proposal. This proposal outlined that the management of allergic disease might be suffering from health service issues, that an evidence-based allergy care pathway intervention had been implemented, and that there was a desire to transfer the intervention to other areas. Accordingly, I aimed to gain a broad and general understanding of the foundation underpinning all three issues – the quality of healthcare delivery for children with allergies in the UK.

To understand the quality of healthcare delivery for children with allergies in the UK, I performed a case study of the Itchy Sneezy Wheezy project in which my PhD supervisors were both gatekeepers and key informants. I retrospectively explored the Itchy Sneezy Wheezy project, using a single-case design, to describe some of the key theoretical mechanisms and relationships underpinning the delivery of allergy care for children with allergies in the UK. The project was selected as an unusual case (Yin, 2018), contrived as a pilot project to implement the RCPCH national allergy care pathways into local UK health services (Warner & Lloyd, 2011; Warner & Spitters, 2017). Moreover, this project was led and supported by my PhD supervisors, who acted as gatekeepers and key informants in this study (O'Reilly, 2009). Both my supervisors have a wealth of theoretical knowledge and practical experience in the fields of child allergy care and healthcare improvement. Prof John Warner, was appointed Professor of Child Health in 1990 and he has continued both his clinical practice as a paediatric allergist and his academic research on child allergies since (e.g. Van der Poel and Warner, 2012; Warner et al., 2006; Warner and Turner, 2017). From 2009-2011, he chaired the board of the RCPCH allergy care pathway project that was commissioned by the Department of Health. In 2011, the project published 8 national allergy care pathways for children with allergies based on an evidence review, critical appraisal and expert opinion (Warner & Lloyd, 2011). Prof Warner's latest endeavours have focused on the local implementation of these pathways to improve child allergy

health services in the UK. In 2011, he acquired funding for a pilot implementation project – the Itchy Sneezy Wheezy project (Gore et al., 2016; Warner & Spitters, 2017). The project sponsor was the NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC) North West London (NWL). The NIHR CLAHRC NWL (2008-2020) was established as part of a national research programme to understand and improve the translation and implementation of research evidence into clinical practice and social care (Caldwell & Mays, 2012; Kislov et al., 2018). In NWL, this issue was tackled through a quality improvement collaborative acting as central research management hub (Oborn et al., 2013). The collaborative funded, studied and supported 18-month long projects to apply the NIHR CLAHRC NWL systematic quality improvement approach for the implementation of research evidence and the improvement of local healthcare delivery (Howe et al., 2013). Itchy Sneezy Wheezy was one such project. Dr Julie Reed was deputy director and academic lead of the NIHR CLAHRC NWL. With her expertise in the science and practice of improvement and implementation (Reed & Bell, 2013; Reed, Howe, et al., 2018a), she advised and supported Prof Warner and his team in their efforts to improve the local health services for children with allergies as part of the Itchy Sneezy Wheezy project. It should be noted that this PhD is also part of the NIHR CLAHRC NWL research portfolio.

To explore healthcare delivery for children with allergies in the UK, I triangulated case study evidence and evidence from published literature. The case study evidence I collected included project documentation; informal discussions with my supervisors as key informants; and observational notes from presentations they ran. A key presentation that helped me make sense of the Itchy Sneezy Wheezy project was delivered by Prof Warner at a collaborative learning event. These events were organised quarterly by the CLAHRC NWL team to support the healthcare improvement teams they funded in learning about quality improvement by sharing their own improvement experiences, by networking with other improvement teams and by attending expert-led quality improvement presentations and workshops. At this particular event, Prof Warner presented on the Itchy Sneezy Wheezy project and discussed questions on next steps with the audience and the CLAHRC NWL external advisory group, which were followed up during networking opportunities throughout the event. A key mechanism that allowed me to learn about the implementation approach that the Itchy Sneezy Wheezy project team utilised, was provided by Dr Reed. She set-up and coordinated an in-house training course of 12 weekly training sessions for the CLAHRC NWL team to learn about the tools, methods and principles that comprise the CLAHRC NWL systematic quality improvement approach. This presentation and these training sessions gave me a foundational understanding that helped me make sense of the project documents I reviewed as part of the case study. The project documents included 10 quality improvement artefacts, 15 data documents, 13 intervention artefacts,

9 meeting minutes, and 15 official project documents and publications. A more detailed specification of these documents can be found at the end of this Appendix. Alongside my review of these documents, I had regular meetings with my supervisors acting as key informants. I met Prof Warner every two months and Dr Reed roughly every three weeks. During these meetings, I was able to ask informal questions to help me contextualise the project, to clarify issues I was unsure about, to elaborate where information was lacking, and to validate/correct my developing understanding. My supervisors also referred me to key publications for me to develop a better understanding of the case and its wider context. Prof Warner initially referred me to the RCPCH allergy care pathway publications that underpinned the Itchy Sneezy Wheezy project and to the national allergy health service reviews that motivated the commissioning of the RCPCH allergy care pathway project (Department of Health, 2006a; House of Lords, 2007; Royal College of Physicians, 2010; Warner & Lloyd, 2011). Dr Reed on the other hand, referred me to key policy documents and scientific publications that underpinned the CLAHRC NWL research programme and to help me familiarise myself with the implementation and improvement science literature (Berwick, 2008; Cooksey, 2006; Damschroder et al., 2009; Department of Health, 2006; Ferlie and Shortell, 2001; Kaplan et al., 2012). These publications also helped me to contextualise, clarify, elaborate, and validate my understanding of the Itchy Sneezy Wheezy project and healthcare delivery for children with allergies more generally. The literature review brought up new concepts, ideas, and insights to unravel in my case study data, while my case study data would bring up new themes for me to explore further in policy and science publications, creating this iterative alternating between the investigation of case study data and literature.

To deepen my understanding of healthcare delivery for children with allergies in the UK, I explored a range of different literature, which was guided by the Itchy Sneezy Wheeze case study in several ways. Initially, the case study evidence raised many basic questions that directed me to review specific topic areas in the literature to get up to speed with the Itchy Sneezy Wheezy project team. This team lives and breathes healthcare delivery for children with allergies. As part of the Itchy Sneezy Wheezy project, they cared for children with allergies, they worked within the wider structures of the UK health services and they operated at the forefront of health service innovation and improvement. Hence, the case study evidence they developed contained a lot of implicit assumptions and underlying knowledge for me to unpick and understand by asking and answering questions about it. For example, the Itchy Sneezy Wheezy project set out to improve the care for children with allergies. The first questions this raised for me, included *'Why is that an important priority? Which children suffer from allergies? How do these children suffer? And what exactly are allergies?'*. To answer these questions beyond what was expressed in the case study evidence, I

reviewed medical and epidemiological literature to better understand allergic disease in children. The above statement also implies that the allergy care for children in the UK was not as good as it could be, which made me question *'What allergy care do children receive ideally? What care do they receive currently? Why does a gap exist between the two?'*. To answer these questions beyond the local experiences of the Itchy Sneezy Wheezy case study, I reviewed the abovementioned national allergy reviews as well as descriptive studies and other policy documents. To improve local services, the Itchy Sneezy Wheezy team successfully implemented several RCPCH allergy care pathways. However, implementation was discontinued due to implementation issues, mainly around integration. These findings relate to healthcare delivery on a deeper causal level, and to the relationship between healthcare delivery, care pathways and integrated care. I explored these issues by questioning *'What are care pathways? Do they really improve care? How do they bring about these improvements?'*. Regarding integration, I questioned *'How comes healthcare integration is lacking? Why is integration important for allergy care? What do care pathways have to do with integration?'.* To answer these questions, I explored systematic reviews of observational studies, conceptual publications, and policy documents on care pathways and integrated care interventions, while making connections to the literature I had already explored. The answers to these questions are presented in Chapter 1 of this thesis.

The Itchy Sneezy Wheezy case study also directed my literature review by guiding me to understand the mechanisms that drive the change and improvement of healthcare delivery generally. After investigating care pathways and integration as mechanisms to improve healthcare delivery for children with allergies, I could not ignore that the Itchy Sneezy Wheezy intervention was discontinued despite using an implementation strategy and demonstrating evidence of success. This made me question more generally *'What does it take to implement interventions sustainably and make lasting healthcare improvements?'*. To answer this question, I explored literature on implementation, improvement and the diffusion of innovations. This selection of disciplines was influenced by the Itchy Sneezy Wheezy case study findings. When exploring multiple case study documents, I became confused as to what the team was doing exactly. In the Action Effect Diagram, the project aim wrote *"improved quality of life for children with allergic conditions"* achieved through *"Education/training sessions, Online resources, Develop professional networks[,] […] Training and history taking tools [and] […] Establishment of Itchy, Sneezy, Wheezy Network in NWL"* (AED v0.6). In the team's internal protocol, though, the aim wrote *"Improve the patient pathway for all children with allergic conditions […] achieved by increasing the clinical knowledge, diagnostic and management skills through training and the building of professional networks"* (ISW protocol). Finally, in the project funding application, the project was described as *"Intervention: implementation*

of the care pathway in a supported network" aiming to *"improve the equality and reliability of care across the system"* (Application form). So, in the application form, the care pathways were to be implemented. In the protocol, the pathways were to be improved. And in the Action Effect Diagram, care pathways weren't mentioned at all. Generally, though, I gathered the project aimed to improve the care for children with allergies by implementing the RCPCH allergy care pathway locally. To achieve this, the Itchy Sneezy Wheezy team used the *"CLAHRC NWL systematic approach to quality Improvement [that comprises] Quality Improvement Tools and Methods [to support] Achieving Sustainable Healthcare Improvements From Translating Evidence-Based Medicine into practice"* (CLAHRC NWL Team Training Intro, 09/06/2015). So, to implement or 'translate' the evidence-based RCPCH care pathways into local practice, the team used a set of improvement tools and methods. This use of language got me confused. In practice there seemed to be significant overlap between improvement and implementation, while in the scientific community each concept had their own scientific journals and community. Furthermore, it was difficult for me to unpick what was implemented exactly. The intervention activities were multi-faceted, which didn't seem to fit my literature-based understanding of care pathway interventions, and I was wondering whether a potential misalignment was problematic. A similar concern around intervention fidelity was shared by the Itchy Sneezy Wheezy team, who discussed at the CLAHRC NWL collaborative learning event, a tension between replicating the intervention as an evidence-based package and allowing the adaptation and picking-and-choosing of intervention elements to achieve sustainability and diffusion. Hence, to understand the reality of the Itchy Sneezy Wheezy case study and how they improved healthcare delivery, it was necessary for me to unpick the overlap, differences and contradictions between implementation, improvement and diffusion of innovations by exploring each scientific discipline. The findings of this part of the literature review are presented in Chapter 2 of this thesis.

Finally, the Itchy Sneezy Wheezy case study also validated certain literature review findings. Firstly, the data exploration of the Itchy Sneezy Wheezy team, had captured the local expression allergy knowledge lacking in primary care and coordination lacking along the patient journey, as identified in the national allergy reviews (Department of Health, 2006a; House of Lords, 2007; Royal College of Physicians, 2003). More specifically, they found GP practices with low rates of allergy diagnosis often had high rates of hospital referral, indicative of a lack in confidence managing child allergies and failure to recognise allergic disease. Moreover, an audit of GP referral letters demonstrated that often allergy severity or complexity was not reflected, clinical history not described, and children under-treated (Allergy Care Pathway presentation, 16/07/2015; CLAHRC final report v0.4). Furthermore, a Patient Reported Experience Measure (PREM) showed that primary and emergency allergy care were equally less well perceived compared to tertiary care (Gore et al., 2016). These

findings not only highlighted that specialist-level care was not delivered in primary and emergency care. They also reflected a lack of integration and specialist support as noted by Prof Warner (Allergy Care Pathway presentation, 16/07/2015). He recounted a story of a mother in his specialist clinic. Her child had experienced an allergic reaction and followed the care plan discussed in clinic. When she arrived at A&E, however, the doctor told her the plan was incorrect. Such clinical experiences mirrored the clinic's PREM results, which demonstrated that while patient satisfaction in the tertiary clinic was excellent, communication with other healthcare professionals was less well-rated (Allergy Care Pathway presentation, 16/07/2015). Secondly, the Itchy Sneezy Wheezy case study reflected how literature-based implementation barriers and facilitators (Damschroder et al., 2009; Kaplan et al., 2012) express in reality. For example, it took time for the project to engage GPs and other frontline stakeholders (Project Board Meeting minutes). Moreover, the team recognised the need for financial resources beyond the duration of CLAHRC NWL funding (Sustainability Evaluation v0.2). They subsequently achieved commissioning of the Itchy Sneezy Wheezy intervention as a community services pilot (select committee paper). Despite successful outcomes, however, the pilot was not re-commissioned, due to the Health and Social Care Act 2012 implementation, whereby Primary Care Trusts (PCTs) were replaced by Clinical Commissioning Groups (CCGs), as well as due to misalignment of financial incentives, competing service offers, and staff turnover (key informant interview, 19/05/2015). Finally, the Itchy Sneezy Wheezy case study validated the flexible and creative nature of using quality improvement methods in real-life (Boaden et al., 2008; Howe et al., 2013). The application form, for example, reflected how the CLAHRC NWL methods operated collectively to address different aspects of healthcare improvement projects. The form also demonstrated how insights specific to healthcare improvement for children with allergies, were elicited by these methods (Application form). Moreover, the case study highlighted experiences of using quality improvement methods. The sustainability model, for example, was initially considered low-priority and inappropriate. Opinions changed, however, after the team experienced how the method elicited useful discussions (Sustainability Evaluation v0.2). Measurement, though, was considered important from the start. Nevertheless, it was complicated moving from high-level measurement concepts, to a specific measurement plan with concrete actions for accessing, collecting and analysing data, to the implementation of those actions (Application form; measures plan v3; Matrix break even analysis).

The understanding of quality in children's allergy services that developed through this process is presented in Chapters 1 and 2. This discussion answers the first research question of this study and it reflects the results of 1M of MELD. Moreover, it informed the four ethnographic case studies that followed. Finally, the following project documents were collected and reviewed as part of the exploratory Itchy Sneezy Wheezy case study.

- 10 quality improvement artefacts
    - 5 versions of an Action Effect Diagram
    - 2 process maps: one generic and one local patient pathway map
    - 3 versions of a stakeholder map
- 15 data documents, including
    - 2 Patient Reported Experience Measure (PREM) surveys and the survey results
    - A measurement plan
    - Rough data collected on intervention related process measures
    - Intervention analysis slide decks and reports
- 13 intervention artefacts, including
    - A healthcare professional training programme
    - Outreach clinic descriptions
    - Clinic letter templates
    - Patient care plans
    - Clinic referral criteria
    - A GP recruitment letter
- 9 meeting minutes of
    - 8 project board meetings
    - 1 sustainability evaluation meeting
- 15 general project documents
    - 1 scientific journal publication on the PREM findings
    - 1 BMJ award submission
    - 2 published abstracts for the RCPCH Annual Conference 2014, 2016
    - 3 conference posters for RCPCH 2012, BSACI 2013, and CLAHRC Show & Tell 2014
    - 5 CLAHRC NWL sponsor reports and documents
    - 1 CCG committee report on project commissioning
    - 1 vision and planning document
    - 1 newspaper article

Appendix F. Generic interview guide

Imperial College London

NIHR CLAHRC for Northwest London

Implementing care pathways for children with allergies
Interview guide

Introduction – 10 minutes

- Greetings
- Introduction of one selves
- Go verbally through information sheet:
    - Introduction to the study
    - Explain role and importance of participant
    - Confidentiality
    - Explain voluntary participation – notify us if you want a break and contact us via e-mail if you reconsider participation after we have left.
    - Audio-recording
    - Procedure for today's session
- Get informed consent

Interview/ focus group – 50 minutes

Interviews and/ or focus groups with participants either have an exploratory focus or a theory refining focus (Manzano, 2014). The stage of theory development, the gaps in the theory and a participant's role within a project will influence the strategy used for interviewing a particular participant. In total three strategies are used: exploring individual experiences, exploring team experiences and refining theory. All strategies cover the following topics:

- Intervention components
- Stakeholder engagement
- Implementation processes, barriers and facilitators
- Intervention impact
- Intervention sustainability

In one interview a mixture of strategies can be used. However, time constraints are considered in the design of each individual interview/ focus group.

Exploring personal experiences

For exploring personal experiences in interviews/ focus groups, the following questions are asked. Questions can be rephrased to match the understanding of the participant and probing questions can be asked to get a fuller understanding of the participant's experiences. An overview of the questions can be sent to the participants beforehand to give them time to reflect on the questions and to consider study participation being fully informed.

Intervention

1. Can you briefly explain your project [x] and what changes [interventions/ activities/ components/ work streams] were implemented?
2. What was your role within the project?

Engagement

3. How did you get introduced to the project?
    - Probe: e.g. When did you first hear of the project? Who told you about it?
4. Did you decide to further engage with [get involved with] the project? What made you decide or put you off getting involved?
5. Did you stay involved with the project throughout? What kept you involved or resulted in you leaving the project?

Impact

6. In what part of the project [intervention/ activities] were you personally most involved in?

Focus the rest of the interview on this intervention component. If people were highly involved in many parts of the project, make them pick one and focus on this.

7. How would you describe the impact [results, outcomes, consequences, effects] of this work? Remember, the impact can be positive as well as negative.
    - Probe for: impact on different stakeholders (e.g. individual, patients, project team, NHS staff, hospital management) and probe for impact on (health) outcomes and processes.

Implementation

Still thinking of the work you did for the project:

8. What were the one or two main challenges [barriers] you personally experienced doing your work for the project?
9. What did you do to overcome these challenges [barriers]?
10. And what were one or two things that really helped [facilitated] you doing your work?
11. Was there anything you planned to do that did not happen? What do you think was the reason?

Sustainability

12. Now the project officially has finished, what parts of the project [interventions/ activities/ components/ work streams]are still in place?

If the intervention that the individual mainly worked is still in place, continue asking about this. Otherwise, continue the discussion on the project in general

13. What were the one or two main challenges [barriers] for you personally to sustain these parts of the project [interventions/ activities/ components/ work streams]?
14. What did you do to overcome these challenges [barriers]?
15. What were one or two main things [facilitators], that helped you sustain this?

Exploring team experiences

For exploring team experiences in interviews/ focus groups, the questions and strategies as for exploring personal experiences are largely used. However, for the topics impact, implementation and sustainability, the focus is shifted from individual efforts to team efforts.

Question 6 will be omitted. Instead the researcher will emphasise that all following questions consider the project as a whole, and questions on personally experiences barriers and facilitators are rephrased as barriers and facilitators experienced by the team.

Refining theory

Interviews/ focus groups with the aim of refining theory will still cover the same topics, but have less standardised questions. Potential strategies used here are the following:

- The researcher's current understanding and interpretation of the project (his/her theory) are shared with the participant (verbally and potentially accompanied with other media to increase clarity). The participant is then asked to comment on this theory based on their own

experiences and their best knowledge. They can be asked to fill in gaps, to clarify certain aspects, to correct errors, to validate interpretations or to give their opinion.

- Based on other sources of analysis (observations or document analysis) the researcher identified specific topics or issues that he/she thinks are relevant for his/her theory, but needs more information on. These issues are then brought back to the participant for him/her to validate, clarify and elaborate on.

Appendix G. Code list and code definitions for my theory-based analytic phase

Category	Code	Definition
Implementation	Coherence	Decisions to adopt a new or adapted intervention model and/ or 'work'
	Collective Action	Implementation actions & strategies and decisions to adopt new or adapted actions & strategies (e.g. sense-making activities)
	Cognitive Participation	The roles that individuals have, get assigned or take within the implementation process and decisions to adapt these
	Reflexive Monitoring	How the intervention model and/ or 'work' and the implementation process itself is understood, assessed and evaluated.
Intervention	Model	The high-level design of the intervention
	Tools	Any new or adapted 'thing' that is used to complete intervention 'work' or intervention purposes
	Work	The new or adapted roles, actions and activities related to the intervention that are intended to be sustained
Stratified Context	Capacity: Social Norms	The social norms that exist in teams or the working environment
	Capacity: Social Roles	The existing professional, social or other roles of individuals or teams
	Capacity: Material Resource	The material resources that are available to the implementation team, either existing within the team or externally available (e.g. other parts of the organisation or other implementation teams)

	Capacity: Cognitive Resource	Expertise that is available to the implementation team, either existing within the team or externally available (e.g. other parts of the organisation or other implementation teams)
	Capacity: Structures and Processes	The existing clinical, administrative, or other processes and structures
	Potential: Individual Commitment	The value that individuals attach to the intervention and/ or to the QI approach (valence) and/ or the confidence that individuals have that they can personally embed the interventions and/ or to the QI approach within their existing tasks and resources (efficacy)
	Potential: Shared Commitment	The value that the implementation team, organisation or other relevant stakeholder group attaches to the intervention (valence) and/ or to the QI approach and/or the confidence that the implementation team, organisation or other relevant stakeholder group has that they can personally embed the interventions and/ or to the QI approach within their existing tasks and resources (efficacy)
Outcomes	Outcomes	The qualitative and quantitative consequences of the activities and actions undertaken and/or intervention(s) implemented
Integration	Integration	Negotiations around the interactions between context of use & the intervention model (does it fit within our organisation, practice & roles; can we do it, who is accountable)
Workability	Workability	Negotiations around the interactions between users & intervention 'work' (role allocation, what do users have to do; how does their work change; how is the system embedded)

Codes refer to the concepts in Normalisation Process Theory (NPT) (May, 2006, 2013, May et al., 2007, 2009, 2016; Murray et al., 2010)